



HOW TO REGULATE?

Version 2021

Regulatory Institute

A handbook presenting
regulatory techniques
of 47 jurisdictions
and a basic universal
method

REGULATE

2nd Edition



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**REGULATORY
INSTITUTE**

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FOREWORD TO THE SECOND EDITION OF THE HANDBOOK 2021

Officials in possession of an inventory of regulatory techniques have more choices and can conceive of better regulation. The same goes for officials disposing of methodological knowledge. This Handbook strives to provide both an inventory of regulatory techniques and a basic method of law-making.

The second edition goes beyond the first edition of 2014 by presenting two additional perspectives on regulation:

- ◆ a macro-view: an introduction into the topic of regulatory architecture (Chapter 2) that can help in the harmonious configuration of different pieces of regulation,
- ◆ a micro-view: a typology of requirements and other provisions (Chapter 3) that helps to complement or otherwise improve individual provisions.
- ◆ These two new¹ chapters and about 70 new sections or sub-sections complement the inventory of regulatory techniques and methodology of the first edition.

The second edition is edited by the Regulatory Institute. It builds on the first edition written by Manfred Kohler, an official of the European Union with more than 20 years of experience in law-making in various national and international contexts. The second edition integrates knowledge and in particular good examples of regulation identified by the Regulatory Institute. The number of jurisdictions referred to has thereby increased from nine to 42. Likewise, the number of sectors² covered by the referenced regulations has increased to 82. For details about the jurisdictions and sectors, see [Subsection 1.3](#).

The identification of generally interesting and useful regulatory techniques in so many different and diverse jurisdictions and sectors confirmed a basic assumption of this Handbook: the topic “regulatory techniques” is universal, not limited to specific sectors. Regulators can all learn from each other, across jurisdictions and sectors, by profiting from the remarkable intelligence laid down in existing legislation.

¹ Chapter 2 also contains, at the end, some Sections which were already present in the first edition.

² For the definition of “sector”, see the following [Section 1.1](#).

1. INTRODUCTION

1.1 Terminology

In this Handbook, we use the following expressions:

“Jurisdiction” means a nation state or a conglomerate of nation states that has its own regulatory empowerments. A part of a nation state that has autonomy to regulate is also referred to as a:

- ◆ “jurisdiction”.
- ◆ “Geographic entities” refers to parts of a jurisdiction.
- ◆ Geographic entities are, for example, the various states in a federal state like the U.S, Brazil, Canada or Argentina or the member states of the Mercosur, the ECOWAS, the EU, ASEAN or of another conglomerate of nation states with its own regulatory empowerments. Geographic entities necessarily have autonomy in the execution of law, but not necessarily the autonomy to regulate. Thus some geographic entities are also jurisdictions whereas most are not. Geographic entities can be part of other geographic entities.
- ◆ We borrow the expression “centre” from the Indian and Canadian political and administrative practice to refer to the central government in the case of a nation state or to the central organs in the case of a conglomerate of nation states with its own regulatory empowerments.
- ◆ We call a “sector” a certain rather limited regulatory subject matter, which however encompasses a variety of issues. For example, the “safety of cars”, covering issues like braking, steering, and crash-test-behaviour, can be distinguished from the sector “emissions of cars”. Similarly, the sector “telephone services” is separate from the sector “internet services”. The issues of a certain sector are usually the same across various jurisdictions.

The expression “sector” is thus not related to one single jurisdiction.

- ◆ The expression “field” refers to several parallel sectors which fall under the same more generic topic, e.g. environmental protection, product safety, or telecommunication services. For example, the sector “safety of cars” pertains to the field of product safety. The expression “field” is also not related to one single jurisdiction.

We strive for a consistent use of the following terms which fit for various jurisdictions:

- ◆ **Regulation:** Legal acts of general applicability (thus not only for individual cases). Regulation consists either of legislation (= legislative acts) or of regulatory acts. We use “act” or “a regulation” for an individual piece of regulation and “regulation” for the abstract category of text.
- ◆ **Legislation (legislative acts):** regulation adopted by the respective legislative power(s).
- ◆ **Regulatory acts:** regulation adopted by the administration (ministry, department, agency etc.).
- ◆ **Regulatory measures:** regulation or other measures that influence behaviour in more than just individual cases. We sometimes also use the expression “regulatory measures other than regulation” whose meaning can be deduced from the previous definitions.

Decisions on individual cases are mostly not dealt with in this Handbook, though they might, in exceptional cases, also have a regulatory effect, e.g. if they are published and thereby influence the behaviour of operators other than those formally addressed. We sometimes refer to them as “administrative acts”.

In some chapters, finally, we refer to legislative and regulatory acts jointly as “acts” (although the term “acts” normally includes administrative acts, we never mean to include administrative acts unless we explicitly say so).

1.2 Development of a practical method of regulating

There are millions of lawyers in the world. However, only a very small fraction of them are involved in law-making or regulating in general. Law-making or regulating

in general is mostly not part of university law studies. Law studies focus on the application of law, not on regulating. Studies of political science also do not prepare for the activity of regulating at an operational level. Only some administrative schools do so. Unfortunately, most of them only offer training for specific aspects. A few schools deal with the general method and with the tools (regulatory techniques). There seems to be a vacuum at the level of professional training, maybe with the exception of a few jurisdictions such as Australia, the U.S. and Switzerland. To respond to that need, the Handbook includes methodological recommendations. The Handbook presents a basic universal method encompassing the following branches:

- ◆ analysis of the sector ([Section 5.1](#)),
- ◆ identification of possible goals, objectives, measures, requirements, incentives, and information or enforcement tools ([Section 5.2](#) and [5.3](#) and [Chapter 10](#) to [12](#)),
- ◆ conception of regulatory measures with a focus on regulation (from [Section 5.3](#) to [Chapter 14](#)),
- ◆ basic quality verification ([Chapter 15](#)),
- ◆ basic analytical and planning elements regarding the topic of regulatory architecture ([Chapter 2](#)), helping to better embed a new regulation,
- ◆ an analytical grid for individual provisions and in particular conditions and requirements ([Chapter 3](#)), presenting possibilities for fine-tuning of individual provisions, and
- ◆ an overview on regulatory measures and incentives.

The method presented here is admittedly basic. The seven branches could be extended by ever more details and alternatives. We refrained from presenting more details for a specific reason: some jurisdictions have developed regulatory policies. If we had presented more details, the presented method would come into conflict with the regulatory policies of the various jurisdictions. By tackling only the top level of the methodology pyramid and the detailed regulatory techniques which are below the radar of regulatory policies, this conflict is hopefully avoided. Readers are of course invited to complement or even to correct the method in view of the practice and the regulatory policies of their jurisdiction.

1.3 Jurisdictions and sectors

The second edition of this Handbook has come very diverse in terms of jurisdictions and regulatory sectors referred to.

It refers to examples from the following 47 jurisdictions:

Alberta (Canada), Argentina, Armenia, Australia, Belgium, Bermudas, Bhutan, Bosnia and Herzegovina, Brazil, Canada, China, Costa Rica, ECOWAS, European Union (EU), France, Gambia, Georgia, Germany, India, Indonesia, Israel, Japan, Kerala (India), Malaysia, Maldives, Mexico, New Zealand, Pakistan, Panama, Philippines, Senegal, Serbia, Singapore, South Korea, St. Kitts, Taiwan (China), Tanzania, Thailand, Tunisia, South Africa, Uganda, UNECE, United Kingdom, United States of America, Uruguay, Victoria (Australia), and WTO/TBT³.

Overall, our selection of references is geographically balanced. The most frequently quoted or referred to jurisdictions are the EU (37x), Canada (27x), Brazil (16x), Philippines (14x), Singapore (14x), India (12x) and Uganda (10x). Regulation of the European Union, recognisable by the letters “EU” or “EC” before or after the number of the act, is technically interesting and merits this lead-role in so far as it combines best practices of its Member States. However, the second edition of this Handbook is not dominated anymore by its EU roots, as was the first edition. In terms of continents, the Americas lead with 61 quotes or referrals⁴, followed by Asia with 55, Europe with 53⁵, Africa with 23 and Australia/Pacific with five. Three additional references to UN provisions bring us up to a total of 200 quotes or referrals⁶.

The regulatory examples stem from the following 82 sectors or sub-sectors:

Access to information, accounting, agriculture in remote regions, air navigation security, air navigation services, aircraft – airworthiness and environment,

³ World Trade Organisation / Technical Barriers to Trade.

⁴ 31 quotes or referrals relate to Canada (27) and the US (4) and thus from the North, 25 from the South and 4 from Middle America.

⁵ If UNECE was to be counted as regional UN organisation though developing cross-continental regulation in the examples quoted in this Handbook, Europe would also come up with 53 quotes or referrals.

⁶ In order to facilitate the retrieving of original examples, the same examples have in many instances been referred to several times. Therefore, the overall number of texts referred to should be just above 100.

alcoholic drinks – labelling and marking, anti-bullying, anti-trust law, (dormant) bank accounts, baby bottles and their nipples, blood, border control, (anti) child abuse, status of children and assisted reproduction, classification, labelling and packaging of substances and mixtures, corporations’ law, compensation for land acquisition and resettlement, consumer protection, contractual law, cosmetics, credit institutions, credit rating agencies, customs (including rules of origin), data protection, disaster alert via mobiles, doping control in sports, eco-design of televisions, eggs (marketing), electricity and gas inspection, electricity marketing, electro-magnetic compatibility, electronic documents and signatures, emissions caused by the production of cement, lime and magnesium oxide explosives, emissions of road vehicles, endangered species protection, energy efficiency, energy savings in buildings, fire arms and ammunition, fire safety (of petroleum and materials), food contact materials, food - residues of veterinary drugs, food security, graphic health warnings, invasive alien species, investment funds / firms, investment transparency, labour law (making conventions generally applicable), liability of legal persons (for acts against the national or international authorities), medical devices, mineral water, (anti-) money laundering, nuclear materials, organ donation, organic products, pensions, pharmaceuticals, pipelines, product conformity declaration, professional law, public tenders or services for authorities – model contracts, right to public consultation, recognition of foreign documents and marks on conformity, refugee law, research risks, revenue taxation, road traffic, road vehicles safety, road vehicles minimum noise / sound, securities trade, seeds, sodium consumption, technology risks, (anti-) terrorism, tobacco products labelling, traceability and verification (of used medical devices), transparency in public life, tire retreading, victim and witness protection, whistle-blower and informant protection, and wine (marketing).

1.4 Correlation table: first and second edition

Quite some articles on the Regulatory Institute’s website howtoregulate.org refer to specific sections or sub-sections of the first edition of the Handbook. In order to permit readers of these articles to retrieve the corresponding sections or sub-sections of the second edition can be retrieved with the help of the following chart:

Chapter or (sub-)section of the 1st edition	Chapter or (sub-)section of the 2nd edition
Section 1.2	Section 1.1
Section 1.3	Section 1.2
Section 1.4	Section 1.3
Sections 2.1 to 2.5	Chapter 5
Section 2.6	Section 7.1
Section 2.7 to 2.9	Chapter 6
Section 2.10	Section 2.8
Section 2.11	Section 7.3
Section 2.12	Section 7.2
Sections 3.1 to 3.8	Sections 8.1 to 8.8
Sections 3.9 to 3.13	Sections 8.10 to 8.14
Section 3.14	Section 9.3
Section 3.15	Section 9.4
Sections 3.16 and 3.17	Sections 8.16 and 8.17
Section 3.18	Section 9.2
Section 3.19	Section 8.18
Section 7.1	Section 11.1
Sections 7.2 and 7.3	Section 10.2 and 10.3
Section 7.4	Section 10.1 and 10.4
Sections 7.5 to 7.7	Section 10.5
Section 7.8	Section 10.6
Section 7.9	Section 12.8
Section 7.10	Section 11.2
Section 7.11	Section 11.4
Section 7.12	Sections 11.5 and 11.6
Section 7.13	Section 11.9
Section 7.14	Section 11.8
Section 7.15	Subsection 11.5.3.5
Section 7.16	Subsections 11.5.3.4, 11.5.3.6 and 11.5.3.8
Section 7.17	Subsection 11.5.3.3
Section 7.18	Subsection 11.5.3.10

Section 7.19	Section 11.10
Section 7.20	Section 11.14
Section 7.21	Section 11.16
Section 7.22	Section 12.2
Section 7.23	Section 12.1
Sections 7.24 and 7.25	Sections 11.11 and 11.12
Section 7.26	Section 11.5
Section 7.27	Subsection 11.5.3.1
Sections 8.1 to 8.3	Sections 12.3 to 12.5
Section 8.4	Section 12.9
Section 8.5	Section 12.7
Section 8.6	Section 12.10
Section 8.7	Section 12.14
Section 8.8	Section 12.13
Section 8.9	Section 12.15
Section 8.10	Section 12.16
Section 8.11	Section 12.11
Section 8.12	Section 12.12
Section 8.13	Section 12.17
Section 8.14	Subsection 12.12.2
Section 8.15	Subsection 10.6.3.2
Section 8.16	Section 12.18
Sections 9.1 to 9.4	Sections 13.1 to 13.4
Sections 9.5 to 9.7	Sections 13.6 to 13.8
Sections 10.1 to 10.6	Sections 14.1 to 14.6
Sections 10.7 to 10.9	Sections 14.8 to 14.10
Sections 11.1 to 11.3	Sections 15.1 to 15.3

2. THE ARCHITECTURE OF REGULATION



“It must be considered that there is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to handle, than to initiate a new order of things. For he who innovates will have for his enemies all those who are well off under the existing order of things, and only lukewarm supporters in those who might be better off under the new.”

Niccolo Machiavelli

2.1 Introduction to the topic of regulatory architecture

Legislative and regulatory acts (hereafter jointly called “acts”) rarely exist in an isolated way. Hence, when conceiving them, it is important to fit them well into the overall regulatory architecture for the given sector or field. We examine in this Chapter how best to position an act in the overall regulatory architecture. To that end, we need to look more closely at how acts relate to each other.

Acts can relate to each other in different ways. One parameter of distinction is the degree of independence between the two acts. The different acts can be applicable in parallel, they can apply independently from one another, e.g. when they deal with different sectors or when they deal with different aspects regarding the same sector, or one act can refer to the other and make the other act thus applicable. In between are cases where two acts in principle apply independently and in parallel, but one act modifies to a certain extent the other.

Another parameter is the degree of abstraction. The different acts can occupy different levels of abstraction. For example, the requirement that “manufacturers shall supply only correct information to consumer” has a higher level of abstraction than “car manufacturers shall inform consumers about fuel efficiency”.

Already from these two parameters, we can derive a multitude of architectures.

Hence, the question arises how the overall architecture of regulation is best built. “Best” means here: consistent, efficient, based on best practices across various sectors, without redundancies and user-friendly. There are quite some choices to be made with regard to the architecture of regulation.

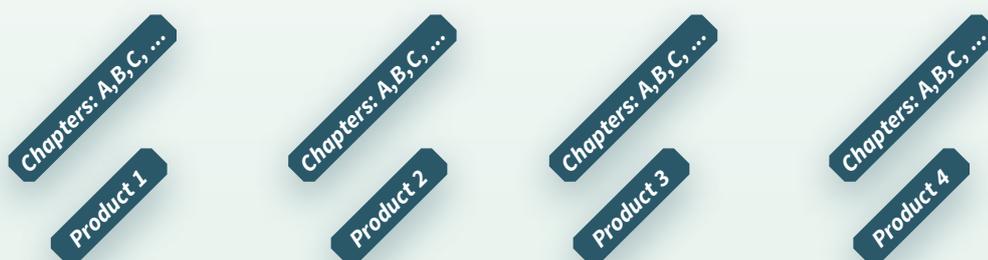
In order to develop a good architecture, it is necessary to analyse the degree of similarity between the provisions to be applied to the relevant sectors (in the following, we refer only to requirements whilst other provisions might also need to be taken into account). This analysis influences the decision on the best architecture. The more that requirements are similar or even identical, the easier it is to place them at a higher level of abstraction, into horizontal or semi-horizontal acts.

Regulators of a particular sector may overestimate the specificity of their requirements. Many regulators of specific sectors think that their sector requirements are extremely specific. They often do so because they have not extensively studied the requirements set up in other sectors. The more one reads regulation of different sectors, the more one recognises that requirements are in essence similar, but just formulated in different ways. These differences are to a certain extent due to the sector’s specificities and thus justifiable. But often they are also simply due to the fact that the regulators of one sector conceive of requirements better or worse than in another.

2.2 Four basic models of architecture

We present first two extreme models (A and D). The remaining two models (B and C) fall between these extremes.

MODEL A EXAMPLE: vertical regulations only



Model D: Different acts can apply either to a single specific sector or to several sectors, and these acts have different positions in the graph below. Some acts apply to many or all sectors of the same type (horizontal acts), some acts apply to a few sectors (semi-horizontal acts), and finally there are acts that apply only to one sector (vertical acts). Individual provisions are placed at the highest possible level, meaning in horizontal acts where they apply to all sectors, in semi-horizontal acts where they apply only to a few sectors, or in vertical acts where they apply only to one sector. We illustrate Model D with a potential architecture for products and services that unfortunately we have not yet seen anywhere in the world:

MODEL D EXAMPLE: regulatory architecture for products and services

Regulation on products and services

Definitions, responsible authorities, conformity assessment bodies, pre-market certification / authorisation, enforcement, penal provisions and other sanctions, inner-state and international cooperation, databases for economic operators, instructions for use, core obligations of economic operators, limits/conditions for outsourcing, interference with other economic operators (software update etc.) and products or services, product-service interface provisions, product-service combined procedures, collision rules amongst acts under architecture, collision rules with other regulation, transitional provisions.

Horizontal products regulation

Generic product requirements, markings, components, replacement parts, interoperability

Horizontal services regulation

Services specific obligation, resiliation, adaptation of contracts in case of change of circumstances, transfer of contract to other economic operators or clients

Semi-horizontal regulation(s)

e.g. on electromagnetic compatibility

Semi-horizontal regulation(s)

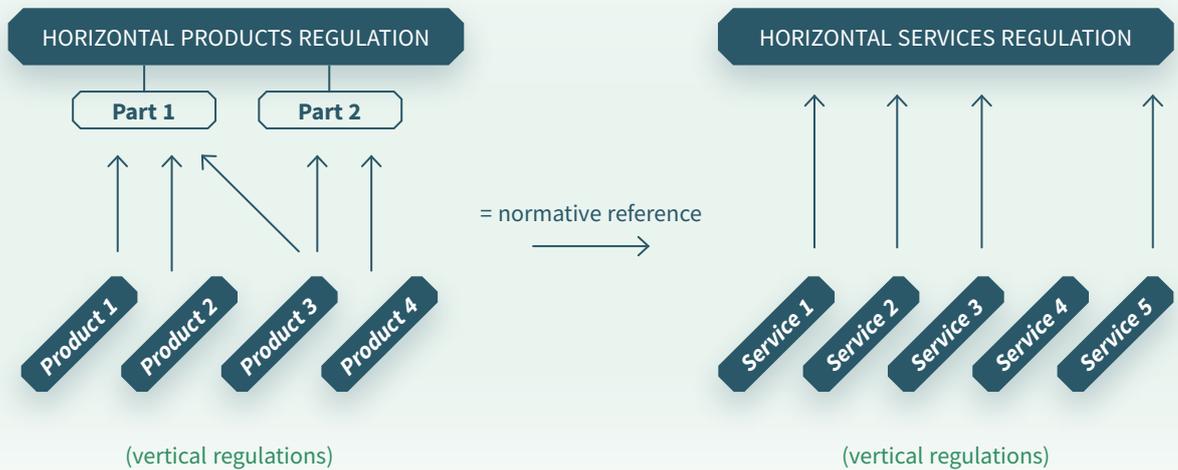
e.g. on internet marketing/services



Model C: In Model D, the horizontal and semi-horizontal acts are applicable by themselves (“eo ipso”). In Model C, however, they are not applicable by themselves, but by virtue of the fact that vertical acts normatively refer to them. See as an example Section 10 of the [Brazilian Portaria INMETRO / MDIC Number 247](#) of 26/05/2014 on the conformity assessment for the retreading of tires. In addition to certain sector specific provisions, it normatively refers to a horizontal act (the “RGDF”):

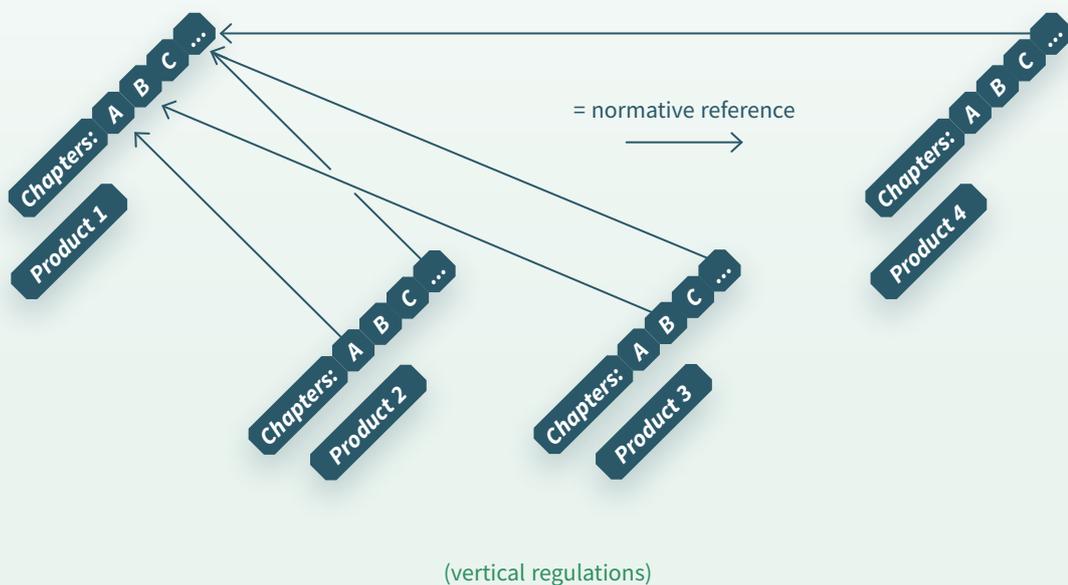
“The criteria for responsibilities and obligations must follow the ones below and those established by the RGDF.”

MODEL C EXAMPLE: horizontal acts applicable by reference only



Model B: Similar to Model A, Model B consists only of vertical acts. In Model B, however, there is a “lead act” to which the other “following acts” normatively refer. The normative reference can be triggered by provisions like: “Chapter A of Act XYZ applies” or “Chapter A of Act XYZ applies by analogy”.

MODEL B EXAMPLE: vertical regulations refer to lead vertical regulation



2.3 Advantages and disadvantages of the different models

Model A has the advantage that users only need to read one single act. Moreover, there is no risk that the sector is exposed to inappropriate horizontal requirements. But Model A also has several disadvantages:

- ◆ There is a risk that the different sectors (vertical acts) develop unjustified specificities and other deviations so that economic operators and persons are exposed to a variety of inconsistent requirements leading to inefficiency. This is especially problematic for economic operators or persons who are active in multiple sectors, particularly if these sectors belong to or impact on the same supply chain.
- ◆ The overall text mass will be unnecessary large.
- ◆ Finally, the updating of the relevant acts is unnecessarily cumbersome where the provisions to be updated are basically the same or very similar.

Model B is similar to Model A except that, in Model B, users will have to read two or more acts, which takes away the main advantage of Model A. On the positive side, Model B avoids, within the scope of its normative references, the downsides of Model A. For example, it will often suffice to modify the lead act to implicitly change all the acts referring to it (provided that the normative references to the lead act are dynamic and that dynamic normative references are allowed in the respective jurisdiction). In cases, however, where the modification in the lead act is outside the scope of the existing normative reference and that reference is still necessary, a new or adapted normative reference might be needed in the different following acts as well. Furthermore, modifications in the lead act might not necessarily fit the following acts and therefore the normative references in the following acts might need to be limited or be made subject to conditions. Finally, Model B can cause quite some damage across sectors where the lead act or its modifications do not represent the best regulatory techniques.

With Model C, the regulator of the sector-specific act still has the full control of the requirements because the requirements of the horizontal and semi-horizontal acts apply only in so far as outlined in the sector-specific act. This is important in particular where there are different regulatory competencies. At the same time, there is no unjustified duplication of text. Economic operators or persons are mostly exposed to identical requirements across sectors. If the horizontal and semi-horizontal acts genuinely reflect the (generally) best regulatory techniques,

Model C also ensures a high regulatory standard. The downside of Model C lies mostly in the regulatory management which becomes, as for Model B, cumbersome where the modification of the horizontal or semi-horizontal act does not fully fit to the act that normatively refers to it. Furthermore, users need to read several acts to have the full picture.

Model D is certainly the most easy to manage regulatory architecture with a minimum of text and consistent requirements across sectors. It is logic and straightforward, as long as the horizontal and semi-horizontal acts do not, willingly or unwillingly, overrule sector specificities that merit being reflected. Due to the cross-sector applicability of horizontal or semi-horizontal acts, it is likely that sector specialists will protest where these acts fall behind the regulatory standard of the vertical acts. But this alone will not ensure that the horizontal and semi-horizontal acts reflect best regulatory techniques.

To conclude, we must come back to the previous subsection. The more the envisaged requirements (and other provisions) are the same or very similar across the various sectors, the more the choice should tend towards Model C or even D. The more there are sector specificities, the more the choice should tend towards Model B or even A.

Under Model B and even more so under Model C and D, it should be checked that the lead act (Model B) or the horizontal and semi-horizontal acts (Model C and D) reflect the best regulatory techniques. Sub-optimal regulatory techniques in the lead act or in horizontal and semi-horizontal acts brings the regulatory level down on a large scale.

2.4 Combining different model architectures

Model A cannot be combined with Models B, C, and D. Models B, C, and D, on the other hand, can be combined. For example, it might make sense that for a certain horizontal aspect Act 1 applies by itself to all sectors, whereas Act 2 only applies to the extent that the vertical (sector) acts refer to it, because some sector specific adaptation needs to be made. It is even conceivable that an Act 3 applies semi-horizontally by itself to a broad range of sectors (Model D) and that other sectors refer to parts of the same Act 3 according to Model C. An architecture combining in this way Models C and D can also still make use of Model B as well. For

example, where only very few sectors have the same type of issue and this issue has been extremely well solved in a vertical Act 4, why not let the other few vertical acts refer to the respective provisions of this Act 4 instead of creating another semi-horizontal Act 5 for such a limited scope?

2.5 Application of the different models to a single act (intra-regulation architecture)

The analysis and the models described above with regard to entire acts can also be used with regard to the different sections and subsections of a single act. Amongst the sections, there are typically horizontal or semi-horizontal ones. But there can also be vertical sections or annexes that apply only to a part of the scope. Furthermore, it might be useful to follow Model B in some cases, namely where a few sub-sections or annexes have elements in common that do not merit a sub-section of higher order. Only Model A does not make sense in a single act.

INTRA-REGULATION ARCHITECTURE

CHAPTER I – General on products and services

Definitions, responsible authorities, conformity assessment bodies, pre-market certification / authorisation, enforcement, penal provisions and other sanctions, inner-state and international cooperation, databases for economic operators, instructions for use, core obligations of economic operators, limits/conditions for outsourcing, interference with other economic operators (software update etc.) and products or services, product-service interface provisions, product-service combined procedures, collision rules amongst acts under architecture, collision rules with other regulation, transitional provisions.

CHAPTER II – General on products

Generic product requirements, markings, components, replacement parts, interoperability

CHAPTER IX - General on services

Services specific obligation, resiliation, adaptation of contracts in case of change of circumstances, transfer of contract to other economic operators or clients

CHAPTER III to VIII – Semi-horizontal on products

e.g. on electromagnetic compatibility

CHAPTER X to XIII – Semi-horizontal on services

e.g. on internet marketing/services



(vertical regulations)



(vertical regulations)

2.6 Technical annexes

Another architectural question is: what to place in the annexes and what to place in the main part of the act? Evidently, there can be rules on this in each individual jurisdiction. To the extent that these rules do not prescribe one way or the other, the following considerations might help:

Readers would expect the key elements of an act to be at least mentioned in the main part. If the key element is technically too complicated to be dealt with entirely in the main part, the main part can succinctly mention the element and refer to the annex for elaboration. In some jurisdictions, it is even legally necessary to outline the key elements in the main part of the act.

For readers, it is not necessarily easy to be referred to an annex and then to come back to the initial place of reading. Thus it might be worthwhile checking whether the content of an annex is short enough to be displayed in the main part of the act. Potential evolution should however also be taken into account. If the content is currently rather short, but is likely to become longer, it is preferable to place it into an annex from the beginning.

In particular provisions with relevance for only some readers may, generally speaking, be well placed in an annex. This is particularly the case if the act covers several different products, services or situations and each of them requires specific vertical provisions. Here we come back to our Model D.

2.7 Subordinate acts versus annexes

Annexes can also compete with subordinate acts and vice-versa.

It is often more efficient and user-friendly to cast technical content into an annex rather than into a separate act: the reader does not have to jump between two acts – everything is in one place. However, sometimes the technical content is not yet ready when the main act is adopted or simply too complicated to be processed by parliamentarians or the legislator (e.g. test cycles for emission testing of vehicles). Hence, it makes sense for the legislator to include an empowerment for the administration to adopt subordinate acts (regulation other than legislation) at a later point in time, see e.g. [here for Australia](#). Another reason for such a structure is that the technical content needs frequent updating, e.g. to technical progress.

In this situation, the legislative procedure might be too slow or too cumbersome. The drawback of creating empowerments for subordinate acts is that such acts risk incompatibility with the main act or become broader in scope than the main act. This can be legally problematic. Careful scrutiny is accordingly paramount. An elegant compromise solution consists in placing the technical content into an annex, but to give the administration the empowerment to modify or even complement the annex. The annex thus becomes a hybrid text, partly (and in essence) adopted by the legislator and partly (for the details) adopted by the administration. This solution also gives the legislator the opportunity to overrule, in a new legislative procedure, the content of amendments made by the administration in the meantime. In terms of democratic control, this is an advantage. See as an example Article 42(1) of [Regulation \(EU\) 2019/1009](#) of 5 June 2019 laying down rules on the making available on the market of EU fertilising products.

2.8 Referring to or integrating other regulation

We have seen in Sections 2.1 to 2.5 that references are crucial elements of a fit for purpose architecture. Here we shed more light on the issue of references and its alternative, the integration of other regulation.

An act can declare other regulation to be applicable. If the other regulation is already applicable by itself, the declaration is just confirmatory. If it is not, the declaration itself constitutes the applicability. We speak in this case of a “normative reference” that lets the text referred to in substance become part of the referring text.

A declaration of applicability can be partly confirmatory and partly normative.

Regulation can also integrate substantial or procedural requirements of a pre-existing regulation by referring to it, whether the pre-existing regulation is applicable by itself or not. Once the reference is made, the pre-existing regulation might still be applicable by itself. This means that pre-existing and new regulation might be applicable in parallel. The parallel applicability is not necessarily superfluous. For instance, the requirements of the pre-existing regulation might be looked at under a slightly different angle. The additional applicability by reference can also be meaningful if the act referred to is about to be repealed. However, it is usually better to avoid the parallel application of pre-existing and new regulation if they deal with the same requirements.

The [Argentinian Law 26.906 of 13 November 2013 on the Rules on Traceability and Verification of Technical Abilities of Used Active Medical Devices](#)⁷ contains, in its Article 5, an explicit dynamic reference to future ordinances (“... o la que en un futuro se dicte.”). As elegant as this might seem at first sight, such explicit references may raise legal questions for other parts of the same act: lawyers may argue that as there is no such explicit dynamic reference in other parts, future ordinances shall not be applied.

For a more detailed typology of references, see [Section 9.1](#).

2.9 Reference and architecture diagrams

In the previous sections we have seen different models of basic architecture for the aggregation of different acts. We have seen that three out of the four presented models can also be used within one and the same act. We have examined the topic of annexes and subordinate acts as well as the topic of normative references. If we take all these elements together, the overall structure can become quite complicated. In order to keep good oversight diagrams might become useful if not indispensable.

The necessity is increased if the acts which form part of the architecture contain references. In particular, if somewhere a normative reference is made to an international standard, things become even more difficult. Very few international standards do not refer to other standards. They do so either in a dynamic way (which is legally problematic in many jurisdictions as the regulator loses control), in a static way, or in a way that is not determined so that readers must guess whether a dynamic or static reference is meant. A static reference to a dated or otherwise unequivocally determined version of an international standard is of course preferable under the aspect of legal certainty. However, the devil is in the detail: the dated versions of the standard are often superseded by new standards in a few months or years. This can have dramatic consequences. They may lose formal validity and might possibly even not be accessible anymore creating other issues of legal certainty. Moreover, where different normative references interact and international standards normatively referred to contain further normative references, one can easily end up with situations in which different versions of

⁷ “Régimen de Trazabilidad y Verificación de Aptitud Técnica de los Productos Médicos Activos de Salud en Uso”.

the same standard are normatively referred to – a source of confusion or even contradiction. To avoid these many pitfalls, we recommend again to make use of diagrams. See as examples the graphs found in [this publication](#) (they would merit further refinement in case different sections of the same standard would refer to different versions of other standards). Furthermore, we recommend periodic review of normative references as the texts normatively referred to might change or might lose their status or accessibility.

3. THE SMALL SCALE BUILDING BLOCKS OF REGULATION: THE REQUIREMENTS AND OTHER PROVISIONS



“Ruling the country is like cooking a small fish.”

Lao Tse

In the previous chapter, we looked at the macro-level of regulation. In this chapter, we follow the opposite approach by zooming in for a microscopic view on regulation. Though it may be more logical to analyse regulation step-by-step from the macro to the micro level, we believe it necessary to present first the two poles before presenting regulatory techniques at the intermediate levels. The intermediate levels can be better understood when one is familiar with the macro and the micro view on regulation.

Regulation consists mostly of requirements. However, we have tried the utmost to keep the following presentation open to other provisions.

In order to facilitate the communication, we start with a standard sentence which contains a condition on the left side and a consequence on the right:

“When a citizen reaches the age of 16,

s/he must apply for an identity card.”

In the following, we will first analyse the condition side of requirements or other provisions. In a second step, we come to the consequence side. By analysing separately the condition side and the consequence side, we obtain a deeper understanding of the molecules of regulation.

3.1 Conditions and characteristics used for establishing requirements or other provisions

Conditions cannot only be used to build requirements, they can also trigger other legal consequences, for instance a certain privilege (e.g. access to a grant), a status change (e.g. marriage), or a legal presumption (e.g. to have fulfilled an obligation). Conditions are essential building blocks for any kind of legal provision, not just requirements.

Conditions and characteristics have the same function because they can be interchanged. E.g. the condition “If a house is higher than 5 metres, the house ...” can be transformed into a fully equivalent characteristic “houses higher than 5 metres ...”. The conditions and characteristics can inter alia refer to organisations, natural persons, geography/physical presence, objects or processes or a combination thereof:

3.1.1 – Organisational conditions and characteristics

Consider the following example: *“To be eligible as an external expert, applicants must be independent from any authority, company or other organisation”*.

Though the condition is here on the right side, the sentence follows our classic pattern presented above: a consequence is based on a certain condition. This is even the case where the sentence is further shortened: *“Applicants must be independent from any authority, company or other organisation”*.

This sentence should not be understood as a “requirement” in our terminology because nobody is obliged to become an external expert; we reserve the term “requirement” for provisions establishing an obligation or making such an obligation more concrete.

Within the group of organisational conditions, there is a particular subgroup: system conditions such as “Applicants must set up a quality management system. The verb “must set up” is a condition for approval, thus as such not a requirement.

System conditions are often combined with a system obligation, see the following example: *“Applicants must set up and maintain a quality management system”*. The verb “must maintain” establishes a continuous obligation which has nothing

to do with the approval, hence it is a requirement. N.B.: The examples considered in this section would be considered requirements if they are linked with an obligation for, as an example, manufacturers to undergo an application procedure⁸.

3.1.2 – Personal conditions and characteristics

*(“4.1 In order to qualify and acquire a license to own and possess a firearm or firearms and ammunition, the applicant must be: a) a Filipino citizen; b) at least twenty-one (21) years old at the time of the filing of his/her written application ...”)*⁹

With regard to the persons, various characteristics can be applied:

- ◆ nationality,
- ◆ origin,
- ◆ residence (legal presence) or place of business,
- ◆ physical presence,
- ◆ age,
- ◆ education level,
- ◆ professional training,
- ◆ professional experience,
- ◆ having exerted another (non-professional) activity or function a certain number of times or for a certain time,
- ◆ economic and other functions,
- ◆ disposing of a recommendation (letter) by a trustworthy person or institution.

⁸ See examples of Sections 93 to 97 of the [Canadian Food and Drugs Act, Blood Regulations, P.C. 2013-1065 October 9, 2013](#) or Sections 6.1 to 6.6 of the [Canadian Regulations Amending the Onshore Pipeline Regulations, 1999, P.C. 2013-308 March 21, 2013](#), 1999, P.C. 2013-308 March 21, 2013. The latter is slightly more comprehensive than the first, but still manageable.

⁹ Section 4 of the Philippine [Implementing Rules and Regulations of Republic Act No. 10591](#) (the “Comprehensive Firearms and Ammunition Regulation Act”), published on December 7, 2013.

3.1.3 – Geographic conditions and characteristics

(“A high risk facility may not be authorised if located at a distance of 20 km or more from the next fire brigade.”)

Geographic conditions and characteristics can refer to a stable state (a presence at a certain place) or a movement (somebody or something moves / is moved from one place to the other).

3.1.4 – Physical conditions and characteristics

(“Goods marked with the XYZ mark are deemed to fulfil the requirements set out in this regulation.”)

Anything that describes the appearance or the interior including the performance with regard to certain criteria can become a physical condition or characteristic. Examples are: resistance to fire, maximum speed, composition of materials, inner structure, coating, components.

3.1.5 – Legal conditions and characteristics

(“Goods approved by the XYZ authority are deemed to fulfil the requirements set out in this regulation.”)

Legal conditions and characteristics describe an object or a person with regard to the legal definitions of the respective jurisdiction. These legal conditions and characteristics are as such not visible, but can be expressed by symbols: e.g. a ring can express a marriage.

One particular object condition or characteristic is price. On the condition side, regulation can refer a price agreed by contractual partners or to the price at which a natural or legal person offers a good or service. Example: *“Where the rent is more than 20% higher than the average rent as fixed by XYZ index, the owner shall ...”*.

3.1.6 – Process conditions and characteristics

(“Medicines manufactured in accordance with the Good Manufacturing Practices may...”)

Frequently, technical regulation refers to the application of quality management standards such as [ISO 9001](#)¹⁰. These quality management standards describe one comprehensive process which is composed of various individual processes.

The condition “use of a certain standard” can have a positive legal consequence such as dispensation from the obligation to undergo a certain conformity assessment procedure. But typically, the use of a certain standard is on the consequence side so as to establish an obligation.

3.1.7 – Time-related conditions and characteristics

(“Applications can be submitted from May 1 to June 30 of each year.”)

In this example, we see simple fixed start dates and end dates. A “deadline” is the most common variant of an end date. But we also find conditions or characteristics which are not fixed, either because they are dynamic such as “submitted within three months after application” or because they are imprecise, subject to interpretation such as “submitted within due time”.

3.1.8 – Behavioural conditions and characteristics based on circumstances

(“Where a dog is biting a human or is about to bite a human, it may be killed.”)

Behavioural conditions and characteristics are limited to beings that can move which includes some plants.

¹⁰ ISO is the International Organisation for Standardization, an international standard-setting body composed of representatives from various national standards organizations.

3.1.9 – Logical links between conditions and characteristics

Conditions and characteristics may be interlinked by “and” or by two types of “or”: “A or B → C” usually means “If there is A or B or both A and B, there will be C”; “A or B” may exceptionally also mean “A or B but not A and B”.

Conditions and characteristics may be formulated and linked as positive conditions and characteristics (A and B → C) or as partly positive and partly negative conditions and characteristics (A and not B → C) or just as negative conditions and characteristics (not A and not B → C).

See as an example how different personal and geographic conditions and characteristics can be combined the following extract of the [Accounting for Imported Goods and Payment of Duties Regulations](#):

“Paragraphs 10.5(2):

(2) For the purposes of paragraph (1)(b), an importer shall meet the following requirements:

(a) if the importer is an individual, the importer ordinarily resides in Canada or the United States or, if the importer is a partnership, the importer has at least one partner who is an individual who ordinarily resides in Canada or the United States;

(b) if the importer is a corporation, the importer has its head office in Canada or the United States or operates a branch office in Canada or the United States; ...”

3.2 The distinction between conditions and consequences

We have seen in [Subsection 3.1.1](#) how thin the line between a condition for achieving a certain status and an enforceable obligation can be. Subject to the context, the same sentence can contain, for example, a personal condition (see the example in [Subsection 3.1.2](#)) or an obligation to take a certain action where a certain characteristic is fulfilled. Here is another, intentionally unclear formulated example to illustrate the distinction: “All majority-aged citizens must have at hand an identity card. Minors from 16 years must also obtain an identity card”. The second sentence can mean “Where a citizen has reached the age of 16, s/he may apply for an identity card and will receive it.” But it can also be understood

as extending the obligation to apply for an identity card and to have it at hand to minors from the age of 16 upwards. Under the second assumption/interpretation, the question would arise how this obligation is to be enforced, a question that would never arise under the first assumption/interpretation. Furthermore, sanctions are at stake only under the second assumption/interpretation. It is therefore important to distinguish the two cases:

- ◆ Is a sentence or part thereof establishing a condition for a certain consequence to be drawn without creating an obligation (i.e. when you turn 16, you can apply for an identity card)?
- ◆ Or is the relevant consequence the creation/activation of an enforceable obligation (i.e. when you turn 16, you must have an identity card)?

If a certain sentence is not clear in this respect, it is worthwhile reformulating it until it is clear for everybody.

3.3 Typology of consequences I: the descriptors

A first typology of various consequences can be developed in parallel to that of the various conditions and characteristics set out in [Section 3.1](#). This typology looks at the descriptors used for determining a consequence.

3.3.1 – Parallels between conditions and characteristics on one side and consequences on the other

The example of [Subsection 3.1.1](#) and the one provided in [Section 3.2](#) also illustrate another important point: all the subcategories of Subsection 3.1 are mirrored on the side of the obligations or other consequences. Obligations and other consequences can relate to:

- ◆ organisation: *“Companies with a capital of ... or more must have a controlling body.”*;
- ◆ personal characteristics: *“Manufacturers of medicines must employ at least one pharmacist with specialisation in good manufacturing characteristics.”*;
- ◆ physical characteristics: *“Products must be labelled with the XYZ mark.”*;
- ◆ legal characteristics: *“After declaring the loss of the passport at the next police*

station, the citizen must obtain a confirmation of his identity from the local administration of his place of residence.”;

- ◆ *processes: “Service providers shall undergo annual auditing and appropriately reflect the findings of the audit in their day-to-day management.”;*
- ◆ *time: “The citizen shall apply for a new passport within three months.”;*
- ◆ *behaviour: “Employers shall refrain from directly or indirectly sanctioning employees who have used their right to ... ”.*

The reference to time in consequences can also take forms similar to the ones seen on the condition-side:

- ◆ A consequence may be timed: “Manufacturers shall limit value X until ... and limit value Y thereafter”.
- ◆ Consequences and in particular obligations may be dynamic and evolve over time without any predetermination: examples of such conditions are clauses like “best available techniques”, “state-of-the-art”, and dynamic reference to documents under control of other institutions such as Codices elaborated by the United Nations.
- ◆ Time references within consequences can be voluntarily imprecise to provide a margin of interpretation to the administration.

3.3.2 – Particular aspects of this typology

3.3.2.1 – Positive or negative consequences

Consequences and in particular obligations can be formulated positively or negatively. The positive or negative formulation can (badly) interact with the logic links between different consequences therefore negative formulations should be avoided to the extent possible.

3.3.2.2 – Logical links between consequences

Similar to conditions and characteristics, consequences may be interlinked by “and” or by two types of “or”. “A → B or C” can mean “If there is A, there will be B

or C, but not B and C”. Example 1: “Applicants fulfilling the minimum professional training requirements may be nominated as X or as Z, subject to their professional experience.” In example 1, it is clear that the successful applicant cannot be nominated both as X and Z.

However, sometimes “or” is not excluding B and C together and thus means “If there is A, there will be B or C or both B and C”. Example: “The merit of veterans can be rewarded by a medal or by a 10% increase of their pension”. It would not make sense not to also give a medal to a veteran who has even merited a 10% pension increase. To avoid legal uncertainty “and/or” is an international standard commonly used in such situations.

3.3.2.3 – *Process versus procedural obligations*

Process obligations (obligations based on a process characteristic) are not to be confused with procedural obligations that we will present in more detail in the next sub-section.

Section 10.B of the [Implementing Rules and Regulations of the Anti-Bullying Act of 2013 of the Philippines \(Act 10627\)](#) contains an interesting case of a procedural obligation that contains built-in process obligations and thereby illustrates the difference between procedural and process obligations:

“B. Procedures.

Consistent with Sections 3 and 4 of the Act, all public and private kindergarten, elementary and secondary schools shall adopt procedures that include:

a. Immediate Responses: [...]

b. Reporting the bullying incident: [...]

...

g. Due Process:

In all cases where a penalty is imposed on the bully or offending student, the following minimum requirements of due process shall be complied with:

a) The student and the parents or guardians shall be informed of the complaint in writing;

b) The student shall be given the opportunity to answer the complaint in writing, with the assistance of the parents or guardian; ...”

Thus, whereas procedural obligations relate to the setting up or running of a certain procedure, process obligations relate to how such procedures are conducted.

3.4 Typology of consequences II: aspects of procedure / process and aspects of substance

In the following, we present a second typology of consequences. Therein, we distinguish mainly between consequences which are procedural or process-based and consequences that deal with aspects of substance. Both types of consequences in practice mostly fall under the term “obligation.” For each obligation, however, we also found at least one other example that contains a consequence other than an obligation. Therefore, we illustrate the consequences mostly with obligations, whilst maintaining the abstract term “consequences” to highlight that consequences other than obligations might also be meant.

3.4.1 – Procedural consequences

There are many types of procedural consequences. We only list a few that occur frequently:

3.4.1.1 – Registration

One typical obligation both for citizens and economic operators is to register. Registration is often used by regulators as a first, low-level step towards control. Registration ensures that the authorities can contact the citizen or the economic operator and that they obtain some essential information which might indicate a need to act or not. Registration as a consequence other than obligation occurs where regulation foresees that an authority needs to register a certain person or fact.

3.4.1.2 – Consultation

Consultation procedures go a step beyond registration in so far as they give the occasion to react and thus the possibility for feedback. The feedback must at least be

taken note of. To make a consultation procedure more meaningful and effective, regulators can stipulate that deviations from the opinion given must be justified. Thereby a consultation procedure becomes a semi-coercive tool, in-between simple registration and the imposition of more severe procedural consequences.

3.4.1.3 – *Agreement*

Below the level of a formal authorisation procedure (see below), the simple agreement of an authority can be made mandatory by regulation. Likewise, some administrative decisions might require the agreement of another authority, often of the supervising authority. It is also possible that regulation foresees the mandatory agreement of another natural or legal person.

3.4.1.4 – *Authorisation*

A formal authorisation procedure is the most severe procedural obligation that can be imposed on citizens and economic operators. The procedure can be strengthened by additional agreements to be obtained within the authorisation procedure, e.g. the agreement of a specialised committee can be required. In particular where various aspects need to be verified with different competent authorities, such built-in agreements are a suitable solution to avoid several parallel authorisation procedures.

3.4.1.5 – *Certification by entrusted bodies*

Certification by entrusted bodies can be seen as a variant of the authorisation procedure. However, there are important differences and therefore we deal with this legal tool separately. Where economic operators or, in some cases, citizens, have a choice between different entrusted bodies from which to obtain obligatory certification, the procedure is often less severe. There are two reasons for this: First, unless it is explicitly excluded, there is a second or third chance for unsuccessful applicants. Second, the resulting competition between the different bodies easily leads to a downward spiral in terms of stringency. Complex mechanisms are needed to avoid this downward spiral and to establish, in more general terms, harmonised decision-making (see the article “[How to harmonise decision-making of authorities and conformity assessment bodies?](#)”).

We heard from the CEO of India's [National Accreditation Board for Certification Bodies](#) that India has, for some products, taken another path: the responsible certification body is centrally attributed so that economic operators do not have a choice but to undergo the procedure with the body attributed to them. Hence, the certification body loses its commercial interest in pleasing the economic operator. Instead it is interested in pleasing the entity which decides on the attribution. This is a major improvement.

3.4.1.6 – *Information*

On a completely different level and independently from all the above, there are many types of information obligations, in particular for economic operators. It starts from the simple obligation to inform authorities about certain facts, e.g. incidents. Information obligations exist both vis-à-vis the authorities or third parties. For the latter some frequent sub-types are labelling, instruction for use, the obligation to establish a website containing certain information. This brings us to a special information sub-type: the publication. Publication can occur in official or in unofficial media. It can be the subject of an obligation or just be a consequence to be provided by the authorities. In some cases, it is up to an authority to provide certain information. Hence, information consequences are also not limited to obligations. Finally, we note that information obligations or other information consequences can be part of an authority procedure or can foresee a procedural role for an authority, but they can also relate to or constitute a simple process without the intervention of any authority.

3.4.1.7 – *Training*

Another possibility is to include the obligation to provide or to undergo (quality controlled) training. Obligations of this type should be clearly distinguished from the condition to have undergone training, e.g. in order to obtain a licence. Here we refer only to independent training obligations that are not related to any specific result.

3.4.1.8 – *Quality management*

Equally unrelated to a specific result (e.g. obtaining a licence), and on a purely procedural side, there exists the obligation of economic operators to apply a quality management system or a simplified form of quality management. As quality management might also be necessary for authorities, quality management can also be the topic of a consequence other than an obligation, e.g. in the field of airspace surveillance or flight control.

3.4.1.9 – *Verifications*

A simplified form of quality management might be to require certain specific, possibly periodic, verifications. Such verifications might both be relevant within administrations and for economic operators or even citizens. Again, verifications can relate both to obligations or other consequences.

When it comes to the question “what is to be verified?”, we approach the thin line between process consequences and consequences of substance. A sentence can contain a process consequence and a consequence of substance at the same time. It does so where the consequence of substance is presented together with the verification. Example: “The authority shall verify at least every three months whether its IT safety is state-of-the-art.” If, however, a consequence of substance is only referred to whilst being introduced elsewhere, the sentence would qualify as pure process consequence. Example: “The fulfilment of Articles 7, 8 and 9 is to be verified on a periodic basis, at least three-monthly.”

3.4.2 – Consequences of substance

There are other consequences than process or procedural consequences. Here we call them consequences of substance. They can be further subdivided into quantitative and qualitative consequences.

3.4.2.1 – *Quantitative consequences*

Mostly, the consequences of substance will be in the form of an obligation for a natural or legal person. However, they can also be consequences other than obligations. As we will not show examples for consequences other than obligations

for all the following sub-types, we illustrate it with the first.

- ◆ **Minimum values:** An obligation containing a minimum value is, e.g., the obligation not to drive below a certain speed on the motorway. A consequence other than an obligation could be: the pension authority shall automatically increase the pension to the level of minimum social aid where the pension is lower.
- ◆ **Maximum values:** A speed limit or a maximum radiation limit can be cited as examples of consequences containing maximum values.
- ◆ **Bandwidths:** if there is both a minimum and a maximum value, e.g. for speed, the consequence contains a bandwidth.
- ◆ **Average values spread over time:** They are often used in environmental law, in addition to maximum values. E.g., where a certain substance is immediately toxic only with a high value, whilst medium-term toxicity starts a lower level with exposure during a certain time, it might be useful to fix both a maximum value for short-term exposure and another, lower one, for average medium-term exposure. Evidently, average values can also refer to minima.
- ◆ **Balance values or ratios:** Balance values or ratios are defined by two or more values for which, jointly, a minimum or maximum is fixed. The values can be linked by any kind of mathematical formula or symbol (+, -, x, :, ...).

3.4.2.2 – Qualitative consequences

Qualitative consequences have no quantitative descriptor. E.g.: *“Where s/he prescribes medicine X, the physician shall inform on the most likely side-effects and verify that the patient has fully understood the information.”*

3.4.2.3 – Combined qualitative/quantitative consequences

Evidently qualitative and quantitative consequences can be combined. E.g.: *“The physician shall not prescribe more than a dose of 20 mg per day and shall inform on the most likely side-effects and verify that the patient has fully understood the information.”*

3.4.2.4 – *Semi-quantitative consequences*

We distinguish from combined qualitative/quantitative consequences the semi-quantitative consequences. Semi-quantitative consequences describe or target a quantitative consequence, but they do so by words that do not define a precise quantity. E.g.: “The physician shall limit the dose of medicine X to the minimum necessary to reduce the pain to an acceptable level.”

3.4.3 – Logical links between various consequences

Both quantitative and qualitative consequences can be interlinked with any logical function such as and, or, if, if not. Drafters do this of course instinctively. However, we believe it important to consciously analyse the logical functions between different consequences. Sometimes a conscious analysis detects inconsistencies, redundancies or other possibilities for simplification.

4. A TYPOLOGY OF INCENTIVES AND REGULATORY MEASURES



“That government is best which governs the least, because its people discipline themselves.”

Thomas Jefferson

4.1 Types of incentives

A core parameter for the understanding of regulation and other regulatory measures are the incentives used. Inversely, enhanced knowledge about the full range of incentives that can be used in regulation dramatically improves the quality of draft regulations.

Regulation steers behaviour through incentives. Incentives can be negative, like classic sanctions applied in case of non-fulfilment of obligations. Incentives can also be positive.

Incentives can be provided in two ways. First incentives can be provided through regulation. Evidently, incentives can also be provided through regulatory measures other than regulation. E.g. contracts and subsidies can be alternatives to unilaterally imposed obligations. An administration may be able to give an advantage by a simple administrative decision. It can thereby create an incentive. E.g. an administration can decide to process those requests of operators or citizens faster that are based on a fully filled-in form and for which a certification body has already verified basic requirements.

The two ways of providing incentives constitute two overlapping circles. Some advantages can lawfully only be provided if regulation provides for a specific legal basis. Some advantages can, by their nature, only be provided by measures other than regulation. Regulators who exclusively think in terms of unilateral obligations to be imposed by regulation are likely to miss opportunities. Therefore it

is very important to analyse the right behavioural incentives in conjunction with appropriate requirements before deciding on the measures to be taken.

Inter alia the following advantages or risk of disadvantages can constitute incentives:

4.1.1 – Reputational advantages or risk of disadvantages

- ◆ Reputational advantages (e.g. in the context of marketing of products: fulfilling highest level requirements instead of the legal minimum requirements leading to positive publicity or praise from authorities or business associations); and
- ◆ The risk of reputational disadvantages (possible “naming and shaming” by authorities¹¹, business associations, NGOs etc.).

4.1.2 – Positive feelings or risk of negative feelings

- ◆ Feeling fashionable or morally good (e.g. millions of Europeans classify their daily garbage without being obliged to simply because it is common practice and good for the environment);
- ◆ Praise, going from a simple “thank you for respecting the speed limit” to formal awards; and
- ◆ The risk of being blamed as such, without reputational consequences.

4.1.3 – Status advantages or disadvantages

- ◆ Safer or broader market access, like presumption of conformity with legal requirements provided by the fulfilment of standards under the New Approach, or access to a broader market;
- ◆ Longer validity of certificates or approvals;
- ◆ More legal certainty (e.g. through an optional state authorisation procedure instead of self-certification);

¹¹E.g. the UK is naming and shaming employers who do not pay the minimum wage, see <http://www.bbc.com/news/uk-27751722>.

- ◆ Better protection of rights;
- ◆ Better control of competitors or opponents (e.g. via the voluntary accession to a self-regulatory body having a Code of Conduct and enforcement mechanisms);
- ◆ Exclusion from public tenders or contracts; and
- ◆ Privileged access to public tenders or contracts (e.g. for green procurement).

4.1.4 – Indirect financial advantages

- ◆ Lower insurance rates;
- ◆ Lower liability risks;
- ◆ Lower damage risk;
- ◆ Lower risk of future compensation claims or of claims aiming at the internalisation of external costs;
- ◆ Privileged access to subsidies / grants;
- ◆ Tax incentives; and
- ◆ Better access to public tenders.

4.1.5 – Indirect non-financial advantages

- ◆ Access to valuable know-how (consultants, handbooks and training);
- ◆ Access to IT infrastructure and artificial intelligence; and
- ◆ Access to facilities like offices, libraries, laboratories.

4.1.6 – Combination of incentives

Several of these incentives can be combined. For example, the voluntary application of “the top world standard” may, at the same time, give access to various jurisdictions at the same time, may prolong the validity of approvals and may provide for a better reputation (with or without labelling) and thus better marketing opportunities. There are situations in which the three incentives combined trigger a shift in behaviour whereas one of the incentives alone does not. Using or

combining such incentives sometimes enables the design of a package of non-coercive measures which have the same or more effect than unilateral coercive measures.

The [Canadian Food and Drugs Act](#) provides for an intelligent procedural incentive not to use certain substances beyond certain limit values:

“When a veterinary drug that is set out in column I [...] is present in a food that is set out in column III, the food is exempt from the application of paragraphs 4(1)(a) and (d) of the Food and Drugs Act [...], if the amount of the substance present in the food does not exceed the maximum residue limit that is set out in column IV.”

For more information on behavioural incentives, see this 2014 OECD publication: [“Regulatory Policy and Behavioural Economics”](#).

4.2 Types of regulatory measures

Being aware of the full range of available measures is a precondition for making the right choice. Therefore, it is advisable to invest some time into the question: which measures are at my disposal? The answer to this question is of course different from one jurisdiction to the next, and often from one sector to the next within the same jurisdiction. However, it is possible to set up a typology of measures.

The first important distinction to be made is between regulation (4.2.1) and measures other than regulation (4.2.2)¹².

4.2.1 – Regulation

Regulation consists either of legislation (= legislative acts adopted by the respective parliaments) or of regulatory acts (= regulation adopted by the administration). Subject to the jurisdiction and the legal setting for the sector in that jurisdiction, there are one or more types of legislation for which the respective parliament needs to be involved. Furthermore, there are one or more types of regulation

¹² See also our terminology explained in [Section 1.1](#).

adopted by the administration. These measures are both of general applicability, thus not only targeting a pre-defined limited number of natural or legal persons. They are thus to be distinguished from decisions on individual cases. Decisions on individual cases are not dealt with in this Handbook though they might, exceptionally, also have a regulatory effect, e.g. if they are published and thereby influence the behaviour of all operators.

4.2.2 – Regulatory measures other than regulation

Once confronted with a new issue, those who are familiar with regulation tend to immediately think of new regulation as a solution. Alternatives to regulation are regarded as less valuable, though they might better serve the pursued goal(s). Due to this attitude, alternatives to regulation are quite often not examined.

Measures other than regulation can be subdivided into those dealing with information and others. The importance of information can hardly be overestimated. Information as such can influence behaviour, as we will see in some of the following examples. Even when we have fully-fledged regulation and enforcement thereof, information measures should be considered. Informing natural and legal persons of their obligations is cheaper than enforcement and sometimes even a precondition for enforcement. Here is a basic typology of measures other than regulation (as so far defined):

4.2.2.1 – Voluntary agreements / self-regulation / co-regulation¹³

Industry and other professional associations often claim that they are able to reach a certain political goal just by an agreement concluded on behalf of their members. Regarding the co-operation between social partners, voluntary agreements are common practice and work well in quite a few jurisdictions. However, in other regulatory sectors, experiences are less positive. The following means can trigger readiness to adopt voluntary agreements/self-regulation: (1) Letters to business associations, suggesting voluntary agreements/self-regulation and indicating that otherwise regulation will be adopted or (2) public consultations or announcements indicating the readiness to adopt regulation.

¹³ Self-regulation is the regulation established by those to be regulated. Co-regulation is a variant of self-regulation in which the authority validates the result of the self-regulatory process.

An intermediate form of regulation is co-regulation. Co-regulation is a form of self-regulation with involvement of or validation by an authority. One specific form of co-regulation consists of making a self-regulatory agreement between social partners mandatory for all workers or for all workers who wish to apply the rules of the agreement. An example of the latter can be found in the [Argentinian Decree 110/2014 of 29 January 2014](#) that includes the homologation of the Agreement Act of the Negotiating Commission of the General Collective Labor Agreement for the National Public Administration.

4.2.2.2 – *Voluntary labelling and marking*

Labelling and marking can be introduced on a mandatory basis¹⁴, but it can also be introduced on a voluntary basis through a private initiative (mandatory in this context meaning that the conditions for using a certain label are set by law rather than private agreement). E.g. some of the current organic farming labels are based on initiatives of private associations. Labels can also be developed by a private-public partnership, e.g. based on a joint analysis of quality issues in a certain sector. As with many other alternatives to regulation, financing may help to initiate voluntary labelling and marking.

Both mandatory and voluntary labelling can be linked to incentives, e.g. with regard to public tenders¹⁵. In order to reach a high-standard of voluntary labelling and marking, it is sometimes necessary to develop stringent draft regulation signalling the quality level expected.

4.2.2.3 – *Naming, shaming, praising and rating mechanisms*

Public rating creates an incentive for operators to perform better, even when the rating is made by a private institution (see e.g. [Euroncap](#)). Subject to the legal system, public rating undertaken by an authority may require a legal basis. Some types of ratings will hardly require a legal basis in any jurisdiction. E.g., authorities are normally free to rate chemicals according to their respective risk, and it can nonetheless have a strong regulating effect, steering away from certain products

¹⁴ See e.g. [Regulation EC/106/2008](#) of 15 January 2008 on a Community energy-efficiency labelling programme for office equipment.

¹⁵ See Article 6 of the same [Regulation EC/106/2008](#).

and favouring others (in the same way as specialised information systems do). We have seen under “incentives” that rewards can also constitute a behavioural incentive. Thus praising as a positive counter-part to shaming should not be neglected.

4.2.2.4 – *Training measures for operators, professionals or citizens*

Training for operators, professionals or even citizens can be cheaper and more effective than enforcement, above all if the number of operators or professionals is rather limited and if the legal or technological setting is complicated. Training can be provided, among others, by authorities, by business associations, by other associations, by conformity assessment bodies or by independent service providers.

4.2.2.5 – *Guidelines / interpretative documents*

In some sectors, geographic entities, authorities and private actors apply guidance as if it were regulation. If this is the case, it is no longer always necessary to develop regulation which is cumbersome to adopt and to update.

4.2.2.6 – *Supervision of geographic entities / authorities*

Supervision of geographic entities or authorities can also help to reach policy goals. If the geographic entities or authorities interpret the legislation differently, the supervision can be used to enforce one of the possible interpretations. A supervision measure against one geographic entity or authority can be perceived as a warning to others and can thus have a harmonising effect. A supervision measure aimed at the understaffing of enforcement agencies can increase the degree to which the geographic entities/authorities or operators comply with legal obligations if the lack of compliance is due to insufficient resources on the part of such agencies.

4.2.2.7 – *Empowering authorities*

Empowering authorities can take place in different ways, e.g. by training, by defending the independence of the authorities and by engaging in favour of a

sufficient staffing of the enforcement authorities, above all if they are influenced by politicians or by other administrations in the geographic entities. Authorities of geographic entities sometimes wait for the support of the central authority to defend their budgetary interests against the regional or local finance department. If the lack of staff at the regional or local level is the major system deficiency, such support measures by the Centre are of utmost importance.

4.2.2.8 – *Administrative bench-marking*

Administrative bench-marking is a tool by which administrations are compared to each other with regard to parameters or good practices. Manifold examples of administrative bench-marking can be found in the remit of the [OECD](#).

4.2.2.9 – *Coordination of geographic entities / authorities / conformity assessment bodies*

Coordination of geographic entities, of authorities and of conformity assessment bodies can help to reach a harmonised interpretation of law, a harmonised and equally stringent administrative or decision-making practice, an increase of average knowledge, better verification techniques (e.g. to counter fraud), more exchange of data so as to avoid double verification by different geographic entities, different authorities, or different conformity assessment bodies. Coordination can happen by means of more or less advanced electronic tools (from emails through wikis to databases). Where fewer tasks are centralised, the more coordination will be needed. However, coordination is also needed within big central authorities if different departments start developing their own practices and policies. The statement “different people have different views” also applies to central authorities even if the people are only half a corridor apart.

Who is best placed to coordinate? The answer is to be given taking account of the concrete situation, once available human resources, impartiality, abilities and system oversight of the candidates have been analysed. Often the central administration or agency acting on behalf of the central administration is best placed to coordinate. Sometimes coordination is better ensured by one of the geographic entities or administrations to be coordinated, e.g. if specific knowledge is required and if that knowledge is only available in a particular geographic entity or administration. Sometimes coordination happens by open P2P processes.

Very rarely, external service providers are used to ensure coordination. To get a deeper understanding of coordination, see the article [“How to harmonise decision-making of authorities and conformity assessment bodies?”](#).

4.2.2.10 – *Declarations announcing a political or regulatory intention*

These declarations can have an effect similar to regulations, though they are only intentions, not cast in law, and modifiable at any moment. An announcement stating that “in future public tenders, special attention will be paid to aspects of ...” or a press release indicating that “market access will be more severely regulated with regard to criterion X” will deter certain operators from investing and invite others to invest more, but on the basis of the anticipated future criteria. It goes without saying that the influencing effect will vanish if the institution or person making the declaration has lost its credibility. Reliability and trust is of the utmost importance. Declarations can be made publicly or in private towards representatives of the targeted persons or operators.

4.2.2.11 – *Press releases (e.g. on risks linked to products, services or behaviours)*

Press releases can provide information which influences behaviour of operators, of professionals or even of citizens. Many governments launch alerts regarding products which are disseminated via the media. Some of these alerts, e.g. those of the U.S. agency [FDA](#), have repercussions worldwide.

4.2.2.12 – *Classic awareness raising campaigns (e.g. regarding risks linked to products, services or behaviours)*

If a consumer is informed by classic awareness raising campaigns about the risk linked to the use of a certain type of toy, he will probably not buy it anymore. Even a shopkeeper might stop ordering that type of toy. Coming to know about potentially unsafe, though not yet banned products or chemicals and their comparatively safe alternatives might make manufacturers move away from unsafe substances without any regulation obliging them to do so. Unlike regulation, awareness raising campaigns can also deter from using products or chemicals which are suspected to be harmful, but cannot yet be banned as some evidence is still missing. Equally, they can deter from using products or chemicals during

the ban procedure. Classic awareness raising campaigns use the classic media like television, radio, and printed material disseminated by authorities, schools, trade unions, associations, NGOs etc. Classic awareness raising campaigns are nowadays deemed to be less efficient than internet campaigning, though internet campaigning does not reach certain parts of the population.

4.2.2.13 – *Internet campaigning*

The internet offers a large and ever expanding variety of tools to influence the behaviour of citizens and of operators. Besides classic websites and databases accessible online, authorities could, in theory, use short message services like Twitter. They could also proactively use social media to disseminate information that influences behaviour. They could share their views on fora and independent mailing lists. They could post comments here and there to draw attention to risks, legal requirements and indicators for non-compliance. Through all these tools they could also direct people to their domestic website which contains more solid and comprehensive information than what normally circulates via social media and the other tools mentioned thus far. However, subject to the legal system of the respective jurisdiction, there are legal constraints. Authorities might become liable for information that is not fully correct, not comprehensive or not totally fair. The legal benchmark for information activity of authorities might be very high. How can they circumvent the risk of liability? An elegant solution can consist of paying NGOs or media for undertaking information work. In many jurisdictions, NGOs and media have a lower liability risk as long as they act in good faith and in the boundaries of their mandate. But even in case of severe liability risks authorities should not necessarily shy away from alerting citizens or economic operators via the range of internet media listed. If the facts clearly indicate a high risk for persons, alerts are justified. In some jurisdictions there might even be a legal obligation to inform the public or operators of risks and non-compliances by all appropriate means, and this will include the internet media listed.

4.2.2.14 – *Information systems*

Information systems can be an excellent tool to influence the behaviour of certain target groups, be they professionals, operators, administrations or even citizens. See as an example www.ecoi.net which has influenced the decision making of asylum and refugee administrations, judges and attorneys on four continents since

1999. If information is clearly presented and is of interest to the target groups to make use of it, information may have the same behaviour-influencing effect as a legal obligation. As information can be presented faster than legal measures can be adopted, the behaviour influencing effect can even occur earlier.

4.2.2.15 – *Financial instruments*

Financial instruments can complement and partly replace regulatory tools. Accordingly, they should be integrated into the regulatory picture for a certain sector¹⁶.

4.3 Comparison of regulatory measures and selection of the right regulatory measures in individual cases

To compare the various potential measures, it is useful to assess the measures according to a variety of criteria which should include at least the following:

	Measure 1	Measure 2	Measure 3	Measure 4	Measure 5	Measure 6	Measure 7	Measure 8
Months needed to generate effects								
Longevity of effects								
Degree of binding effect								
Flexibility for adaptation								
Short term resources needed (launch)								
Medium term resources needed (implementation)								
Long term resources needed (maintenance)								
Type and availability of human resources needed								
Best to be used for								

The following chart indicates how some measures available in a certain nation state could be assessed:

¹⁶ Financial instruments have, on purpose, not been integrated into this Handbook. They constitute a field on their own and are very much subject to jurisdiction-specific rules.

	Legislation	Regulatory acts	Self-regulation	Supervision of geographic entities	Guidance documents	Information services / awareness raising campaigns	Voluntary labelling and marking	Press releases and alerts
<i>Months needed to generate effects</i>	12 to 48	6 to 24	12 to 36	3 to 24	3 to 24	6 to 18	12 to 36	1
<i>Longevity of effects</i>	very long	very long	medium	short to medium	short to medium	medium	long	short
<i>Degree of binding effect</i>	high	high	low to medium	high	low to medium	low	low	low
<i>Flexibility for adaptation</i>	low	medium	medium	low	high	high	medium	high
<i>Short term resources needed (launch)*</i>	high	medium to high	low	medium	low to medium	medium	low to medium	low
<i>Medium term resources needed (implementation)*</i>	medium to high	medium	low	medium	low	medium	low	low
<i>Long term resources needed (maintenance)</i>	medium	medium	low	low	low	low	low	low
<i>Type of human resources needed</i>	subject matter specialists lawyers negotiator	subject matter specialists lawyers negotiator	subject matter specialist negotiator	lawyers	subject matter specialists	subject matter specialists communication experts	subject matter specialists negotiators	communication experts
<i>Best to be used for</i>	setting a long-lasting legal framework	creating binding rules	setting binding targets whilst keeping the ways open	if reality lags behind a good legal standard	for legal interpretation or if guidance is followed as if it was law	fast evolving, complex information that can influence behaviour immediately	situations in which the public application of stable criteria influence operators	provoking ad hoc action of autonomous decision makers

* The resources needed will depend very much on the concrete measure.

In addition to the aspects listed above, what are the aspects that might or should influence the selection of measures? The measures taken should evidently not overstretch the available budget, one's own management or administrative capacity, or the enforcement capacities of geographic entities or administrations. If these aspects set limits, it is advisable to select the measures which are most cost-efficiently or capacity-efficiently pursuing the goals. Of course, the measures should not either overstretch the adaptation capacity of those who will be targeted by the measures and should not constitute a disproportionate burden for them. Finally, the selection of measures will have to respond to political needs such as acceptability by lobby-groups, decision making organs or committees and the wishes of politicians or of the heads of the administration.

5. THE METHOD OF REGULATING



*“Be creative while inventing ideas,
but be disciplined while implementing them.”*

Amit Kalantri

5.1 Analysing the issues of the sector

Taking regulatory measures without proper prior analysis of the issues resembles prescribing a medical treatment without diagnosis. Both in the regulatory and the medical world, it is risky to omit the analysis / diagnosis. The instinct of the physicist or of the regulator might be right in most cases. In some other cases, however, s/he would have detected by a proper analysis / diagnosis that the issue identified by her/him is not the real one, not the most important one or at least not the only important one. Consequently, s/he might have taken other measures than the ones s/he took or s/he might have modified elements of the measure taken.

Hereafter, readers will find a list of questions which may help to get a more complete picture of the situation of their sector. Ideally, readers will take time for each of the questions raised – a slow approach ensures a deeper insight. Furthermore, readers might consult stakeholders on their views with regard to the identified questions and the sector as a whole. Stakeholders often have a different perspective than the officials in charge. A stakeholder consultation can take place in the classic written form or in more modern, participatory forms. More on the latter is to be found in Sections [5.5](#) and [14.1](#).

5.1.1 – The questions helping to analyse the sector

5.1.1.1 – *Up-coming developments – presenting the future*

Which new developments are to be expected for your sector in the years to come, e.g. in terms of:

- ◆ technology?
- ◆ economy?
- ◆ behaviour of today's actors?
- ◆ entry into play and behaviour of new actors?

5.1.1.2 – *The landscape of political operators*

Describe the landscape of political actors:

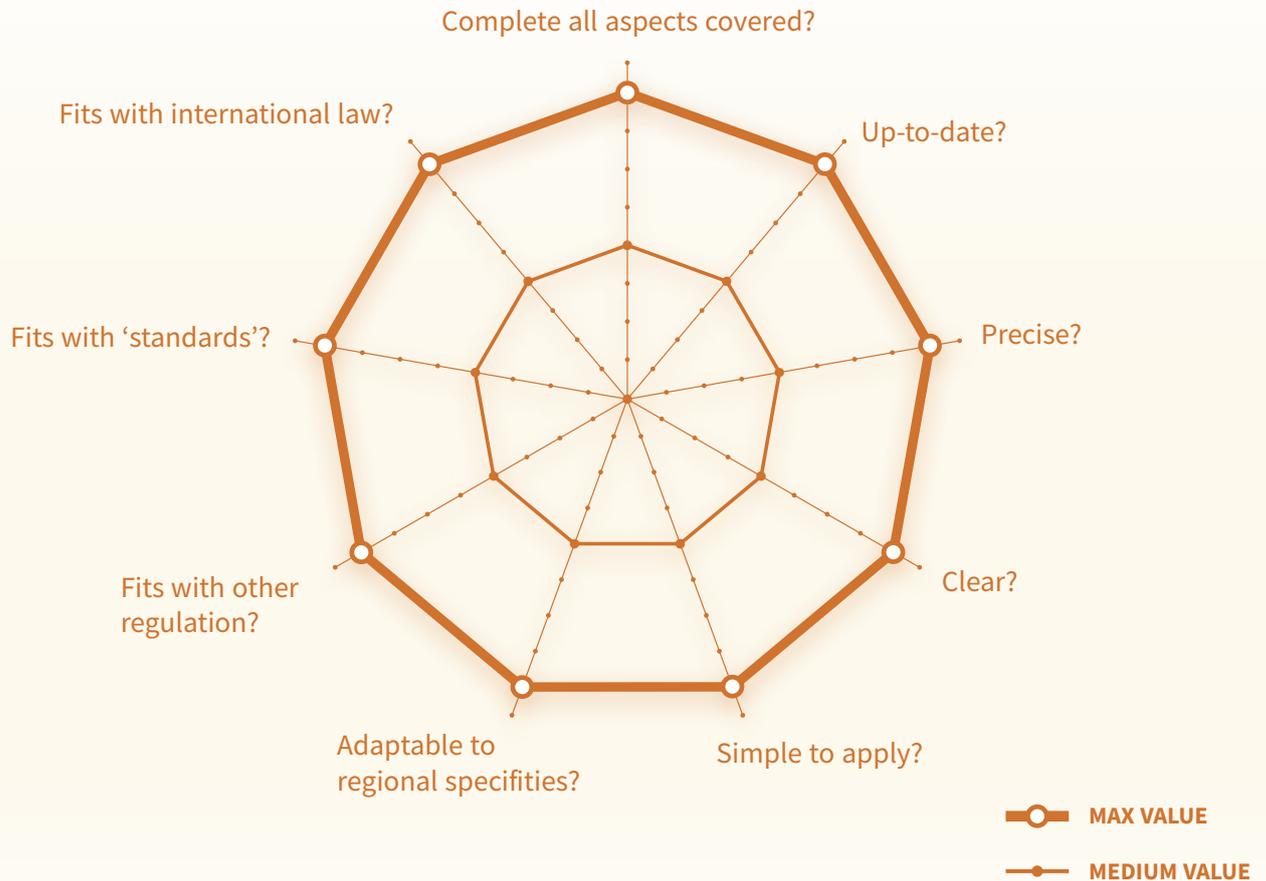
- ◆ Who has some control or influence? Describe the control or influence.
- ◆ Who are the leaders? What are their interests?
- ◆ What are the interests of the “heavy-weights” amongst the followers?
- ◆ What are the interests of the other followers?

5.1.1.3 – *The state of the current regulation*

- ◆ Is the regulation complete? Does it deal with all relevant aspects?
- ◆ Is the regulation up-to-date? Does it take account of recent and upcoming technological, economical or other developments?
- ◆ Is the regulation precise?
- ◆ Is the regulation clear?
- ◆ Is the regulation simple to apply?
- ◆ Is the regulation optimised as to its adaptability to regional specificities?
- ◆ Is its relationship to other regulation optimised?
- ◆ Is its relationship with or reference to international standards or similar documents optimised?

- ◆ Is its relationship to international treaties optimised?

Insert your estimations into the following graph – the better the performance, the further to the outside:



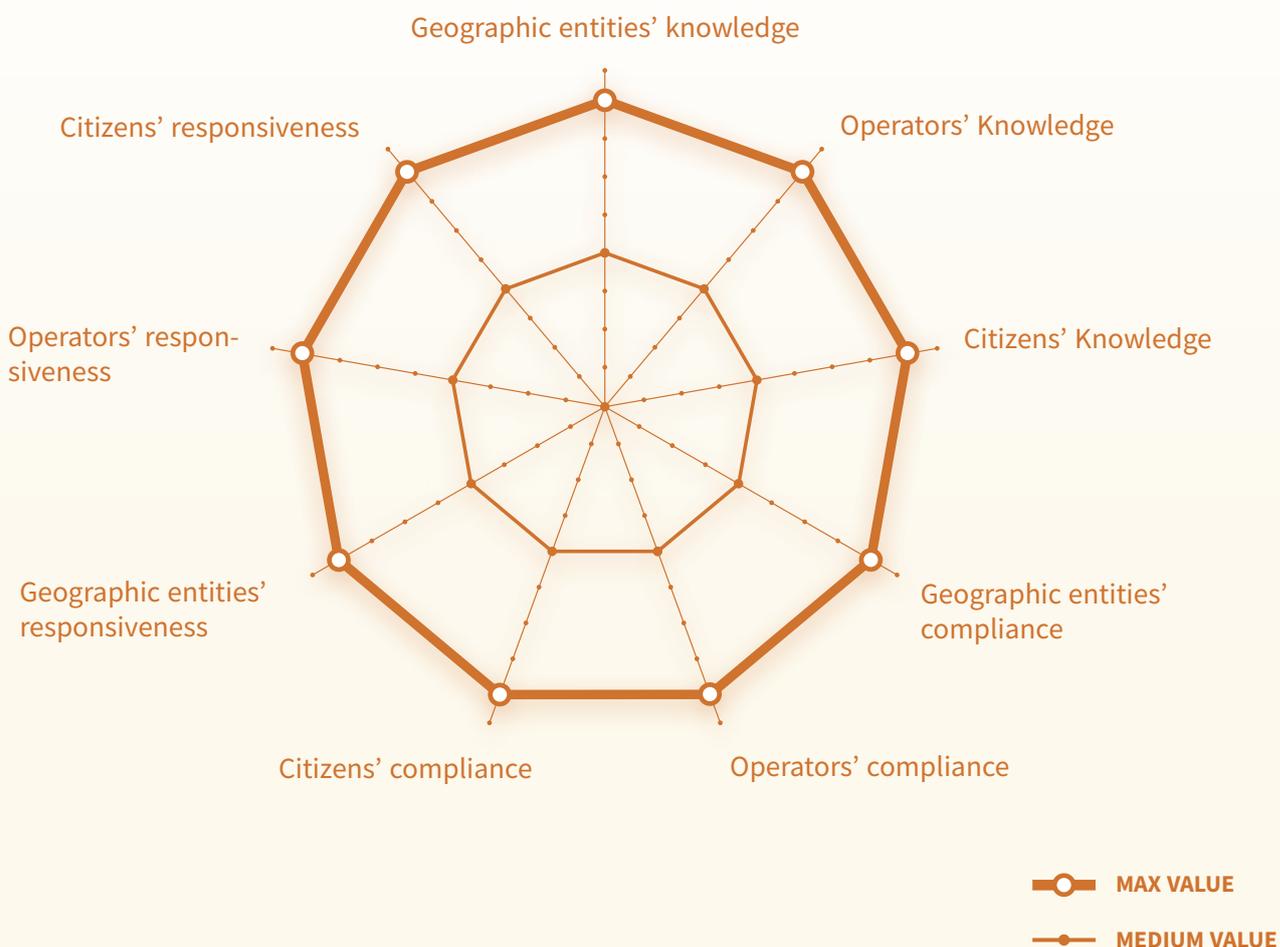
The analysis of the current legal system can be enhanced by the use of artificial intelligence, see [this report](#) of the New South Wales Treasury from July 2020. Artificial intelligence has been used to identify outdated mechanisms and words, potentials for burden reduction and simplification, inter alia by eliminating duplication.

5.1.1.4 – Knowledge, compliance and responsiveness

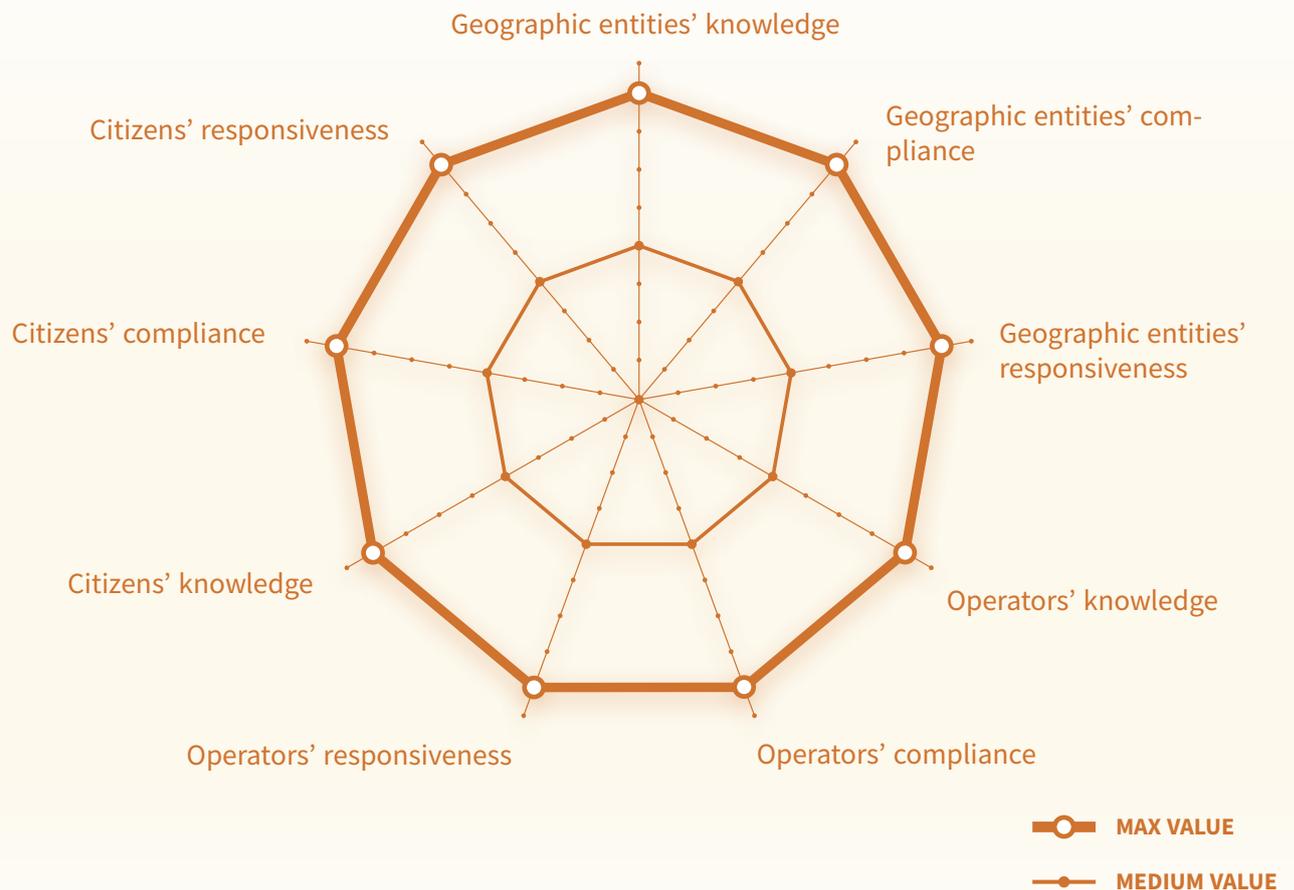
- ◆ How well do geographic entities know their rights and obligations?
- ◆ How well do operators know their rights and obligations?

- ◆ How well do citizens know their rights and obligations?
- ◆ To what extent do geographic entities comply with their obligations?
- ◆ To what extent do operators comply with their obligations?
- ◆ To what extent do citizens comply with their obligations?
- ◆ How responsive are geographic entities to soft steering (e.g. via guidance, recommendations and information)?
- ◆ How responsive are operators to soft steering (e.g. via guidance, recommendations and information)?
- ◆ How responsive are citizens to soft steering (e.g. via guidance, recommendations and information)?

Insert your estimations into the following graph – the better the performance, the further to the outside:



In order to see whether the deficiencies are specific to a certain target audience, also insert your estimations into the following graph – the better the performance, the further to the outside:



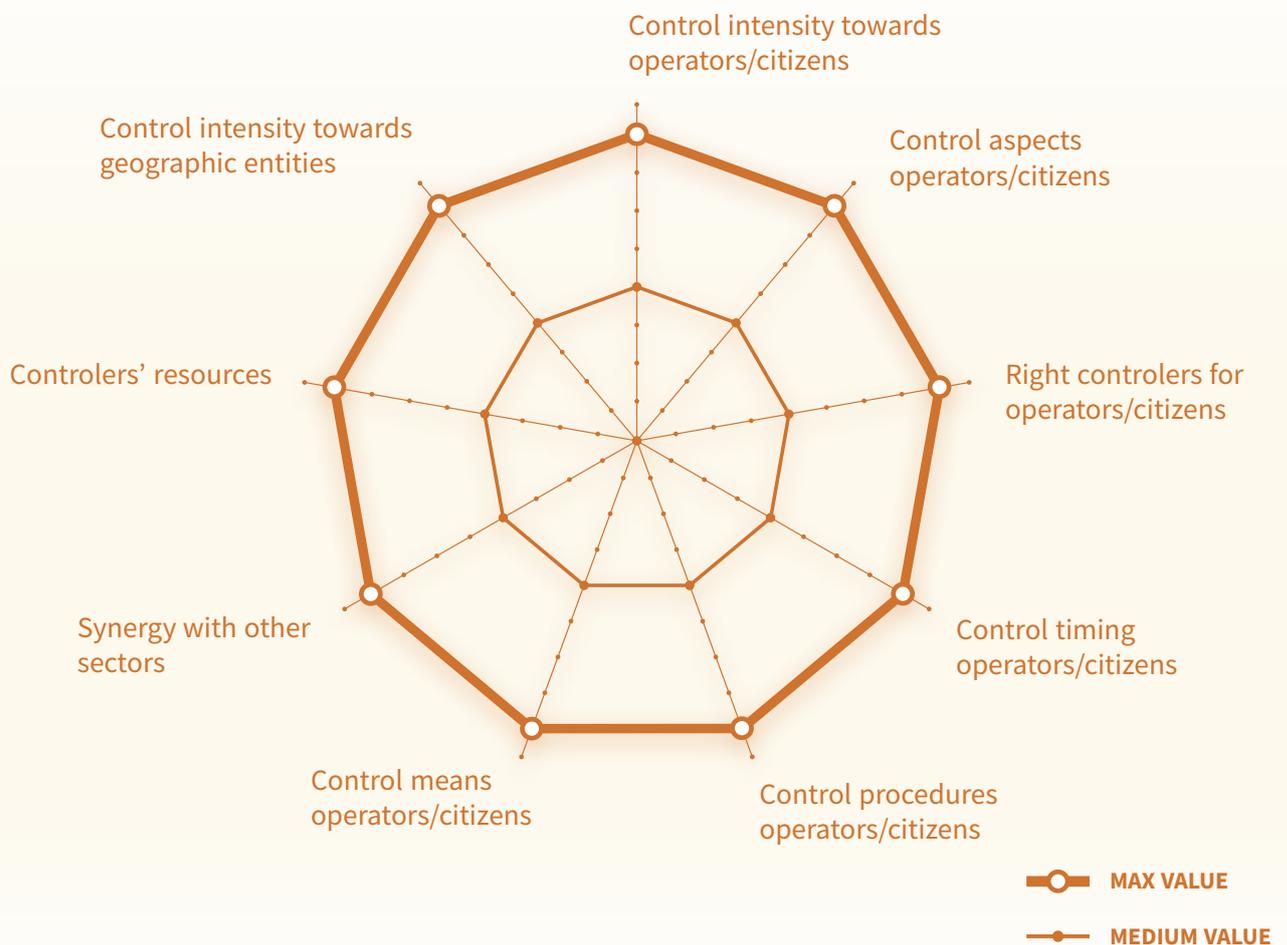
5.1.1.5 – Verification

Is the verification of compliance of operators and of citizens:

1. intense enough?
2. targeting the right aspects?
3. executed by the right authorities or entrusted to the right private bodies?
4. executed at the right time and the right step of the processes regulated?
5. executed in the right procedure?
6. provided by the right means?

7. optimised in terms of synergy with other sectors' verification and supervision?
- Do the authorities or entrusted private bodies have enough staff, equipment and money at their disposal to efficiently execute their verification and supervision function?
 - Is the verification of compliance of geographic entities intense enough?

Insert your estimations into the following graph – the better the performance, the further to the outside:



5.1.1.6 – Top problems and potentials

Looking back at the answers to questions listed in [5.1.1.1](#) to [5.1.1.5](#) or other weak points identified:

What are the top five problems of the sector?

What are the top three development potentials for the sector, taking upcoming developments into particular account (see [5.1.1.1](#))?

5.1.2 – Follow-up to the analysis: first steps towards a response

There are many ways to find responses to the outcome of the analysis. Basically, all management approaches can be applied. We present here an approach that is item-oriented and an integral approach. Both approaches can also be combined. One can also use one method to verify the result of the other.

5.1.2.1 – *The items-oriented approach*

- ◆ What are the necessary political, legal, managerial, and informational steps and means to solve each of the top five problems?
- ◆ Which of the steps and means identified for the previous question are useful or even necessary to resolve more than one problem?
- ◆ What are the necessary political, legal, managerial, and informational steps and means to realise each of the top three potentials?
- ◆ Which of the steps and means identified for the previous question are useful or even necessary to seize more than one potential?
- ◆ How can the relevant steps and means best be combined so as to strengthen one another?
- ◆ Can some of the non-top-five-problems also be elegantly solved?
- ◆ Is it even necessary to integrate solutions to the non-top-five-problems, e.g. to avoid negative repercussions on the system?
- ◆ What resources do we have at our disposal, at the level of the Centre and in the geographic entities?
- ◆ How can the available resources be used so as to optimise the system?

The items-oriented approach is the one that many of us instinctively apply. It provides a feeling of “being in control of things”. However, we tend to limit the number of problems that we are willing to analyse or process. Accordingly, there is a risk of overlooking “secondary”, non-top-five-problems, or to underestimate the systemic relevance of such problems. To illustrate this with an analogy: if you

have to repair a pot with many holes, it might give you a good feeling to repair the five biggest holes, but the pot still cannot be used after your attempt to repair it.

5.1.2.2 – *The integral approach*

- ◆ What would be the best scenario that you can imagine for your sector for the next five and for the next ten years?
- ◆ What would be the second best?
- ◆ What resources are needed to ensure that these two scenarios will become a reality?
- ◆ Which elements of the scenarios are important, but can be realised with few resources?
- ◆ Which elements of the scenarios are important, but need many resources?
- ◆ Which elements of the scenarios are less important, but can be realised with few additional resources?
- ◆ What resources do we have at our disposal, both at the level of the Centre and in the geographic entities?
- ◆ How shall we use the available resources so as to optimise the system?

If readers find it difficult to answer the questions raised in [Subsection 5.1.2](#) without thinking of concrete measures, they are invited come back to these questions once they have read the other parts of this chapter in which the various types of measures are presented.

5.1.3 – Examples

The training sessions on regulatory techniques that were based on the first edition of this Handbook contained a practical part. In this practical part, one, two or three real cases were presented by the participants and analysed in group work. Though this type of mini-analysis is not as systematic and comprehensive as the previously outlined sector analysis, the experience gained in the group work illustrates why a sector analysis is useful: it triggers a new perspective on the issues. During the group work, the primary topic was often shifted and always comple-

mented by secondary topics. Mostly new candidate measures were identified. The following, partly fictional¹⁷, examples illustrate this.

5.1.3.1 – Example 1: “The method gap”

When the training course participant presented her case to her peers, she feared that the parliament would accuse her department of being inactive with regard to risks linked to the size of particles used as coating for certain devices falling under the relevant sector regulation. The sector regulation indeed had no provisions on micro- and nanoparticles, but contained general clauses which could be understood as obliging one to reduce risks linked to particle size. Evidently, no specific risk evaluation methods were set out. Individual manufacturers have undertaken research both on risks and risk assessment, but were reluctant to share the results. They feared that their products would be regarded as unsafe by authorities. To anticipate pressure from the parliament, the superior of the participant wanted to launch an amending regulatory act. The participant felt uncomfortable: what should the regulatory act be about given that risk assessment methods were not yet well established? And how could the method, once laid down in the future regulatory act, be updated given that science was still evolving so fast? Despite these questions, she was constantly thinking in terms of an amending regulatory act.

After the discussion with her peers, the participant came to the conclusion that, instead of adopting a new regulatory act, it would be more appropriate to draft a short guidance document explaining why and how risks linked to particle size were to be evaluated under the current regulation. In parallel thereto, she envisaged developing, together with the industry and stakeholder associations, a website that would inform users of the methodological state of the art. Beyond scientific literature, industry methodological instructions, so far kept secret, would also be made available in an anonymised form by the respective industry association. The sector could thus defend itself against pressure from the parliament by demonstrating that law cannot contain more than the general safety requirement which already exists, that this general safety requirement is basically sufficient and that the crucial issue of methodology can best be dealt with by a dynamic internet based information platform.

¹⁷ The real cases were modified in such a way (e.g. by changing topics and merging similar cases) that the text presented here cannot be regarded as representing a real situation whilst still exemplifying the learning effects of analysing the system.

5.1.3.2 – *Example 2: “No empowerment for the real thing”*

The participant presented a dilemma: she had to deal with a three-step decision making and information process. There was an empowerment to regulate by regulatory acts the second and the third step which both dealt with pure information transmission. However, there was no empowerment to regulate on the first which was the crucial step in the process. The crucial first step fell under the competence of geographic entities. Geographic entities were extremely vigilant as to their prerogatives in this respect. Unfortunately, the steps 2 and 3 could not be correctly processed unless the communication regarding step 1 is standardised and channelled. Otherwise there would be a high risk of misunderstandings and mistakes.

In the discussion with her peers, the view was broadened. Instead of simply reflecting in terms of instruments (“Which tool to choose?”), the entire process was looked at. The question arose: How to convince geographic entities to manage all three steps in an integral way? A solution consisted in developing a form and making it mandatory for steps 2 and 3. But this form should also cover the communication needs of step 1! Geographic entities could of course decide not to use the form for step 1, but the form would allow them to economise in terms of time and human resources. Furthermore, it would be risky for them to use another form just for step 1: mistakes could occur when transferring data from this other form to the form to be mandatorily used for steps 2 and 3. Thus it would be simply irrational for geographic entities not to also use the form for step 1. Finally, by presenting the criteria relevant for step 1 in a non-binding way in the form, it might even influence the substantive decision making for step 1. Although there is no formal empowerment to regulate for step 1 and the criteria to be applied therein, the simple informal listing of all relevant criteria might have a harmonising effect on the practice of the various geographic entities.

5.1.3.3 – *Example 3: “Not only clarification needed”*

According to the initial view of the participant, there was a need for legal clarification with regard to certain rules. This was perceived as the major issue by the course participant when he presented his case. The clarification could be achieved by new legislation or by guidance. A deeper analysis showed that some operators, namely those based outside the jurisdiction, were not willing to comply with the existing rules or were not even aware of them. Nor would they respect new guid-

ance. Clarification by new legislation would not be better unless the enforcement by certain geographic entities was strengthened. Thus the enforcement came into the focus of the course participant.

At the end of the case study, the participant recognised that new legislation would further deepen the already uneven playing field, unless the new legislation were to set up minimum resource and activity requirements for authorities in charge of ensuring compliance. The participant seemed more inclined to investigate possibilities of exerting pressure on certain geographic entities with weak authorities so as to get them to increase their enforcement efforts. The question of whether new legislation was needed for purposes of clarification or whether guidance would be sufficient remained open for the time being. But the participant could not exclude the fact that, with stronger enforcement, guidance might be sufficient. Thus he left the course with the intention (1) to firstly check possibilities of exerting pressure on geographic entities to address the enforcement issue. If this was successful, he would (2) need to assess whether guidance would be sufficient to reach the clarification goal. Only if (1) or (2) turned out not to work would he suggest to his superiors the proposal of new legislation (3). But this legislation would have a second chapter on the geographic entities' enforcement obligations to address the newly identified issue of enforcement.

5.2 Identifying the policy goals

Policy goals can either be predetermined, e.g. by politicians or superiors in the administration (5.2.1), or still to be determined (5.2.2).

5.2.1 – Analysing predetermined policy goals

Officials working for administrations are often told to follow a certain policy goal. In this case it is useful for identifying the appropriate regulatory measures to analyse what is behind the set policy goal: the “goals behind the goals”, so to speak. Some of the “goals behind the goals” build chains. The goals which do not depend on other goals, at the end of the chains, shall be called primary goals in this text. The goals which are between the primary goals and the officially set goals shall be called intermediate goals.

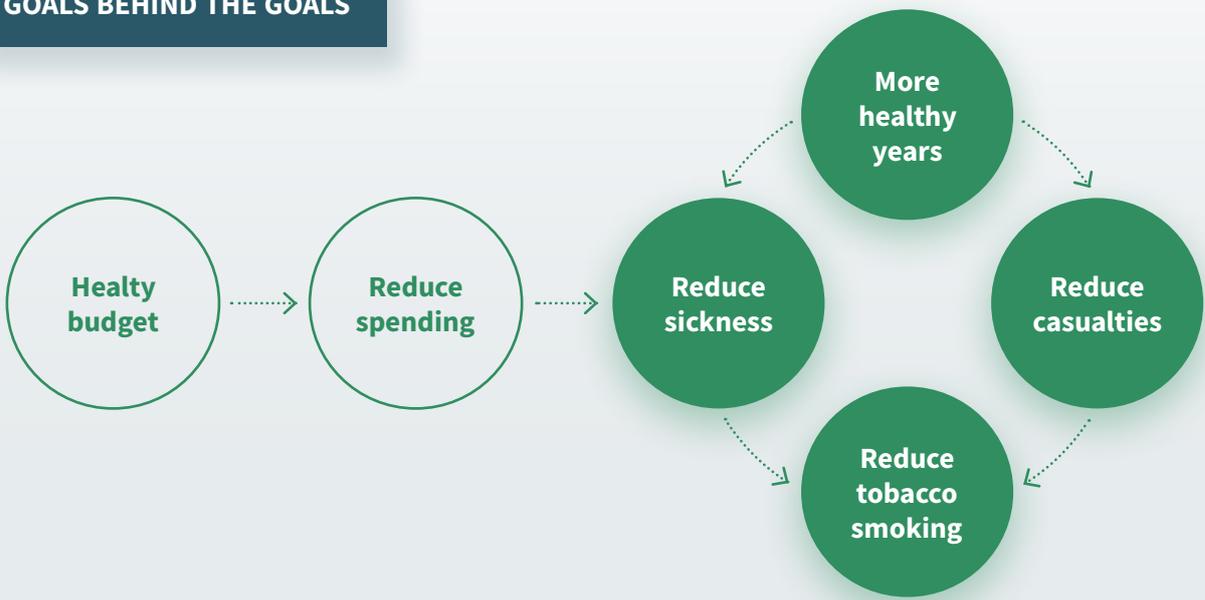
Let us take a simple example: politicians may declare the following goal to be pursued: “to reduce tobacco smoking as much as possible”. Behind the declared goal we can identify two other goals: to reduce casualties and to reduce illness.

GOALS BEHIND THE GOALS



But these two goals might just be intermediate goals. They might have, subject to the views of the politicians, a common primary goal: to increase the number of healthy years in life. Behind the second intermediate goal is another intermediate goal: to reduce public spending on health. Behind this goal, there is another goal: to achieve a healthy public budget. This goal can be regarded as a primary goal.

GOALS BEHIND THE GOALS

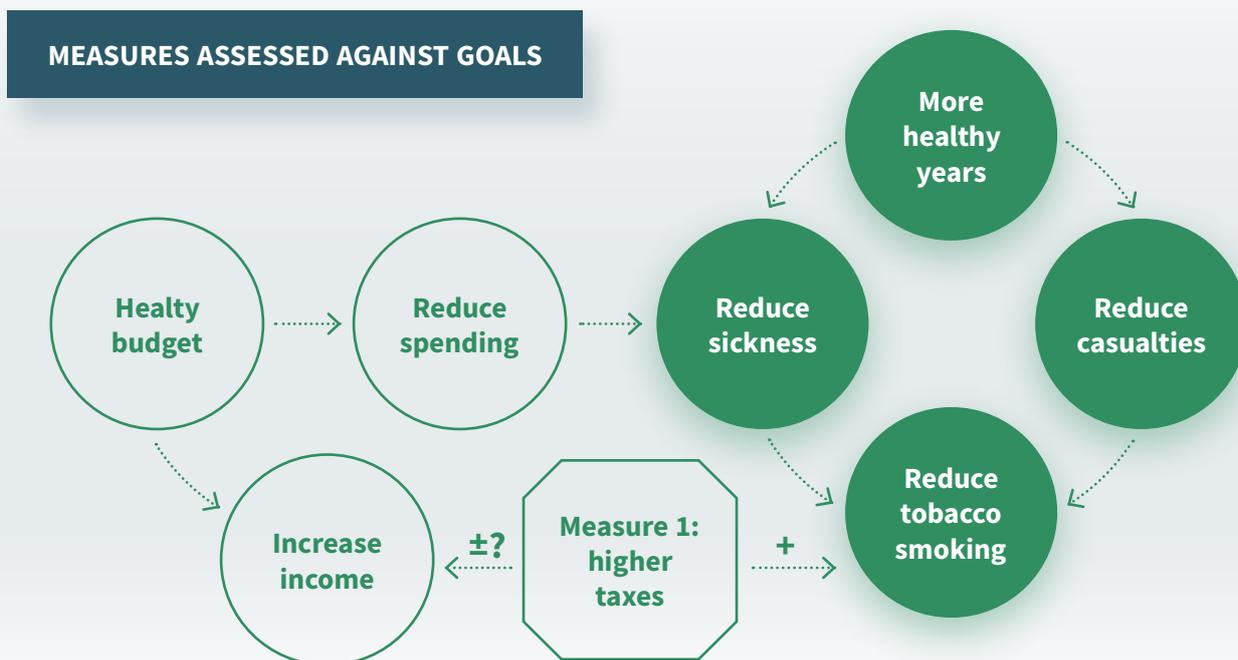


To see how the analysis of primary and intermediate goals can widen the range of policy choices, let us examine an imagined case. Imagine that an official in an autonomous nation state's ministry is in charge of proposing measures *“to reduce as much as possible the use of smoking tobacco”*. S/he has so far considered a panel of possible measures:

- ◆ Increase taxes¹⁸ on tobacco products, creating a financial incentive to smoke less;
- ◆ Offer lower health insurance rates for non-smokers, creating another financial incentive to smoke less;
- ◆ Oblige manufacturers of tobacco products to place warnings and deterring images on the packaging with a view to deterring smokers;
- ◆ Launch information campaigns managed by media, health insurances and schools; and
- ◆ Offer anti-addiction courses (e.g. managed by health insurances).

Let us look at the first of the possible measures. Increasing taxes on tobacco will increase the overall tax revenue, but it will only increase it up to a certain taxation rate. From a certain taxation rate onwards, any further increase will decrease the overall revenue, as economists have found out and as the political reality in some high tax states has also proven. This is because the taxation rate becomes either too prohibitive or because it becomes too appealing to commit tax fraud when taxes are extremely high. Accordingly, from a certain level onwards there can be a conflict between “creating by higher taxes a financial incentive for not smoking” and “increasing the overall revenue”. As the official has detected this potential conflict, the official may quantify the two contrary financial effects. When doing so, the official can also analyse secondary financial effects of the measure, namely the effect of the costs of less smoking on the health insurances. Different theories have been circulated in this respect: subject to the overall costs triggered by an increased longevity, health insurances might win or lose with the increased taxes.

¹⁸ We use here the commonly used expression “taxes” although “excises” would be the right expression in most states.



Even when higher taxes have a negative financial effect overall, it might be good for the health of the population to increase the taxes beyond the critical level. Thus the official can offer the politicians a useful choice to make: optimise revenue or optimise positive health effects or choose a compromise in between.

A similar analysis can be undertaken for the four other measures that our official is considering. All the other four measures will evidently cost money. Their respective benefit-cost-ratio merits can be examined individually and comparatively (comparing the measures against each other) so that the politicians (or the administrative decision maker) can select the most cost-efficient ones.

Thus we can deduce already from this relatively simple example that knowing the primary goals of the politicians can trigger second thoughts. The official can offer the decision maker(s) a wider range of measures and thus a wider choice. S/he can point out trade-offs that nobody would have detected without analysing the primary goals of the politicians.

In a second example, we will go further and show that the analysis of the goals can even trigger collateral measures which are useful to optimise the pursuit of the goals. Let us imagine a fully autonomous nation state with some domestic oil production and the power to fix oil prices on the internal market. In this state, politicians are in favour of the goal: “reduce private transport in cars”.

The politicians are in favour of this goal for a wide range of reasons:

- ◆ Some politicians wish to reduce congestion with a view to reducing the loss of working-time of employees.
- ◆ Some wish to slow down climate change.
- ◆ Some wish to reduce toxic pollution and noise in cities to avoid illness and casualties.
- ◆ Some wish to reduce the number of accidents in order to avoid injuries and casualties.
- ◆ Some wish to keep the internal fuel prices low. In this group, the politicians follow different primary goals: some wish to keep industry production costs low, some have the same wish for agricultural production costs, and other politicians aim at keeping food prices low so that the poor can afford their food¹⁹.

The immediate response to the request of the politicians could consist of suggesting the following measures:

- ◆ Increase the price of petrol and diesel on the internal market;
- ◆ Establish a vehicle taxation system which is based on fuel consumption as primary or sole parameter;
- ◆ Limit the right to circulate in a certain car to every second working day in order to promote commuter communities; and
- ◆ Tax or circulation right privileges for electric cars or for cars with fuel consumption at least 50% below the average.

But in view of the primary goals pursued by the politicians, more (groups of) measures could be offered:

- ◆ In view of local noise and toxicity reduction: Introduce limitations for car circulation subject to noise and fuel consumption (no cars with medium or high noise or toxic emissions in the inner city, no cars with high noise or toxic emissions in cities at all);

¹⁹ There is a double correlation between food and oil prices: a high oil price makes food production more costly and agricultural surfaces can be used either for food or bio-fuel production, thus both markets are linked.

- ◆ In view of reduction of cancer provoking fine particles mainly emitted by diesel engines: give an incentive to use petrol instead of diesel cars, either by tax incentives or by extended circulation rights; and
- ◆ In view of industry and agricultural production costs: determine different price levels for oil, subject to its use.

In addition, the official can inform his superiors or the politicians of the subtle trade-off which has to be made in order to optimise the result in view of the different, partly conflicting goals. Here are two of them:

- ◆ Weight is an important factor for fuel consumption of vehicles. But safety features increase weight.
- ◆ NOx optimisation of engines is to a certain limited extent counter-productive for fuel consumption reduction and vice-versa.

We stop the analysis here as we do not aim at presenting all possibilities and side-effects. We simply aimed to show that the analysis of primary and intermediate goals can lead to new measures and to the optimisation of measures.

5.2.2 – Determining further policy goals

Even if some goals are pre-determined by politicians or the head of the administration, officials should examine whether further goals need to be determined or spelled out (sometimes goals have not been consciously set, but are implicitly expected). It is very unlikely that the politicians or the head of the administration have undertaken a complete analysis of the sector, that they are aware of all the problems and that they see all the possible positive developments (potentials). By examining whether further goals should be set, officials can inform their superiors and/or the politicians of further possibilities to improve the sector.

The best basis for setting goals is the analysis of the sector. Each of the problems identified in the sector analysis can be turned into a goal. But one should not limit oneself to the problems. As we have also seen in the sector analysis, there can be potentials for improvement which are not linked to a problem.

If properly done, a sector analysis will detect so many problems and potentials for improvement that it is hardly possible to manage them all in the regulatory

process. Therefore, it can be advisable to split problems and potentials into two groups: major and minor issues.

5.3 Determining objectives, measures, requirements and incentives

To illustrate what is meant by “objectives”, “measures”, “requirements” and “incentives”, let us use an example. Imagine that local politicians have decided to pursue the political goal “to reduce the number of traffic accidents in town”. Together with the local administration, they have developed different objectives that are deemed to concretise the goal. One of the objectives is to ensure that vehicles do not drive too fast. One of the requirements concretising this objective could be: vehicles should not drive faster than 30 km/h in an area of 100 meters surrounding schools. Respect of the requirement shall be ensured by three measures:

- ◆ Establishment of a zone with reduced maximum speed by speed limit indications;
- ◆ Enforcement of the speed limit by radar surveillance, vehicle identification and financial sanctions; and
- ◆ Establishment of radars displaying: “Thank you for respecting the speed limit”.

The first two measures are based on the incentive “avoid sanctions”. The last measure uses the incentive “praise”.

Once the goals have been determined, officials might think of determining the objectives. Objectives are, like goals, determining targets, but they are more concrete and measurable than goals. Objectives are sometimes explicitly laid down in regulation²⁰. Determining objectives can be mandatory according to the planning or impact assessment mechanism of the respective jurisdiction. However, objectives are not always necessary for the identification of measures, requirements and incentives. If the goals are already quite concrete, it might be easier to skip the level of objectives and think immediately in terms of measures, requirements and incentives. Furthermore, it is sometimes impossible to establish ambitious but realistic objectives without having examined requirements, their incentives and the measures which are to refer to them. If the enumeration of objectives is

²⁰ See as example Article 2 of the [Uruguayan Law N° 19855 on alcohol consumption](#) (Creacion de marco regulatorio para el consumo problematico de bebidas alcoholicas) of 23/12/2019.

mandatory according to applicable regulatory policies, but the official does not need them for his personal planning, the official might also proceed without enumerating the objectives and might deduce the objectives later, thus filling in the gap for the official planning process or impact assessment.

Is it best to start with the measures, requirements or the incentives? It is difficult to establish an order that is valid and best for all cases. Instinctively, one might think that measures come first. But starting with the measures might focus the view automatically on the requirements and incentives that fit with the measures identified. Other requirements and incentives are lost to sight. Accordingly, it might be better to note the measures which have come to mind naturally when doing the system analysis or the analysis of the goals, but to put these measures “into the fridge” until the requirements and incentives have been analysed and cast into measures.

As for the order in which requirements and incentives should come, it is advisable to undertake two exercises:

- ◆ Examining requirements and attributing to them the appropriate incentives; and
- ◆ Identifying suitable incentives and inventing appropriate requirements. These requirements invented on the basis of incentives may differ from the requirements so far identified under the first indent. They may differ in nature or in terms of stringency.

Once the requirements and incentives have been identified, one can think anew on the measures. It is possible to deduce appropriate measures from the requirements and incentives. During this exercise, one may also reflect on the measures that were put aside. If some of the latter do not match with the requirements and incentives whilst still felt to be worthwhile, there is a certain likelihood that some requirements and incentives have been missed in the previous step. Here again, double-checking and back-tracking may help to identify loopholes.

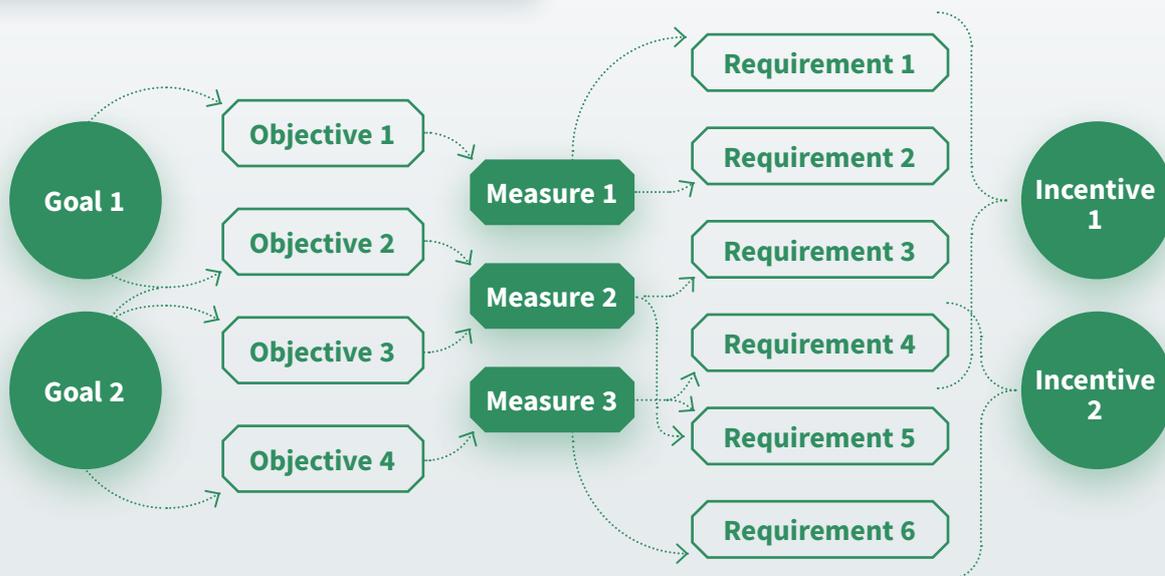
Whatever order has been chosen, it is always advisable to try, in addition, a different starting point. Different starting points usually lead to the identification of additional requirements, incentives and even measures. By using different starting points, there is a wider choice and therefore more possibilities to get positive policy results. The use of this method reduces the likelihood of missing opportunities.

5.4 Keeping the oversight on goals, objectives, measures, requirements and incentives

We have seen, by the sheer number of parameters presented so far, how complex decision-making can be. We will see throughout the Handbook how these and many more aspects can be taken into account content-wise and how they are interlinked. How can one maintain oversight and perspective?

One way to maintain oversight and perspective is to write the different goals, objectives, measures, requirements and incentives on cards and to pin the cards on a wall, board or big sheet of paper. Goals would be placed on the left, objectives on the medium left, measures in the middle, requirements on the medium right and incentives on the right²¹. All five should be linked by lines or arrows going from left to right or right to left to express relationships and impacts. Accordingly, the best vertical arrangement is the one with the least crossing of lines. The least crossing of lines can often best be achieved if similar goals are close to each other, if similar objectives are also close to each other etc. A similar picture can of course also be developed electronically. The downside of the method is: one needs a lot of space. The major advantage is the visual impression.

OVERVIEW ON GOALS, MEASURES ETC.



²¹ It is possible to extend the graph even further so as to include information and enforcement tools. These tools will be dealt with in [Section 11.1](#).

Another, more classic way consists of numbering and listing the different goals, objectives, measures, requirements and incentives in separate charts and indicating how they are linked:

THE CHART OF GOALS*

Goal No	Goal title / description	Rationale / remark	Concretised by objective(s)	Leading to measure(s)
G1			e.g. O1, O2	e.g. M1, M3, M4
G2				
G3				
G4				
G5				

THE CHART OF OBJECTIVES*

Objective No	Objective title / description	Rationale / remark	Serving goals	Leading to measure(s)	Applying requirement(s)
O1			e.g. G3	e.g. M4, M5	e.g. R2, R5
O2					
O3					
O4					
O5					

THE CHART OF MEASURES*

Measure No	Measure title / description	Rationale / remark	Serving goals	Serving objective(s)	Applying requirement(s)
M1			e.g. G3	e.g. O4, O5	e.g. R2, R5
M2					
M3					
M4					
M5					

THE CHART OF REQUIREMENTS

Requirement No	Requirement title / description	Rationale / remark	Set up in measure	Applying incentive(s) (describe e.g. based on following typology)
R1			e.g. M3	
R2				
R3				
R4				
R5				

THE CHART OF INCENTIVES

Incentive No	Incentive title / description	Rationale / remark	Used in measure(s)	Used in conjunction with requirement(s)
I1			e.g. M3	
I2				
I3				
I4				
I5				

* For these charts: subject to whether objectives are used or not in the planning process of the respective jurisdiction, the column on objectives can be skipped or deleted.

5.5 Finding the right regulatory process

There is not yet a commonly recognised process for regulating. We cannot validly establish a method either. However, we can describe what happens in practice once the political goals have been set or identified and once the sector has been analysed (5.5.1). Based on the description, we will identify a range of approaches with regard to different parameters (5.5.2).

5.5.1 – Description of regulatory processes

Regulatory processes can focus on major issues (problems and potentials) or on dealing with all issues.

They can be run “top-down” (by deduction) or “bottom-up” (by induction) in terms of their content. The “top-down” approach consists in determining the abstract political goals first, then more concrete objectives. From the objectives individual measures and particular requirements in the measures can be deduced. The “top-down” approach is often followed when there are pre-determined political goals. But even when there are predetermined political goals, there can be some openness to arguments derived from the sector analysis. There can also be openness as to the fine-tuning of the political goals. All this very much depends on the political context and leadership of the administration. Rarely are regulatory processes run 100% top-down.

A process without predetermined political goals is more likely to follow the opposite inductive method “bottom-up”. It consists in identifying what could be required to improve the sector (e.g. based on the sector analysis and examples of other jurisdictions and examples of other sectors of the same jurisdiction). The attribution of the requirements to various measures comes next. Therefrom officials can deduce the political goals, with or without passing by the intermediate step of “objectives”. The political goals and measures are thereafter offered to the persons politically responsible for decision-making.

The regulatory process can be more or less driven by political considerations. To give an example of a political consideration: politically responsible persons sometimes prefer to take ineffective measures rather than no measures simply to give the impression that “something is being done about the problem”. This happens in the field of security policy.²² Politicians must care about the feeling of insecurity because this constitutes a political risk. They tend to be in favour of visible measures even if the security specialists are of the view that security is not improved by the measure, e.g. because the measures can be easily circumvented. This attitude of politicians is legitimate – they have to care about the political risks as well as the actual risks. The sector specialists have naturally the actual risks in mind. Political considerations come second.

The regulatory processes can be open to options or be directed towards a predetermined result (which can either be political or not). The more they are open to options, the higher the likelihood that the processes overstretch the working and processing capacities of those involved. In case of complex issues or in cases in which a high number of issues need to be dealt with, the intellectual and psychological absorption capacity of those involved also plays a role. Above all, in comprehensive legislative projects the participants sometimes cannot bear more complication or options and therefore agree to proposals without checking alternatives or add-ons. The capacity limitations of the persons involved can become the decisive factor in the outcome of a process, particularly if there was not wise budgeting of the capacities at the beginning of the process.

Very often both the decision on the measure(s) to be taken and the content of the measure(s) are influenced by one single example of the past, of other sectors

²² See Fiona HAINES, *The Paradox of Regulation*, Edward Elgar Publishing, Cheltenham (UK) 2012.

or even of other jurisdictions. This might lead to a biased approach unless one strives for a broader comparison of the measures and requirements of different sectors or even of different jurisdictions.

Regulatory processes can be fast or slow and thus more reflective. Most regulatory processes accelerate. But some processes accelerate fast, some slowly.

Regulatory processes can have one single track, one single track with various (auxiliary) sub-tracks or several tracks that go their own way.²³ A single-track approach facilitates the overview of all representatives on what is going on. A multi-track approach can speed up the overall process. But it can also lead to mismatches, frictions and duplication. The single-track approach combined with sub-tracks seems to be the best intermediate solution, but it can also lead to duplication. What has been stated by a group of delegates in charge of a sub-track is often questioned by the delegates of the main track. Discussions may start again.

Regulatory processes can have more or less cross-references, e.g. amongst different tracks, or loop-backs (sometimes this is useless duplication, but sometimes it is necessary for adjustment).

Regulatory processes can be more or less influenced by requirements for impact assessments or planning instruments used in the administration.

The regulatory processes can be more or less open for stakeholders and be more or less participatory, meaning open to contribution based on equality of all participants. For these aspects of regulatory work, see [Section 14.1](#).

Finally, regulatory processes can be based on electronic working tools like wikis or be prepared in classic ways.

5.5.2 – Developing a tailor-made regulatory process

The various parameters can be listed in a chart. By marking crosses between the extremes, readers can determine in advance how their regulatory process should look. They thus develop their own tailor-made regulatory process. Readers can also use the chart during the process to benchmark the reality of the process against the planned process.

²³ In the extreme case, the separate tracks have additional sub-tracks.

One extreme		The other extreme
Focusing on major issues		Dealing with all issues
Content developed “top-down”		Content developed “bottom-up”
Driven by political considerations / risks		Driven by sector thoughts / actuarial risks
Oriented towards a predetermined result		Open to new options
Influenced by example of the past		Independent from example of the past
Influenced by other sector(s)		Independent from other sector(s)
Influenced by other jurisdiction		Independent from other jurisdiction
Fast		Slow
Fast accelerating		Slowly accelerating
One single track		Several tracks
Without sub-tracks		With sub-tracks
Process without cross-references		Process with many cross-references
Independent from impact assessment tools		Influenced by impact assessment tools
Independent from planning instruments		Influenced by planning instruments
Authorities only		Open to stakeholders
The formally responsible decides on drafts		Drafts elaborated on the basis of equality
Classic drafts and comments		Electronic co-working tools

What is the right regulatory process if the goal is primarily good quality? If the regulators have enough time and the primary goal is good quality, the regulators will tend to fill in the chart above mainly in the right-hand columns. The regulators will not be influenced by one single example of the past, of another sector or of another jurisdiction, but compare many of them to choose the best solutions.

What is the right regulatory process when there is time pressure? To take a conscious decision on the regulatory process takes time, but it will make economies in terms of time later. Even under time pressure it is a worthwhile investment. However, time-pressured regulators will tend to fill in the chart mainly in the left-hand columns.

6. THE SCOPE



“The government is merely a servant - merely a temporary servant.”

Mark Twain

We use the following definition of an act’s scope: “The subject matter is what the act deals with, whilst scope refers to the categories of situations of fact or of law and the persons to which the act applies”. The scope is the most important descriptor of a legislative or regulatory act. Hence, utmost care should be applied when defining the scope. Any mismatch between the actual content and the scope of the act should be remedied to avoid legal uncertainty and other major issues.

The scope should be designed in view of:

- ◆ the legal basis (not going beyond the legal basis, see also [Section 7.1](#)),
- ◆ the overall regulatory architecture (see [Chapter 2](#)), or
- ◆ the content intended to be placed into the legislative or regulatory act which, ideally, would have been determined with the help of the method described in [Chapter 5](#).

Let us read some examples of scopes to understand better what scopes are about.

6.1 Distinction by complexity

Scopes can be simple (like the first example below) or complex (like the last) or in-between (second and third):

1. [Commission Regulation EC/642/2009](#) implementing Directive 2005/32 EC of the European Parliament and of the Council with regard to eco design requirements for televisions:

“Article 1 - Subject matter and scope:

This Regulation establishes eco design requirements for the placing on the market of televisions.”

2. The [Philippine “Lemon Law” on the protection of consumers buying motor vehicles](#) (Act 10642):

“Section. 4. Coverage. – This Act shall cover brand new motor vehicles purchased in the Philippines reported by a consumer to be in nonconformity with the vehicle’s manufacturer or distributor’s standards or specifications within twelve (12) months from the date of original delivery to the consumer, or up to twenty thousand (20,000) kilometers of operation after such delivery, whichever comes first. The following causes of nonconformity shall be excluded:

(a) Noncompliance by the consumer of the obligations under the warranty;

(b) Modifications not authorized by the manufacturer, distributor, authorized dealer or retailer;

(c) Abuse or neglect of the brand new motor vehicle; and

(d) Damage to the vehicle due to accident or force majeure.”

3. The [Senegalese Law No. 2014-01 of January 6, 2014](#) relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU):

“Art. 2. - La présente loi a pour objet de fixer les règles applicables aux comptes dormants détenus dans les livres des organismes financiers des Etats membres de l’UMOA, tels que définis à l’article premier ci-dessus.

Ne sont pas visés par la présente loi:

- le compte qui n’a subi aucune intervention de la part de son titulaire depuis au moins dix (10) ans, lorsque celui-ci a effectué, pendant cette période, une intervention sur les autres comptes qu’il détient dans les

livres du même organisme financier ou a eu un contact avec ledit organisme;

- le compte soumis à une surveillance particulière du fait d'une décision de justice ou de l'administration;

- les dépôts à terme sur la période contractuelle de dix (10) ans ou plus.

Amended machine translation:

Art. 2 - This Act aims to establish the rules for dormant accounts in the books of financial institutions of member states of WAMU, as defined in Article 1 above.

Not covered by this law:

- The account that has not undergone any intervention on the part of the holder for at least ten (10) years, when he has performed, during this period, an intervention on other accounts held in the books of same financial institution or has had contact with said body;

- The account subject to particular scrutiny because of a court or administration decision;

- Term deposits over the contractual period of ten (10) years or more."

4. [Regulation EC/1272/2008](#) on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006:

"Article 1: Purpose and scope

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and articles as referred to in Article 4(8) by:

(a) harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures;

(b) providing an obligation for:

(i) manufacturers, importers and downstream users to classify substances and mixtures placed on the market;

(ii) suppliers to label and package substances and mixtures placed on the market;
(iii) manufacturers, producers of articles and importers to classify those substances not placed on the market that are subject to registration or notification under Regulation (EC) No 1907/2006;

(c) providing an obligation for manufacturers and importers of substances to notify the Agency of such classifications and label elements if these have not been submitted to the Agency as part of a registration under Regulation (EC) No 1907/2006;

(d) establishing a list of substances with their harmonised classifications and labelling elements at Community level in Part 3 of Annex VI;

(e) establishing a classification and labelling inventory of substances, which is made up of all notifications, submissions and harmonised classifications and labelling elements referred to in points (c) and (d).

2. *This Regulation shall not apply to the following:*

(a) radioactive substances and mixtures within the scope of Council Directive 96/29/Euratom ...”

The last example demonstrates that it is possible to express the purpose together with the scope in one single article. But there is a downside of this approach: the content of the articles following the scope article is partly reflected in the scope article. This makes it quite long. Furthermore, it is necessary to check whether an extensive scope like this one is fully in line with the subsequent, more detailed articles. To avoid misinterpretation, an extensive scope needs to be checked for compatibility with these articles.

6.2 Distinction by elements

Scopes can comprise personal, geographic, temporal, legal, situational, process or activity related elements. All the conditions and characteristics presented in the context of [Section 3.1](#) can be used to determine the scope. Thus we can refer to that Subsection. However, we need to have a closer look at the geographic parameter as the typology developed in [Subsection 3.1.3](#) does not cover entirely the geographic scope aspects of regulation.

In terms of geography, scopes can relate to activities or situations which take place:

- ◆ inside the jurisdiction: all activities or situations (covered by the subject matter) within the respective jurisdiction;
- ◆ outside the jurisdiction: activities or situations that involve persons or objects outside of the territory of the jurisdiction;
- ◆ inside or outside the jurisdiction: activities or situations that involve persons or objects either inside or outside of the territory of the jurisdiction;
- ◆ inside and outside the jurisdiction (cross-border): activities or situations that involve persons or objects being both inside and outside of the territory of the jurisdiction.

Regulation can explicitly foresee its extra-territorial application. See e.g. the new Section 2B of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#):

“Extra-territorial application of Act

2B.

(1) Except as otherwise expressly provided by sections 2D and 2E, this Part and Part II also extend to —

(a) every foreign registered aircraft specified in any 83 bis agreement that has the effect of transferring functions or duties to Singapore;

(b) every Singapore registered aircraft outside Singapore, subject to any 83 bis agreement that has the effect of transferring functions or duties to another Contracting State;

(c) every holder of an aviation safety instrument while outside Singapore and exercising or purporting to exercise privileges accorded by that instrument;

(d) every person in, or any of the crew of, any Singapore registered aircraft or aircraft operated by a Singapore operator, wherever they may be, in so far as this Act prohibits, requires or regulates the doing of anything by such persons in, or by any of the crew of, Singapore registered aircraft or aircraft operated by a Singapore operator; and

(e) every other person wherever they may be, in so far as any provision of this Act prohibits, requires or regulates the doing of anything in relation to any Singapore registered aircraft or aircraft operated by a Singapore operator, by such other persons.”

We thus have a multi-dimensional structure in which many combinations are possible – too many to be displayed here. It is preferable to start the process of scope determination with a first draft combining the most evident elements of the three dimensions. In a second step, extensions and restrictions to the provisional scope should be examined until the scope seems to be optimised. The listed terms can be used to make sure that all parameters are consciously decided upon.

6.3 Distinction by preciseness and flexibility

Whatever scope is chosen, it should not be defined with reference to subjective or changing conditions. Clauses like “as defined by the manufacturer” or “in accordance with regional law” trigger disputes on the right interpretation and an unequal application.

The [Status of Children \(Assisted Reproduction Technology\) Act 2013 of Singapore](#) contains, in its Section 3 Subsection (2), a legal presumption as part of the scope with a view to ensuring clarity about the applicability of an act:

“(2) For the purposes of this Act, a citizen of Singapore shall be presumed to be domiciled in Singapore, unless the contrary is proved.”

In other parts, the act turns out to be a masterpiece for the intelligent use of rebuttable and non-rebuttable presumptions, including rules on priorities in case of conflicting presumptions (the purpose being to avoid double-parent-hood).

6.4 Scopes with or without exemptions or clarifications

Regulation should sometimes exempt the military, police or customs or the government, e.g. the new Section 2D of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#) in which “state aircraft” is defined as an aircraft of the military, the police or the customs:

“2D. This Act, with the exception of Part IIA and the provisions of any aviation safety subsidiary legislation shall not apply to any state aircraft or navigation by state aircraft; and shall not limit the privileges or immunities of any foreign state aircraft and the officers and crew of any foreign state aircraft.”

It can make sense to clarify explicitly whether certain aspects are part of the scope or not. See examples 2, 3 and 4 presented in [Section 6.1](#). See furthermore the [Status of Children \(Assisted Reproduction Technology\) Act 2013 of Singapore](#) which clarifies, in its Section 3 Subsections (4), (5) and (6), various collateral aspects of applicability:

“(4) This Act shall not apply to a child to the extent that the child is treated by virtue of adoption as not being the child of any person other than the adopter or adopters.

(5) The application of this Act shall not by itself affect the citizenship of a child.

(6) For the avoidance of doubt, nothing in this Act shall affect any right or remedy that a person may have against any other person in relation to a fertilisation procedure which resulted in the birth of a child.”

New Zealand has made the applicability of the main obligations of a charter binding authorities subject to a very particular condition: the result of a certain risk assessment, see towards the end of [Section 12.8](#). This regulatory technique could in theory also be applied to entire regulations. However, it might enter into conflict with legal principles, like the principle of legal certainty.

6.5 Scopes followed by subject matter and purpose

In addition to the various scopes, regulation sometimes contains a description of its content. This description is sometimes also called “scope”, but the term “subject matter” is more frequently used. See as example Article 1 of [Regulation EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine ...:

“1. This Regulation lays down specific rules applying to the production and marketing of the products referred to in part XII of Annex I to Regulation (EC) No 1234/2007.

2. As regards the products referred to in paragraph 1, this Regulation provides for:

- (a) support measures;*
- (b) regulatory measures;*
- (c) rules on trade with third countries;*
- (d) rules governing production potential.”*

This extract is followed by definitions of the scopes for each letter (a-d).

To indicate the subject matter, as in paragraph 2, helps the reader to know what the regulation is about. It can also limit the potential legal effect of detailed prescriptions contained in the regulation to those items mentioned in the scope.

However, drafting a subject matter is risky. The risk is twofold:

- ◆ It happens that the regulation, via its subject matter, pretends to completely regulate a certain area whilst not doing so in reality. The over-broad subject matter creates a kind of void where there are no legal provisions whereas, to judge from the subject matter, there should be some. This creates legal uncertainty.
- ◆ It happens that a regulation covers a wider area than the one indicated in the subject matter.

Given the two opposite risks, the utmost care must be applied when drafting the subject matter at the very beginning of the process. A second verification should take place at the end of the negotiation process: is the content of the final draft of the legislative measure still correctly covered by the subject matter and vice versa? In the regulatory process amendments might have been introduced that require a modification of the subject matter.

The two risks referred to above also extend to the scope. Accordingly, the verification exercise recommended for the subject matter should also take place with regard to the scope: the content of the act may have been modified in the regulatory process so that the scope also needs to be revised.

The risk of inconsistencies is not as high if the purpose(s) of the regulation is indicated at the beginning of the regulation. Above all in jurisdictions influenced by the U.S. we can find, in the main part of regulation, a paragraph on the purpose(s). See for example the [Graphic Health Warnings Law of the Philippines](#) (Act 10643):

“Section. 3. Purposes. – The purposes of this Act are:

(a) to have Graphic Health Warnings that effectively warn of the devastating effects of tobacco use and exposure to second hand smoke;

(b) to remove misleading or deceptive numbers or descriptors like “low tar”, “light”, “ultra lights” or “mild” which convey or tend to convey that a product or variant is healthier, less harmful or safer; and

(c) to further promote the right to health and information of the people.”

6.6 Scopes with or without references to other regulations

A scope can be formulated with or without reference to other regulations. Examples:

“This Regulation applies to ... covered by ordinance”;

“This Regulation applies to ... not covered by ordinance”;

“This Regulation applies to ... for aspects other than those covered by ordinance”

The case of reference to or integration of other regulation has to be distinguished from simple statements on the applicability or non-applicability of other regulation; see [Section 9.4](#).

6.7 Relationships between scopes of other regulation

Reference is first made to the [Chapter 2](#) which explains how legislative or regulatory acts can relate to others.

To establish a scope that overlaps with the scope of other regulation is not desirable. Such an overlap is often unnecessary or even involuntary. If new regulation partly overlaps with existing regulation, this may have negative effects in terms of legal uncertainty as well as double procedures. The key to avoiding involuntary double coverage is the precise analysis of the scopes, the subject matter and of the risks covered (on the subject of risks see [Chapter 8](#)). Very exceptionally, however, an overlap is unavoidable, e.g. if the regulator wishes to cover, in new

regulation, a slightly different aspect than the one covered by the existing regulation.

It is not always easy to fit a new piece of regulation into a regulatory landscape. [Directive 2004/108/EC](#) on electromagnetic compatibility gives a good example of how this can be done without creating overlaps:

“4. Where, for the equipment referred to in paragraph 1, the essential requirements referred to in Annex I are wholly or partly laid down more specifically by other Community directives, this Directive shall not apply, or shall cease to apply, to that equipment in respect of such requirements from the date of implementation of those directives.

This Directive shall not affect the application of Community or national legislation regulating the safety of equipment.”

The design of the scopes is often intricately linked to the choice of the legal basis. See [Section 7.1](#).

7. OTHER BASIC QUESTIONS OF REGULATION



“It may be true that the government that governs best governs least. Unfortunately, the same is also true of the government that governs worst.”

Jane Auer

7.1 Selection of and reference to the legal basis

The “legal basis” is the provision which mandates the adoption of regulation. The legal basis is therefore also referred to as the “empowerment”.

Once the regulators have identified the goals they wish to achieve for their sector and once they decide that new regulation is needed, the regulators need to find an appropriate legal basis. There is a bilateral relationship between the goals and the legal basis. The legal basis determines what can be done with the legal act and which goals can be lawfully pursued. Example: If the legal basis says “In order to achieve a high level of safety, the authority may ...”, the authority may not pursue the goal of environmental protection. The legal basis determines what content can be placed in a measure. Sometimes the legal basis also determines the level of detail, the type of regulation to be adopted, or, in an international context, the harmonisation approach to be chosen.

7.2 Density of regulation

Evidently, regulation can go into more or less detail. The less it goes into detail, the more room it leaves for implementing or complementing measures of geographic entities and for legal interpretation. These advantages are to be weighed against more legal uncertainty and the risk of an uneven playing field for operators. Detailed law is not always preferable. It very much depends on the concrete

circumstances. It is often preferable not to regulate on details, especially if the regulatory topic is influenced by technological progress or similar fast modifications. In these cases, it is more practical to just set the general principles at legislative level and leave it to regulatory acts, to standardisation or to informal guidance documents to fill in the gaps and to provide for updates thereof. In some cases, it can even be preferable to have a three- or even four-level approach: legislation for the basic principles, regulatory acts for the first level of concretisation and standardisation and/or guidelines for the further concretisation.

7.3 Harmonisation approaches

Harmonisation approaches are hereafter explained for the international context, such as UN conventions, and for conglomerates of nation states such as the EU. However, the harmonisation approaches can also be used within Federal States, where different regions have regulatory autonomy and thus might develop diverging approaches. The following list of harmonisation approaches is not deemed to be complete. In addition, there are many variants. Harmonisation approaches can also be combined in many ways.

7.3.1 – Notification procedures

Notification procedures give other jurisdictions the possibility of scrutinising the national measure envisaged or taken. One famous example of this procedure is the notification obligation for new technical regulation under the WTO Technical Barriers to Trade (TBT) Agreement.

The advantage of notification procedures is that no substantial harmonisation is needed, but that a certain harmonisation effect can still be observed as soon as some kind of scrutiny criteria are set up. The disadvantage is that the supervision of these notifications is very work-intensive. Furthermore, without any kind of scrutiny criteria the supervision is meaningless.

Despite their weakness, notification procedures can be regarded as a first step towards harmonisation. Therefore it is useful to think of them as part of the harmonisation toolbox.

7.3.2 – Mutual recognition of decisions

This harmonisation principle sets out that decisions of other jurisdictions are recognised as being equivalent to domestic decisions. As an example, see Chapter IV of the [UNECE Convention on Road Traffic](#) of 1968 that provides, under certain conditions, for the recognition of driving licences.

Mutual acceptance creates a common legal space without cumbersome or impossible harmonisation. The major disadvantage is the frequency of disputes on the precise interpretation.

The mutual recognition can be made subject to an administrative condition such as the translation of the respective document.

Mutual recognition can also be made subject to conditions to be fulfilled by contracting parties (in the international context) or by geographic entities. If this is done, the mutual recognition integrates optional harmonisation (see just below). The Economic Community of West-African States (ECOWAS) [Regulation C/REG.4/05/2008 of 18 May 2008](#) on the harmonisation of rules governing quality control, certification and marketing of vegetable seeds and seedlings in the ECOWAS Space provides for an example of such a construction:

“Article 5: Principle of Free Movement of Pesticides

For the purpose of organization of a common market as defined in the Community agricultural policy, there shall be free movement of seeds in the territory of ECOWAS Member States as soon as the seeds meet the quality standards applicable in the Community.

Article 6: Principle of Mutual Recognition and Equivalence

Member States shall implement the principle of mutual recognition of certifications based on the technical specifications and Community standards on plant seeds as well as on the registration conditions and procedures applicable in ECOWAS, and shall recognize such conditions and procedures as equivalent.”

7.3.3 – Optional harmonisation

Optional harmonisation obliges jurisdictions to legislate in a certain way, but allows them to set up or to maintain alternative requirements in parallel. This type of harmonisation legislation could be observed in the field of product safety legislation, e.g. in UNECE Regulations on wheeled vehicles under the [Agreement concerning the Adoption of Uniform Technical Prescriptions for Wheeled Vehicles](#)²⁴ of 1958. Contracting parties of the so-called 1958 Agreement are obliged to accept on their market cars that fulfil certain requirements and their regulation must be constructed accordingly. But they are free to admit cars based on another set of national requirements.

The advantage of optional harmonisation is that the free circulation of products or services can be ensured relatively easily even if full harmonisation cannot be reached. The disadvantages are twofold. Obviously, regulation based on the principle of optional harmonisation does not fix a minimum level of stringency. Therefore, it cannot ensure a minimum level of environmental, consumer, health or workers' protection. Instead such regulation sets a stringency ceiling for jurisdictions: manufacturers can always refer to the content of the optionally applicable (UNECE or other optional harmonisation) law as an alternative to more stringent national law, if it exists. Furthermore, a lower level of protection in some jurisdictions, authorised by optional harmonisation, can have negative spillover effects on other jurisdictions. E.g. emissions in one jurisdiction may affect the territory of other jurisdictions, and products fulfilling only the low level requirements of one jurisdiction might be sold as used / second hand products to other jurisdictions which have a higher level protection. Despite these disadvantages, optional harmonisation has a role to play if more ambitious forms of harmonisation cannot (yet) be achieved.

Optional harmonisation will thus always play an important role in the framework of international harmonisation if the discrepancies between jurisdictions are large. Combining the highest standards of the jurisdictions can provide for mutual recognition of product or service authorisation or certificates whilst increasing the average quality of these products and services. The reason for this positive effect is that economic operators strive for big scale and uniform production. They

²⁴ The Agreement itself is to be found in the second row of that webpage (follow the link there).

also have marketing advantages when fulfilling “the top world standard” for a certain product or service. Therefore they sometimes fulfil “the top world standard” though they are legally not obliged to do so.

7.3.4 – Minimum harmonisation

Minimum harmonisation obliges jurisdictions to take certain measures, but gives them leeway to take more stringent measures. There is no specific advantage only of going for minimum harmonisation. It is better than nothing, and sometimes the only achievable harmonisation – especially if jurisdictions have very different levels of stringency.

The major disadvantage is that it sets only a ground, minimum level. To allow jurisdictions to maintain or to introduce a higher level of stringency can lead to friction with other jurisdictions.

7.3.5 – Total harmonisation

Total harmonisation establishes all requirements within the given scope. It gives jurisdictions no leeway upwards or downwards.

The advantage of total harmonisation is that free circulation of products and services amongst the jurisdictions is ensured and that the same level of protection or performance is also ensured, to the benefit of the users, consumers etc. The disadvantage of total harmonisation is that it is rarely possible to take local conditions into account. Jurisdictions wishing to protect their citizens by more stringent criteria are hampered in doing so. Sometimes, they try to bypass the international legislation by regulating side-aspects. This triggers cumbersome negotiations on the lawfulness of these national regulations.

8. UNDERSTANDING RISKS, QUANTIFIED REQUIREMENTS AND MULTI-DIMENSIONAL IMPACTS



*“There is good government when those who are near are made happy,
and when those who are afar are attracted.”*

Confucius

Much regulation tries to limit risks emerging in certain situations of life, be they linked to activities or to objects. Often, regulation also tries to establish quantified requirements in relation to the relevant risks. Dealing with risks and quantified requirements is key in some sectors. In many others, however it is not necessary.

We have seen in Chapter 3 how requirements are constructed and what they may contain. In this chapter we examine more thoroughly certain substantive elements of requirements. We focus on risks and quantified requirements and issues connected thereto. We also deal with the selection of measures where different risks are at stake and if there are multi-dimensional effects on entire policies or trade-offs between different policy goals or requirements.

Some parts of this chapter refer to mathematics, which is, admittedly, slightly unusual in a law-making context. Risks and quantified requirements can be described in a very precise way in mathematical terms. Sometimes mathematics is even the only way to express them appropriately. The use of mathematics in this chapter is not intended to endorse the use of quantification in all situations. The purpose is simply to improve the understanding of quantitative expressions and correlations.

8.1 Responding to various types of risks

There is a double reflection to be made with regard to the integration of different risks:

- ◆ Which risks shall be covered by the regulation? This question should be dealt with in the same way as the determination of the scope: by a precise analysis of what should be covered and by double-checking that readers interpret the description of the covered risks in the same way. Special care must be taken with abstract terms like “safety”.
- ◆ How shall the covered risks be balanced against one another if one risk can only be reduced at the expense of another?

The question of which risks shall be covered can be linked to the issue of integration of other regulation (see also [Section 2.8](#)). Regulators can decide:

- ◆ to only cover risks that are not covered by other regulation;
- ◆ to cover also the risks that are covered by other regulation and to make the other regulation non-applicable; or
- ◆ to keep the other regulation applicable, but complement it, e.g. by requirements which are more targeted for the specific scope.

It is useful to list all the risks that might appear to be covered and to verify whether these risks are really fully covered or more appropriately dealt with in other legislation or regulatory measures. In case of doubt, the solution c) should be favoured.

Inappropriate risk coverage can evidently be observed with regard to horizontal legislation (e.g. on chemicals or the environment). Horizontal regulation is hardly ever as fine-tuned to cover risks in a tailor-made way. It can also exist in relation to vertical legislation. E.g. it happens that legislation on one big product group only incompletely covers certain risks that are specific only to certain types of products that fall within this group.

8.2 Full safety principle or other fixed risk limits

We return to what regulators can require in their regulation. Regulators can try to fix a limit of acceptable risk. For example, the legislator can request to reduce the risk:

- ◆ as much as possible, or
- ◆ as much as reasonably possible - which implies an economic consideration: disproportionate efforts to reduce the risk are not needed²⁵, or
- ◆ to zero (full-safety principle).

For products that have no other use or utility than entertainment or providing fun the full-safety principle can be applied (e.g. for toys). However, some people question whether there can ever be “zero risk”.

Though it is not always possible to reach full safety, the idea of full safety should be kept for certain products and services. Especially if the potential damage is high (e.g. for bungee ropes), it might be a wise legislative decision to require full safety. If the full safety cannot be ensured for bungee ropes, bungee ropes should not be placed on the market. A manufacturer who is not able to ensure full safety should not place “bungee ropes” on the market. Views are different if goods or services imply a certain risk, but are still seen as an expression of one’s personality. Piercing and tattooing are to some extent risky, but free societies would not like to ban them.

In theory, it might be possible to fix a quantified risk limit. E.g. it would be possible to require that a certain hazard does not become reality in more than one out of 1000 or one out of 1000000 cases.

8.3 Risk-benefit analysis

There is an alternative to the full-safety principle. It is called risk-benefit analysis. The risk-benefit analysis requires comparing the benefit with the risks. More precisely, the benefit is weighed against an individual risk or the sum of the risks (all types of risks combined). A risk can be defined as the hazard (damage) multiplied by the likelihood of the hazard becoming a reality.

A benefit is evidently difficult to state if a product or service only provides for well-being, fun or pleasure. Accordingly, the risk-benefit principle is so far not ap-

²⁵ The so-called ALARP principle is frequently used in standards, sometimes in contradiction with legal requirements. ALARP stands for “as low as reasonably possible”.

plied to products that only provide for well-being, fun or pleasure²⁶.

The risk-benefit principle is often regarded and applied as a rough assessment without a proper methodology, examination points etc. However, it is possible to develop a precise risk-benefit assessment methodology. As an example, see the guidance developed by the US Food and Drug Administration: “[Making Benefit-Risk Determinations in Medical Device Premarket Approval](#)”. This guidance contains elements that could be transposed into other sectors’ guidance or even regulation.

8.4 Basic risk management obligations of operators

What kind of risk management obligations should regulation impose on operators? It might help to have a look at international standards (for more general information on standardisation see [Section 9.3](#)). On average, international standards clearly spell out what an operator needs to do:

- ◆ Risk identification,
- ◆ Risk evaluation,
- ◆ Risk avoidance, e.g. by inherently safe design, manufacturing and service providing,
- ◆ Risk reduction / mitigation,
- ◆ Providing information on the residual risk, or
- ◆ Instructing customers on how to minimise residual risk.

Risk management obligations for operators in regulation should follow this simple logical sequence. It is thus useful for regulators to check what has been done in the parallel world of standardisation²⁷. At the same time, an automatic incorporation of the sets of obligations contained in the standards should be avoided. Industry and other lobbyists try to push for such incorporation. However, a simple

²⁶ This might change in the future. Improving the subjective well-being correlates with the reduction of pain on the other side of the scale. Therefore, there is no obstacle to the application of the risk-benefit analysis. It is thus a political question whether positive feelings shall be regarded as benefit.

²⁷ See [Section 9.3](#) for more information on standardization. Industry standards mostly pursue the goals safety and interoperability, and sometimes also other goals like the protection of the environment. They contain technical requirements and assessment methods.

incorporation can be against the common interest: the standards do not necessarily cover all risk aspects. Furthermore, they can contain deficiencies that should not be incorporated. E.g. industry often lobbies for rather limited risk reduction obligations, namely for the so-called ALARP concept (risk reduction as low as reasonably possible) which includes economic aspects. International standards also tend to give operators a discretionary power regarding the question of whether a risk is negligible. It is thus advisable to review the content of standards critically.

8.5 Risk uncertainty and the precautionary principle

Certain jurisdictions apply the so-called precautionary principle. The precautionary principle authorises regulators to take a preventive measure which cannot (yet) be 100 percent justified by science. According to this principle, the regulators may take account of societal, economic, cultural, ethical and environmental factors in case of uncertainty. The precautionary principle is a derivate of the discretionary power of the regulator. But is it always wise to apply the precautionary principle?

It depends on the situation:

Situation A: All possible measures deal with just one single risk or cause just one single risk.

Situation B: The possible measures deal with different risks or cause different risks.

In Situation B, a complex assessment is needed. Situation B is more frequent than one may initially think. Here are some examples:

- ◆ Which of the different exhaust gases of cars, each of them triggering different risks, should the legislator primarily try to reduce? Or which type of fuel should the fiscal system privilege? Diesel engines produce less CO₂ for consuming less fuel. However, the NO_x emissions of diesel engines are higher.
- ◆ Everywhere in the legislation regarding chemicals we are confronted with uncomfortable choices to be made: the ban of a certain substance as conservative, e.g. colour, plasticiser etc. might trigger the use of another substance which is not necessarily safe in view of the same or another risk.

- ◆ Are Genetically Modified Organisms (GMO) more or less risky than pesticides and herbicides that would otherwise be used?

At least in situations in which different measures deal with or cause different risks, a precise impact analysis of the affected legal positions and interests is needed. To “blindly” apply the precautionary principle with regard to one risk can tragically backfire on other risks, and may thus cause more harm than good.

8.6 Choosing amongst measures that deal with or cause one single risk

If the possible measures deal with or cause only one single risk, risk managers should compare the effects of each potential measure against the scenario of doing nothing in order to find the best possible scenario. To make this comparison more precise, it might be useful to refer to mathematics:

Risk managers are invited to firstly assess the hazard “H” (how big is the damage at stake?) and the likelihood “L” of the hazard to occur if no measure is taken. Secondly, hazard and likelihood need to be multiplied (“H x L”). As this is the scenario in which no measure is taken, we can call it “H₀ x L₀”. In a third step, the product “H x L” is to be assessed under the assumption that different possible measures (M₁, M₂, M₃, ...) are taken. Let us call the result for M₁ “H₁ x L₁”, the result for M₂ “H₂ x L₂”, the result for M₃ “H₃ x L₃” etc. To decide whether one of these measures should be taken, it is advisable to subtract from “H₀ x L₀” (the product hazard x likelihood of the situation without any measure) first “H₁ x L₁”, in a second operation “H₂ x L₂”, in a third operation “H₃ x L₃” ... etc.. “H₀ x L₀” minus “H₁ x L₁” thus measures the safety gain if the measure M₁ is taken. “H₀ x L₀” minus “H₂ x L₂” thus measures the safety gain if the measure M₂ is taken. The higher the result, the more safety can be ensured by taking the respective measure. If the result is below 0, the risks are increased and no measures should be taken (unless the risks are outweighed by a benefit).

Let us imagine that “H₀ x L₀” minus “H₁ x L₁” is the highest figure (which means that the safety is best preserved) if the measure M₁ is taken. If the different potential measures do not impact free circulation or other economic rights, the examination ends here. Risk managers just need to take the measure for which the difference is highest.

If economic or other rights or simple interests are affected by one of the potential measures, the safety won is to be weighed against the negative impact on these rights and interests. New measures usually impact at least economic interests.

It is reasonable to take the measure if “ $H_0 \times L_0$ ” minus “ $H_1 \times L_1$ ” > ERI (legitimate “economic rights and interests”).

One might argue that the mathematical model presented here does not really help insofar as the effect of the different potential measures cannot be estimated. Indeed, there might be situations in which it is impossible to estimate the effect of potential measures. However, if the measure is not at least with a certain likelihood deemed able to reduce $H \times L$, it simply should not be considered. In all other cases, some effect is likely. Accordingly, there is an effect that needs to be quantified both in terms of hazard reduction and likelihood reduction. A rough estimate is still better than no estimate and blind decision-making. Accordingly, it is preferable to maintain a mathematical model to set estimations on the right track.

8.7 Choosing between measures that deal with or cause different risks

The assessment to be made is basically the same. But we need to compare the possible measures not just with regard to one hazard and its likelihood, but several. It is a situation of interconnecting links. Each of the various measures will impact several risks. We have to ask ourselves: do we really increase the overall safety by applying the measure?

Data is of the utmost importance for reasonable decision-making in situations involving different risks. If I cannot assess the consequences of a measure against the use of Substance A as plasticiser in product X, the regulator runs the risk of doing more harm than good. It might well be that the alternative Substance B does more harm as plasticiser in product X, though linked to another type of toxicity.

The need for comparative data is, legally speaking, not given in areas where the full-safety principle is applied. Under the full-safety principle, a product (or technology or substance) is deemed to be legal if, with a certain safety margin, a risk can be excluded. If a risk cannot be excluded, the product (or the technology or substance) cannot be lawfully marketed. This is very clear from the legal

perspective. However, if the alternative (product, technology or substance) cannot be fully assessed as to its risks, authorities might cause more harm than good by applying the law.

To come back to the initial example of substances, there is a need for comparative risk assessments and data collection combining the parameters (1) substance with (2) function and with (3) product type. This seems to be burdensome. But the effect of comparative data would go far beyond the mere legal sphere. If made public, industry would extensively use such comparative data. There are three reasons why industry would look for substances with comparatively good risk assessments. To use substances with comparatively good risk assessments prevents future damage of reputation, future liability claims and the need to modify the products when the use of the substance has become unsustainable. To provide a public platform for the collection of comparative data could thereby be a valid and effective non-legislative measure that influences the behaviour of economic operators. Such a platform cannot substitute classic bans of substances, but can complement these bans. This measure makes sense, not only where a policy of bans fails to produce adequate results (be it due to a lack of resources or too high a scientific complexity).

8.8 Multi-dimensional impacts

As we can see in the case of “GMO versus herbicides and fertilisers”, sometimes different potential impacts are to be weighed one against the other. These environmental impacts will appear on different time-scales. The decision on GMO versus herbicides and fertilisers may also have various economic consequences that are very difficult to assess. E.g. the GMO seeds are subject to patent rights. These patents might influence the economic structure of agriculture and, in the long term, maybe even the availability of seeds which are not protected by patent rights. A lack of cheap seeds may hamper the development of poorer regions of the world, but the large scale use of GMO could also favour the development of medium income countries. What we see here is just one chain of economic impacts. There are certainly many more, both positive and negative ones. Furthermore, there might be causal chains which are positive in the view of some and negative in the view of others.

This basic analysis of potential effects demonstrates that causal chains may go from one policy to the second and the third. Such causal chains and related feedback loops are extremely difficult to take into account in the decision-making process. Thus we can only slowly train ourselves in this type of multi-dimensional impact analysis. To learn, we need to get familiar with quantifying diagrams, close loop mechanisms and scenario simulations.

The previous sentence hints at what might be needed as future instruments for policy making. But we can now already identify a few tricky legal questions:

- ◆ In which cases must negative effects for other policy areas (than those the regulators are in charge of) be taken account of when evaluating a measure and when applying the proportionality principle?
- ◆ If these negative effects must be taken account of, another question arises: to what extent must a negative effect in another policy area be taken account of? Is there a “discounting factor” to be introduced?

Some regulation includes explicit obligations to take multi-dimensional impacts into account at the administrative level. These examples can help us to understand how the analysis and decision-making in case of multi-dimensional impacts of regulation can work. The [Indian right to fair compensation and transparency in land acquisition, resettlement and rehabilitation Act](#) of 2013, provides, in its Chapter II, for the obligation to undertake Social Impact Assessment studies in case of certain requisitions of land. The act contains detailed provisions on conditions to be fulfilled, including composition of the committee, publication and language requirements. It stipulates, in its Chapter II Section 8 Paragraph 1, that the legitimate purpose must outweigh the adverse social impact. Furthermore, the measure may not encompass more land than strictly necessary, and no previously confiscated alternative land must be available. How is the social impact integrated into the overall decision-making? Chapter II Section 6 states that the result of Social Impact Assessment is to be made available to the authority in charge of environmental impact assessment. Accordingly, we can presume that the social impact takes part in the overall weighing process undertaken by the latter authority. The multiple social impacts are thus integrated into the overall weighing process, though this weighing process was initially established merely for environmental impacts.

8.9 Trade-off decisions between different quantifiable requirements

In the previous section, we have analysed multi-dimensional impacts and macro-decisions on which goals or policies should be taken into account. Basically the same questions arise at a micro-level, when there is a conflict or trade-off between different requirements. The issue becomes particularly complex, but also instructive, where there can be a range of limit values with regard to several requirements. Therefore, we examine in the following these different situations.

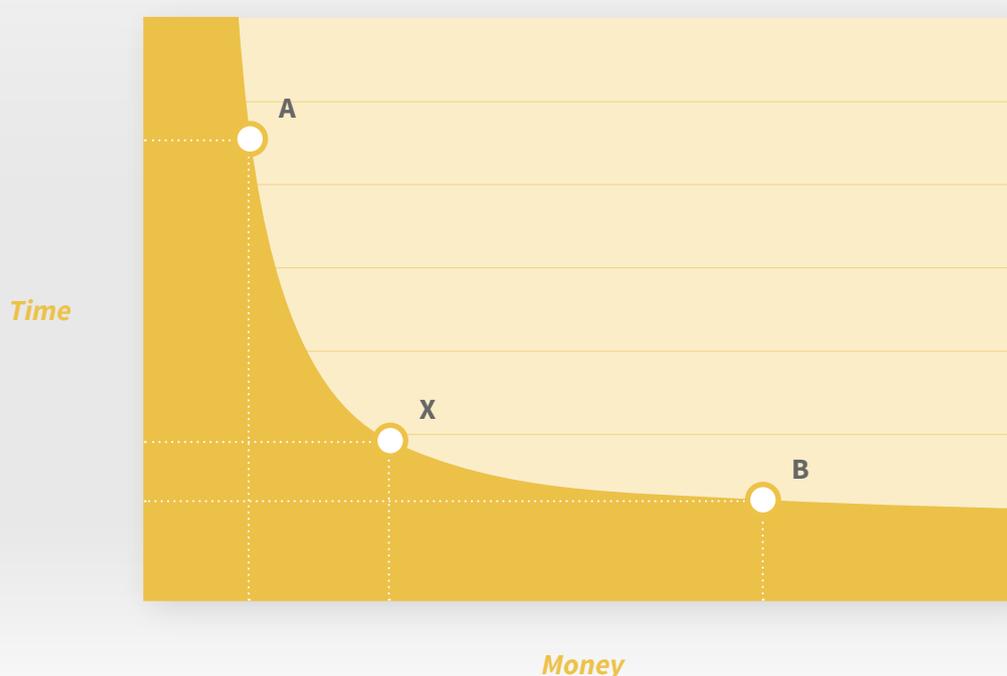
8.9.1 – Trade-off between two goals

Firstly, let us consider the relatively simple situation involving two parameters. Where there are only two parameters, the introduction of a limit value for the first parameter does not always lead to a negative result for the other, second parameter. For example, the parameter of carbon dioxide (CO₂) emissions for diesel vehicles is aligned with the parameter for oxides of nitrogen (NO_x) emissions so that the introduction of a limit value for one also improves the results for the other parameter. However, such situations are rather rare. The introduction of a limit value for one parameter will usually be neutral for the second. However, sometimes the opposite is true, the limit value for one parameter triggers a negative result for another, requiring a decision about trade-offs. It is this latter situation that we wish to focus on when considering the introduction of a limit value for a parameter. Evidently we first should check whether there is really a trade-off with any other parameters. In some situations it might make sense to ask whether a requirement (containing a limit value) could be established that avoids a trade-off with another relevant parameter?

However, in the majority of situations, there is no leeway to amend the requirements in such a way that the trade-off is avoided. Hence, we must decide where to put the trade-off. How to optimise between two, possibly inter-dependent parameters? Let us expand our earlier example of diesel vehicles to diesel and petrol vehicles. Petrol vehicles previously had higher fuel consumption, which caused higher CO₂ emissions, but lower emissions of the health damaging, and to some extent deadlier, NO_x. Here regulators had to develop an approach for determining the best possible trade-off between optimising or reducing the two types of emissions.

The trade-off the regulators had to consider, between emissions of CO₂ and NO_x, is analogous to decisions that we all make in our day-to-day life when deciding between different modes of travel. For example, Diagram 1 represents a decision-making process about travel from city Y to city Z by bus (cheap, but slow, see point A of Diagram 1), by plane (expensive, but fast, see point B) or by train (quite fast and still relatively cheap, here point X).

DIAGRAM 1



The curve represented can also be bent to the other side or be a straight line, subject to the situation.

The key to clear decision-making in the situation visually represented at Diagram 1, between different transport modes, is the exchange rate between time and money. If a person believes that one hour is worth \$40, s/he may decide differently to a person that believes one hour is worth only \$10. But when the person has found the exchange rate, it can measure the “money” in units corresponding to one time unit. For example, one hour will be expressed by one centimetre on the vertical axis and one centimetre on the horizontal axis corresponds to \$40. Thereby one can not only proceed with a clear mathematical calculation for the

optimisation between time and money, but this will automatically already be expressed geometrically by the graph. In our example, the optimisation takes place slightly left from the point X, thus the train is the optimal mode of transport in terms of time and money. In more abstract terms: the best point on the curve is where the rectangle created when one draws a straight line between the relevant point on the curve and the two axes is smallest.

To develop an exchange rate between different parameters²⁸, one can apply different techniques as we illustrate again with the help of the transport example of before:

- ◆ Where policy decisions touch upon the interests of many people, whilst it is impossible to ask them all for their exchange rate, statistical methods can be used to obtain the relative best guess for the average subjective (hypothetical) exchange rate. With such methods, we might find out that the average subjective exchange rate between time and money is maybe \$15 in one country and \$23 in another. In absence of any better guess, regulators can take these average subjective values as a basis for determining the optimised trade-off in a certain jurisdiction.
- ◆ Both CO₂ and NO_x emissions cause deaths, though each have different causality chains. Thus deaths or, more precisely, lost life-years can become the common denominator which indirectly determines the exchange rate.
- ◆ Alternatively, money units can be chosen as a common denominator. Money as a common denominator has the advantage that simple economic effects can easily be taken into account, though the issue of fair distribution or equality remains problematic. The disadvantage is of course that everything needs to be monetised, even a life or life-year, suffering etc. Again, a statistical method can be used to determine a “best-guess” or “average price”.
- ◆ Where both life-years or lives and money are at stake, there is no help: one has to define a price for a life or life-year. Again the price will depend on the respective jurisdiction. Strikingly, the value of a life (known as the value of a statistical life or VSL and value of a statistical life year or VSLY) is normally

²⁸ We here discard the complicating factor that the exchange rate might vary with quantity. E.g. a person might decide that, with an increasing income, s/he only is ready to work at a higher hourly rate.

estimated at US\$4.8 million²⁹ in the United States, in Australia AU\$4.9 million³⁰ whereas the VSL in Europe is much lower, at €1 million³¹.

All these approaches have a common goal: to compare apples and pears with a view to making relatively reasonable and relatively acceptable trade-off decisions. They are not ideal from the outset, but can be endlessly fine-tuned. Unfortunately, regulators have no choice: either they apply methods of this kind or they make their trade-off decisions instinctively which is, on average, worse.

Evidently, a precise mathematical calculation in accordance with the paragraphs above will not always be possible. However, it helps to keep the mathematical models in mind when developing pragmatic best guess approaches. We present below some approaches for pragmatic best guesses:

- a) We can try to identify a zone where limit values for one parameter have almost never any effect on the other, whilst the effect is very limited where an effect does occur.
- b) We can try to identify a zone where limit values for one parameter almost never have any effect on the other, whilst the effect is not necessarily limited.
- c) We can try to identify a zone where limit values for one parameter have an effect only in a minority of cases on the other, whilst the effect is very limited where an effect occurs.
- d) We can try to identify a zone where limit values for one parameter have only in a minority of cases any effect on the other, whilst the effect is not necessarily very limited.
- e) We can try to identify a zone where limit values for one parameter have an effect on the other, whilst the effect is very limited.

²⁹ United States Environmental Protection Agency, “Guidelines for Preparing Economic Analyses, Office of the Administrator”, EPA 240-R-00-003, September 2000 p. 90. <https://www.epa.gov/environmental-economics/guidelines-preparing-economic-analysis-2000>.

³⁰ Australia Prime Minister & Cabinet, “Best Practice Regulation Guidance Note Value of statistical life”, October 2018, p. 1, <https://www.pmc.gov.au/sites/default/files/publications/value-of-statistical-life-guidance-note.pdf>.

³¹ See <https://www.oecd.org/env/tools-evaluation/env-value-statistical-life.htm>.

- f) We can try to identify a zone where the trade-off is such that limit values for one parameter will never disproportionately harm the values of the other. In order to reach this goal, it might be necessary to set up precise requirements.
- g) We can try to identify a zone where the trade-off is such that limit values for one parameter will on average not disproportionately harm the values of the other. In order to reach this goal, it might be necessary to set up precise requirements.
- h) We can try to identify a zone where the trade-off is such that limit values for one parameter will on average not disproportionately harm the values of the other, but provide for the possibility to ask for an exemption where such is the case.
- i) We can try to identify a zone where the trade-off is such that limit values for one parameter will on average not disproportionately harm the values of the other, but give the possibility to rebut the assumption that there is no disproportionate harm for the other; and if there is such disproportionate harm for the other, the limit value would be reduced / increased or completely devaluated.

How can the requirements, referred to at letters f) and g), change the trade-off between two goals? Let us illustrate this with a real-life example. At least until 2015, there was a trade-off between the environmental goal of reducing the dissemination of mercury and the goal of optimised dental cures in cases where dental holes needed to be filled. Despite rare allergic reactions, dental amalgam (containing mercury) was regarded by dentists as the best possible filler in many situations. Despite many statements to the contrary in popular media, toxicity was found to be extremely low in virtually all of the more than 1000 studies about toxicity. Unlike most of the other fillers, dental amalgam does not shrink over time, which was important for dental care as shrinking triggered the risk for new caries. In fact, dental amalgam even expands and thus further reduces the risk of new caries forming. Dental amalgam containing mercury is more robust than other fillers. Still, there was a lot of debate between environmental policy defenders and those policy actors who had mainly dental health in mind. The debate could have been avoided by more regulatory awareness.

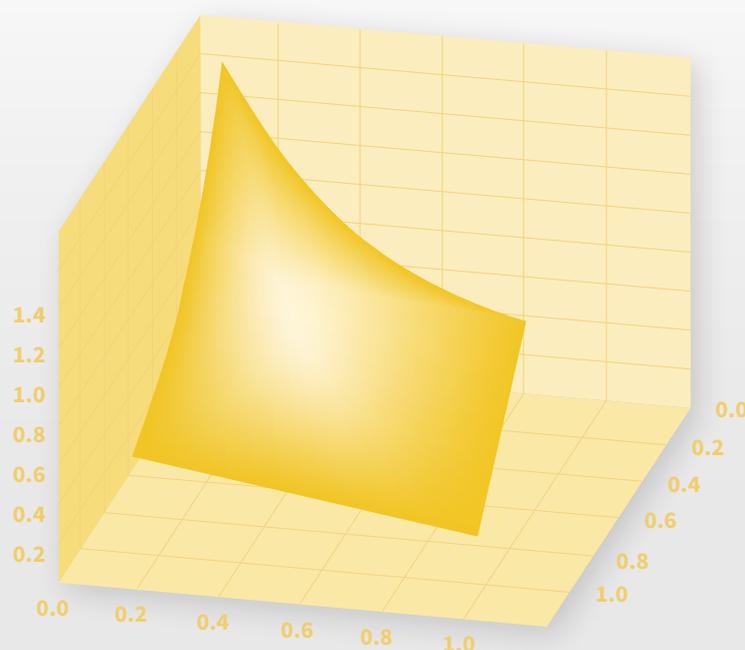
To optimise the trade-off between the two goals, environment and dental health, two types of requirements could have been set:

- ◆ Requirements for advanced placement techniques reducing the loss or emission of mercury at the time of placement: These requirements could reduce the negative effects on the environment and thus shift the trade-off.
- ◆ Requirements requesting other fillers not to shrink or even to expand: These requirements reduce the comparative advantage of dental amalgam when compared to other fillers so that the environmental considerations can more easily prevail. This type of requirement, touching alternatives and thus even not the problematic product/item, is often not considered, though it can be equally effective.

8.9.2 – Trade-offs between three or more goals

So far, we have only dealt with trade-offs between two goals. How about situations where three parameters are inter-dependent? In terms of mathematical model, we need to expand the graph at Diagram 1, to include a third axis, e.g. aiming at measuring “discomfort of travel” borrowing our earlier example about different modes of transport. The two-dimensional curve at Diagram 1 becomes a bent surface which can only be represented in a three-dimensional way (see Diagram 2 below). All points on the bent surface (the yellow coloured middle part) express trade-offs for the three parameters time, money and discomfort.

DIAGRAM 2



A precise preference structure is already difficult to establish for one single person. Already for one person, this would require a multitude of questions and answers covering a high number of alternative situations to be considered. More difficult still would be to estimate the (average) trade-off bent surface for a multitude of persons. It would require sophisticated statistical methods that regulators mostly do not use. Still, it might be helpful to have a clear mathematical illustration to guide us and the clearest we found is the bent surface at Diagram 2.

Regulators should aim to avoid making any trade-off decisions between different parameters that are subject to limit values merely by instinct. We present a rational approach for deciding any trade-offs between limit values using mathematical models in two-dimensional form (for two parameters) and in three-dimensional form (for three parameters). Such a decision-making approach is transparent, introduces rigour where instinct was previously used and enables the regulator to decide how to approach the task of optimisation.

8.10 Translating risk assessment reports into measures (risk management)

The considerations of a risk manager go beyond these complex reflections if s/he receives a risk assessment. Subject to legal empowerments and to the measures that already exist, s/he has to choose the level of action. Sometimes there is a need to use several levels, e.g. an easy-to-implement but incomplete administrative measure and a measure that resolves the issue completely through regulation.

We have already mentioned two criteria for choosing the right level of intervention, the time-line and degree to which the measure resolves the issue. There are more, e.g. the availability of the human resources and the durability of the risk assessment. If the risk assessment is likely to be substantially revised in the next two years, it is risky to go for legislation. Risk management is thus a complex optimization task.

8.11 Safety margins in risk assessment and risk management

To apply a safety margin is sometimes possible and useful. For the assessment of risks with regard to chemical substances, a safety margin of factor 100 or 1000 is

frequently used, meaning the estimated risk is multiplied by 100 or 1000. This is adequate if the full safety principle is applied. If a substance should only be authorised when absolutely safe, a safety margin is normally appropriate.

However, a safety margin should not be applied if its application would disproportionately increase another risk or disproportionately reduce the benefit achieved with the substance, product or service in question. If such a downside is noted, a comparative risk-benefit analysis is needed.

In addition, the application of the precautionary principle might be simply disproportionate if measured against the economic interests or legal positions of those who would have to pay the price for it.

A special problem arises if applying a safety measure or a safety margin would overall be beneficial and the most cost-efficient, but the price is to be paid by somebody who has not caused the risk or who is not in an appropriate position to pay it. E.g., regulation may impose on distributors or professional users certain maintenance or customer information obligations that they are not really able to comply with. The interest of the third party might be protected by formal rights or fundamental rights.

8.12 The proportionality principle

Contrary to the precautionary principle, the proportionality principle has to be applied on a mandatory basis in many jurisdictions. It is derived from fundamental rights. According to the proportionality principle, it must be established that new regulation is suitable to achieve the objective(s) sought, and that the same objective(s) may not be as effectively achieved by measures which are less restrictive. Furthermore the disadvantages caused may not be disproportionate to the objective(s) pursued.

The previously mentioned aspect of the proportionality principle is difficult to apply if there are multiple uncertainties and probabilities involved. Most regulators will rely on their rough appraisal when assessing whether the disadvantages of a measure are disproportionate. A rough appraisal is usually sufficient because the balance falls clearly on one side. However, regulators may also face situations that are not clear-cut. Regulators may wish to go for a precise analysis of effects in order to ensure that disadvantages are not disproportionate to the aim pursued (or reached).

Once again, mathematics can serve as an instrument to sharpen our judgement. To start, let us assume that there is only one disadvantage triggered. This disadvantage needs to be evaluated. According to the proportionality principle, this disadvantage has to be proportionate when weighed against the benefit that is pursued with the measure. If there is only one certain disadvantage, the formula is easy. Proportionality (P) is given if the benefit (B) is higher than the disadvantage (D).

$$P: B > D$$

In a second step, let us assume a case in which there is no certainty about the disadvantage taking place. There is only a certain likelihood. Let us also assume that there is only one theory on the likelihood of the disadvantage taking place. Proportionality is given if the benefit B is higher than the disadvantage D multiplied by the likelihood L of the disadvantage occurring.

$$P: B > D \times L$$

If there are different potential disadvantages (D1, D2, D3, ...), each of them being linked to a different likelihood, the formula becomes slightly more complicated:

$$P: B > D1 \times L1 + D2 \times L2 + D3 \times L3 \dots$$

If there are different theories about potential disadvantages, the same formula has to be applied for all theories Ta, Tb, Tc, The result according to the different theories Ta, Tb, Tc, ... needs to be multiplied by the likelihood of the respective theory being right. The results shall be added up. Proportionality is given if the sum is still lower than the benefit B.

$$P: B > LTa \times (D1 \times L1 + D2 \times L2 + D3 \times L3 \dots) \quad (\text{for } Ta)$$

$$+ LTb \times (D1 \times L1 + D2 \times L2 + D3 \times L3 \dots) \quad (\text{for } Tb)$$

$$+ LTC \times (D1 \times L1 + D2 \times L2 + D3 \times L3 \dots) \quad (\text{for } Tc)$$

+ ...

For each of these cases, it might be that the benefit is also uncertain. If this is the case, we just need to substitute, on the left side of the equation, the “B” by “B x L”. If there are different potential benefits, we substitute, on the left side of the

equation, the “B” by “ $B1 \times L1 + B2 \times L2 + B3 \times L3 \dots$ ”. The further split in accordance with different theories is equally possible.

8.13 Overview: the adaptation of risk and performance requirements to technical progress

Adaptation to technical progress can happen in many ways. It can be achieved by the constant drafting of new regulation. However, the constant drafting of new regulation is relatively cumbersome. Regulators can instead try to build in a kind of automatic adaptation to technical progress by using a variety of techniques:

- ◆ Expressions that imply an automatic update like “state of the art”, “best available techniques”, “technically most advantageous”, “to reduce as much as possible the risk ...”,
- ◆ Mandatory dynamic reference to international standards (“... comply with to the most recent international standards”³²),
- ◆ Mandatory static reference to standards plus update of the reference once the standard has been updated,
- ◆ Mandatory dynamic references to international agreements, codices and other documents of high reputation, or
- ◆ Mandatory static references to international agreements, codices and other documents of high reputation plus update of the reference once the reference text has been updated.

8.14 Quantitative and qualitative risk and performance requirements

Regulation can be more or less stringent. The right degree of stringency should be determined by a conscious decision and not simply by copying previous requirements. This statement seems to be evident for regulation fixing precisely performance requirements, e.g. via limit values or other quantitative targets (1.). It is less evident in the case of qualitative risk and performance requirements,

³² See for example Art. 7 of [Commission Regulation \(Euratom\) No 302/2005](#) of 8 February 2005 on the application of Euratom safeguards, OJ L54/1 of 28.2.2005.

meaning abstract terms fixing the targeted risk or performance level (2.). A third path consists in using abstract terms, but empowering for a definition thereof (3.).

(1) The clearest way of setting performance requirements is to set quantitative limit values or other quantitative targets. At first sight this seems simple. The disadvantages appear after some time: the limit value might be impossible or too easy to be fulfilled so that an unforeseen adaptation procedure is needed. This is cumbersome, even if the adaptation can be made by regulation.

In some sectors, a limit value does not have any meaning as such without definition of the measurement methodology. Fuel consumption and emissions of vehicles is such a sector. Fuel consumption and emissions depend on the so-called test cycle and other testing parameters. To define these in regulation is extremely difficult, as they are extremely detailed and too comprehensive. This difficulty has led in some jurisdictions to the following practice: the legislator decides on limit values and obligations and the test method is determined by regulatory acts in parallel or even ex post. Such a practice is justified if the test method has to be adapted to the limit values in order to ensure that the limit values can be reached. However, feasibility arguments are often only put forward by industry to obtain a lenient test method. The intention of the legislator thus risks being undermined.

An example of a regulatory act imposing a certain test method is to be found in [Commission Regulation EU/10/2011](#) of 14 January 2011 on plastic materials and articles intended to come into contact with food (see its Article 18 and Annex V).

(2) Regulators are often hesitant to use quantified criteria. Sometimes they are hesitant because they fear that each quantification might need to be updated, e.g. because there is technical progress. In such a situation, there can be a trade-off between legal preciseness and enforceability of legal requirements and the goal of automatic adaptation to technical progress that can be reached by vague expressions like “state of the art”. In such a trade-off situation, regulators sometimes prefer to use abstract terms.

Especially when performance requirements are described in abstract terms, it seems to be normal to require the highest performance (e.g.: ...to reduce as much as possible the risk of...). However, it is sometimes not necessary, in view of the regulatory goal, to request the most stringent fulfilment, and sometimes it is even counter-productive for another goal. Thus a conscious decision is needed, as stated at the beginning of this Section.

As soon as the regulation does not simply require the most stringent fulfilment of a criterion, the margin of interpretation becomes wide. See as an example the term “state of the art” and its alternatives mentioned in [Section 8.13](#). The term “state of the art” is so often used because it has two advantages:

- ◆ It aims at a high performance level; and
- ◆ It is dynamic in time.

Unfortunately, there are uncertainties as to the use of this term: Does it mean that the highest possible performance level has to be fulfilled? Or is it sufficient to fulfil a fairly high, not sub-standard level?

This question of interpretation has sometimes led regulators to look for alternative formulations such as “technically most advanced”. However, this is equally problematic. There might be a very modern, “advanced” new technology which is nonetheless not especially well-performing in certain performance aspects. To refer to the “state of the art” would clearly permit the banning of this technology whereas it would be subject to legal debate whether it could be banned under the term “technically most advanced”. There are also sectors in which a very old technology is still performing very well, be it in general or for some special purpose. In these cases it would be difficult to argue that the technology is “technically most advanced” whilst it would be unwelcome to ban it.

Another alternative to the term “state of the art” is “technically most advantageous”. This term makes quite sure that the highest performance level has to be sought for in case of a one-dimensional performance scale. The term might nonetheless give rise to interpretative questions if there are different goals or performance scales and if the optimisation for one goal leads to lower results with regard to another. In this case, it is advisable that the regulator indicates how the two goals should be valued. The regulator should especially express to what extent economic considerations (or simply: cost) may influence the definition of “state for the art” or “technically most advantageous”.

Moreover, the practice and the terms used so far in a given sector should be taken account of. If the term “state of the art” was so far understood in the best possible way, it might create useless legal uncertainty to replace this term by “technically most advanced”. Introducing a different term might be misunderstood as a call for a different criterion. In such a situation, it might be a good option simply to

fix the right legal interpretation of “state of the art” by a definition or by informal guidance documents.

The dynamic aspect (the “spiral upwards”) is better built-into the term “state of the art” than other terms. If another term than “state of the art” is used, it might be necessary to stress the dynamic aspect.

Furthermore, it can be clarified whether the criterion “state of the art” or “technically most advantageous” is to be applied only once for a given product or service type or whether it can also be stated later in the lifecycle that the product or service no longer fulfils the criterion (e.g. on the occasion of a authority surveillance operation). The regulator can refer, in the case of products, to the time the product type is designed, to the time that the individual product it is constructed, to the time it is sold or installed, to the time it is used, etc. For more on this, see [Section 9.2.](#)

(3) There is an intermediate path between 1 and 2: establishing the criterion “best available technique” in legislation, and providing an empowerment to define this term in a regulatory act. See as an example [Commission Implementing Decision 2013/163/EU](#) of 26 March 2013 establishing the best available techniques (BAT) conclusions under Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions for the production of cement, lime and magnesium oxide.

8.15 Establishing risk classes with different procedures

Not all risks are equally grave. Risks and in particular the harms they refer to can be very minor and go up to the level of endangering the survival of mankind. Accordingly, they can and should not be dealt with in the same way. Where regulation deals with a large variety of risks, it might be commendable to establish risk classes as a basis for a different procedural processing of risks. See as example [this prototype regulation](#) on research and technology risks and the [risk classification](#) it is based on.

8.16 High risk products and processes

High risk products and processes require particular care with regard to the substantial criteria to be applied. A good example of what can be required for high risk products and processes surrounding these products can be found in the [Canadian Explosives Regulations](#), P.C. 2013-1283 November 26, 2013. In addition to classic product-related requirements, these regulations require manufacturers to set up and to apply mandatory operating procedures to reduce accidents (Articles 86 to 89) and to consciously operate change management (Article 87). Articles 101 to 105 set up requirements for workers, visitors and other persons entering a manufacturing site. The Articles 186 onwards contain requirements for the transport and for the persons involved in this transport. The Articles 213 onwards contain rules for sellers and users of specific explosives.

We can see here an example of a general tendency: the riskier the product or process, the more groups of persons and side-processes need to be targeted by the regulation. Another example of this very tendency is the [Canadian Food and Drugs Act - Regulations Amending the Food and Drug Regulations](#) (1475 — Good Manufacturing Practices). It contains detailed obligations for packagers, labellers, distributors and importers. These obligations go up to the level of product testing.

The riskier a certain product or process is, the higher the likelihood that regulators deem it to be appropriate to require a quality management system. Quality management systems are required by some Canadian legislation. See as examples Sections 93 to 97 of the [Canadian Food and Drugs Act, Blood Regulations, P.C. 2013-1065 October 9, 2013](#) or Sections 6.1 to 6.6 of the [Canadian Regulations Amending the Onshore Pipeline Regulations](#), 1999, P.C. 2013-308 March 21, 2013. The latter is slightly more comprehensive than the first, but still manageable.

8.17 Bearing and causing risks

Those who bear certain risks are rarely exactly the same as those who cause them. If guns killed only those who manufacture them, who would continue to manufacture guns? If the risks caused by vehicles were concentrated in the cities where the vehicles are manufactured, would these cities still produce vehicles? If car manufacturers were to bear the indirect costs and long-term damages that are caused by their cars, would they still find liability insurance?

Many economic operators let others pay for risks, but keep the profit for themselves. Some jurisdictions timidly react here and there against this business model; see e.g. in the banking sector where taxpayers' money is now better protected against rescue calls by "too-big-to-fail" banks than before 2008. However, there is still no general awareness as to the extent to which this business model is spread. In hardly any sector of regulation related to devices, products, chemicals or services is the principle of responsibility of the operator fully implemented. Classic tort law, requesting proof of causality and of negligence, usually fails in practice as it is too complicated. The principle of strict liability is applied in certain states for certain niche sectors (like oil drilling or nuclear activities), but not in all sectors. Mandatory collective insurance schemes, developed in Europe in the 19th century to protect workers against financial consequences of occupational accidents, often establish too high hurdles for the victims, namely in terms of burden of proof. Nonetheless only the principle of strict liability and mandatory insurance schemes may slightly remedy the unfairness of a situation where some make the profit and others bear the risks. Both are more successful if paired with a reduced/low burden of proof for causality or even a reversal of burden of proof once the damage has been proven. These techniques are still relatively little used. But from a cross-jurisdiction perspective, they are not exotic. They show up in quite a range of sectors (e.g. labour law, medical liability law, environmental liability law, animal liability law, copyright law, anti-corruption law, anti-trust law).

8.18 Typology of risks related to devices, objects, substances

We have seen in [Section 8.1](#) that it is of the utmost importance to identify all the risks that should be covered by regulation. The following list might facilitate the task regarding risks related to devices, objects and substances, as it creates a kind of typology of risks:

- ◆ Mechanical risks (e.g. failing of brakes, failing of steering, squeezing mechanisms, cutting mechanisms),
- ◆ Software failure risks,
- ◆ Risks of software manipulation,
- ◆ Risks of electric failure,
- ◆ Risks linked to unintended charge of electricity,

- ◆ Risks linked to electricity supply breakdown,
- ◆ Risks of incompatibility of devices, connectors, chemical substances etc.
- ◆ Risks linked to electro-magnetic radiation (risk of interference with devices, risks for ultra-sensitive persons),
- ◆ Risk of radioactivity,
- ◆ Risk of other tissue destroying radiation (e.g. by protons or other parts of atoms),
- ◆ Risk of optical disturbance by beams and other light(s),
- ◆ Risk of too high or too low temperature,
- ◆ Risk of fire,
- ◆ Risk of spreading disease by use of human, animal or synthetic tissues,
- ◆ Risk of uncontrolled proliferation of living tissues or beings,
- ◆ Risks of bio-compatibility of chemicals,
- ◆ Risk of too high pressure (e.g. in case of explosion),
- ◆ Risk of not performing as intended (e.g. medicine),
- ◆ Risk of misunderstanding instructions for use,
- ◆ Risk of unintended inappropriate use, and
- ◆ Risk of intended inappropriate use (“off-label use”).

9. REFERENCES



“The best soldier does not attack. The superior fighter succeeds without violence. The greatest conqueror wins without struggle. The most successful manager leads without dictating. This is intelligent non aggressiveness. This is called the mastery of men.”

Lao Tse

Elegant referencing can avoid lengthy, duplicated texts, and not only in technical regulation. Good knowledge on referencing techniques can substantially improve regulation. Therefore we present here a typology of references (9.1), followed by a short analysis of the timing/staging aspect of references (9.2), before presenting in more detail references to standards (9.3) and to other non-legal documents (9.4).

9.1 Typology of references

In this Section we examine in a detailed and systematic way referencing techniques. The following typology aims at raising awareness of the different methods and objects of referencing so that referencing can be improved, based on a wider choice.

9.1.1 – Targets of references

9.1.1.1 – *Other acts of the same jurisdiction*

Regulation mostly refers to acts of the same jurisdiction.

9.1.1.2. – *Acts of other jurisdictions*

Exceptionally, it refers to acts of other jurisdictions.

9.1.1.3 – *Documents of international or supranational organisations*

Regulation can refer to hard law, soft law or other documents of international or supranational organisations (organisations created by international law that supersede national law).

9.1.1.4 – *Standards*

Regulation can refer to (mostly semi-public) national or international standards of generally recognised standardisation organisations like [ISO](#) or [IEC](#). However, regulation can also refer to private standardisation organisations like [GS1](#). There is no strict line to the next case, but rather a continuum. Regarding references to standards, see the dedicated [Section 9.3](#) and this [dedicated comprehensive article](#).

9.1.1.5 – *Other technical specifications or codes of conduct elaborated by private bodies*

Sometimes, business associations or individual companies like insurances or other associations develop technical specifications or codes of conduct that are worthwhile to refer to. In particular in the field of ethics one can even observe codes of conduct that have been elaborated by business and other associations jointly, to ensure a plurality and balancing of views.

9.1.1.6 – *Official publications / data*

All kinds of notices in official journals, official databases like company registries, public price indices and public publications can be referred to, subject to the practices of the respective jurisdiction.

9.1.1.7 – *Private publications / data*

Trust ratings by private rating agencies, private price indices e.g. for the housing market can be referred to.

9.1.1.8 – *Administrative acts*

Sometimes, regulation refers to an act that does not fall under the definition of regulation, thus an administrative act.

9.1.2 – Static and dynamic references

References can be static, meaning referring to a document that cannot change in time. They can also be dynamic, thus referring to a document that evolves in time. The latter are often regarded as legally problematic in so far as the regulator might lose control of the content of the regulation. The issue is absent or less grave if the document referred to is another act adopted by the same regulator or a superior regulator.

If there is a legal issue, an appropriate solution can be found by prescribing an act or at least an administrative act that confirms the shift from the previous to the new version of the document referred to. Such an intermittent act can also be used to determine the transition period during which both versions can be applied and other transition issues (for more details see Sections [13.1](#) and [13.2](#)).

Dynamic references do not necessarily need to refer just simply to the latest version of a document. They can also permit the use of the two latest versions or make the use of the latest version possible with a lead time (necessary for adaptation of verification mechanisms) and mandatory after further months or years. There is no limit to creativity here, and such creativity is sometimes needed to permit a smooth and effective transition.

Though static references seem to be advantageous in general terms, there are also some pitfalls. This is best illustrated with the example of international standards. The dated versions of the international standards referred to often become superseded in a few months or years. This can have dramatic consequences. They may lose formal validity and might not even be accessible anymore which creates

other issues of legal certainty. Moreover, where different normative references interact and international standards normatively referred to contain further normative references, one can easily end up with situations in which different versions of the same standard are normatively referred to – a source of confusion or even contradiction.

9.1.3 – Starting points for using references

9.1.3.1 – *References within conditions*

A reference can be built into the condition of a legal provision. Example:

“Where the rent is more than 20% higher than the average rent as fixed by XYZ index, the property owner shall ...”

9.1.3.2 – *References within consequences*

A reference can be built into the consequence part of a provision. Example:

“Where the conformity assessment body ceases to operate under this Regulation, the economic operator shall within six months undergo a new conformity assessment procedure with one of the back-up conformity assessment bodies listed in the latest relevant publication in the Official Journal.”

9.1.3.3 – *References within conditions and consequences combined*

The same or another reference can be placed in both parts of a provision. Example:

“Where the rent is more than 10% higher than the average rent as fixed by XYZ index, the property owner shall retribute half of the difference between the rent and the average rent.”

9.1.3.4 – References within definitions

References can be placed in definitions. Example:

“For the definition of ‘Quality system’, see ISO 9001 in its latest version.”

9.1.4 – End points for using references

9.1.4.1 – References to entire provisions or texts

A reference can be made to an entire provision or text so that the conditions of that provision or text must be fulfilled to trigger a certain consequence.

Example 1:

Sentence 1: *“When A is given, then Sentence 2 applies / applies by analogy.”*

Sentence 2: *“When B is given, then C.”*

Result: When A and B are given, C applies. A alone does not trigger the consequence C.

9.1.4.2 – References to the consequence side of provisions or texts

But a reference can also be limited to the consequence side of a certain provision or text.

Example 2:

“When A is given, than Sentence 2 applies with regard to its legal consequence C.”

Result: To trigger the consequence C, B might be given or not. B is not needed to trigger the consequence C. Otherwise said: only the consequence side of Sentence 2 applies.

Unfortunately, references are not always clear as to whether they follow the example 1 or the example 2.

9.1.5 – Full or partial applicability of the provision or text referred to

Full applicability means that the provision or text referred to is to be applied without any modification.

Partial applicability means that the provision or text referred to applies with one or several limitations.

Example: *“When A is given, than Article X applies with exception of its last paragraph.”*

In conclusion, when making a reference, external to the piece of regulation, the regulator should take into account the following considerations:

- ◆ What kind of reference do you wish to make? Noting the typology of references presented in above.
- ◆ Is the reference static or dynamic?
- ◆ What are the implications for legal certainty should the reference become dated or change too quickly?
- ◆ If making references to conditions or consequences, is the reference clear in its meaning?

References in regulation are a useful and efficient regulatory technique that defers expertise to the relevant body or organisation or standard, making regulation, if done correctly, more consistent and easier to manage.

9.2 Reference time / reference stages

Requirements in regulation always have a reference time or reference stage, whether explicitly or implicitly. For services and other processes, the reference time/stage is usually the time when these are provided or take place. But sometimes an earlier time is referred to: the time of offer or the time of application for authorisation to an authority. To refer (also) to the time of offer can help to prove infringements. If a conformity assessment body professes in its publicity material to be very lenient in certain regards, it can counter authority remarks by claiming that its practice is more severe than indicated in the publicity or the offers. It cannot counter critical authority remarks if the legal requirements are at least also applicable to publicity or offers.

Some services or other processes take a long time. Thus the question arises of which legal requirements have to be applied if the legal requirements have been changed in the meantime: those applicable at the beginning or those at the end of the process? Transitional provisions should normally sort this question out unless it has been sorted out by the core text of the regulation.

For the purchase of products, devices, materials and substances we can distinguish different reference times: the time of advertisement/offer, the time when a purchase contract is concluded, the time when the contract is fulfilled, the time when the product, device, material or substance is handed over, the time when it is first used and the time when it is used thereafter, or even simply the time of inspection by an authority or entrusted body.

In all cases so far mentioned regulators also have the possibility of referring to the time span between the mentioned reference times / stages. Whatever the preference is, it makes sense to make a conscious choice regarding the reference time(s) or reference stage(s). It avoids complications and legal uncertainty at the level of enforcement.

9.3 References to standards

Jurisdictions have developed two techniques on how to refer to standards:

- ◆ establishing a mandatory reference to a standard, thus integrating the content of the standard into the legal text; and
- ◆ establishing a presumption of conformity for standards, meaning that products, services or other processes fulfilling the standard are presumed to comply with certain, precisely defined legal requirements.

Most jurisdictions create mandatory references to standards rather than providing for a presumption of conformity with legal requirements to those applying the standards. See as an example the [U.S. Federal Motor Vehicle Safety Standards, Minimum Sound Requirements for Hybrid and Electric Vehicles](#):

*“§ 571.5 Matter incorporated by reference. ...
ISO 10844:2011 “Acoustics—Test Surface for Road Vehicle Noise Measurements,” into § 571.141.”*

In certain jurisdictions, a mandatory reference to standards may even be dynamic, meaning to the version as last amended even if the last amendment takes place after the adoption of the regulation. See as example the [Canadian Regulations Amending the Onshore Pipeline Regulations of 1999](#) (P.C. 2013-308):

“CSA Z246.1” means CSA Standard Z246.1 entitled Security Management for Petroleum and Natural Gas Industry Systems, as amended from time to time. (norm CSA Z246.1)”

Both techniques of reference to standards require a good deal of work and time investment on the part of the authorities. In either case, the authorities need to verify whether the requirements set up by the standardisation bodies are in line with the legal requirements. The international standardisation machinery has become more and more disconnected from the legal requirements of the various jurisdictions. Therefore, standards are not necessarily aligned with requirements of regulation. It may help, in this case, to establish a rule of conflict, as provided for in the [Canadian Regulations Amending the Onshore Pipeline Regulations of 1999](#) (P.C. 2013-308):

“Subsection 4(3) of the Regulations is replaced by the following:

(3) If there is an inconsistency between these Regulations and a standard referred to in paragraph (1)(b), (c), (d) or (e), these Regulations prevail to the extent of the inconsistency.”

One major issue of standardisation is updating it. Updating a standard is not always less cumbersome than updating regulation. Standards should always reflect the “state of the art” or the otherwise abstractly defined performance requirements. Standards are mostly drafted by persons working for the respective industry. This is basically good inasmuch as these people have the best technical insight. However, the weak presence of other persons or institutions having a similarly high degree of technical understanding has downsides. To what extent is there still legitimacy if what is to be regarded as “state of the art” is (mainly) defined by industry representatives? Do these representatives have an interest in defining “state of the art” in a progressive way? Also, most standardisation bodies work by consensus, not only at the level of formal voting by states’ delegates, but also at the working group level. One single active industry delegate can thereby prevent technical progress being reflected in a standard. Prior to referring to standards, the regulator should verify whether he has the administrative means

to follow up the standard development and the means to successfully intervene in case of standards are adopted that do not completely reflect the performance requirements defined by the term “state of the art” or by other terms.

The following questions might help regulators to make a conscious decision on whether to refer to a standard:

- ◆ Is the standard in contradiction with requirements set up by regulation?
- ◆ Does the standard concretise correctly the abstract expressions and requirements set up by regulation?
- ◆ Does the standard concretise correctly the discretionary powers set up by regulation?
- ◆ Does the standard provide for a discretionary power where the regulation does not foresee a discretionary power?
- ◆ Does the text of the standard reflect technical progress?
- ◆ Do the standards and other documents referred to in the standard reflect technical progress?
- ◆ Does the standard and the standards therein referred to refer to the same version of further/third standards?
- ◆ Does the standard refer to documents other than standards that cannot be referred to in a valid way? E.g. international standards sometimes refer to reports or national standards that cannot necessarily be accessed.
- ◆ If dynamic references in standards cannot be accepted for legal reasons: does the standard contain dynamic references?
- ◆ In jurisdictions like Brazil and the EU where standards can provide for a presumption of conformity with legal requirement: does the standard really fully cover (for all aspects and for all cases) the legal requirements that it claims to cover? and
- ◆ In jurisdictions like Brazil and the EU where standards can provide for a presumption of conformity with legal requirement: does the standard distinguish between the specifications aiming to support the legal requirements and other specifications?

It goes without saying that the continuous supervision of standards under these aspects can become quite cumbersome. Therefore, alternative techniques of referencing standards might be worthwhile being examined: see this [dedicated comprehensive article](#).

9.4 References to non-legal documents other than standards

Regulators are often tempted to refer to non-legal documents to further specify requirements. References to other documents may help to set up requirements without much regulatory work, above all if the reference is dynamic. The [Brazilian draft Portaria INMETRO / MDIC Number 247 of 26/05/2014](#) on the conformity assessment for the retreading of tyres contains an undated and therefore probably dynamic reference to technical manuals of certain bodies:

“A.3.1 Para qualquer um dos três processos de reforma de pneus (recapagem, recauchutagem e remoldagem), é respeitada a tolerância da diminuição do índice de velocidade conforme a Tabela “Símbolo de Velocidade” do Manual de Técnico da ALAPA.

Nota 1: podem ser utilizados dados dos Manuais Técnicos da ETRTO, TRA e da JATMA, no caso de serem omissos os constantes no Manual Técnico da ALAPA.”

Amended machine translation:

“A.3.1 For any of the three reform processes tires (retreading, retreading and remoulding) is respected the tolerance index decrease speed as Table” Speed Symbol “Technical Manual of ALAPA.

Note 1: data can be used from the ETRTO, TRA and JATMA Technical Manuals; if they are missing, those contained in the Technical Manual ALAPA can be used.”

Sometimes regulators make the reference to both standards and other non-legal documents in one strike. The Economic Community of West-African States (ECOWAS) [Regulation C/REG.4/05/2008](#) of 18 May 2008 on the harmonization of rules governing quality control, certification and marketing of vegetable seeds and seedlings in the ECOWAS Space provides for an example of a dynamic and generic reference both to international standards and other international reference documents:

“Article 7: Principle of recognizing International Standards

To ensure the free movement of seeds within Community and foster regional and international trade thereon, Member States shall anchor their seed technical regulations on international standards, directives and recommendations.”

Generic reference clauses like the one of ECOWAS may cause disputes on which documents are to be regarded as referred to. Therefore, regulators may consider establishing a mechanism for the acceptance of reference documents (see below the example of Singapore).

Regulation can do more than just refer to non-legal documents. It can provide for explicit rules on the effect of respecting codes, standards, and guidance documents in procedures establishing the civil, penal or administrative responsibility of persons or operators. The most advanced example found is the new Section 3C of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#).

“3C. (1) This section applies to and in relation to any code, standard, rule, requirement, specification or other document issued by the Authority for the purpose of providing practical guidance or certainty in respect of any one or more of the requirements of this Part or any duty or other requirement prescribed in any aviation safety subsidiary legislation.

(2) Subsection (4) shall have effect where — a person is alleged to have committed an offence under this Part or any aviation safety subsidiary legislation — by reason of a contravention of any provision of this Part or of any aviation safety subsidiary legislation; or by reason of a failure to discharge or perform a duty or other requirement imposed by this Part or any aviation safety subsidiary legislation; and the matter to which the alleged contravention or failure relates is one to which, in the opinion of the court in the criminal proceedings, a code, standard, rule, requirement, specification or other document referred to in subsection (1) relates.

(3) Subsection (4) shall have effect where — a holder of an aviation safety instrument is alleged to have not satisfied any requirement of this Part or any aviation safety subsidiary legislation applicable to holders of that aviation safety instrument — by reason of a failure to discharge or perform a duty or other requirement imposed by this Part or any aviation safety subsidiary legislation; and the matter to which the alleged contravention or failure relates

is one to which, in the opinion of the Authority or Minister in any administrative proceedings involving the exercise of any power under section 4C, 4D, 4E, 4H, 4J, 4K, 4L or 4N, a code, standard, rule, requirement, specification or other document referred to in subsection (1) relates.

(4) In criminal proceedings referred to in subsection (2) or administrative proceedings referred to in subsection (3) compliance with a provision of such a code, standard, rule, requirement, specification or other document found by the court, Authority or Minister (as the case may be), to be relevant to a matter to which a contravention or failure alleged in the proceedings relates; or a contravention of or a failure to comply with, whether by act or omission, any such provision so found, may be relied on by any party to those proceedings as tending to negative or establish any liability which is in question in those proceedings.”

Instead of referring to the non-legal texts itself, legislation can provide for an empowerment to incorporate, in subordinate regulation, non-legal text by reference. The advantage of this technique is that updating of the subordinate regulation is easier procedure-wise. The most advanced legal text found in this regard is the new Section 3B of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#):

“3B.—(1) Any aviation safety subsidiary legislation may make provision for or in relation to a matter by applying, adopting or incorporating by reference, with or without modification, any matter contained in any code, standard, rule, requirement, specification or other document, as in force at a particular time or from time to time, which relates to any matter with which the aviation safety subsidiary legislation deal, even if the code, standard, rule, requirement, specification or other document does not yet exist when the aviation safety subsidiary legislation is made...”

This Section 3B also contains detailed prescriptions on how non-legal texts can be referred to and how they must be made available. Even dynamic incorporation is possible, but accessibility to a certified copy must be ensured.

The [Fire Safety \(Petroleum and Flammable Materials\) Regulations 2013 of Singapore](#) replaced, in Chapter 109A Section N 61(1), an old way of making reference to “codes of practice” with a new one. Both ways are of interest. The previous version of the act apparently contained the concept of – presumably informal

– “acceptance” of a certain code of practice by the administrative authority; see the definition: “accepted code of practice”, meaning any code of practice, standard, guide or handbook that is accepted by the Commissioner for the purpose of providing practical guidance to persons engaged in the storage, keeping, transport or dispensing, or conveyance by pipeline of any class of petroleum or flammable material. This concept of informal “acceptance” makes management easy. Regardless of whether this was the case in Singapore, “acceptance” can already be expressed by simple listing of certain Codes of Practice on a website of the authority, without any formal administrative procedure or decision-making. However, informal acceptance might, in some jurisdictions, be regarded as insufficient under aspects of legal certainty. This could have been the reason for Singapore to shift from mere “acceptance” to the presumably rather formal “adoption” of code of practices by the authority.

Section 55 of the [Singapore Fire Safety Act](#) further sets up a priority rule in case of conflict between different Codes of Practice by stipulating that one of them will prevail over the others:

“(4) Unless otherwise provided in any regulations made under section 61, in the event that any code, standard, rule, specification or provision adopted under subsection (1) is inconsistent with the Code of Practice for Fire Precautions in Buildings published by the Commissioner, the Code of Practice for Fire Precautions in Buildings shall prevail.”

Subject to the case, there can even be an obligation to use standards and similar non-legal documents. Both standards and other international non-legal documents are covered by the expression “standards” in the meaning of Article 2.4 of the Technical Barriers to Trade Agreement; see WTO dispute ruling “WT/DS231, EC Trade Description of Sardines”. The ruling was based on Article 2.4³³ of the TBT Agreement, which lays down an obligation to use international standards as a basis for domestic technical regulations except if such international standards would be an ineffective or inappropriate means for the fulfilment of the legitimate

³³ Article 2.4 of the TBT Agreement provides: “Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except if such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.”

objectives pursued. In this ruling, a voluntary standard of the Codex Alimentarius Commission for the marketing of canned sardines and so-called sardine-type products (Codex Stan 94) has been regarded, by the WTO Appellate Body, as a standard in the meaning of the TBT Agreement. The WTO Appellate Body took the view that international standards need not be adopted by consensus. As a result, all TBT signatories have to base their technical regulations on relevant international standards unless they are not effective or appropriate for the fulfilment of legitimate goals so that deviations are justified. The TBT signatories are even bound by standards that they formally opposed in the adoption process. The fact that the term “standard” has to be interpreted in a broad sense, also covering binding legal UN instruments, cannot be excluded.

10. VERIFYING CONFORMITY IN ADVANCE (EX ANTE)



“I am not an advocate for frequent changes in laws and constitutions, but laws and institutions must go hand in hand with the progress of the human mind.”

Thomas Jefferson

We deal in this chapter with the in advance (ex ante) verification of conformity of natural or legal persons, their behaviour, their products, services or other activities before they undertake the activity which is – possibly – to be verified. We deal in this chapter both with procedural aspects and aspects of substance. We put concrete procedures at the end as the right procedure depends very much on aspects of substance.

10.1 Distinction between ex ante and ex post verification

There are two approaches to conformity verification:

- ◆ Ex ante: First we control, then we let things go; and
- ◆ Ex post: First we let things go, then we control.

Both approaches can be found in any jurisdiction. To our knowledge, no jurisdiction always uses one or the other approach. But the borderline between the sphere governed by one or the other approach is set differently in different jurisdictions.

The first approach tends to establish a tougher control. It is therefore often applied for risky behaviour, activities or products. But it can also create an unjustified impression of security in so far as the reality often deviates from what is

presented to the verifying instance in advance. For example, world legislators deemed their type approval system for vehicles and their components or systems to be the best and at any rate fully sufficient means of conformity verification until they discovered counterfeit components on the market. Counterfeit components, often imported from abroad, can to some extent be blocked by ex ante involvement of importers. But mostly they can only be detected ex post, once they are already in the distribution chain. Also the worldwide scandal of breast implants manufactured by the manufacturer PIP with other silicone and in another production chain than the ones which were the subject of ex ante procedures shows that the reality might well deviate from what is assessed ex ante.

Accordingly, the old opposition between regulators defending the “just ex ante” or the “just ex post” approach has become obsolete. The best solution is often a mix. Some aspects are better verified ex ante (if this is not too burdensome), whereas others are better verified ex post. See for further details [Section 10.4](#).

10.2 Basic decisions to be taken with regard to the conformity verification

One can set up a simple sequence of relevant questions to address the most important aspects of conformity verification and enforcement, put this sequence in a chart and investigate systematically in each individual case how to approach conformity verification best. The reader is invited to use this chart:

What needs to be verified? See 10.3	When shall the verification happen? See 10.4	By whom? See 10.5	In which procedure? See 10.6

Please note that there can be logical feedback from the assessment of the third and fourth question into the assessment of the first two.

10.3 What needs to be verified?

Basically, there are two approaches to verifying conformity. The first is to verify the result, e.g. the final product or service. The second is to verify the steps leading to the result, e.g. the production and the quality verification which are part of the production process. Sometimes only one of the two approaches can or needs to be used. Sometimes both need to be combined to ensure conformity, e.g. if regulation sets up requirements both for the result and the way to the result or if the conformity of the result can only be verified on the way thereto.

At first sight it might appear strange that the verification of the way to the result can ensure the conformity of the result. And strictly speaking, we have to admit that it cannot do so with 100% certainty. However, the verification of the way to the result can ensure a high likelihood of conformity. If a carefully working state authority or conformity assessment body designated by the state finds the production process, including the quality verification, to be good, the risk of unintended deviations of the final products from the product type is very low. If, as part of the production process, the manufacturer has also set up a good system of verification of compliance of the product type with legal requirements, the likelihood of the product type to be in conformity with the legal requirements is also high. This can be verified by random checks of product documentation. Both elements together ensure a high likelihood of compliance of the final products with the legal requirements.

The topic “verification of the conformity of the result” can be endlessly declined if we take all the parameters into account. Parameters are inter alia: the different characteristics of the product or service which are relevant for stating “conformity”, the number of samples to be verified, the ratio of still acceptable deviation (e.g. 1/1000) if any, the degree or types of deviation which trigger a non-conformity with regard to the many characteristics.

10.4 When shall this verification happen?

10.4.1 – Better ex ante or better ex post?

We have seen in Section 10.1 that there are two approaches: ex ante and ex post verification. We have also learnt that the ex ante and the ex post conformity verification must, together, ensure compliance with the legal requirements, but should

not go beyond what is necessary to ensure conformity with legal requirements. It is not proportionate to have an extensive ex ante state authorisation procedure that ensures the conformity of the product types with legal requirements and to verify this conformity again by ex post conformity verification. However, there is room for ex post conformity verification for the conformity of the individual product with its product type if this has not been ensured in the ex ante procedure. Even if the conformity of product types has been verified in advance, there is still room (and a need) for verifying that the products on the market are not counterfeit and that they are identical to the verified type. Similarly, it is sometimes not sufficient to verify the Standing Operating Procedures for services or other processes as the actual services and processes can easily deviate from the Standing Operating Procedures.

Accordingly, the legislator needs to decide what needs to be verified in advance and what ex post. The overall verification intensity should be sufficient to ensure conformity, but should not constitute a disproportionate burden. As a general rule, we can recommend the following:

- ◆ Is a certain aspect rather static? Then it can well be examined in advance.
- ◆ Will a certain aspect have heavy consequences on the subsequent actions? Then it should be examined in advance e.g. to avoid mis-investment or costly corrections.
- ◆ Can there be heavy consequences to others early on, even before the first ex post control takes place? Then all the elements potentially causing these heavy consequences should rather be examined in advance.
- ◆ Do the natural or legal persons subject to the regulation tend not to comply? If so, ex ante control might be necessary.
- ◆ Do the natural or legal persons subject to the regulation tend to comply and to be well informed of their obligations? Ex post control should be sufficient.
- ◆ Are verification resources rather scarce? Subject to the case, they are better invested in advance or ex post, but often ex post verification with high publicity for detected non-conformities might be most effective.

10.4.2 – When best to use ex ante?

Within the sphere of ex ante verification, there are several points, sub-processes or other anchors for ex ante verification. Take the example of the building of a house. The overall conformity of the construction plan can and should best be verified before any work starts. The fulfilment of most requirements applicable to the building can only be checked when the building is ready. But some requirements must be looked at at an intermediate stage. The pillars used will mostly not be visible anymore at the very end of the construction process.

Accordingly, readers are invited to sub-divide the ex ante phase and to ask again, just for the ex ante phase: what is best to be verified by when?

N.B.: The parallel question “When best to use ex post?” will be raised and answered in [Chapter 11](#).

Considerations similar to these can be made for the ex post verification. When do non-conformities typically become visible? Maybe, economic operators tend to abide by the rules very strictly at the beginning, but become less vigilant over time so that some delay in the verification is appropriate. Maybe the non-conformity can only be proved after a certain time so that, again, a certain delay in the verification is opportune. But if the non-conformity can cause tremendous damage, relatively early verification is imperative.

If we think all these questions through, we come to a multi-parameter system in which inter alia the following parameters might play a role:

- ◆ periodicity or non-periodicity of verification;
- ◆ with predictable or unpredictable timing;
- ◆ announced or unannounced;
- ◆ frequency influenced by past infringements or not;
- ◆ frequency influenced by other factors linked to the likelihood of infringements or not; and
- ◆ frequency and selection of targets influenced by available resources or not.

Evidently, it does not make sense to establish at the level of the regulator an exact planning for executing authorities (e.g. market surveillance authorities). However,

it would make sense to require authorities to establish such planning, and this can be done in a more or less restrictive way. E.g. the regulator can mandate the use of all of these parameters or particular ones only. The regulator can also set minimum frequency benchmarks.

10.5 Who shall verify?

10.5.1 – A choice frequently to be made:
conformity assessment bodies or state authority?

The right choice between a conformity assessment body's in-advance verification or state in-advance verification depends on the relevant body's designation and supervision practice and on the relative quality of the relevant authorities and bodies. The concrete situation has to be assessed. For instance, conformity assessment bodies tend to be better placed for assessing the quality management of operators than authorities. Subject to the sector, either the authorities or again the conformity assessment bodies have more technological knowledge.

To involve conformity assessment bodies does not necessarily mean that the verification is weaker than that of a state agency / authority. The question of the stringency of the conformity assessment routes has to be distinguished from the question of who is verifying the conformity. Both authorities and bodies can be stringent or can be too lenient.

The reason why conformity assessment bodies are mostly deemed to be less severe is that they receive fees from their clients and are subject to competition amongst themselves. Therefore, some conformity assessment bodies choose to be quite lenient with their clients. However, the same phenomenon can be observed in old-approach sectors where authorities receive substantial fees for authorisation procedures. Thus it is more the financial and the competitive situation that may lead to an over-lenient application of law and standards. This pitfall could be remedied if the economic operators were to pay fixed fees to an authority in charge of deciding which conformity assessment body will take over a certain economic operator³⁴.

³⁴ We have heard that India has at least intended to establish such a system.

10.5.2 – Mixed regimes combining conformity assessment bodies and state authority

We are familiar with classic state authorisation procedures and with conformity assessment bodies verifying the compliance of products or services. We are less familiar with procedures combining elements of the two procedures. Basically, there are two combinations possible:

(1) Authorities are, for specific aspects, involved in a procedure run by conformity assessment bodies. See as example Article 5-4 of the [Commission Regulation \(EU\) 722/2012](#) of 8 August 2012 concerning particular requirements as regards the requirements laid down in [Council Directives 90/385/EEC](#) and [93/42/EEC](#) with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin:

“4. Before issuing an EC design-examination certificate or an EC type examination certificate, the notified bodies shall, through their competent authority, hereinafter ‘coordinating competent authority’, inform the competent authorities of the other Member States and the Commission of their assessment carried out pursuant to paragraph 2 by means of a summary evaluation report in accordance with Annex II to this Regulation.”

This Regulation is an interesting example, because it obliges one to seek out not only the opinion of one authority of one geographic entity, but of different geographic entities together. Based on this model, a variety of further possibilities are imaginable:

- Geographic entities might obtain the right to veto the issuing of a certificate during a given period.
- Geographic entities might only be able to veto with a certain quorum, e.g. if one third of them oppose the issuing of the certificate.

(2) Conformity assessment bodies or test laboratories are involved in a procedure run by authorities. E.g. [Regulation 168/2013/EU](#) of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles contains another interesting prototype of a mixed state-private authorisation regime; see Articles 61 to 71: technical services work on behalf of the approval authorities. They are assigned and supervised by the approval authorities. This authorisation regime is also used by other jurisdictions³⁵.

For much technical regulation, the use of accredited test laboratories has become a fashionable procedural step. Regardless of issues of control (which are basically the same as for conformity assessment bodies), test laboratories are seen as a good tool for either outsourcing technical assessments of authorities or bringing neutrality and reliability into the applicants' self-certification. We present here as example the [Brazilian Portaria INMETRO / MDIC Number 247](#) of 26/05/2014 on the conformity assessment for the retreading of tires. It contains the obligation to use accredited test laboratories. It contains provisions on:

- who is in charge of accrediting (14.1 and 14.3),
- what the test laboratories need to do (14.2), and
- under which conditions test reports of internationally accredited test laboratories can be accepted as equivalent (14.3):

“14.1 Quando do uso de laboratório de ensaio, é responsabilidade do fornecedor a seleção do laboratório a ser contratado para a realização dos ensaios que serão utilizados no processo de registro da Declaração da Conformidade do Fornecedor, devendo ser contratado laboratório acreditado pela Cgcre, para o escopo específico.

14.2 Os laboratórios devem verificar, informando no relatório de ensaio, se a amostra do pneu reformado contém as seguintes informações gravadas no pneu:

I. Designação do pneu;

II. Índice de carga (exceto para pneus diagonais);

[...]

14.3 Para os ensaios realizados por laboratórios estrangeiros devem ser observadas e documentadas a equivalência do método de ensaio e da metodologia de amostragem estabelecida. Além disso, esses laboratórios devem ser acreditados pela Cgcre ou por um acreditador que seja signatário de um acordo de reconhecimento mútuo do qual o Inmetro também faça parte.”

³⁵ To our knowledge, this regulatory technique was first developed by the U.S.

Amended machine translation:

“14.1 Where there is use of a testing laboratory, it is the supplier’s responsibility to select, amongst those laboratories which are accredited by Cgcre for the specific scope, the laboratory to be hired for the tests that will be used in the registration process of the Declaration of Conformity of the Manufacturer.

14.2 Laboratories must verify, stating in the test report, that the sample of the retreaded tire contains the following information written on the tire:

I. Description of the tire;

II. Load Index (except for diagonal tires);

[...]

14.3 For the tests carried out by foreign laboratories, the equivalence of the test method and of the established sampling methodology should be observed and documented. In addition, these laboratories must be accredited by Cgcre or by an accreditor that is a signatory to a mutual recognition agreement to which INMETRO is also party.”

The Portaria (ordinance) does not contain provisions on the criteria and the procedure for accreditation. This is probably a topic regulated elsewhere horizontally. Regulation on the criteria and the procedure for accreditation of test laboratories is often similar to regulation on the designation of conformity assessment bodies. For both but more often for test laboratories, quite a few jurisdictions give an important role to national or international accreditation bodies. Some of these accreditation bodies work for a continent or part of it (see for example: [IAAC](#)) and most cooperate with a worldwide accreditation organisation (see for example: [ILAC](#)). For some sectors, the worldwide accreditation organisation itself provides for accreditation too. For others, the worldwide accreditation organisation just has the role of coordinating, training and supervising the accreditation bodies and developing common principles and guidelines etc. Accreditors mostly accredit against standards and the criteria contained therein, not against regulation. Regulators who rely on accreditation often give up their own power³⁶. This can make sense in many

cases and in particular if the regulators feel less competent than accreditors. However, it does not make sense if the technical competence requirements needed for a certain sector are so specific that the international standard or accreditation bodies cannot grasp them.

Very complex and dense provisions on conformity assessment are to be found in the [Commission Regulation \(EU\) No 748/2012](#) of 3 August 2012 laying down rules to be implemented for the airworthiness and environmental certification of aircraft and related products, parts and appliances.

10.5.3 – Other third party ex ante verification

Whilst conformity assessment bodies are often used by regulators in technical regulations, there are other, partly even older traditions of third party ex ante verification. Other third party ex ante verification can be used as replacement or as addition to verification by conformity assessment bodies or by the state. We list here some examples:

- ◆ Professional or business organisations (“chambers”) are often called upon to give their authorisation prior to a new professional or businesses being permitted to start their activity³⁷;
- ◆ Via the obligation to be insured, insurances can become verifiers with or without their wish. They can be explicitly be mandated to verify or just verify in their own interest, to reduce risks³⁸;
- ◆ Airlines Economic operators eg. and their – partly external – service companies like Swissport became verifiers of passports, visas and sometimes even vaccinations since certain states obliged, since the 1990s, airlines to take back at their own expense passengers who are not in conformity with immi-

³⁶ Exceptionally, accreditation bodies accept to accredit against criteria set up by the regulator.

³⁷ This is e.g. the case for lawyers / attorneys or architects in Germany. The chamber is entrusted to verify the legal conditions and even executes itself the enrolment. In some federal states, they may even establish conditions for enrolment on their own, as para-state regulators. We found only one [webpage](#) in English with further explanation, managed by the (private) association of the regional public chambers of architects.

gration or other travel rules;

- ◆ Public consultation obligations can invite natural or legal persons concerned or even everybody to have a look at certain environmental, construction or infrastructure projects. Indirectly, the consulted persons will become verifiers because they will bring forward spotted non-conformities if this is in their interest. See the [Aarhus Convention](#) as an example of an international legal framework obliging the consultation of the general public; and
- ◆ The same applies where the regulator establishes a need for a certain other person, e.g. a neighbour, to agree, whilst limiting the reasons for refusal to certain legal grounds (e.g. minimum distance with regard to buildings).

The examples given here are certainly not exhaustive. Subject to the regulatory sector and jurisdiction, it is more or less likely that other potential third-party verifiers can be identified.

We consider it to be important to identify potential third-party verifiers because the resources of state authorities are mostly limited and rather declining over time, whilst the number of sectors and operators in these sectors tends to increase in quite some jurisdictions. Hence, there is an enforcement mismatch or loophole at the level of resources. Furthermore, third parties are sometimes simply better qualified or placed to identify non-conformities.

10.5.4 – Special focus : involvement of insurers as ex ante verifiers and rule-setters

The involvement of insurers listed above merits a deeper analysis because it has high utility potential in times of declining state resources. It goes back to the 19th century³⁹. The European industrialisation in the 19th century created suddenly manifold risks that did not exist before, mainly in relation to machinery. Presumably, it was difficult to assess the manifold risks and to cover them with regulation. Some states reacted by a smart combination of minimally invasive regulatory

³⁸ E.g. vehicle insurance companies tend to become verifiers of certain formal requirements when the vehicle owner needs a proof of insurance. To avoid unnecessary paper work, the insurance companies verify points that might lead to rejection of the inscription of the vehicle later-on. In some states, e.g. in Belgium, the inscription procedure even passes exclusively via the insurance companies.

³⁹ The remainder of this Subsection is a reprint of the Part B of this [article](#).

measures that led to an efficient outsourcing of damage avoidance. They established public or semi-public insurance companies and obliged the owners of factories to sign contracts with these insurance companies or even to become a member of insurance cooperatives. The insurance companies or cooperatives then set-up mandatory rules for their clients or members.

Based on this historic model, which still exists today for certain professional activities, one could imagine the following system:

- ◆ Regulation makes liability insurance for risky products mandatory;
- ◆ The insurance companies will react to damages by setting-up recommendations or mandatory rules;
- ◆ The insurance companies will also supervise the respect of the recommendations or mandatory rules and will react to non-compliance, e.g. by non-prolongation of contracts, by additional fees or by imposing further costly control mechanisms; and
- ◆ Insurers will probably use the most effective path for risk reduction. When more promising, insurances might use information campaigns for specific risks rather than establishing complicated sets of recommendations or mandatory rules.

In particular for new products, services or risks, the liability insurers might have an interest in sharing their experience and in particular the data on various types of incidents and damages. This common interest might even lead to the joint establishment of specialised institutes that help to develop recommendations or mandatory rules for risk reduction.

10.5.5 – Self-certification as an alternative or complementing element

Both the ex ante verification undertaken by the conformity assessment bodies and the ex ante verification undertaken by state authorities can be combined with elements of self-certification. Self-certification can also become an alternative to ex ante verification altogether, provided that the intensity of ex post conformity verification is high enough to ensure compliance with the legal requirements. Even a very low intensity of ex post conformity verification may be sufficient if the operators in the sector are all very responsible, e.g. with a view of preserving their reputation or because the costs of an infringement stated by

the authorities would be so high that there is a strong deterring effect. For this reason it was possible, in the U.S., to base the safety legislation for cars entirely on self-certification. In Europe too, self-certification has become an important element of product legislation. However, pure self-certification is mainly applied for low-risk products or services.

When should self-certification be applied? There cannot be a conclusive answer to this question without taking into account the situation of the respective sector. However, a few general statements can be made:

1. Self-certification is a good complementary tool for those elements of conformity that are not subject to an ex ante verification.
2. If neither the state nor the conformity assessment bodies nor any other third-party verifiers have the capacity to ensure an ex ante verification for all products on the market, self-certification plus a relatively bold ex post verification based on random checks might be a good solution.
3. The same is true if the ex ante verification would substantially delay the market entry of life-saving products or services, e.g. for products of medical technology. The medical benefit of faster availability may outweigh the increase in safety triggered by verifying in advance.
4. The stronger the ex post verification, the higher the likelihood that self-certification will be sufficient.
5. The bigger the disadvantage and the higher the likelihood of being sanctioned following ex post verifications, the higher the likelihood that self-certification will be sufficient.
6. The more the operators behave in a responsible way, the higher the likelihood that self-certification will be sufficient.

If self-certification has been chosen, it should be ensured that the economic operator consciously assesses the legal conformity of her/his product or service. Regulation may oblige making a detailed declaration of conformity, as seen in Chapter V of [Commission Regulation EU/10/2011](#) of 14 January 2011 on plastic materials and articles intended to come into contact with food. Regulation can also oblige the operator to establish a “product information file” which is based on a safety assessment as done in Article 10 of [Regulation EC/1223/2009](#) of 30 November 2009 on cosmetic products.

An intermediate solution consists in letting the economic operator do the testing (and subsequent certification) himself, but to ensure that the testing is occasionally or systematically observed, be it by conformity assessment bodies, state agencies, or accredited test laboratories (see Section 10.6 below). This solution is sometimes unavoidable, namely if the conformity assessment bodies or the state agencies do not have the necessary test facilities at their disposal.

10.6 The procedure of in-advance verification

The advance verification is better executed if there is a verification procedure to be applied⁴⁰. A common procedure makes the ex ante verification more reliable, faster and fairer.

10.6.1 – A basic typology of procedures

In terms of types of procedures, we can distinguish amongst the following, becoming ever more stringent:

- a) information procedures;
- b) notification including registration procedures without waiting time (registration being a sub-type of notification);
- c) notification procedures with waiting time (see e.g. the [notification procedure](#) of the Technical Barriers to Trade Agreement of the WTO);
- d) authorisation/certification procedure with automatic authorisation after expiry of a deadline;
- e) authorisation/certification procedure with deadline, but without automatic authorisation after expiry of a deadline; and
- f) authorisation/certification procedure without a deadline.

The procedures a) to c) should evidently be complemented with empowerments

⁴⁰ Exceptionally, the same may be true for ex post verification. However, ex post verification should instead be mostly unpredictable, in order to have the utmost deterrent effect. A reliable procedure might be counter-productive.

to act against infringements. See for the typology of empowerments below [Section 11.5](#).

10.6.2 – Parameters applicable to procedures

What are the further parameters determining in-advance procedures?

- ◆ Regulation can determine the modalities of application / notification. E.g. it can foresee that the application has to be made in writing or by electronic means.
- ◆ Regulation can set up time-limits for applications / notifications (e.g.: at least three months before the start of the activity in question).
- ◆ Regulation can set up precise lists of what needs to be contained in the application / notification.
- ◆ Regulation can set up rules for the communication between the authority or the conformity assessment body and the applicant (e.g. on the technical means of communication, the deadlines for responses).
- ◆ Regulation can set up rules on how conformity is to be verified (e.g. test procedures, verification limited to documentation).
- ◆ Regulation can impose preliminary self-certification procedures, meaning procedures in which the natural or legal person verifies and confirms elements of conformity, as a precondition for the main procedure.
- ◆ Regulation can impose to go for the views or even agreements of private natural or legal bodies or public bodies to be provided as precondition for the procedure.
- ◆ Regulation can set up time-limits for the authorisation / certification to be delivered, with or without “stop-the-clock” mechanisms when the applicant has to deliver more data or documents.
- ◆ The procedure can foresee that there is a formal authorisation by an authority or certification by a conformity assessment body or that the operator only has to notify its intended activity. In the latter case, regulation can foresee that the authority may only intervene during a certain lapse of time in order to ban or restrict the activity in question.

10.6.3 – Special procedural techniques

10.6.3.1 – *Simplified renewal and transfer procedure*

Bhutan has an [act](#) and supplementing [regulations](#) on the admission of medicines that can serve as a good example for various procedural techniques. The regulations contain a range of specific provisions that can help greatly in practical terms, e.g. on simplified renewal or transfer of registrations from one person to the other (see Sections 46 and 52 respectively).

10.6.3.2 – *Recognition of foreign approvals or certificates*

The same Bhutanese [regulations](#) provide for a simplified procedure for medicines previously authorised by a group of foreign medicines agencies (see Section 35). This is first of all a good feature for countries which have less than top-level technological competency. However, it should be ensured that a certain medicine or substance can already be banned or its licence be withdrawn if one of the foreign medicines agencies has done so (and not just when the last one of the group has done so) and that the foreign medicines agencies provide for updates on their bans and licenses.

But the recognition of foreign certificates and approvals is also an interesting regulatory technique for highly developed jurisdictions. The recognition of foreign certificates and approvals can be decided unilaterally or in conjunction with the state whose certificates or approvals shall be recognised. To reduce unnecessary burden for the exporting industry, it can be useful to negotiate with trade partners bilaterally on the recognition of certificates and approvals. The negotiations can lead to formal or informal bilateral agreements.

As formal bilateral agreements tie up a lot of resources and are not easy to manage, it is preferable to foresee an empowerment to decide upon the recognition of foreign certificates by regulatory acts. The empowerment should not be limited to the case of mutual recognition. According to theories of free trade, it is advantageous in all cases to recognise foreign certificates and approvals provided that these fulfil the same requirements and are based on an equal or higher level of stringency as the domestic certificates and approvals. Furthermore, if the domestic industry exports more to the third country than vice versa, the domestic

industry will profit more from the recognition of the foreign certificates than the industry of the third country. It can substantially reduce costs by applying only for the certificate or the approval of the third country. The only necessary condition is that the certificate or the approval must be based on an assessment that is at least of an equivalent level of stringency as requested by domestic law.

We present here as an example of the recognition of foreign certificates the [Brazilian Portaria INMETRO / MDIC Number 247 of 26/05/2014](#) on the conformity assessment for the retreading of tires:

“14.3 Para os ensaios realizados por laboratórios estrangeiros devem ser observadas e documentadas a equivalência do método de ensaio e da metodologia de amostragem estabelecida. Além disso, esses laboratórios devem ser acreditados pela Cgcre ou por um acreditador que seja signatário de um acordo de reconhecimento mútuo do qual o Inmetro também faça parte. São eles:

- a) Interamerican Accreditation Cooperation – IAAC;*
- b) International Laboratory Accreditation Cooperation – ILAC.”*

Amended machine translation:

“14.3 For the tests carried out by foreign laboratories, the equivalence of the test method and of the established sampling methodology should be observed and documented. In addition, these laboratories must be accredited by Cgcre or by an accreditor that is a signatory to a mutual recognition agreement to which INMETRO is also party. They are:

- a) Interamerican Accreditation Cooperation - IAAC;*
- b) International Laboratory Accreditation Cooperation - ILAC.”*

The technique of recognising foreign certificates has also been used in the Canadian [Heavy-duty Vehicle and Engine Greenhouse Gas Emission Regulations of 2013 \(SOR 2013/24\)](#):

“13. (1) Subject to subsections (4) and (8), a heavy-duty vehicle or heavy-duty engine of a given model year that is covered by an EPA certificate and that is sold concurrently in Canada and the United States must conform to the certification and in-use standards referred to in the EPA certificate instead of to the following standards, whichever apply: ...”

Strictly speaking, this paragraph goes even further than a simple recognition in so far as this paragraph declares the domestic law inapplicable if the product is to be sold both in Canada and in the U.S.

The recognition of foreign certificates can be subject to translation requirements for some or all foreign languages. See as an example Section 6.1.1.3 of the [Brazilian Portaria INMETRO / MDIC No. 649 of 12/12/2012](#), “General Requirements for Declaration of Conformity by Provider of Products”⁴¹, which exempts English and Spanish documents from the requirement of translation:

“6.1.1.3 Os documentos para a solicitação do Registro a serem anexados ao Sistema Orquestra são:

2) No caso de apresentação de Certificado do Sistema de Gestão da Qualidade emitido por OAC acreditado por signatários do acordo de reconhecimento mútuo (Multilateral Recognition Agreement – MLA) do International Accreditation Forum – IAF, este deve estar acompanhado de tradução juramentada no idioma português, quando este for emitido em idioma distinto do inglês ou espanhol. O Certificado deve ser válido para o processo produtivo na unidade fabril do objeto da Declaração da Conformidade do Fornecedor, de forma inequívoca. Os demais documentos referentes ao Sistema de Gestão da Qualidade, que estiverem em idioma distinto do inglês ou espanhol, devem estar traduzidos para o português.”

Amended machine translation:

“6.1.1.3 The following documents must be uploaded to the Orchestra System in order to request registration:

2) In case of filing of the Certificate of Quality Management System issued by CABs accredited by signatories of mutual recognition (Multilateral Recognition Agreement agreement - MLA) of the International Accreditation Forum - IAF, this must be accompanied by a sworn translation in Portuguese language when it is issued in a different language than English or Spanish. The certificate must be unequivocally valid for the production process in the factory of the object of the Declaration of Conformity Supplier. The other documents related to the

⁴¹ “Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos”.

Quality Management System which are in a language other than English or Spanish must be translated into Portuguese.”

Serbia’s [Regulation 98/2009](#) concerning the manner of recognition of foreign documents of conformity and marks of conformity is an example of a broad approach that is resource light and not specific to a certain regulated product. Important elements of the regulation include:

- ◆ Recognising foreign documents of conformity issued in line with a ratified international agreement signed by Serbia, an agreement signed by Serbia is determined by the relevant Ministry (Article 3);
- ◆ Article 6 allows for recognition of foreign technical regulations that the economic operator, or its product, is purporting to comply with and which form the basis for which conformity assessment was approved in that foreign jurisdiction;
- ◆ All foreign documents are to be translated into Serbian by a certified court translator;
- ◆ Foreign documents will then be considered by a Commission of a minimum of three members, to include at least one representative of the competent Ministry to which the foreign document concerns, a representative of the Accreditation Board of Serbia and an expert representative for the area regulated by the corresponding Serbian technical regulation (Article 7);
- ◆ Article 11 provides that the decision of the Commission remains valid until the expiry of validity of the foreign document or in the absence of such a date, valid for three years from its date of issue;
- ◆ The Commission is to determine whether (Article 8):
 - the foreign documents refer to requirements equivalent in degree of safety, life and health of humans, protecting animals and plants, environment protection, protection of consumers and other users and protection of property, as regulated by the corresponding Serbian technical regulation; and
 - requirements of the foreign technical regulation which the foreign conformity assessment body shall comply with in order to perform the conformity assessment procedure of product, provide at least the equivalent degree of compliance with requirements as

determined in the corresponding Serbian technical regulation for the designated or authorised conformity assessment body.

An interesting feature of Serbia's regulation for recognising foreign documents is that it permits foreign technical regulation (translated) to be submitted. This is particularly useful for situations where a jurisdiction may not yet have a regulation in place and provides an opportunity for the competent government authority to consider the standard of the foreign technical regulation. Expanding on Serbia's model for recognising foreign documents connected with foreign technical regulation, it could be specified that where no national technical regulation exists, prospective registrants should provide at least 2 examples of foreign technical regulation to which the sensitive product conforms. The downside of this approach, is that the domestic market will have inconsistent standards applied to certain products, depending on what foreign regulation is taken as a standard. This can be remedied by specifying particular jurisdictions as we will see in the following approaches.

Australia's approach to recognising foreign certificates depends on the regulated product. E.g. for medical devices, [Australia](#) permits the use of market authorisation evidence only from comparable overseas regulators / assessment bodies for medical devices, specifically:

- ◆ Certificates issued by certain Notified Bodies designated by the medical device regulators of European member states, under the medical device regulatory frameworks of the EU (Medical Devices Directives, Medical Device Regulation, or IVD Regulation);
- ◆ Decisions of the United States Food and Drug Administration (FDA);
- ◆ Approvals and licences issued by Health Canada;
- ◆ Pre-market approvals from Japan (issued by the Ministry of Health, Labour and Welfare (MHLW), Pharmaceutical and Medical Devices Agency (PMDA) or Registered Certified Body (RCB), whatever is applicable); and
- ◆ Certificates and reports issued under the Medical Device Single Audit Program (MDSAP).

There is no suggestion that market authorisation in the jurisdictions listed will automatically lead to Australian market authorisation. But authorisations by these jurisdictions are credible evidence of quality and conformity. Australia's approach

to recognising foreign authorisations requires a jurisdiction to already have own regulation to which it can compare the regulation of other jurisdictions. This approach is more suited to jurisdictions with a mature system of regulation for which there are benefits in getting sensitive products to market quicker by recognising authorisations of comparable jurisdictions.

If the recognition of foreign certificates and approvals is desired in international negotiations, several of the harmonisation approaches presented in this Handbook can be used. In case of doubt, the Optional harmonisation gives the best chance of reaching an agreement. It does not hurt anyone's interests to recognise certificates and approvals if they are based on the top level of the world's product requirements or standards. For details see the [Subsection 7.3.3](#).

If the recognition of foreign certificates is not possible, one might consider, as a second best possibility, joint conformity assessments so as to lower the burden for economic operators. Joint conformity assessments can be provided through legislation, by administrative arrangement, or, if in one of the jurisdictions the conformity assessment tasks are delegated to private bodies, by intelligent company and contractual law arrangements.

Where several jurisdictions practice unilateral recognition of foreign certificates and approvals, some jurisdictions can become certification or even approval hubs, being recognised by several other jurisdictions and thus operating also in their interest. For more details on the topic of unilateral recognitions in conjunction with certification hubs, see [this article](#).

10.6.4 – The results of procedures

10.6.4.1 – Authorisations and other endings of procedures

Procedures have either no specific result other than somebody being informed (letters a) to c) of [Subsection 10.6.1](#)); or they end with:

- ◆ the certification by private or public conformity assessment body,
- ◆ the authorisation by a delegate of the state, or
- ◆ the authorisation by the state itself, or

- ◆ the award of a certain amount of money by the state (so-called grants, which also could be regarded as a sub-type of authorisations).
- ◆ We examine in the following various aspects of authorisations by the state. These aspects are mostly also relevant for the other endings of procedures.

10.6.4.2 – Aspects to be considered in authorisation systems

If the principle of authorisation is chosen, there is a variety of additional elements to be thought of:

- ◆ Shall authorisations be mandatory for the entire scope or only for a part of it? Or shall authorisations be just voluntary or just voluntary for a part of the scope?⁴²
- ◆ Shall authorisations be delivered for each individual service or product or groups / families of services or products? See the Brazilian [Portaria INMETRO / MDIC No. 649](#) of 12/12/2012, “General Requirements for Declaration of Conformity by Provider of Products”⁴³, which defines:

“4.9 Família de Produto

Agrupamento de modelos do produto, para um mesmo fim, de um mesmo fabricante, de uma mesma unidade fabril, de um mesmo processo produtivo, que possuem em comum alguma(s) da(s) seguinte(s) característica(s): memorial descritivo, projeto, dimensões, massa, matéria-prima, configuração, uso, entre outras, conforme definido em cada Requisito de Avaliação da Conformidade específico.”

⁴² Voluntary authorisations can under certain circumstances make sense as well. We have not found any example of voluntary authorisations, but we did for voluntary certification. Brazil adopted an ordinance ([Portaria INMETRO No. 307 of 1/7/2014](#)) which foresees the voluntary certification of families of mineral water:

“1.2.2 A certificação deve ser realizada para cada família de água mineral natural envasada, que se constitui como um agrupamento de modelos de água mineral natural de mesma classificação e oriunda de mesma fonte, envasados em uma mesma unidade fabril, com mesmo processo produtivo, e acondicionados em embalagens de mesma matéria prima.”

Amended machine translation:

“1.2.2 The certification must be made for each family of bottled natural mineral water, which is constituted as a grouping of models of natural mineral water with the same classification and coming from the same source, packaged in the same factory, with the same production process, and packaged in the same raw material.”

⁴³ “Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos”.

Amended machine translation:

“4.9 Product Family

Grouping of product models for the same purpose, of the same manufacturer, of the same plant, of the same production process, having in common some of the following characteristic(s): technical description, design, size, weight, raw material, configuration, usage, among others, as defined in each specific requirement of Conformity Assessment.”

- ◆ Can / must the documents relevant for the application be submitted electronically? See the Brazilian [Portaria INMETRO / MDIC No. 649](#) of 12/12/2012, “General Requirements for Declaration of Conformity by Provider of Products”⁴⁴, which provides:

“6.1.1.6 A apresentação dos documentos relacionados é de responsabilidade do fornecedor e deve ser feita pelo Sistema Orquestra. Na impossibilidade de encaminhá-los por esse meio, o fornecedor deve entrar em contato com a Dipac / Dqual para receber orientações sobre a melhor forma de encaminhar os documentos.”

Amended machine translation:

“6.1.1.6 The presentation of related documents is the responsibility of the manufacturer and must be made by the Orchestra System⁴⁵. Failing to process through this, the manufacturer must contact the Dipac / Dqual to receive guidance on how best to forward the documents.”

- ◆ Shall there be deadlines for the decision-making or the authority?
- ◆ Shall the authorisation be automatically given if the administration does not decide in time?
- ◆ Shall there be fees as a precondition for the authorisation?

⁴⁴ “Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos”.

⁴⁵ The relevant database “Orchestra” can be visited under: www.inmetro.gov.br/qualidade/regobjetos.asp

- ◆ What proof of authenticity shall be requested for the application ([See Section 13.4](#))?
- ◆ Which information has to be provided with the application, and which information just on request?
- ◆ Which declarations (e.g. of good faith) have to be provided?
- ◆ What proof of authenticity shall be requested for these declarations ([See Section 13.4](#))?
- ◆ What are the conditions under which the application must be rejected?
- ◆ What are the conditions under which the application may be rejected?
- ◆ May the authorisation be subject to certain conditions, imposed by the authority on the basis of its discretionary power? If so, what are the acceptable criteria and considerations?
- ◆ Can the authorisation be suspended (temporarily non-valid)? If so, what are the acceptable criteria and considerations?
- ◆ Can the authorisation be withdrawn (consequence: non-validity as from the moment of the withdrawal decision)? If so, what are the acceptable criteria and considerations?
- ◆ Under what conditions must the authorisation be withdrawn (consequence: non-validity as from the moment of the withdrawal decision)?
- ◆ Can the authorisation be revoked (consequence: non-validity from the beginning), e.g. in cases of fraud? If so, what are the acceptable criteria and considerations?
- ◆ Under what conditions must the authorisation be revoked (consequence: non-validity from the beginning)?
- ◆ Is the authorisation automatically invalid under certain conditions, e.g. in cases of fraud?
- ◆ For how long is the authorisation valid?
- ◆ What is the earliest moment for application for renewal?
- ◆ What is the latest moment for application for renewal?
- ◆ Which procedure applies to renewals?

- ◆ Shall there be intermediate inspections between the first authorisation and the renewal and between the renewals?
- ◆ For technical authorisations: should accredited test laboratories play a role in any of these steps?

Many of these aspects are illustrated in the [Accounting and Corporate Regulatory Authority \(Amendment\) Act 2014 of Singapore](#), which could thus serve as an example:

“28G.

(1) An application to be registered by the Chief Executive as a registered qualified individual, or for the renewal of such registration, shall —

(a) contain such information and be made in such manner as the Chief Executive may determine;

(b) be accompanied by a declaration in such form as the Chief Executive may specify; and

(c) be accompanied by such application and registration fees as may be prescribed.

(2) A person shall not be registered as a registered qualified individual, or have his registration as such renewed, unless —

(a) the person is a qualified individual; and

(b) the person has completed such courses and training as may be prescribed.

(3) The Chief Executive may refuse to register or renew the registration of an individual as a registered qualified individual if —

(a) the individual has been convicted (whether in Singapore or elsewhere) of any offence involving fraud or dishonesty punishable with imprisonment for 3 months or more;

(b) the individual is an undischarged bankrupt, whether in Singapore or elsewhere; or

(c) the Chief Executive is otherwise not satisfied that the individual is a fit and proper person to be so registered.

(4) In determining whether an individual is a fit and proper person under subsection (3)(c), the Chief Executive may consider such factors as may be prescribed.

(5) The Chief Executive shall refuse to register a person as a registered qualified individual if –

(a) that person's previous registration as a registered qualified individual had been cancelled because of –

- (i) a breach of a prescribed term or condition of registration; or*
- (ii) a failure to pay a financial penalty imposed because of a breach of a prescribed term or condition of registration; and*

(b) less than 2 years has elapsed since the date on which the registration was cancelled.

(6) The registration, or renewal of registration, of a registered qualified individual shall be valid for such period as the Chief Executive may specify.

(7) An application for the renewal of registration of a registered qualified individual must be made not earlier than 60 days before the date of the expiry of registration.

(8) The Chief Executive may impose on any registered qualified individual such restrictions pertaining to the use by that individual of the electronic transaction system as the Chief Executive thinks fit.

(9) Every registered qualified individual shall comply with such terms and conditions as may be prescribed.

(10) Without prejudice to subsections (12), (13) and (14), the Chief Executive may cancel the registration of a registered qualified individual –

(a) if the person ceases to be a qualified individual;

(b) if there exists any ground on which the Chief Executive would have been entitled to refuse registration or renewal of registration under subsection (3); or

(c) if the registered qualified individual applies to the Chief Executive for his registration to be cancelled.

(11) The Chief Executive may refuse to cancel a registered qualified individual's registration under subsection (10)(c) if the Chief Executive suspects that the registered qualified individual has breached any of the terms and conditions prescribed under subsection (9) and until –

(a) the Chief Executive has investigated the suspected breach; and

(b) the Chief Executive –

(i) has determined that there was no breach; or

(ii) has determined that there was a breach and has either –

(A) taken action against the registered qualified individual under subsection (12) for the breach; or

(B) decided not to take action against the registered qualified individual under subsection (12) for the breach.

(12) Where a registered qualified individual has breached any term or condition prescribed under subsection (9), the Chief Executive may –

(a) cancel the registration of the registered qualified individual;

(b) suspend the registration of the registered qualified individual for a period not exceeding 12 months;

(c) restrict the registered qualified individual's use of the electronic transaction system to such extent as the Chief Executive thinks fit;

(d) require the registered qualified individual to pay, within such period as the Chief Executive may specify, a financial penalty not exceeding \$10,000 for each breach of such term or condition; or

(e) censure the registered qualified individual."

See for another example of a straightforward authorisation system [this prototype regulation](#) on research and technology risks, and in particular Article 6 thereof.

10.6.4.3 – Special focus: authorisations with conditions

In regulatory systems which use authorisations, authorities sometimes feel it to be inappropriate to provide a full/regular authorisation. For instance, authorities are sometimes not sure whether the applicant economic operator is really reliable

or whether s/he possesses the adequate knowledge. To cope with these situations, the authorities may wish to provide for a temporally limited or conditioned authorisation instead of a full/regular authorisation. To do so they need, in many jurisdictions, a special empowerment. Such an empowerment should be foreseen by regulation. The empowerment might allow deviation from the rule of full authorisation, with or without specified conditions.

In some jurisdictions, it might even be necessary to enumerate precisely in the regulation the conditions that the authorities may refer to in a conditional authorisation. Regulation may empower authorities to set up one or more of the following conditions:

- ◆ Provide an additional certificate within X months;
- ◆ Employ a qualified person to close knowledge gaps;
- ◆ Undergo a specific training to close knowledge gaps;
- ◆ Review the quality system or the processes applied for certain items;
- ◆ Modify the physical installation for certain items; or
- ◆ Exchange certain components or ingredients.

When enumerating conditions to be used for conditional authorisations, regulators need to keep in mind the conditions they have set for the full/regular authorisation. Do the two sets of conditions fit well together? Can the conditional authorisation be abused by circumventing the minimum requirements of the full/regular authorisations? Furthermore, it is worth checking whether the conditional authorisations open the door to corruption.

Conditions can also be used with suspensive effect. Any kind of condition used for conditional authorisations can be combined in different ways with time limitations.

11. EX POST VERIFICATION / ENFORCEMENT



“Nothing is more destructive of respect for the government and the law of the land than passing laws which cannot be enforced.”

Albert Einstein

The effectiveness of regulation is limited if its content is not put into practice. To ensure that its content is put into practice, enforcement is needed. Subject to the type of obligations contained in the regulation, the enforcement mechanisms have to be designed differently.

11.1 Information and enforcement

Regulatory measures other than regulation can become effective when they are made known to the target population. If an authority creates an administrative incentive, it must ensure that its target population comes to know about the incentive. Information is crucial.

For classic regulation which imposes obligations, the aspect of information tends to be regarded as secondary by regulators. Regulators instead tend to immediately reflect in terms of enforcement. Enforcement is, of course, necessary. However, informing the target population about legal obligations might be more cost-effective than only providing for enforcement. Many citizens, economic operators or professionals are ready to abide by the law. They just need to know about it. Instead of being expensively targeted by enforcement measures, it would suffice to inform them. Accordingly, regulators should think about information as a preliminary step to enforcement. For some measures of enforcement, e.g. for sanctions, preliminary information is also required for reasons of fairness. One cannot expect everybody to read Official Journals.

The Economic Community of West-African States (ECOWAS) [Regulation C/REG.4/05/2008](#) of 18 May 2008 on the harmonisation of rules governing quality control, certification and marketing of vegetable seeds and seedlings in the ECOWAS Space contains basic provisions on information and is thereby one of the relatively rare examples of regulation that recognises the importance of preliminary information:

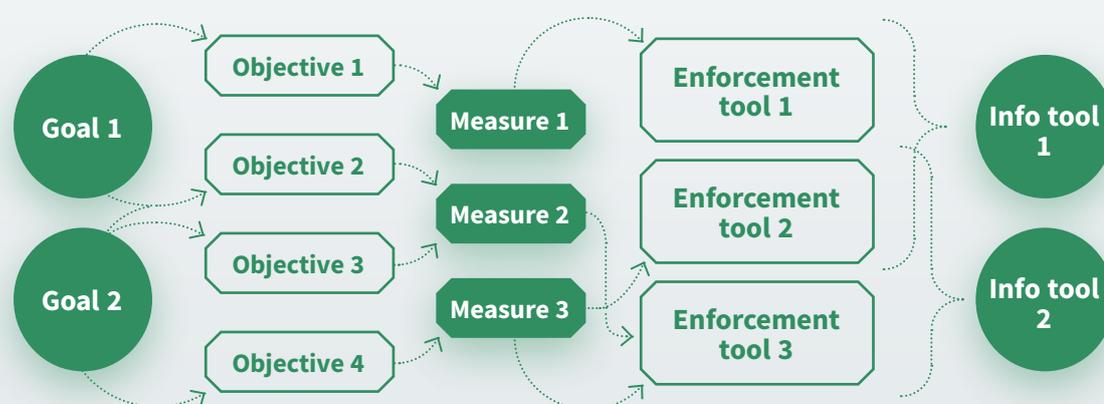
“Article 8. - Principle of Participation and Information

- 1. Member States shall ensure the full participation of the pesticides sector players in the process of public decision-making in matters of pesticide.*
- 2. Member States shall organize public access to pesticide information available to public authorities.*
- 3. Member States shall help train and build the awareness of pesticides sector players.”*

Similarly, the Turkish law on energy labelling prescribes very specific measures covering public awareness:

“Television and radio channels making national and/or regional broadcast shall broadcast training programs, contests, short films and/or cartoons prepared or procured to prepare by the General Directorate between 07.00 and 23.00 hours not to be less than thirty minutes in total in a month.”⁴⁶

OVERVIEW ON GOALS, MEASURES, ENFORCEMENT AND INFORMATION TOOLS



⁴⁶ See <https://policy.asiapacificenergy.org/node/2286>.

We have seen in [Chapter 5](#) how goals, objectives, measures, requirements and incentives interrelate. We can now build on the graph used there, and modify the graph so as to include two new types of items: information and enforcement.

We can also develop charts similar to the ones presented in Chapter 5 to cover the aspects of information and enforcement. It is usually best for information and enforcement to be related to entire regulatory measures. However, in certain cases, information and enforcement need to relate to individual requirements. E.g. requirements can be addressed to different types of persons which need to be addressed separately. Accordingly, readers will find hereafter two charts: the measures-information-enforcement-chart and the requirements-information-enforcement-chart.

The measures-information-enforcement-chart

Measure No	Measure title / description	Information tool(s) to be used to make the measure known	Enforcement tool(s) to be used
M1		e.g. internet campaign	e.g. supervision by competitors + right to sue at court
M2		e.g. press release	e.g. state in advance verification
M3			
M4			
M5			
M6			

The requirements-information-enforcement-chart

*	Requirement title / description	Information tool(s) to be used to make the requirement known	Enforcement tool(s) to be used
R1			
R2			
R3			
R4			
R5			
R6			

* Requirement No

What to fill in? For the information column, readers might get some inspiration from the catalogue of regulatory measures in Section 4.2. Some of the information related to regulatory measures could well serve here for the chart, regardless of whether they are deemed and processed as independent regulatory measures or just as information means.

For the enforcement column, it is preferable to study first the full range of possibilities presented in this chapter. Considerations on enforcement can easily become very complex when all possibilities are really investigated prior to decision-making. The chart can serve to summarise the considerations, to keep the oversight and to ensure that nothing is forgotten.

Considerations on enforcement can even sometimes trigger the need to revisit goals, objectives, measures, requirements and incentives. This happens e.g. if it turns out that some requirements can hardly be enforced at all or that they can only be enforced for a part of the target population, thus causing an uneven playing field. Enforcement can also turn out to be disproportionately costly. It is thus risky both in terms of efficiency and costs not to integrate enforcement into the overall planning for a certain sector. The looping-back from considerations on enforcement to the overall planning and the development of the regulatory measures is often essential for a successful sector policy.

11.2 Content and density of state ex post verification

Most regulation does not determine precisely what the authorities have to do to supervise operators or citizens. The vagueness can be noted both with regard to the content of surveillance activities and their intensity. Not to determine the minimum verification intensity and the methods of supervision leads to disparities in verification intensity. At worst, the entire system is put at risk because some regional or local authorities do not supervise intensely enough or not in the same way as others. In this situation, a legal intervention of the Centre is not always an option. E.g. if the obligations for ex post verification (“surveillance”) are not precisely defined in the legal act, it would be hazardous for the Centre to intervene legally against geographic entities. To prevent these unfortunate situations, regulation should determine the content and the intensity surveillance obligations of the geographic entities’ authorities in as much detail as possible. Representatives of geographic entities are not always opposed to precise obligations. Precise obligations help them to justify more human resources.

There are relatively few examples of precise surveillance obligations. [Commission Regulation EC/589/2008](#) of 23 June 2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs is a good example:

“Article 24 - Checks

1. The Member States shall appoint inspection services to check compliance with this Regulation.

2. The inspection services referred to in paragraph 1 shall check the products covered by this Regulation at all stages of marketing. Apart from random sampling, checks shall be carried out on the basis of a risk analysis, taking into account the type and throughput of the establishment concerned, as well as the operator’s past records as regards compliance with the marketing standards for eggs.

3. For Class A eggs imported from third countries, the checks provided for in paragraph 2 shall be made at the time of customs clearance and prior to the release for free circulation. Class B eggs imported from third countries shall be released for free circulation only after checking at the time of customs clearance that their final destination is the processing industry.

4. Apart from random sampling, operators shall be inspected at a frequency to be determined by the inspection services on the basis of a risk analysis as referred to in paragraph 2, taking account, at least, of:

(a) the results of previous checks;

(b) the complexity of the marketing channels followed by the eggs;

(c) the degree of segmentation in the production or packing establishment;

(d) the quantity of eggs produced or packed;

(e) any substantial changes from previous years in the type of eggs produced or processed or in the marketing method.

5. Inspections shall be conducted regularly and be unannounced. Records referred to in Articles 20, 21 and 22 shall be made available on first request to the inspection services.

Article 25 - Decisions on non-compliance

1. Decisions by inspection services following inspections provided for in Article 24 indicating non-compliance with this Regulation may only be taken for the whole of the batch which has been checked.

2. *Where the checked batch is deemed not to comply with this Regulation, the inspection service shall prohibit its marketing, or importation if the batch comes from a third country, unless and until proof is forthcoming that it has been made to comply with this Regulation.*
3. *The inspection service which made the check shall verify whether the rejected batch has been or is being made to comply with this Regulation.”*

This Regulation contains a complete surveillance system which is based on marking that ensures traceability. Another good example is [Commission Regulation EC/642/2009](#) implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to eco design requirements for televisions. It describes precisely what has to be tested and the consequences of negative tests:

“ANNEX III -VERIFICATION PROCEDURE

When performing the market surveillance checks referred to in Article 3(2) of Directive 2005/32/EC, the authorities of the Member States shall apply the following verification procedure for the requirements set out in Annex I.

1. *Authorities of the Member State shall test one single television unit.*
2. *The model shall be considered to comply with the provisions set out in Annex I, if:*
 - (a) *the result for on-mode power consumption does not exceed the applicable limit value set out in Annex I, points 1 and 2 of Part 1 by more than 7 %; and*
 - (b) *the results for off-mode/standby conditions, as applicable, do not exceed the applicable limit values set out in Annex I, points 1(a), 1(b), 2(a) and 2(b) of Part 2 by more than 0,10 Watt; and*
 - (c) *the result for the peak luminance ratio set out in Annex I, Part 3 does not fall below 60 %.*
3. *If the results referred to in point 2(a) or (b) or (c) are not achieved, three additional units of the same model shall be tested.*
4. *After three additional units of the same model have been tested, the model shall be considered to comply with the requirements set out in Annex I, if:*

(a) the average of the results for the latter three units for on-mode power consumption does not exceed the applicable limit value set out in Annex I, points 1 and 2 of Part 1 by more than 7 %; and

(b) the average of the results for the latter three units for off-mode/standby conditions, as applicable, do not exceed the applicable limit values set out in Annex I, points 1(a), 1(b), 2(a) and 2(b) of Part 2 by more than 0,10 Watt; and

(c) the average of the results for the latter three units for the peak luminance ratio set out in Annex I, Part 3 does not fall below 60 %.

5. If the results referred to in point 4(a) and (b) and (c) are not achieved, the model shall be considered not to comply with the requirements.

6. For the purposes of checking conformity with the requirements, the authorities of the Member States shall use the procedure set out in Annex II and reliable, accurate and reproducible measurement procedures, which take into account the generally recognized state of the art measurement methods, including methods set in documents the reference numbers of which have been published for that purpose in the Official Journal of the European Union.”

[Commission Implementing Regulation \(EU\) No 392/2013](#) of 29 April 2013 amending Regulation (EC) No 889/2008 concerning the control system for organic production contains a detailed programme for enforcement with the help of entrusted private verification bodies, supervision of entrusted private verification bodies, exchange of information between these verification bodies and authorities, risk management, and percentage of verifications and of unannounced verifications.

A useful tool for facilitating the verification by authorities is to oblige operators to provide certain information on the occasion of registering themselves and/or their products, services or other activities. See as example the Brazilian [Portaria INMETRO / MDIC No. 649](#) of 12/12/2012, “General Requirements for Declaration of Conformity by Provider of Products”⁴⁷ and the database “[Orchestra](#)”.

The [Argentinian Law 26.905](#) of 13 November 2013 on the promotion or the reduction of the consumption of sodium by the population enumerates clearly, in its Article 5, the tasks incumbent on implementing authorities. Article 10 provides

⁴⁷ “Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos”.

for the empowerment and duty to establish administrative provisions on the investigations of infringements and subsequent sanctions.

Sometimes it is useful to provide, in the regulation, for an empowerment for enforcement measures such as provided for by Article 20 of the [Commission Implementing Regulation \(EU\) No 391/2013](#) of 3 May 2013 laying down a common charging scheme for air navigation services.

“Article 20 - Facilitation of compliance monitoring

Air navigation service providers shall facilitate inspections and surveys by the national supervisory authority concerned or by a qualified entity acting on the supervisory authority’s behalf, including site visits. The authorised persons shall be empowered:

(a) to examine the relevant accounting documents, asset books, inventories and any other material relevant to the establishment of air navigation charges;

(b) to take copies of or extracts from such documents;

(c) to ask for oral explanations on site;

(d) to enter relevant premises, land or vehicles.

Such inspections and surveys shall be carried out in compliance with the procedures in force in the Member State in which they are to be undertaken.”

[Regulation \(EU\) No 228/2013](#) of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 contains, in its Article 8, an empowerment for the European Commission to determine by regulatory acts detailed provisions on the monitoring of operators:

“The Member States shall conduct verifications by means of administrative and on-the-spot checks. The Commission shall adopt implementing acts regarding the minimum characteristics of the checks to be carried out by the Member States. The Commission shall also adopt implementing acts regarding the procedures and physical and financial indicators in order to ensure that the implementation of the programmes is monitored in an effective manner. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).”

Whatever is regarded as the most suitable reference example, surveillance mechanisms need to be adapted to the respective sector and market. There cannot be a standard type of surveillance program for all sectors in all jurisdictions.

11.3 When best to use ex post verification?

In this subsection, we do not deal with the choice between ex ante / in advance verification and ex post verification; this choice was dealt with at the beginning of [Chapter 10](#). Instead we deal here with the question when exactly in the ex post phase the verification is best placed.

Considerations similar to the ones made in [Subsection 10.4.2](#) can be made for the ex post verification. When do non-conformities typically become visible? Maybe, economic operators tend to abide to the rules very strictly at the beginning, but become less vigilant over time so that some delay in the verification is appropriate. Maybe the non-conformity can only be proved after a certain time so that, again, a certain delay in the verification is opportune. But if the non-conformity can cause tremendous damage, relatively early verification is even more imperative.

If we think these questions further, we come to a multi-parameter system in which inter alia the following parameters might play a role:

- ◆ periodicity or non-periodicity of verification;
- ◆ with predictable or unpredictable timing;
- ◆ announced or unannounced;
- ◆ frequency influenced by past infringements or not;
- ◆ frequency influenced by other factors of likelihood of infringements; or
- ◆ frequency and selection of targets influenced by available resources or not.

Evidently, it does not make sense to establish at the level of the regulator an exact planning for executing authorities. However, it would make sense to impose on authorities to establish such a planning, and this can be done in a more or less restrictive way. E.g. the regulator can mandate the use of all or just some of these parameters. The regulator can also set minimum frequency benchmarks.

11.4 Policing other than by authorities or conformity assessment bodies

Regulation can provide competitors or associations or other operators with the right to act in order to ensure the compliance of operators. These third parties may act because they are legally obliged to do so (11.4.1). Or they may act voluntarily (11.4.2).

11.4.1 – Mandatory surveillance by third parties

For some products, it is possible to make importers and distributors responsible for the conformity of products. See as an example Articles 13 and 14 of [Regulation EU/305/2011](#) laying down harmonised conditions for the marketing of construction products. Another approach ensuring enforcement consists in obliging private operators to notify non-compliances or incidents and to publish these notifications thereafter so that other operators can react to these notifications as if they were warnings. Similar mechanisms are to be found in the [Commission Regulation EU/16/2011](#) of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed.

See as an example of a relatively modern enforcement regime involving economic operators the [Regulation \(EU\) 2017/745 on medical devices](#). Read together, Article 10 to 15 suggest that importers, distributors, authorised representatives of the manufacturers and so-called “responsible persons” are in charge of certain verifications and thus ensure the enforcement of manufacturers’ obligations.

[Commission Delegated Regulation EU/231/2013](#) of 19 December 2012 supplementing Directive 2011/61/EU of the European Parliament and of the Council with regard to exemptions, general operating conditions, depositaries, leverage, transparency and supervision (of alternative investment funds) contains an obligation not of the operators, but of its agents to verify that third parties fulfil their obligations; see its Article 26(2) second subparagraph.

With regard to the involvement of third parties, Argentina goes even further. The [Argentinian Law 26.912 on the legal regime for the prevention and Control of Doping in Sport of 13 November 2013](#) contains, in Article 2, the obligation of sports associations to incorporate certain provisions of a law into their statutes. The law also says that no financial or other public aid may be provided unless there is incorporation of the law into the statutes and full respect thereof.

On the same line, the [Maldives](#) and [Bermuda](#) oblige even charities to report activities suspicious in view of financing terrorism. [Israel](#) includes insurers to report in the sector concerning the fight against money laundering, [Mexico](#) has set-up a long list of businesses or activities obliged to report. It has set-up various limit-values to avoid disproportionate information flows which is certainly a useful technique. But the best example in terms of scope of organisations obliged to report is to be found in the law of [Armenia](#) against money laundering and financing of terrorism. Armenia has established a comprehensive list of institutions covered by its law and thereby constitutes best practice in this regard. See for more details this [article](#). Evidently, all these examples can only serve as inspiration for other sectors. Subject to the sector, different natural or legal persons or authorities need to be obliged to report.

11.4.2 – Voluntary surveillance by third parties

It is difficult for state authorities to achieve high intensity surveillance, especially in sectors where there are many actors. Entrusted public utility associations, other associations or simply competitors can fill in the gap. They may exert intense surveillance in their own interests provided they have a powerful tool to enforce legal compliance. One way to achieve this is to give them the right to sue at court. To do this may trigger a completely new industry, like the law against unfair competition did in some jurisdictions. Less of an industry has emerged in the field of environmental law. In this field, some associations received the right to pursue goals of public interest without being themselves concerned (in legal terms) by a measure. A less radical step might consist in giving legal or natural persons the right to complain to and to alert authorities in a centralised procedure. The considerable workload triggered by these complaints has to be weighed against the compliance favouring effect.

A good example of an effective complaint right provided by the UK government is “the right to contest” the use of public land and buildings; see [here](#). In this case, the state invites the citizens to control the state.

The first crucial element of a voluntary reporting or even whistle-blowing mechanism consists in providing everybody with the right to report, as done by the [Philippine “Free Mobile Disaster Alerts Act](#):

“Section. 5. Report of Violations. – Any natural or juridical person may report before the NTC any violation of this Act.”

This first step should be accompanied by a clear indication of to whom and by which means the whistle-blowing mechanism can be initiated. See e.g. the standard text in Brazilian regulation under responsibility of the metrology institute INMETRO:

“14 DENÚNCIAS

A Ouvidoria do Inmetro recebe denúncias, reclamações e sugestões, através dos seguintes canais:

e-mail: ouvidoria@inmetro.gov.br

telefone: 0800 285 18 18

sítio: www.inmetro.gov.br/ouvidoria

endereço para correspondência:

*Ouvidoria - Instituto Nacional de Metrologia,
Qualidade e Tecnologia (Inmetro)
Rua Santa Alexandrina, 416 – térreo
Rio Comprido - Rio de Janeiro – RJ
CEP 20261-232*

Translation:

14 COMPLAINTS

The Ombudsman of INMETRO receives accusations, complaints and suggestions through the following channels:

email: ouvidoria@inmetro.gov.br

Phone: 0800 285 18 18

site: [www.inmetro.gov.br / ombudsman](http://www.inmetro.gov.br/ombudsman)

mailing address:

*Ombudsman - National Institute of Metrology,
Quality and Technology (INMETRO)
Rua Santa Alexandrina, 416 - ground
Long River - Rio de Janeiro - RJ
CEP 20261-232”*

A second step consists in ensuring confidentiality and protecting whistle-blowers against direct or indirect sanctions. Detailed empowerments for sophisticated voluntary reporting (and “whistle-blowing”) protection regimes are contained in the Sections 13F and 13G of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#):

“Voluntary reporting scheme

13F.

—(1) Rules (referred to in this Act as the voluntary reporting rules) may be made by the Minister under this section to establish a scheme —

for the voluntary and confidential reporting of aviation safety issues;
to identify deficiencies and problems arising out of such reports; and
to provide data for safety improvements to the Singapore aviation system.

(2) The voluntary reporting rules must prescribe for —

the voluntary and confidential reporting of aviation safety issues to one or more persons designated in the rules (referred to in this Part as a designated person);

the manner in which such reports are to be made;

the use and disclosure by a designated person of information contained in such reports and information the designated person obtains or generates in the course of considering any such report, which shall not be inconsistent with section 13G; and

any other matters necessary or incidental to the establishment or operation of a scheme in accordance with subsection (1).

(3) All voluntary reporting rules made shall be presented to Parliament as soon as possible after publication in the Gazette.

Protection for reporting aviation safety issues

13G.

—(1) Subject to subsection (4), the following:

a report of an aviation safety issue made by a person (referred to in

this section as the reporter) to a designated person in accordance with the voluntary reporting rules or any evidence of the contents of such a report; and

the fact that such a report of an aviation safety issue was made by the reporter to a designated person,

shall not be admissible in evidence against the reporter in any administrative proceedings before any tribunal in Singapore, any civil proceedings or any criminal proceedings before any court other than criminal proceedings for an offence under section 29C.

(2) A person is not entitled to take disciplinary action against his employee using information derived from a report of an aviation safety issue made by the employee to a designated person in accordance with the voluntary reporting rules.

(3) A tribunal is not entitled to make a decision of an administrative character (whether or not in the exercise of a discretion) under any written law against a reporter using information derived from a report of an aviation safety issue made by the reporter to a designated person in accordance with the voluntary reporting rules.

(4) For the avoidance of doubt, this section does not prevent the use of information derived from a source that is not a report of an aviation safety issue made to any designated person in accordance with the voluntary reporting rules.

(5) In this section, “tribunal” includes any person or body of persons constituted and vested by or under any written law to make a decision of an administrative character.”

A third, facultative step consists of creating an incentive. The U.S. has gone quite far in this respect. The “whistle-blower bounty program” of the [Securities and Exchange Commission](#) promises an award of 10 to 30% of the resulting sanctions. Likewise the [Internal Revenue Service](#) gives substantive awards. More on the latter mechanism is to be found [here](#).

11.4.3 – Special focus: whistleblowers and witnesses

Whistleblowers have a high potential for helping authorities to detect non-conformities. Hence, a whistleblower regime can become an important tool. For more details, see also the article “[Whistleblower regulations update: strengthening protections](#)”.

11.4.3.1 – *Whistleblower and witness protection*

Whistleblowers detecting non-conformities of economic operators or persons are mostly employed in the private sector and are thus third parties. However, the considerations below will also apply to whistleblowers from within the administration. Even if a state-agent blows the whistle, e.g. on corruption involving other state-agents and economic operators, he merits the same protection as a private whistleblowers.

[Alberta](#) (Canada) foresees that an employee who is considering to make a disclosure may receive advice from a designated officer or the public Interest Commissioner beforehand (see Sections 9 and 15). The law of [Ghana](#) offers legal assistance and police protection to whistleblowers and his/her relatives (see Sections 12 to 19).

In [Bosnia and Herzegovina](#) an individual can request for a particular whistleblower (protection) status (see Article 7). Accordingly, the person is protected against any form of liability even in cases of disclosing an official secret to the competent authority. The law of [Tanzania](#) also provides for the protection of whistleblowers.

The law of [South Korea](#) contains a specific provision on respecting the confidentiality of the whistleblower’s identity and envisages disciplinary actions in case of its violation (see Article 12). Furthermore, South Korea foresees protective measures and the cooperation between different institutions, e.g. administrative authorities, counselling and medical centres, etc (see Article 25). Commendably, the law grants compensation for psychological ill-treatment, litigation fees and moving expenses of a whistleblower (see Article 27). In a situation where whistleblowing leads to the detection of a crime (other than the reported one) perpetrated by the whistleblower, his/her punishment may be mitigated or remitted. The law of [South Korea](#) protects also against a long list of detrimental actions of employers against whistleblowers. The list includes unjustified audits, cancellation of licenses

or training, cancelation of contracts for goods or services, the putting of the whistleblower on a blacklist, etc (see Article 15).

France has introduced an intelligent rule to deal with the issue of hidden retaliation against whistleblowers: certain negative measures are presumed to be triggered by the whistle blowing. See [Article 25 of the ACT no. 2013-907](#) of 11 October 2013 on transparency in public life⁴⁸:

“I – No person may be excluded from a recruitment procedure or denied access to an internship or a period of vocational training, or be disciplined, dismissed or be subjected to a direct or indirect discriminatory measure, in particular concerning remuneration, treatment, training, redeployment, assignment, qualifications, classification, career advancement, transfer, or contract renewal, for having reported or recounted, in good faith, to his/her employer, to the authority responsible for ethics within the organisation, to a non-profit organisation that combats corruption which is approved in accordance with sub-section II of Article 20 of this Act or of Article 2-23 of the Criminal Procedure Code or to the judicial or administrative authorities, matters relating to a conflict of interest, as defined in Article 2 of this Act, concerning one of the persons referred to in Articles 4 and 11, of which s/he may have been aware in the performance of his/her duties. All employment contract terminations that result therefrom or all instruments to the contrary shall be automatically null and void.

In the event of a dispute over the application of the first two paragraphs of this sub-section I, provided that the person proves facts making it possible to presume that s/he recounted or reported, in good faith, information in connection with a conflict of interest, the defendant shall be responsible, in light of said facts, for proving that his/her decision is justified by objective considerations that are unrelated to the declaration or report of the person concerned. The judge may order all relevant investigative measures.”

Whistleblower protection instruments can also be used to protect witnesses or victims. See as example for pure witness protection provisions Articles 40 to 43 of its anti-corruption act of [Indonesia](#). A peculiar witness/victim protection

⁴⁸ This Article was however repealed in 2016.

provision can be found in the [Tunisian law on the elimination of violence against women](#) of July 26 2017⁴⁹. It establishes family violence units within Tunisia's Internal Security Forces to process domestic violence complaints, and provides criminal liability for "any agent of the specialised unit who exercises pressure or any other form of coercion against a woman to force her to abandon her complaint or to change it". [Egypt](#) protects female victims of violence by providing the possibility to conceal their identity in the pre-trial stage. [France](#), by its Law No. 2020-936 of 30 July 2020 aiming at the protection of victims of violence in partnerships protects these victims by the possibility to oblige the (alleged) aggressor to wear bracelets alerting the victim when approached by the aggressor. The law permits furthermore to suspend the right to visit the common children and exempts medical professionals from the obligation to keep professional secrecy. See a summary of the respective provisions in this [article](#).

11.4.3.2 – *Incentives for whistleblowers or informers*

In [South Korea](#) a whistleblower may request a reward if his/her reporting resulted directly in the recovery or increase in revenues for the government (see Article 26). [Uganda](#) foresees a percentage participation to reward the whistleblower, i.e. 5% of the net liquidated sum of money recovered as a result of the disclosure (see Section VII). [Pakistan's](#) Covid-19 (Prevention of Hoarding) Ordinance, 2020⁵⁰ rewards "informers in case their information leads to conviction of a hoarder where 10% of the auction proceeds of the hoarded articles will be given to the informer as reward."

Another type of incentive might be given to natural or legal persons ending their illicit activity, provided that they help to dismantle criminal networks. Such mechanisms have been very successful in anti-trust law in various jurisdictions. [Brazil's](#) law No. 12,846/2013 foresees leniency agreements which might be used to that end.

⁴⁹ See this [article](#) for details.

⁵⁰ Direct link to the ordinance cannot be established, but it is easily retrievable by internet search.

11.4.3.3 – *Mandatory whistleblowing / reporting*

The law of [South Korea](#) qualifies whistleblowing as a duty of every public official (see Article 7). As other laws, it allows the disclosure of past and future public interest violation, i.e. a violation which is just likely to occur.

Mandatory whistleblowing / reporting must not be limited to public officials. Also other professionals like notaries, accredited accountants, and bankers are in several jurisdictions obliged to report on money laundering and terrorism, see this dedicated [article](#). In some jurisdictions, reporting on child abuse is mandatory, see Section E of that [article](#). But already the 19th century penal law of some jurisdictions establishes the obligation of everybody to alert the police on intended heavy crimes, see for example [§ 138](#) of the German Penal Code.

11.4.3.4 – *Secure or even anonymised whistleblowing channels*

Whistleblowing cannot be successful where the information on infringements falls into the wrong hands. Whistleblowing can even become dangerous in this case. Hence, it is of utmost importance to open secure whistleblowing channels towards administrative entities which ensure systematic, fair and efficient follow-up to the whistleblowing, ideally providing also means of whistleblower protection.

The example of Kerala (India) seems in this respect excellent to us. Kerala's Vigilance and Anti Corruption Bureau provides various [secure communication channels](#), including a free hotline and even a dedicated [whistleblowing App](#) and, on the same page, another App that creates a community of those who fight corruption.

One step ahead is the possibility to whistleblowing in an anonymised way. This opens of course the door to defamatory denunciations. However, this risk is not given or at least very much reduced for the anonymised deposit of documents. [Canada](#) has established a reporting channel for confidential disclosure in the energy sector: an online website, a hotline and a confidential postbox are made available to the public.

11.4.4 – On the way to complete outsourcing of enforcement: mutual control systems

The ever increasing number of sectors, reflecting the ever increasing complexity of our life, make it ever more difficult for states to ensure compliance. At the same time, human resources available for authorities tend to shrink. Accordingly, it becomes ever more difficult to enforce law. The limited enforcement makes things unfair for compliant operators. They have a competitive disadvantage when compared to non-compliant operators. This Handbook has since its first edition presented alternative enforcement techniques, particularly those involving the help of third parties. However, the legislator can go further by establishing systems of mutual control where the role of authorities is extremely reduced. This [article](#) explores this possibility in detail.

11.5 Enforcement powers

11.5.1 – General or explicit / detailed enforcement powers

Legislation can provide for general or for explicit and detailed inspection and enforcement powers. General provisions keep the legal text short. More detailed provisions create more legal certainty, above all on the crucial question of how far the authorities may go. The downside of detailed provisions is the risk that some special cases fall through the grid of empowerments. A subsidiary general clause can reduce the risk. An example of very detailed inspection and enforcement powers can be found in the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#). This act contains a wide range of empowerments after the headline “Division 3 — Safety inspections and enforcement powers” (Sections 4J to 4O). In addition thereto, it provides in the sections before that headline for empowerments to exempt, suspend and impose requirements in deviation from the legal text and to make provisional orders to avoid imminent danger (see Sections 4C, 4D, 4E and 4F). Section 4F contains a joint criteria list for Sections 4C, 4D and 4E, which is an elegant construction. Altogether the act constitutes an excellent reference for those jurisdictions that prefer the path of detailed empowerments – or are obliged to take this path for legal reasons.

11.5.2 – Which enforcement powers to think of: a catalogue

Before introducing the catalogue as such, we would like to note that the vast majority of the enforcement measures for which empowerments might be needed can not only be addressed to natural or legal persons infringing the law, but also to:

- ◆ Natural or legal persons responsible for the behaviour of natural persons infringing the law (e.g. parents or associations holding care obligations for minors);
- ◆ Natural persons acting on behalf of the legal persons infringing the law⁵¹;
- ◆ Natural persons who are members in oversight bodies of legal persons infringing the law;
- ◆ Natural or legal persons who voluntarily, negligently or even without negligence endorse or facilitate the infringements committed by a natural or legal person, such as trade partners, internet service providers, banks, notaries, lawyers, and other service providers;
- ◆ Capital owners of legal persons infringing the law⁵²;
- ◆ Subsidiaries (daughter or sister companies) indirectly taking profit from the infringement; and
- ◆ Trade partners taking profit from the infringement.

This means that the the following list of enforcement powers should be applied as a check-list in view of these different potential target populations, subject to the topic of course.

11.5.2.1 – *Investigations and data as preliminary step*

Investigating and collecting data is a necessary preliminary step for enforcement or can already be part of the enforcement. In the field of investigation and data collection, empowerments might be needed for:

⁵¹ See the examples in [11.5.3.8](#) below.

⁵² See the example in [11.5.3.9](#) below.

- ◆ Conducting, or cooperating with persons conducting, research, development, tests, demonstrations and studies and publishing this research or test results;
- ◆ Imposing obligations to cooperate without remuneration with the authority and in particular to permit samples to be taken or provide samples on request, provide information, and to grant access to documentation and premises;
- ◆ Arrest (and financial sanctions) in case these obligations are not fulfilled;
- ◆ Visiting and inspecting offices, factories, warehouses, wholesaling establishments, retailing establishments, laboratories, research institutions and other premises⁵³;
- ◆ Entering and inspecting any vehicle used to transport or hold products or to provide services;
- ◆ Taking samples of the item/products covered by the regulation in question or registering on media a service;
- ◆ Ordering anonymously or via proxy products or services in view of assessing their conformity;
- ◆ Opening parcels or containers unless the content is declared and, if it is a regulated product, information on its conformity assessment – e.g. via a web link - is provided;
- ◆ Radio-scanning parcels or containers to check whether the declared content is identical with the real content and presumably in conformity with substantial legal requirements;
- ◆ Opening, examining and confiscating parcels or containers when there is a suspicion that the product is not in conformity with legal requirements;
- ◆ Seizing and taking possession of all articles which are in non-conformity, be they placed with the person responsible for the infringement or other persons;
- ◆ Seizing and taking possession of all documents, data and objects which

⁵³ See e.g. the Canadian “[Proceeds of Crime \(Money Laundering\) and Terrorist Financing Act](#)” S.C. 2000, c. 17 L.C. 2000.

might serve as means of proof for stating the non-conformity, regardless where they are stored (in particular including cloud-based storage);

- ◆ Compelling the attendance of witnesses and the production by third parties of evidence via a subpoena, when there are reasons to believe or there is first evidence that there is an infringement;
- ◆ Requesting from importers, wholesalers, retailers, trading platforms, website hosting services and domain registrars the disclosure of data both on the identity of the economic operators offering goods or services and on individual transactions;
- ◆ Requesting from importers, wholesalers, retailers and trading platforms access to real-time information about the shipment of goods, even if the shipment is operated by a service provider acting on behalf of the economic operator or on behalf of the client (so that the goods can be captured either when entering the jurisdiction or within the jurisdiction before reaching the client);
- ◆ Compelling the production or delivery of data or documents of any kind, including on property or other rights related to objects and rights, issuing document search warrants and further empowerments needed to search and confiscate documents (see the excellent Sections 44 and onwards of the [Ugandan Anti Money Laundering Act 2013](#));
- ◆ Therein in particular: empowerment to request data from Internet or telecommunication service provider;
- ◆ Supervising the internet communication or telecommunication (meta-data or even content) in a personalised or at least generic/anonymised way;
- ◆ Acquiring data and documents (from third parties) against payment or other advantages⁵⁴;
- ◆ Processing and storing data;
- ◆ Exchanging data with other authorities, courts, natural or legal persons or other jurisdictions and adopting agreements in this regard; and

⁵⁴ The Minister of Finance of Nordrhein-Westfalen, one of the regions (Länder) of Germany, has repeatedly acquired from a former Swiss bank agent lists of Germans who concealed money from the tax authorities. It was questionable whether he was empowered to do so.

- ◆ Personal supervision of persons / monitoring orders (see as example Sections 56 and onwards of the [Ugandan Anti Money Laundering Act 2013](#)).

11.5.2.2 – *Enforcement in its narrow meaning*

Empowerments might be needed for:

- ◆ Requesting from internet or telecommunication service provider blocking of content that is illegal or endorses illegal activities;
- ◆ Empowerment to block certain internet content by own means;
- ◆ Blocking the dissemination of printed illegal information or information that endorses illegal activities;
- ◆ Confiscating printed illegal information or information that endorses illegal activities;
- ◆ Issuing notices of non-compliance and set an appropriate deadline for rectification of the situation;
- ◆ Confiscating and destroying illegal products or means to produce them or means to provide illegal services;
- ◆ Requesting from importers, wholesalers, retailers and trading platforms that they only offer products or services manufactured / provided by natural or legal persons with a clearly defined identity, place of business, internet and email address;
- ◆ Requesting from importers, wholesalers, retailers and trading platforms that they only offer products or services to natural or legal persons who disclose their identity, place of business, internet and email address of their suppliers and service providers upstream the supply chain;
- ◆ Requesting from importers, wholesalers, retailers and trading platforms that they only offer products or services to natural or legal persons who make accessible authorisations, certificates and other proof of conformity of their products or services (e.g. proof of registration in case of a registration obligation, proof of labelling in case of a labelling obligation, instructions for use);

- ◆ Banning certain economic operators from trading platforms or to oblige the trading platforms not to display the offers of these operators to clients from one's own jurisdiction;
- ◆ Obliging trading platforms and other economic operators to display information on the rights of their costumers (e.g. consumer rights);
- ◆ Closing the business of importers, wholesalers, retailers and trading platforms with the assistance of the website hosting service/operator;
- ◆ Confiscating the domain in case of continued fraudulent activity (otherwise the rogue operator can simply engage another website hosting operator and continue his business under the same domain);
- ◆ Forbidding the use of premises or establishments;
- ◆ Closing plants and other premises;
- ◆ Retaining shipments (in particular for customs authorities);
- ◆ Requesting securities (as guarantee for the fulfilment of non-financial obligations);
- ◆ Obliging operators to disclose (better online, but at least to the authorities) the major components and substances/materials used;
- ◆ Obliging operators to disclose (better online, but at least to the authorities) the supply chain for major components or service providers and for substances/materials used, ensuring traceability;
- ◆ Obliging operators to inform their clients of their rights in case of illicit practice; and
- ◆ Imposing immediate, temporary obligations by provisional order (e.g. for reasons of imminent danger).

In between enforcement in its narrow meaning and sanctions are fees which are directly or indirectly related to the infringement. For example, an authority might be empowered to take fees for a laboratory test if the technical documentation for a product does not prove its compliance. If the authority has otherwise no financial means to operate the test, the fee becomes a means of enforcement. If, however, it would be able to undertake the testing without it, the fee has more the character of a sanction. See also Subsection [11.5.3.4.](#)

11.5.2.3 – Sanctions

Penal sanctions are amongst the most common enforcement tools at least since Babylonian times. But the range of sanctions goes beyond penal law as we will see further down this list:

- ◆ Confining natural persons, also when illicitly acting on behalf of legal persons;
- ◆ Issuing travel bans;
- ◆ Imposing social work obligations;
- ◆ Banning from certain honourable public functions or professions⁵⁵;
- ◆ Banning from certain business activities⁵⁶;
- ◆ Withdrawing licences with regard to professional or business activities;
- ◆ Imposing financial penal sanctions;
- ◆ Imposing financial administrative sanctions;
- ◆ Imposing fees that have a deterring / sanctioning effect;
- ◆ Imposing capital export bans;
- ◆ Reducing state pensions or social rights;
- ◆ Confiscating gains obtained for the illicit practice and obliging to compensate savings made due to it;
- ◆ Confiscating capital or other value gains obtained with the help of gains of the illicit action as such (indirect gains);
- ◆ Exclusion from grants and public tenders;
- ◆ Imposing adequate interest rates for all financial sanctions and obligations, including the obligation to retribute or compensate; and

⁵⁵ Around 3 million directors were disqualified and removed under Section 167(1) of the Indian [Companies Act 2013](#) for non-filing of Financial Statements or Annual Returns for a continuous period of three financial years.

⁵⁶ Using the power under Section 248 of the Indian [Companies Act 2013](#) just over 2.2 million companies were struck off the company list for not filing Financial Statement or Annual Returns for a continuous period of two or more financial years.

- ◆ Imposing adequate securities for all financial sanctions and obligations, including the obligation to retribute or compensate.

These sanctions can and should also be applied to enforce cooperation with regard to other enforcement measures for which empowerments are needed (in Subsections [11.5.2.1](#), [11.5.2.2](#) and [11.5.2.4](#)). This means: sanctions can be used to enforce enforcement. Accordingly, it is commendable to check these empowerments / sanctions list at the very end, after having gone through all enforcement tools.

11.5.2.4 – *Information dissemination as indirect enforcement tool*

Information dissemination can be an important tool for indirect enforcement, in terms of sanctioning non-compliant, praising compliant natural and legal persons, and preventing non-compliances. Empowerments might be needed for:

- ◆ Information dissemination to authorities of other jurisdictions so that the unlawful product or service is not dumped there;
- ◆ Information dissemination to media, with or without data concerning natural or legal persons;
- ◆ Information campaigns for the general public or specific target groups;
- ◆ Publishing evaluations of own compliance statistics, compliance reporting by regional authorities and third parties (naming and shaming);
- ◆ Publishing individual infringements;
- ◆ Obliging regional or local authorities to publish stated infringements of operators (“naming and shaming”);
- ◆ Creating a label for those operators who, over a longer period, have not been reported to infringe the law;
- ◆ Creating a label for those operators who undergo a voluntary compliance verification program managed by the chambers of commerce or similar semi-public organisations or by conformity assessment bodies engaged by them (entrusted certification);
- ◆ Obliging economic operators to display information on the conformity assessment of regulated products or services, e.g. by web link;

- ◆ Informing the clients of non-compliant operators of their rights; and
- ◆ Informing the clients of non-compliant operators of the legal requirements applicable for the product in question, inviting them to verify compliance and to report.

Information dissemination can also be used as a top-up to a sanction. See for example the Canadian “[Proceeds of Crime \(Money Laundering\) and Terrorist Financing Act](#)”, S.C. 2000, c. 17 L.C. 2000:

“Publication Publication

73.22 When proceedings in respect of a violation are ended, the Centre may make public the nature of the violation, the name of the person or entity that committed it, and the amount of the penalty imposed.”

11.5.3 – Some particular enforcement powers

Subject to the sector and the jurisdiction, particular enforcement powers are needed that merit a more detailed presentation.

11.5.3.1 – Provisional orders

Regulation can provide for an explicit empowerment to make provisional orders, e.g. to avoid imminent danger. See as a rather complex example the new Section 4E of the Air Navigation Act of Singapore as introduced by the [Air Navigation \(Amendment\) Act 2014](#):

“4E.

—(1) Subject to subsection (4), where it appears to the Authority that a holder of an aviation safety instrument is contravening, or is likely to contravene, any condition of the aviation safety instrument, that there are reasonable grounds to believe there is a serious and imminent risk to air safety and that it is appropriate or requisite, to avoid any actual or imminent occurrence that endangers or threatens to endanger the safety of the public, that a provisional order be made under this section, the Authority shall, instead of taking any decision under section 4C or 4D, by provisional order make such provision as appears to it requisite for securing compliance with that condition.

(2) A provisional order —

shall require the holder of an aviation safety instrument to whom it relates (according to the circumstances of the case) to do, or not to do, such things as are specified in the provisional order or are of a description so specified;

shall take effect at such time, being the earliest practicable time, as is determined by or under the provisional order; and

may be revoked at any time by the Authority.

(3) *In determining whether it is appropriate or requisite that a provisional order be made, the Authority shall have regard, in particular, to the extent to which any person is likely to sustain loss or damage in consequence of anything which, in contravention of the condition of an aviation safety instrument, is likely to be done, or omitted to be done, before a decision under section 4C or 4D may be made.*

(4) *Subject to subsections (5), (6) and (7), the Authority shall, by notice in writing, confirm a provisional order, with or without modifications, if —*

the Authority is satisfied that the holder of an aviation safety instrument to whom the order relates has contravened, or is likely to contravene any condition of its instrument; and

the provision made by the order (with any modifications) is requisite for the purpose of securing compliance with that condition.

(5) *The Authority shall not confirm a provisional order in relation to a holder of an aviation safety instrument if it is satisfied —*

that the duties imposed on the Authority under this Act or the Civil Aviation Authority of Singapore Act 2009 preclude the confirming of such a provisional order;

that the holder of an aviation safety instrument has agreed to take, and is taking, all such steps as it appears to the Authority for the time being to be appropriate for the holder of that instrument to take for the purpose of securing or facilitating compliance with the condition in question; or

that the contraventions were, or the apprehended contraventions are, of a trivial nature.

(6) Before the Authority confirms a provisional order, the Authority shall give notice to the holder of an aviation safety instrument concerned —

stating that the Authority proposes to confirm the provisional order and setting out its effect;

setting out —

the relevant condition of the aviation safety instrument for the purpose of securing compliance with which the provisional order is to be confirmed;

the acts or omissions which, in the Authority's opinion, constitute or would constitute contraventions of that condition; and

the other facts which, in the Authority's opinion, justify the confirmation of the provisional order; and

specifying the period (being not less than 28 days from the date of service of the notice) within which representations or objections with respect to the proposed confirmation may be made,

and shall consider any representations or objections which are duly made and not withdrawn.

(7) The Authority shall not confirm a provisional order with modifications except —

with the consent of the holder of an aviation safety instrument to whom the order relates; or after —

serving on that holder of an aviation safety instrument such notice of the proposal to confirm the provisional order with modifications and in that notice, specifying the period (being not less than 28 days from the date of service of the notice) within which representations or objections with respect to the proposed modifications may be made; and considering any representations or objections which are duly made and not withdrawn.

(8) In this section, "provisional order" means an order under this section which, if not previously confirmed in accordance with subsection (5), shall cease to

have effect at the end of such period (not exceeding 3 months) as is determined by or under the order.”

11.5.3.2 – Confiscation

Confiscations can target:

- a) objects or rights that have a direct connection with the illegal activities,
- b) profits or other rights generated by illegal activities, or
- c) the financial assets of the targeted natural or legal person, including valuable objects or rights, that have no link with the illegal activities.

Thus confiscation can be related to the illegal activities directly a) indirectly b) or not at all c) In the first case a) there is not a clear sanctioning aspect, but the focus is rather ending the infringement as such. Under b) already the sanction aspect becomes more important. Under c) no link with the infringement is given so that we can speak of a pure sanction.

The Canadian “[Proceeds of Crime \(Money Laundering\) and Terrorist Financing Act](#)”, S.C. 2000, c. 17 L.C. 2000, contains interesting provisions on confiscation. Confiscation can here also be regarded as sanction:

“Seizure and forfeiture

18 (1) If an officer believes on reasonable grounds that subsection 12(1) has been contravened, the officer may seize as forfeit the currency or monetary instruments.

Return of seized currency or monetary instruments

(2) The officer shall, on payment of a penalty in the prescribed amount, return the seized currency or monetary instruments to the individual from whom they were seized or to the lawful owner unless the officer has reasonable grounds to suspect that the currency or monetary instruments are proceeds of crime within the meaning of subsection 462.3(1) of the Criminal Code or funds for use in the financing of terrorist activities.

Notice of seizure

(3) An officer who seizes currency or monetary instruments under subsection (1) shall, if they were not imported or exported as mail, give the person from

whom they were seized written notice.

...

23 Subject to subsection 18(2) and sections 25 to 31, currency or monetary instruments seized as forfeit under subsection 18(1) are forfeited to Her Majesty in right of Canada from the time of the contravention of subsection 12(1) in respect of which they were seized, and no act or proceeding after the forfeiture is necessary to effect the forfeiture.”

11.5.3.3 – Sanction schemes

Sanction provisions are often very imprecise, giving a large discretion to the sanctioning authorities. This might be regarded as wishful in some contexts, but may tend towards unequal treatment in other contexts. Therefore we present here two examples for sanction schemes to illustrate an alternative approach.

The [Graphic Health Warnings Law of the Philippines \(Act 10643\)](#) provides for precise provisions on penalties, also covering the case of repeated infringement:

“Section 14. Penalties for Noncompliance. –

(a) The following penalties shall individually apply to manufacturers, importers, and distributors of tobacco products as well as their agents/representatives for any violation of Sections 6 and 7, and Section 11 insofar as they are responsible for providing display materials that are in violation of this Act:

(1) On the first offense, a fine of not more than Five hundred thousand pesos (P500,000.00);

(2) On the second offense, a fine of not more than One million pesos (P1,000,000.00); and

(3) On the third offense, a fine of not more than Two million pesos (P2,000,000.00) or imprisonment of not more than five (5) years, or both, at the discretion of the court: Provided, That the business permits and licenses, in the case of a business entity or establishment shall be revoked or cancelled.

If the guilty officer is a foreign national, he shall be deported after service of sentence and/or payment of applicable fines without need of

further deportation proceedings and shall be permanently barred from re-entering the Philippines.

Each withdrawal or importation into the Philippine customs territory of non-compliant tobacco packages, regardless of size, for sale to the market, after the compliance date shall constitute one (1) offense. An additional penalty of One hundred thousand pesos (P100,000.00) per day shall be imposed for each day the violation continues after having received the order from the Department of Trade and Industry (DTI) notifying the company of the infraction.”

The [Senegalese Law No. 2014-01](#) of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) provides for a simple and precise sanction scheme. It also determines who shall decide on the sanctions and whereto the money shall go:

“Art. 19. - Est passible d’une sanction pécuniaire dont le montant est égal au quart du montant du solde créditeur du compte dormant concerné, tout organisme dépositaire qui contrevient aux dispositions de la présente loi.

En cas de récidive, la sanction visée à l’alinéa précédent est fixée à cent pour cent (100%) du solde dudit compte.

Les sanctions pécuniaires à l’encontre d’un Etablissement de Crédit ou d’un SFD sont prises, selon le cas, par la Commission Bancaire, la BCEAO ou le Ministre chargé des Finances. Les sanctions pécuniaires à l’encontre d’un service financier de la Poste ou d’une Caisse Nationale d’Epargne sont prises par le Ministre chargé des Finances.

Les sommes correspondantes sont recouvrées pour le compte du Trésor public du lieu de tenue du compte dormant, selon le cas, par la Banque Centrale ou par le Ministère chargé des Finances.”

Amended machine translation:

“Art. 19 -. Any depository body who contravenes the provisions of this Act shall be liable to a penalty of an amount equal to one quarter of the amount of the credit balance of the dormant account concerned.

In case of recidivism, the penalty referred to in the preceding paragraph shall be one hundred percent (100%) of the balance of the account.

Monetary sanctions against a Credit Institution or SFD are taken, as appropriate, by the Banking Commission, the BCEAO or the Minister of Finance. Monetary sanctions against financial service of the Post or of a National Savings Bank are taken by the Minister of Finance.

The corresponding sums are collected on behalf of the Treasury of the place of holding of the dormant account, as appropriate, by the Central Bank or by the Ministry of Finance.”

11.5.3.4 – Administrative sanctions

Below the level of penal sanctions, administrative sanctions can be a useful tool to enhance the fulfilment of obligations. Sanctions can target geographic entities, natural or legal persons. As they can also target legal persons, they can be effective in a sector where penal provisions do not suffice.

See as an example of detailed provisions on administrative sanctions (administrative penalties and other administrative measures), Article 66 of [Directive 2013/36/EU](#) of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms:

“Administrative penalties and other administrative measures for breaches of authorisation requirements and requirements for acquisitions of qualifying holdings

1. Member States shall ensure that their laws, regulations and administrative provisions provide for administrative penalties and other administrative measures at least in respect of:

(a) carrying out the business of taking deposits or other repayable funds from the public without being a credit institution in breach of Article 9;

(b) commencing activities as a credit institution without obtaining authorisation in breach of Article 9;

(c) acquiring, directly or indirectly, a qualifying holding in a credit institution or further increasing, directly or indirectly, such a qualifying holding in a credit institution as a result of which the proportion of

the voting rights or of the capital held would reach or exceed the thresholds referred to in Article 22(1) or so that the credit institution would become its subsidiary, without notifying in writing the competent authorities of the credit institution in which they are seeking to acquire or increase a qualifying holding, during the assessment period, or against the opposition of the competent authorities, in breach of Article 22(1);

(d) disposing, directly or indirectly, of a qualifying holding in a credit institution or reducing a qualifying holding so that the proportion of the voting rights or of the capital held would fall below the thresholds referred to in Article 25 or so that the credit institution would cease to be a subsidiary, without notifying in writing the competent authorities.

2. Member States shall ensure that in the cases referred to in paragraph 1, the administrative penalties and other administrative measures that can be applied include at least the following:

(a) a public statement which identifies the natural person, institution, financial holding company or mixed financial holding company responsible and the nature of the breach;

(b) an order requiring the natural or legal person responsible to cease the conduct and to desist from a repetition of that conduct;

(c) in the case of a legal person, administrative pecuniary penalties of up to 10 % of the total annual net turnover including the gross income consisting of interest receivable and similar income, income from shares and other variable or fixed-yield securities, and commissions or fees receivable in accordance with Article 316 of Regulation (EU) No 575/2013 of the undertaking in the preceding business year;

(d) in the case of a natural person, administrative pecuniary penalties of up to EUR 5 000 000, or in the Member States whose currency is not the euro, the corresponding value in the national currency on 17 July 2013;

(e) administrative pecuniary penalties of up to twice the amount of the benefit derived from the breach where that benefit can be determined;

(f) suspension of the voting rights of the shareholder or shareholders held responsible for the breaches referred to in paragraph 1.

Where the undertaking referred to in point (c) of the first subparagraph is a subsidiary of a parent undertaking, the relevant gross income shall be the gross income resulting from the consolidated account of the ultimate parent undertaking in the preceding business year.”

The [Philippine “Free Mobile Disaster Alerts Act”](#) provides an example of strong administrative sanctions against companies in a quasi-penal context:

“Section 6. Penalties. –

(a) Any person who gives false or misleading data or information or willfully or through gross negligence, conceals or falsifies a material fact, in any investigation, inquiry, study, or other proceeding held pursuant to this Act, shall be punished with ...

(b) If the offender is a corporation, the penalties may range from the imposition of a fine of not less than One million pesos (P1,000,000.00) but not more than Ten million pesos (P10,000,000.00) and/or a suspension or revocation of its legislative franchise and other permits and licenses by the NTC. The maximum penalties prescribed in paragraph (a) shall also be imposed on the members of its board and/or management, as applicable.”

The beginning of (b) is, however, problematic: the formulation “if the offender is a corporation” suggests that persons acting on behalf of the corporation are not subject to punishment and the deterrent effect of the penal provision under (a) is reduced. If this is not intended, regulators should choose another formulation such as: “If the offence has been committed on behalf of a corporation, the corporation is subject to additional penalties. The penalties may range from ...”.

11.5.3.5 – Indemnities

If clients or trade partners have the right to perceive a substantial indemnity in case of infringement of law, operators may refrain from not fulfilling their obligations. In order to have a deterring effect, the indemnity would need to be quite high, but the proportionality principle sets limits in many jurisdictions. Accordingly, this legislative instrument should rather be considered as a complement to enforcement, not as a substitute. See as an example of legislation establishing

indemnities the [Indian right to fair compensation and transparency in land acquisition, resettlement and rehabilitation act](#) of 2013. See furthermore Article 1(22) of [Regulation \(EU\) No 462/2013](#) of the European Parliament and of the Council of 21 May 2013 amending Regulation (EC) No 1060/2009 on credit rating agencies introducing a new Article 35a into the latter. See also [11.4.2.](#)

11.5.3.6 – Fees

Similar to administrative sanctions, fees for administrative procedures may be used not only to obtain funds for authorities, but also to influence the behaviour of private operators. E.g. if manufacturers split their production into many differently labelled “products” which are basically identical, and this in view of protecting a part of their production against authority measures, an administrative fee per product will trigger second thoughts on the part of the manufacturer. Fees for the verification of certain aspects by the authority can create an incentive to perform well and to limit the number of independently labelled “products” or “services”. Where fees are based on effort and the effort is higher in case of infringement, the fees become very similar to sanctions.

Financial sanctions and fees might be appropriate tools for natural persons and companies of small and medium size. But are they sufficient for multinational companies? Particularly in the U.S., there is a debate on how to deal with multi-national companies for purposes of enforcement. Some authors claim that classic sanctions like fines do not deter big multinational companies (“goliath-corporations”) from infringing the law.

11.5.3.7 – Recovering mitigation costs and other liability provisions

The [Japanese Invasive Alien Species Act](#) provides the empowerment to recover mitigation costs, and this even where mitigation is borne by third parties, provided that the mitigation by third parties has been recognised by the competent authority:

“Article 16: In case the need to carry out mitigation under the provisions of Paragraph 1 of Article 11 arises and there is a person who has performed an act causing it, the government may make the person bear the whole or part of expenses within the limits necessary to carry out the mitigation.

Article 17:

1. When intending to make a person bear expenses under the provisions of the preceding Article, the National Government must fix the amount of expenses intended to make the person bear (hereinafter “Expenses Imposed” in this Article) and the deadline for their payment, and order the payment, as stipulated by the Ministerial Ordinance.

[...]

Article 18:

1. On mitigation of IAS which is intended by a local public entity and conforms with matters announced officially under the provisions of Paragraph 2 of Article 11, the local public entity may obtain confirmation to that effect from the competent ministers, as stipulated in the Ministerial Ordinance.

2. A person other than the government and local public entities may obtain the competent ministers’ acknowledgement, as stipulated by the Ministerial Ordinance, on the mitigation of IAS planned by the person to the effect that the person is capable of performing it properly and reliably and that the mitigation conforms with matters announced officially under the provisions of Paragraph 2 of Article 11.

3. When the competent ministers give confirmation under Paragraph 1 or acknowledgement under the preceding paragraph, that fact must be announced officially as stipulated in the Ministerial Ordinance. The same applies to cases where these confirmation and acknowledgement are cancelled under the provisions of Paragraph 2 or 3 of Article 20.”

Mandating the recovery of mitigation costs is only one out of several regulatory techniques using liability as an indirect means for enforcement. For more on this approach, see this dedicated [article](#).

11.5.3.8 – Securities

It is sometimes preferable to foresee not just fees, but also securities/guarantees. [Regulation \(EU\) No.228/2013](#) of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006 contains, in its Article 12, an empowerment for the EU

Member States to request securities:

“2. No security shall be required when applying for import licences, exemption certificates or aid certificates. However, to the extent necessary to ensure the proper application of this Regulation, the competent authority may require a security to be lodged equal to the amount of the advantage as referred to in Article 13. In such cases, Article 34(1), (4), (5), (6), (7) and (8) of Commission Regulation (EC) No 376/2008 of 23 April 2008 laying down common detailed rules for the application of the system of import and export licences and advance fixing certificates for agricultural products shall apply.”

11.5.3.9 – Extending enforcement measures from legal to natural persons and backwards

Sanctions against companies do not always suffice to deter unlawful behaviour. Above all, small companies can easily close business in case infringement of the law is detected. The managers or owners can get away without being harmed and may set up a new company that similarly continues their unlawful business. To prevent this, it might be helpful to set up liability and even criminal responsibility for natural persons in charge of companies committing unlawful acts. This is done in Section 7 of the [Indian Unlawful activities \(prevention\) Amendment Act, 2012](#). This act places even the burden of proof for absence of knowledge and for the fulfilment of due care on the side of natural persons.

[Panama](#) has, in its law against money laundering, set-up an interesting provision which creates a mutual link between corporate and individual responsibility:

“Article 63. Corporate Responsibility. For the sole purpose of sanctions and the regulations adopted in its development, the Laws and conduct of management, officers, executives, administration or operations of the Reporting Entities, are attributable to the Reporting Entities and persons exercising activities on whose behalf they act.

On the other hand, natural persons, perpetrators of such actings and behaviors are subject to civil and criminal liability under the terms provided in this Law and the Criminal Code.”

11.5.3.10 – *Extending enforcement measures to others: the example of associated companies*

We have seen at the beginning of [Subsection 11.5.2](#) that empowerments can be extended to a range of natural or legal persons surrounding the main target person of enforcement measures. This can be nicely illustrated by the case of associated companies. Associated companies have not necessarily contributed to an infringement, but still make profit from an infringement. Moreover, they might be responsible for an illicit practice, but hide behind another natural or legal person, whilst their involvement in the infringement cannot easily be proved. Hence, there is good reason to consider including associated companies or subsidiary companies.

Though the following example does not explicitly include sanctions, it illustrates well the method of extending responsibility to associated companies. This method can likewise be used in the context of sanctions and other enforcement measures:

The [Brazilian Lei N° 12.846](#), of 1 August 2013 “Provisions on the administrative and civil liability of legal persons for the commission of acts against the national or foreign public administration, and other matters”⁵⁷ sets up, in its Article 4 Paragraph 2, a joint and common liability for controlling, controlled, affiliated, or consortium partners. Its Article 4 Paragraph 1 contains the liability rules for cases of merger or acquisition. Any liability in case of merger or acquisition is limited to the value of the company taken over:

“Article 4. The liability of legal entities remains in the event of amendments to their articles of incorporation, corporate changes, mergers, acquisitions or spin-offs.

1. In the event of mergers and acquisitions, the liability of the successor shall be restricted to the payment of applicable fines and to the full compensation for occasional damages, within the limit of the transferred assets, not being subject to the application of other sanctions provided for in this Law related to acts and facts that occurred before the date of the said merger or

⁵⁷ “Dispõe sobre a responsabilização administrativa e civil de pessoas jurídicas pela prática de atos contra a administração pública, nacional ou estrangeira, e dá outras providências”.

acquisition, except in case of simulation or evident fraud intention, which must be duly proved.

2. Parent, controlled or affiliated companies or consortium members, within the scope of their respective consortium agreement, shall be held jointly liable for the perpetration of acts provided for in this Law, being such liability restricted to the payment of applicable fines and to the full compensation for occasional damages.”

11.6 A standard programme for enhanced enforcement

The many parameters and empowerments described so far in this chapter might go beyond what the reader is willing to investigate and to adapt in a tailor-made way to the regulation s/he is in charge of. If this is the case, we recommend the following standard programme for enhanced enforcement:

- a) A single complaints portal per region or geographic entity or unique complaints portal for the entire jurisdiction.
- b) Connected thereto, an independent complaints investigation unit or institution.
- c) A whistle-blowing mechanism that protects against direct or indirect (labour law or criminal) sanctions or discrimination if the whistle-blower acted in good faith (see the example of Singapore in [Subsection 11.4.2](#)).
- d) Entrusting one single NGO with receiving and processing complaints whilst ensuring anonymity of the complainant towards all authorities.
- e) Provide competitors with the possibility of suing under private law if they suffer from a competitive disadvantage due to the non-fulfilment of duties.
- f) Provide environmental organisations with the possibility of suing, as defenders of the public interest, non-compliant operators.
- g) Provide for an exemption from sanctions or at least for reduction of sanctions in case one operator reveals a major infringement joint and commonly organised by different operators (classic competition law mechanism).
- h) Obligation of regional or local authorities to publish stated infringements of operators (“naming and shaming”).

- i) Exclusion of companies from public tenders in case of non-fulfilment of duties⁵⁸.
- j) Creation of a label for those operators who undergo a voluntary compliance verification program managed by the chambers of commerce or similar semi-public organisations or by conformity assessment bodies engaged by them (entrusted certification).
- k) Tax incentives for taking part in a voluntary compliance verification program managed by the chambers of commerce or similar semi-public organisations or by conformity assessment bodies engaged by them (entrusted certification).
- l) Creation of a legal basis for redistribution of verification costs to operators or citizens, thereby improving the financial basis of the enforcement authorities.
- m) Establishment of minimum resource requirements or at least of parameters for determining how many full-time equivalences (FTE) are needed for enforcement at the level of geographic entities. Parameters could include population, number of operators to be verified, or number of administrative districts. Quantified minimum resources could be, for example: 10 FTE per region and 1 FTE per million population at the central level for the overall management of enforcement (with no other tasks of course). 2 FTE per district and 1 per 100,000 inhabitants in each district.
- n) Benchmark regional or local authorities, applying the naming and shaming principle to the geographic entities.
- o) Creation of the legal possibility of steering grants away from authorities not willing to enhance enforcement of those which are strongly engaged.
- p) Designation of reference laboratories so that evaluation practices in the technical field are de facto harmonised on a high level.
- q) Establishment of an information system or information exchange ensuring that verification of compliance undertaken by one geographic entity can also be used by all other geographic entities.

⁵⁸ This is called “debarment” in the U.S.; for examples, see the sources quoted on <http://www.acoel.org/post/2014/05/08/Beware-the-Specter-of-Debarment-.aspx>.

- r) Creation of a coordinating authority or of a coordination mechanism for geographic entities.

11.7 Registration systems embedding artificial intelligence to enhance enforcement

Regardless of the ex ante or ex post verification system chosen, authorities still often have difficulties to get full control of what matters: the conformity of services and products and, for some product types, the performance of products. Registration systems embedding artificial intelligence could trigger tremendous progress in this regard. We outline in the following how such a system could look like. We take products as an example, whilst the basic principles could also be applied to services or even processes falling outside the definition of service. We describe in the following a system which would give authorities control of what matters via data. This system requires a set of measures and mechanisms, some of which are already present here and there in certain jurisdictions and sectors:

- a) Creation of an (ideally internationally operating) incident reporting body, hereafter IRB. Its main task is to collect and pre-evaluate information about the lack of safety or performance of products. This information goes wider than pure incident reporting. The IRB could be an entrusted private, public or semi-public body. There are plenty of possibilities for its financing. Evidently, it can be publicly financed. But it could also be financed by mandatory contributions of the manufacturers or importers of the products. The question of the private, public or semi-public character is to be separated from the financing. All combinations are possible. It is critical that both the legal set-up and the finances should ensure long-term stability and sustainability.
- b) Creation of an unequivocal product identification system. The system must implicitly also identify the manufacturer. Behind the system, there must be rules to determine whether a certain modification of a product may be used by the manufacturer to claim a new product (type) identity. To prevent claims of a new product identity aimed at circumventing unpleasant state measures, there must be a rule according to which a new product (type) identity may only be claimed if there is a noteworthy modification. As a general rule, only modifications which may affect safety and performance

are noteworthy. On the other hand, where ever a pre-market approval or certification system is applied, there must be limits to the keeping of a product (type) identity. It should not be permitted to claim product (type) identity where noteworthy modifications were made.

- c) Mandatory labelling of the internet address of the IRB and of the product identity code. These two elements need to be clearly visible on the products themselves (where possible), their inner, outer and sales packaging and in the instructions for use. The purpose of the two needs to be explained so that all users of the products feel encouraged to report incidents or other safety or performance relevant information to the IRB.
- d) Mandatory product registration in the database of IRB. The registration shall also cover crucial safety information, such as the identification of safety relevant components. Alternatively, manufacturers may also post evidence on sales data so as to put the number of incidents in relation to the overall number of products placed on the market thereby providing some context (there is a need to explain the benefit of providing this information).
- e) Via a user-friendly form, the IRB receives incident reports from users and others from wherever the product is sold, thus from many jurisdictions. The IRB is found by the users via the labelling. The individual product can be identified via the product type number attributed by the product identification system.
- f) IRB processes received data and publicly available data, including data publicly available in social media, with artificial intelligence (AI) software. Thereby, it tries to identify patterns not just for one specific product of one manufacturer, but also for product types, crucial components, coating materials etc. Furthermore, the AI software tries to identify patterns of erroneous use or conscious misuse leading to incidents.
- g) IRB transmits data to market surveillance authorities and manufacturers. The IRB transmits in particular:
 - non-anonymised data to authorities connected to the IRB,
 - the non-anonymised data of the specific manufacturer to this very manufacturer, and

- anonymised data to manufacturers of the product group so that they are informed on incident trends for the product group in question regardless of whether their own products have been subject of incidents or not.
- h) Manufacturers and authorities evaluate data themselves, with or without AI. A mixture of both is likely to be ideal. However, a certain screening with AI has already taken place at the level of the IRB. Hence, there is no need for mandatory use of AI.
- i) Manufacturers and authorities enter into dialogue on corrective measures. They may wish to include authorities of other jurisdictions so that the corrective measures are generally agreed upon – the worst are diverging requirements of different jurisdictions.
- j) Authorities take enforcement measures where necessary. No enforcement measures are necessary where manufacturers and authorities have agreed upon corrective measures or where corrective measures are disproportionate or almost useless.
- k) Authorities inform other authorities linked to the IRB on measures taken and on the evaluation. Ideally, they can do so via the IRB itself.
- l) The advantages of such a system when compared to today's classic enforcement are manifold:
- The system provides a much broader data basis to authorities;
 - Due to the increased data basis, there is a lower likelihood of manufacturers trying to cheat;
 - AI detects patterns across manufacturers and even product groups;
 - Other jurisdictions contribute and take profit from the system;
 - Manufacturers have lower burden by centralised data processing when compared to data processing in many different jurisdictions;
 - Measures of central authorities becomes more effective;
 - There is less likelihood that deficient products are dumped into relatively less stringent jurisdictions.

- m) The system should be introduced, as a first step, through positive incentives such as:
- Dispensation from (certain) pre-market certification obligation if the system is applied;
 - A specific label could indicate that the product takes part in the system and thus has a reduced likelihood to be deficient; and
 - Dispensation from reporting obligations under the various jurisdictions.
- n) It is also possible to build in incentives for not cheating. E.g., pre-market certification and other surveillance measures can become mandatory again once that cheating has been detected.
- o) Once the system has been well established and the cost-benefit-ratio for all parties can be evaluated, it might be useful to make it mandatory.

11.8 Enforcement towards rogue operators

There are many ways for rogue economic operators to circumvent obligations and state measures. One way is to change the company name or even to shift to another company identity. The same can be done just for the product or service identity. The easiest way is to rename a product or service in such a way that state measures against the old product or service cannot be attributed anymore to the “new” product or service. Operators thus start a “catch me if you can” game with the authorities. There are two measures that may help to counter this practice: (1) setting up comprehensive registration obligations and a database via which the identity of products can be detected (this is evidently problematic in the aspect of burden reduction for operators); (2) inviting or obliging geographic entities to take measures not only against an identified non-compliant product (or service), but also against products (or services) that are identical to the identified non-compliant product (or service). This technique requires careful application in order to respect the principle of legal certainty.

To cope with the phenomenon of changing product/service identities, it is necessary to determine what is to be regarded as one and the same product/service. The most differentiated legislation on this issue so far has been developed in

[Regulation 168/2013/EU](#) of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles. It contains, in its Article 3 (73) to (75), a precise definition of “type”, “variant” and “version of a variant”:

“(73) ‘vehicle type’ means a group of vehicles, including variants and versions of a particular category that do not differ in at least the following essential respects:

(a) category and subcategory;

(b) manufacturer;

(c) chassis, frame, sub-frame, floor pan or structure to which major components are attached;

(d) type designation given by the manufacturer;

(74) ‘variant’ means a vehicle of the same type where:

(a) the basic characteristics of the bodywork shape are the same;

(b) the propulsion and propulsion configuration are the same; ...”

Furthermore, this Regulation contains detailed provisions on parts and components and provides for a staged approval thereof.

One of the most frequent weaknesses of regulation consists in permitting outsourcing without further conditions. Outsourcing of tasks makes enforcement more difficult, especially if the tasks are outsourced to natural or legal persons outside the respective jurisdiction. The supervision of outsourcing or delegation is therefore of the utmost importance for any legislation on products or services. [Commission Delegated Regulation EU/231/2013](#) of 19 December 2012 supplementing Directive 2011/61/EU of the European Parliament and of the Council with regard to exemptions, general operating conditions, depositaries, leverage, transparency and supervision contains, in its Articles 75 to 82, very detailed conditions for the delegation of tasks.

If outsourcing is authorised without detailed conditions, rogue operators who have been identified by authorities can find a “proxy” and operate officially as the outsourcing partner of the proxy. At the end of the day, they continue to manufacture products or to provide services, but they do so on behalf of the proxy who assumes the formal responsibility towards customers and authorities. Past

authority measures against the rogue operators thereby become void. Even if they have been banned as operators offering the product or service to the clients, they can still operate as a supplier of services, of product components or even of the entire product to the proxy (if own-brand-labelling is authorised). All this does not mean that regulation should never authorise outsourcing – there is often an economic need for outsourcing. However, the regulators should be aware of the risks for enforcement triggered by outsourcing and, if they decide to permit outsourcing, should consider reducing these risks by setting up detailed conditions for outsourcing.

11.9 Limiting own-brand-labelling to facilitate enforcement

In the case of some products, so-called “own-brand-labelling” has become the nightmare of enforcement authorities: the same product appears under a different product name and under the responsibility of different operators. Instead of one measure, several measures are needed to ban non-compliant products. Incident reporting hardly works because data attributed to one product name and operator are usually not linked to data regarding identical products with different names and their own respective responsible operators (e.g. manufacturers in accordance with the respective definition). Basically, own-brand-labelling can also occur for services and other processes. E.g., many website hosting or name registration services are sold by companies in their own name who do not host anything, but just broker between clients and the host. However, own-brand-labelling is currently still more frequent for products.

How can regulators limit the negative effects of own-brand-labelling?

- ◆ A registration obligation and database system linking the various operators participating in own-brand-labelling prior to the marketing of the product or of the service can facilitate authority verification. See as an example the Brazilian [Portaria INMETRO / MDIC No. 649](#) of 12/12/2012, “General Requirements for Declaration of Conformity by Provider of Products”⁵⁹ and the database “[Orchestra](#)”.

⁵⁹ “Requisitos Gerais para Declaração da Conformidade do Fornecedor de Produtos”.

- ◆ In the case of product legislation, a strict definition of “manufacturer” can help. A strict definition can for instance consist of defining the “manufacturer” as the natural or legal person physically manufacturing the product or assembling it at the final stage.
- ◆ Often legislation permits that a natural or legal person becomes the “manufacturer” although the person never comes into contact with the product. In this case, tough obligations can help: if the “manufacturer” must have full access to the entire technical documentation of the product and its manufacturing process, most of the own-brand-labellers are out of the game – provided that enforcement works. Other obligations that are difficult to be fulfilled by own-brand-labellers are: to be obliged to provide for post-market-follow-up-services with a certain/high degree of technical competence, and obligations to ensure traceability from the raw-materials to the final product and its distribution.
- ◆ If the own-brand-labellers have to undergo a complete new conformity assessment, the interest in own-brand-labelling might be reduced.

Of course it is not a goal in itself to eliminate own-brand-labelling. Instead, regulators should reflect in terms of: what needs to be done and which obligations have to be fulfilled without delegation in order to ensure the safety of products and services? And to what extent does own-brand-labelling hinder efficient conformity verification and enforcement? Once a precise analysis has been undertaken, it might turn out that own-brand-labellers do not provide for the same level of safety; hence the need to be very explicit as to the question of who has to fulfil all the obligations and whether / under which conditions the fulfilment of the obligations can be delegated or outsourced by the own-brand-labellers to others natural or legal persons, e.g. the real/physical manufacturers.

How can regulators counter the lobbyists’ call for accepting own-brand-labelling? The best response might consist in analysing whether there really is an economic need for own-brand-labelling. The following analytical questions might help to assess the situation:

- ◆ Is there a legitimate need to conceal who, in reality, has designed and/or manufactured a product or who provides a service?
- ◆ Would it not be sufficient (for coping with the respective economic interests) for the brands of those who are marketing the product or the service to be

affixed to the products or to the publicity material? Consumers will still take a certain product as the own-brand-labeller's product if the product is labelled as such; and this even if the real manufacturer is identifiable on the packaging of the product.

- ◆ Can the operator who wishes to become an own-brand-labeller really ensure that he fulfils all the legal obligations of a manufacturer or service provider as defined by the respective regulation? Does he really have the technical knowledge and the technical documentation?

11.10 Enforcement challenges in the internet age: e-commerce and private imports

11.10.1 – Learning from extreme cases

The internet has become a big challenge for authorities dealing with products and services. Confronted with the emergence of all kinds of cross-border internet trade and services, authorities tend to wait and see where problems arise, analyse them, think of measures and implement them. This is the classic method, appropriate for classic structures and mechanisms. However, is it appropriate in the case of fast evolving economic phenomena like internet business or financial markets? Does it not lead to a cat-and-mouse game that the economic operators always win? Readers might test another working method: the extreme case method. The extreme case method consists in identifying or imagining the worst that an operator could do, analysing the elements of his business model / construction and think about the means necessary to hinder a rogue operator from being efficient.

Let us take an example. The “meanest” or trickiest business construction we have encountered so far was the following: an economic operator, presumably based in Mauritius, offered products via a website in several languages, amongst them German, to private households and businesses. In absence of other information we therefore must conclude that the operator was targeting the markets in Germany, Austria and Switzerland. In all three states, the respective products are regulated and submitted to a conformity assessment procedure. The manufacturers of the products came from all parts of the world. The products and their manufacturers have not undergone the respective conformity assessment procedure.

The placing on the market in the three states would therefore be illegal for many of the products offered. The business conditions visible on the website stipulate that the purchase contract is concluded under the law of Mauritius, and Mauritius is the place of fulfilment of all obligations. The business conditions furthermore stipulate that the clients have to assess whether the import of the products into the clients' states is legal or not. The operator was aware of the fact that he might face sanctions either for being regarded as a manufacturer placing products on the market or as their importer (as the products do not fulfil legal conditions of the targeted states). Therefore, it was stipulated that the operator does not ship the products anywhere. Instead, the clients had the possibility of ordering separately shipping services provided by a single service provider. Shipping was thus the subject of an additional contract for which the operator is at best liable as a kind of broker, but probably not liable at all under the law of Mauritius.

What else could the operator have done to protect himself? He could have had his web shop hosted by a hosting service provider outside the targeted states and not in Mauritius, making it even more difficult to get his web shop closed. He could have let the clients choose amongst various shipping services and their service providers to stress that the shipping contract is truly disconnected from the purchase contract. He could have offered only brokering services between the manufacturers or distributors and the clients instead of selling any products himself. If there were no manufacturers or distributors ready to sell under these conditions, he could have created a distributor company himself, placed in another state where there is a weak or corrupted judicial system or no applicable laws at all. For some of the products, he could have declared them to be components or spare parts, thus avoiding the formal applicability of the product legislation of the targeted states (most product legislation does not cover components and spare parts yet). For some other products, he might have decomposed them, selling the components separately (by separate contracts) and leaving it to the client to re-assemble the components so that a usable product is created by the client in the targeted states only. Thus, subject to the applicable product definition, no placing on the market of a product would take place. The cornerstone of product legislation, the placing on the market of a defined product, can be circumvented by this technique.

Another extreme case which is already occurring frequently concerns internet-based 3D-printing. Economic operators in or outside the jurisdiction in question may sell data-sets which allow their clients to 3D-print devices on any

3D-printer they have access to. Thus it is not a device that is sold, but a data-set or a blueprint. But not only are these data-sets or blueprints sold; many of them are even made available for free. This dissemination is part of a large citizens' movement for an alternative economy without patents. The dissemination often takes place in accordance with free licences like the creative commons licences. Those making the data-set or the blueprint available are mostly pure (professional or hobby) designers, architects or engineers, not manufacturers. And even worse: many of these data-sets or blueprints have been developed by P2P production, thus they have so many fathers and mothers that you cannot trace it back to an individual anymore. Accordingly, the notion of "manufacturer" dissolves as does the notion of "product" and of the "placing on the market" thereof.

Keeping these two extreme cases in mind, we can develop appropriate measures, countering key elements of current and to-be-expected business practices. We skip here the one-by-one analysis of the elements described in the two extreme cases to present immediately a package of measures which indeed counter many of the elements described and a few more enforcement difficulties that have emerged in the past.

11.10.2 – Clarifying applicability

The first step for successfully countering problematic e-commerce practices consists in ensuring the applicability of the substantive requirements contained in regulation. Problematic e-commerce practices should not fall into a regulatory loophole. To reach that goal, a number of different measures can be considered. See here two examples:

- ◆ Regulation can establish distinct obligations for those bringing products into the jurisdiction, even if they do so for private use. This is common practice in customs law.
- ◆ Regulation can also clarify that it is applicable to products or services offered to clients on the territory of its jurisdiction.

The regulation of a certain jurisdiction is normally applicable as soon as a certain product or service is offered to clients in that jurisdiction. But how to determine whether a product or service has been offered to clients in a certain jurisdiction if the offer is made on the internet? Various criteria may be applied both at the level of legal interpretation or, preferably, when drafting the regulation:

- ◆ The broadest criterion is that the economic operator can only claim not to offer his products or services to clients from the respective jurisdiction if the clients are explicitly excluded.
- ◆ The most restrictive criterion is that the operator must offer the products or services explicitly to clients in that jurisdiction. Otherwise, he would not be regarded as targeting the jurisdiction.
- ◆ In between, one can imagine a variety of vague formulas like “appearing to target the jurisdiction”.

There are at least three subsidiary criteria which may in particular help if a vague formula has been established:

- ◆ If the products or services are also offered in a language which is specific enough to be linked to a jurisdiction, the economic operator cannot claim that he did not intend to target the jurisdiction.
- ◆ If the prices are also indicated in the currency of the respective jurisdiction, the jurisdiction is most probably being targeted.
- ◆ If the shipping of products to the respective jurisdiction is possible, the economic operator cannot claim that he did not intend to deliver to that jurisdiction.

Legislating on services provided outside the respective jurisdiction and on goods delivered from outside the jurisdiction to customers inside the jurisdiction does not normally go beyond the legislator’s capacity / is not “ultra-vires”. This becomes clear if you look at examples in other legal fields: national penal laws punish acts committed outside the legislator’s territory against its own citizens. Forgery of the legislator’s currency and stamps is a sanctioned penalty regardless of where the act was committed and regardless of the nationality of the forger. Likewise, for taxes on services offered from abroad, the destination principle has been introduced recently in various national jurisdictions. The movement apparently started in India⁶⁰, followed by China⁶¹. In these jurisdictions services are to be taxed at the place of residence or business of the customer.

⁶⁰ See https://www.cbic.gov.in/resources//htdocs-servicetax/ovw/ovw1-1_st-ataglance-19may16.pdf.

⁶¹ See <http://www.lexology.com/library/detail.aspx?g=e5c580b0-7432-445e-9615-2e9c6aa58303>.

11.10.3 – Approaching trading platforms

Pending any upstream formal or informal international agreements on cross-border internet trade and services, jurisdictions can separately or jointly approach the major trading platforms of the respective sector to agree informally on conformity ensuring measures with them. It might be that these trading platforms have an interest in responding positively to calls of authorities to counter certain practices of economic operators, above all if these practices may cause damage to the users of the trading platforms. The following measures could be applied by these trading platforms voluntarily via their business conditions and the programming of their websites; they could even be imposed on them by specific regulation:

- ◆ Obliging economic operators to display information on the conformity assessment of regulated products or services, e.g. by web link;
- ◆ Obliging operators to disclose (better online, but at least to the authorities) the major components and substances/materials used;
- ◆ Obliging operators to disclose (better online, but at least to the authorities) the supply chain for major components or service providers and for substances/materials used, ensuring traceability;
- ◆ Informing the clients of their rights;
- ◆ Informing the clients of the legal requirements applicable for the product in question, inviting them to verify compliance; or
- ◆ Establishing an alert mechanism in case clients think they detect non-conformities.

11.10.4 – International cooperation

International cooperation is of utmost importance for the enforcement of obligations in cross-border internet trade and services. See for details the [Section 12.12.](#)

11.11 Assistance by other administrations, public and private entities

Administrations need often assistance in order to find relevant information and means of proof. Sometimes they even need assistance for the enforcement of

administrative acts. Unless it is already covered by existing law, it can be helpful to create an obligation for other administrations or public enterprises to assist in the fulfilment of tasks derived from the new regulation. See as an example the [Philippine “Lemon Law” on the protection of consumers buying motor vehicles \(Act 10642\)](#):

“SEC. 12. Assistance by Other Agencies.– The DOTC and other agencies, political subdivisions, local government units, including government-owned and/or controlled corporations, shall render such assistance as required by the DTI in order to effectively implement the provisions of this Act.”

We have seen in Section 11.4 that administrations sometimes even need assistance from private companies to enforce administrative acts and to obtain information or means of proof. Accordingly, regulators should check whether they need to build specific empowerments into their regulation so that the enforcement authorities can formally request support from other authorities or public or private entities.

See also [Chapter 12](#) where various sections deal with cooperation amongst authorities in a broader sense.

11.12 Attributing enforcement responsibility to courts or to administrations

Subject to the rules in the respective jurisdiction, enforcement tasks can be attributed to courts. This can constitute a suitable alternative to entrusting authorities, in particular if the latter are overburdened or more likely to be open to corruption. However, no general recommendation can be made because all depends on the concrete situation.

It can be necessary to clarify which court or administration is in charge of tasks and responsibilities linked to the regulation. See as example Section 10.A of the [Implementing Rules and Regulations of the Anti-Bullying Act of 2013 of the Philippines \(Act 10627\)](#):

“Complaints of bullying and other acts under this IRR shall be within the exclusive jurisdiction of the Department or the private school and shall not be brought for amicable settlement before the Barangay, subject to existing

laws, rules and regulations. Complaints for acts covered by other laws shall be referred to the appropriate authorities.” ...

“If the bullying incident or retaliation resulted in serious physical injuries or death, the case shall be dealt with in accordance with the provisions of Republic Act 9344 or the “Juvenile Justice and Welfare Act,” as amended, and its Implementing Rules and Regulations, in connection with other applicable laws, as may be warranted by the circumstances attendant to the bullying incident.” ...

“If the student, after an investigation, is found to have knowingly made a false accusation of bullying, the said student shall be subjected to disciplinary actions or to appropriate interventions in accordance with the existing rules and regulations of the Department or the private school.”

The [Senegalese Law No. 2014-01](#) of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) determines who shall decide on the sanctions and to where the money shall go:

“Art. 19. - ...

Les sanctions pécuniaires à l’encontre d’un Etablissement de Crédit ou d’un SFD sont prises, selon le cas, par la Commission Bancaire, la BCEAO ou le Ministre chargé des Finances. Les sanctions pécuniaires à l’encontre d’un service financier de la Poste ou d’une Caisse Nationale d’Epargne sont prises par le Ministre chargé des Finances.

Les sommes correspondantes sont recouvrées pour le compte du Trésor public du lieu de tenue du compte dormant, selon le cas, par la Banque Centrale ou par le Ministère chargé des Finances.”

Amended machine translation:

“Art. 19. - ...

Monetary sanctions against a Credit Institution or SFD are taken, as appropriate, by the Banking Commission, the BCEAO or the Minister of Finance. Monetary sanctions against financial service of the Post or National Savings Bank are made by the Minister of Finance.

The corresponding sums are collected on behalf of the Treasury of the place of holding the dormant account, as appropriate, by the Central Bank or by the Ministry of Finance.”

11.13 Assigning or requiring persons responsible for compliance

Quite a number of jurisdictions use in one or more sectors the technique of assigning or requiring operators to assign persons responsible for compliance. These persons receive a set of tasks and are mandated to execute these tasks independently from hierarchical supervision. They engage their good name for the role of compliance officers or “responsible persons” and thus have a personal interest in ensuring the compliance of the economic operator or other entity for which they work.

The law of [Saint Kitts](#) has established a duty of economic operators to appoint compliance and reporting officers. This is quite special in so far as there is no thematic limitation of these officers. More frequently, jurisdictions establish the obligation to assign a compliance officer for a specific regulation, see e.g. Article 22 of the law of [Georgia](#) against on combatting money laundering and combatting terrorism or Article 37 of the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ... ([General Data Protection Regulation](#)).

We found three interesting variants of this regulatory technique:

- ◆ The legislation of [Japan](#) foresees that a “Designated Heat Management Factory” must have an “Energy manager” at their disposal. Energy managers are responsible for improving and supervising the energy consumption, and this goes beyond mere compliance verification. The goal is continuous optimisation.
- ◆ The Australian Regulator for banks has responded to a Banking Royal Commission recommendation about the many banking products that are on offer but for which - in the past has been a big problem - no bank executives could answer how particular products offered function. The response is that it [proposes](#) for banks to have a registered person responsible for each individual

product so that when a concern is raised they know who to contact about that product. This idea might be quite useful for entities that offer many products or services.

- ◆ Georgia has adopted a [law](#) with extremely detailed requirements regarding persons involved in the processing of and trade of pharmaceuticals. Here the execution of a profession is equally regulated, together with the description of the role and the attribution of empowerments.

The last example brings us close to the traditional technique of requesting operators to undergo annual auditing of their commercial book-keeping, an auditing that must be undertaken by an accredited auditor.

[Panama](#) established an obligation for authorities to provide training to officers of financial institutions, which is a useful complementary tool wherever compliance officers or “responsible persons” are foreseen.

11.14 Enforcement in case of de-constructed products and services

Some manufacturers sell components or ingredients, inviting the clients to compose the components or ingredients into the final product. Some manufacturers do so for legitimate reasons. E.g. voluminous furniture cannot be cheaply transported in one piece. Partly decomposing the furniture is justified. However, where does this end? A furniture market leader sells some products so deconstructed that clients must possess certain crafting skills to assemble them. This example shows that a certain responsibility is shifted onto the clients. Assembling furniture is not without risks, both during the exercise of assembling and afterwards. Is the responsibility shift compatible with a legal requirement to reduce risks for clients? Should regulation set explicit limits for what responsibilities can be shifted onto the clients?

A further issue arises if the products can be assembled in different ways so that either a legal or an illegal product is created. E.g. there are cosmetics which are sold by ingredients. The proportion of a certain ingredient can be increased by the client so that the legal threshold is passed. Should this be tolerated? If not, explicit provisions hindering this practice are needed.

And what about the open source movement that provides for construction instructions for everything up to complicated machines? Shall devices produced in accordance with open source construction instructions be free of all legal requirements? See the [Global Village Construction Set](#) as an example of how far the movement has already gone.

Behind these cases, there is a more fundamental issue: when is a product a product? Starting from which degree of deconstruction can we not refer to a ‘product’ anymore? In the extreme case, only a set of components or ingredients or a set of instructions is made available, and it is up to the clients to decide what they do with them. At first one might think that this is not an issue for product legislation. However, one might have second thoughts when considering that certain ingredients of fertilizers can equally be used for creating explosives and that certain mechanical components can be used for manufacturing arms as well as civil products. At least in cases where the instructions for use give advice on how to create a problematic product, these are situations that should be regulated on the fringe of and in the same vein as classic product regulation.

These questions and the phenomena described in [Section 11.10](#) (and in particular the example of 3D-printing) could trigger more general thoughts: we might need new legislative cornerstones if the notions “manufacturer”, “product” and “placing on the market” lose their meaning. Future legislation might instead set up requirements applicable to devices regardless of the existence of a manufacturer. Future legislation might also refer to another reference point for establishing legal requirements: instead of referring to the placing on the market, legislation might refer to the physical creation or to the putting into service / first use of a device (as some legislation already does today). Future legislation might also set up requirements for devices in use (which would include devices other than new ones). Requirements for devices in use already exist in some sectors, e.g. for vehicles.

Basically, the same considerations need to be applied in case of services. For services, too, economic operators can circumvent law by deconstructing a service into several steps, and offering via different legal entities the separate steps. For example, law establishing consumer protection for the booking of travel packages (flight + hotel + car rental) can be circumvented with a platform that gives access to a flight booking, a hotel booking and a car rental booking by three formally independent economic operators. If the payment is done in one strike via

a fourth economic operator, the responsibility is diluted amongst these four plus the owner of the platform. But if the flight is cancelled without possibility for a replacement flight, the consumer still has to pay for the remainder of the travel package which never was labelled or recognised as such. Here again, the coordinated offer of several, imbricated services or sub-processes of services merits being closely looked at and possibly to be subject to legal requirements.

11.15 The particular case of 3D-printing

3D-printing simply used as a manufacturing technique like other techniques does not trigger any particular issue in terms of enforcement. However, the enforcement of manufacturer obligations is often impossible in the context of 3D-printing where different activities or processes are split amongst different actors. Like in the previous section, the enforcement problems cannot be solved at the level of enforcement alone. Instead, obligations normally incumbent on manufacturers need to be split and attributed to different actors to become enforceable. That is what we investigate in the following.

11.15.1 – Description of the regulatory challenge

3D-printers used for decentralised manufacturing of products can bring about challenges for regulators. 3D-printers are run by software, but this software does not tell the 3D-printers what to print. To really print something, the 3D-printers need a data-set. The data-set instructs the 3D-printers what to print / where to print. It is not software, but pure data indicating at which point in the three dimensions there shall be substance and where not. The data-set can be accompanied by further instructions, e.g. on the material(s) to be used and how the device is to be printed. The data-set together with the further instructions will here be referred to as “instructions”.

To understand the phenomenon of 3D-printers used for decentralised manufacturing of products, one has to look first at the different persons involved:

- ◆ There are first those natural or legal persons who develop the product and accordingly define the instructions, most importantly the data-set instructing the 3D-printers what to print. We call this person the “designer”.

- ◆ Second, there is the person who has acquired the data-set in a view of obtaining a product. We call this person “client”.
- ◆ Third, there is the person owning a 3D-printer, hereafter called the “owner of the printer”. This person can be the owner of a print-shop, thus a service provider / economic operator. However, it might also be the client himself or a friend or family member of the client. In the latter case, the owner of the printer is a private person.

The problem for regulators linked to 3D-printers used for decentralised manufacturing derives from the fact that none of the three persons involved is necessarily a manufacturer or producer in the meaning of traditional product regulation. The designer only develops and disseminates instructions, not devices/products. The client is not an economic operator who makes available products to anybody, but a consumer or other user of devices/products. The owner of the printer is not necessarily an economic operator, but even if s/he is, her/his role is rather that of a service provider, not that of a manufacturer or producer in the meaning of traditional product regulation.

As a consequence, the obligations incumbent on “manufacturers” or “producers” in the meaning of the respective regulation cannot be attached to any single natural or legal person, as would normally be the case. This means that one of the cornerstones of product legislation is falling apart.

The second cornerstone, the process of manufacturing or producing, is also somehow diluted because it is split into two: the design development and the physical production.

As these cornerstones fall apart, regulated products can reach consumers or other users in high numbers without undergoing any conformity assessment procedure. The regulatory requirements are circumvented as there is a regulatory gap for this type of manufacturing. Normally regulators only set-up legal requirements when there is a real risk. Accordingly, there might be a real risk for consumers or other users when a relevant product falls into this regulatory gap. Whether it is worthwhile closing this regulatory gap has to be assessed for each jurisdiction, product type and risk involved on a case-by-case basis.

11.15.2 – How to address the regulatory challenge?

It is possible to close the regulatory gap created by 3D-printing by setting-up specific obligations:

11.15.2.1 – *Obligations for the designer*

The first target of regulatory measures should be the designer because s/he is responsible for the emergence of the product at many different places later-on. Designers could be obliged, by a sector specific provision or by a new regulatory act applicable on all kinds of regulated products:

- ◆ To undergo for their instructions the same conformity assessment procedure that manufacturers/producers have to undergo for their products. If this conformity assessment procedure implies the testing of a physical device or other product, they must present a product printed in accordance with the instructions to the authority or to the private conformity assessment body;
- ◆ To undergo a conformity assessment procedure for the risks specifically linked to the decentralised manufacturing by 3D-printing and by lay-persons. This specific conformity assessment procedure should e.g. verify that the materials recommended for 3D-printing are appropriate in view of the design and the intended use and that the 3D-printing with these materials does not trigger specific health risks, e.g. by evaporation. All printing and assembly instructions should also be clear. It should not be reasonably foreseeable that the lay-persons make mistakes when 3D-printing or assembling the product from 3D-printed products. Thus this conformity assessment procedure could cover both product specific and manufacturing specific aspects; and
- ◆ To ensure that the products may only be printed by licensed qualified 3D-printshops (in cases where the printing and assembling by lay-persons triggers high risks).

The enforcement of the obligations is of course extremely difficult when the designer is not based on the territory of the respective jurisdictions. However, the emergence of internet commerce will make cooperation between jurisdictions ever more important – and why not foresee mutual assistance of jurisdictions for this case as well? Furthermore, more and more jurisdictions will, over time, develop national firewalls to counter illegal activity like terrorism. Once there are such

national firewalls, enforcement via blocking of illicit websites will become possible. Finally, jurisdictions can create obligations for internet operators to block certain content.

But even when the designer is based in the territory of the respective jurisdictions, it will not always be easy to ensure enforcement. It might be helpful to consider measures of alternative enforcement by private persons presented in [Section 11.4](#).

11.15.2.2 – *Obligations for the owner of the 3D-printers*

The owner of the 3D-printers could be obliged:

- ◆ To print only regulated products, i.e. products resulting from printing instructions that have undergone the respective conformity assessment procedure; or
- ◆ To undergo specific training in case of use of high-risk materials or printing of high-risk products.

11.15.2.3 – *Obligations for the manufacturers of 3D-printers*

The manufacturers of 3D-printers could be obliged to affix, on their 3D-printers, a warning that 3D-printing of certain products might be sanctioned or subject to legal conditions, together with a link to a website of the respective jurisdiction with information about:

- ◆ Which products may not be 3D-printed because they are subject to a specific distribution license (e.g. certain arms);
- ◆ Which products may only be printed when the relevant printing instruction have undergone a certain conformity assessment procedure (plus essentials on how to verify whether such a procedure has been completed successfully);
- ◆ Essentials on design protection law so that 3D-printing does not become a booster of counterfeiting;
- ◆ Sanctions and liability provisions;

- ◆ Risks of 3D-printing; or
- ◆ A contact address for whistle-blowers who wish to inform about infringements.

11.15.2.4 – Obligations for the clients

In extreme cases, e.g. for high-risk-products, it might be worthwhile to consider the establishment of obligations for clients. Clients could be informed about these obligations by a warning visible on 3D-printers and the website mentioned above.

11.15.3 – Special cases

11.15.3.1 – *The print-shops are owned by the designer*

In this case, the manufacturing is still decentralised, but the whole business model is quite similar to the classic model of a manufacturer selling a product that has full responsibility for the product. Subject to the contractual arrangements and the product legislation of the respective jurisdiction, there may not be a regulatory gap in this case. However, even if there is no regulatory gap at first sight, jurisdictions might identify a need to regulate: the decentralised manufacturing might trigger particular risks even though the print-shops are owned by the designer.

11.15.3.2 – *Design developed in a peer-to-peer-process*

So far we have assumed that there is one natural or legal person who is the designer. But what if there are many persons who have developed the design in an open peer-to-peer-process and make available the result under a creative commons or similar license? To cope with the phenomenon of peer-to-peer-developed design, the legislation should request, for all instructions made available, the nomination of a responsible natural or legal person taking over the obligations of the designer described above.

11.15.4 – Applicability of the same principles to product kits and pure manufacturing instructions

Subject to the respective law, the delivery of product kits may or may not be covered by product legislation. If product kits do not fall under the respective product legislation, the responsibilities of “designers” as defined above should also be applicable to those natural or legal persons who provide kits. Otherwise these persons can circumvent product legislation by decomposing products into components and selling these components in a kit instead of selling finished products.

In some jurisdictions, there is a movement of citizens who wish to manufacture their products themselves. In these jurisdictions, there is a need and thus a market for manufacturing instructions. In case of very dangerous products (e.g. firework items containing explosives), it could be considered to establish requirements for the author of these manufacturing instructions similar to those proposed here for designers.

11.16 Services and products provided from zones without state control

There are two developments that lead to services and products being provided from zones that are not under control of a state recognised by international public law:

- ◆ States losing control of a part of their territory, e.g. following a secession movement or civil war. Such zones outside the states’ control currently exist in Moldavia (Transnistria, also called Trans-Dniestr or Transdnistria), Georgia (Abkhazia), Somalia (Somaliland which ironically has more characteristics of a functioning state than the remainder of Somalia).
- ◆ Internet and technology giants from Silicon Valley preparing the creation of huge floating platforms in the international sea from which entrepreneurs can operate without being hindered by laws on privacy, worker protection etc. The strategic planning is made by the so-called [Seasteading Institute](#). A first project of this kind is a transformed cruise ship swimming close to Silicon Valley in international waters called [Blueseed](#).

Services and products provided from outside any state-controlled areas raises a wide range of specific issues. Certain legal requirements, e.g. relating to “state of

origin”, cannot be applied to these entities. It might be difficult to find in these entities a negotiation counterpart to tackle issues. The entities are not recognised and not even recognisable under international public law. The entities do not necessarily have any interest in introducing requirements similar to the ones introduced by states, and they have even less of an interest in applying the existing requirements of states.

How can jurisdictions cope with this phenomenon? A range of instruments can be thought of, though none of them are a panacea:

- ◆ Stipulating by regulation that products and services must have a state of origin and attributing products and services by default to the closest recognised state or to the state to which the territory belonged in the past.
- ◆ Obliging shipping operators to alert customs authorities about parcels coming from non-state entities.
- ◆ Informing business and citizens of the particular risks when contracting with operators in non-state entities (e.g. absence of legal guarantees / no enforcement possible).
- ◆ Exerting pressure on shipping operators so that they do not deliver to or from non-state entities which are commonly used for circumventing legal requirements.
- ◆ Exerting pressure on financial service providers so that they do not transfer money to or from non-state entities that are commonly used for circumventing legal requirements.
- ◆ In extreme criminal cases, banning financial transactions with operators in non-state entities in order to oblige the operators to establish a place of business in a state. Of course, this is only efficient if many jurisdictions make this step together.

12. OTHER IMPLEMENTATION QUESTIONS



If you once forfeit the confidence of your fellow citizens, you can never regain their respect and esteem. It is true that you may fool all of the people some of the time; you can even fool some of the people all of the time; but you can't fool all of the people all of the time.

Abraham Lincoln

We start this chapter with a range of topics that are relevant both for ex ante and ex post verification. These are followed by the topic of harmonised interpretation in general and by other topics that influence the effectiveness of implementation.

12.1 Clear, authority friendly rules on burden, means and degree of proof

Both ex ante and ex post verification can easily fail if the applicable rules on the burden of proof are difficult to fulfil on the part of the authorities. Furthermore, the interpretation of the rules on the burden of proof may deviate from one state, region or district to the next. To avoid this, regulators may think about establishing rules on the burden of proof and the degree of likelihood requested to state whether a certain condition is fulfilled.

The [Argentinian Law 26.912 on the legal regime for the prevention and Control of Doping in Sport of 13 November 2013](#) contains, in its Article 16, rules on burden of proof and degree of likelihood requested for assuming doping. Article 17 of that act provides rules on means of proof, mixed with procedural elements. These two articles contain very sophisticated provisions on proof (in regulation outside criminal law):

“ARTICULO 16.- Carga y grado de la prueba del dopaje. Recae sobre la organización antidopaje la carga de probar que se ha producido una infracción de la norma antidopaje. El grado de la prueba debe ser tal que la organización que haya establecido la infracción de las normas convenza al tribunal interviniente teniendo en cuenta la seriedad de la afirmación que hace. El grado de la prueba debe ser mayor al de un justo equilibrio de probabilidades pero inferior a la prueba más allá de cualquier duda razonable. Cuando el presente régimen haga recaer en un atleta o en cualquier otra persona que supuestamente hubiera cometido una infracción la carga de invertir tal presunción o de establecer la existencia de circunstancias o hechos específicos, el grado de la prueba debe ser el justo equilibrio de posibilidades, excepto en los casos contemplados en los artículos 26 y 32 del presente régimen, en los que recae sobre el atleta una mayor carga de la prueba.

ARTICULO 17.- Medios de establecer hechos y presunciones. Los hechos relativos a infracciones de la norma antidopaje pueden probarse por cualquier medio legítimamente obtenido, incluida la confesión. Las siguientes normas de prueba son de aplicación en los casos de dopaje:

a) Se presume que los laboratorios acreditados por la Agencia Mundial Antidopaje realizan análisis de muestras y aplican procedimientos de custodia de conformidad con la norma internacional para laboratorios. El atleta u otra persona pueden desvirtuar esta presunción demostrando que se ha producido una desviación, con respecto a la norma internacional, que podría haber causado razonablemente el resultado analítico adverso. En este caso, recae sobre la organización antidopaje la carga de demostrar que esa desviación no pudo haber sido el origen del resultado analítico adverso;

b) Toda desviación con respecto a cualquier otra norma internacional u otra norma o política antidopaje que no haya supuesto un resultado analítico adverso u otras infracciones a las normas antidopaje, no invalida tales resultados. Si el infractor demuestra que una desviación con respecto a otra norma internacional u otra norma o política de control del dopaje podría haber causado razonablemente el resultado analítico adverso, recae sobre la organización antidopaje la carga de establecer que esa desviación no ha originado la infracción a la norma antidopaje;

c) Los hechos demostrados en una sentencia firme del Tribunal Nacional Disciplinario Antidopaje constituyen una prueba irrefutable contra el atleta o la otra persona a los que afecte la sentencia sobre tales hechos, a menos que alguno de ellos demuestren que dicha sentencia contraviene los principios generales del derecho; ...”

Amended machine translation:

“ARTICLE 16 -. Burdens and standards of proof of doping. Anti-doping Organizations have the burden of proving that there has been a violation of an anti-doping rule. The standard of proof should be such that the organization which has established the infringement of the rules convinces the intervening court, considering the seriousness of the allegation. The degree of proof must be greater than a mere balance of probability but less than “proof beyond any reasonable doubt”. When this scheme places on an athlete or anyone else who has allegedly infringed the law the burden of inverting such a presumption or of establishing the existence of special facts or circumstances, the standard of proof should be the right balance of probabilities, except in the cases specified in Articles 26 and 32 of this scheme, under which a greater burden of proof falls on the athlete.

ARTICLE 17 -. Means of establishing facts and presumptions. The facts relating to anti-doping rule violations may be proved by any means lawfully obtained, including admissions. The following rules of evidence are applicable in doping cases:

a) It is assumed that the laboratories accredited by the World Anti-Doping Agency conducted sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The athlete or other person may rebut this presumption by establishing a deviation from the international standard, which could reasonably have caused the adverse analytical finding. In this case, the anti-doping organization has the burden of establishing that such deviation could not have been the origin of the adverse analytical finding;

b) Any deviation from any other International Standard or other anti-doping rule or policy which did not cause an adverse analytical finding or any other anti-doping rule violation does not invalidate such results. If the offender shows that a deviation from another Inter

national Standard or other standard or doping control policy could reasonably have caused the adverse analytical finding, the Anti-Doping Organization has the burden of establishing that such a deviation did not cause the violation of doping rule;

c) The facts established by a final determination of the National Anti-Doping Disciplinary Tribunal constitute irrefutable evidence against the athlete or the other person whom the judgment on those facts affects, unless any of them show that the judgment is contrary to the general principles of law; ...”

Refugee law is a field where a presumption is widely used for quickly determining whether a person is a refugee or not. See for instance the Refugee Act of [Gambia](#) which contains a clause on prima facie refugee recognition criteria:

“...the Secretary of State may, ..., declare a person or persons belonging to a particular class or nationality, on the basis of objective, prevailing circumstances in that person’s or those persons’ country of origin or nationality, to be a refugee or refugees recognised on a prima facie or group basis.”

Presumptions can be combined with the explicit possibility to counter them. A classic field where this technique is used is the consent to organ transplant after death. In the so-called “opt-out” systems it is stipulated that the consent is presumed unless there is evidence for the contrary. Inter alia [France](#) and [Belgium](#) have created “opt-out” systems.

The Malaysian [Anti-Money Laundering, Anti-Terrorism Financing and Proceeds of Unlawful Activities Act 2001](#) has foreseen provisions on the standard of proof to be applied in the verification of conditions for state action. Similar to classic penal procedural law, it also indicates which documentary evidence and statements are acceptable:

“70.

(1) Any question of fact to be decided by a court in proceedings under this Act shall be decided on the balance of probabilities.

(2) Subsection (1) shall not apply in relation to any question of fact that is for the prosecution to prove in any proceedings for an offence under this Act or any subsidiary legislation under it.

71. Where the Public Prosecutor or any enforcement agency has obtained any document or other evidence in exercise of his powers under this Act or by virtue of this Act, such document or copy of the document or other evidence, as the case may be, shall be admissible in evidence in any proceedings under this Act, notwithstanding anything to the contrary in any written law.

72.

(1) In any trial or inquiry by a court into an offence under this Act, any statement, whether the statement amounts to a confession or not or is oral or in writing, made at any time, whether before or after the person is charged and whether in the course of an investigation or not and whether or not wholly or partly in answer to questions, by an accused person to or in the hearing of an officer of any enforcement agency, whether or not interpreted to him by any other officer of such enforcement agency or any other person, whether concerned or not in the arrest of that person, shall, notwithstanding any law or rule of law to the contrary, be admissible at his trial in evidence and, if that person tenders himself as a witness, any such statement may be used in cross-examination and for the purpose of impeaching his credit.

(2) No statement made under subsection (1) shall be admissible or used as provided for in that subsection if the making of the statement appears to the court to have been caused by any inducement, threat or promise having reference to the charge against the person, proceeding from a person in the enforcement agency and sufficient in the opinion of the court to give that person grounds which would appear to him reasonable for supposing that by making it he would gain any advantage or avoid any evil of a temporal nature in reference to the proceedings against him.”

As inspiration for further investigation of issues of proof that might be worthwhile being regulated, we recommend the part “Title IVB” (Articles 1353 onwards) of this translation of a part of the French Civil Code as recently amended: [The law of contract, the general regime of obligations, and proof of obligations, the new provisions of the Civil Code created by Ordonnance n° 2016-131 of 10 February 2016.](#)

12.2 Clear consequences of non-conformities or negative test results

Enforcement authorities often struggle with cases in which there is no doubt about non-conformity, but for which no clear consequence of the non-conformity has been determined by regulation. In these cases, the question often arises: is the non-conformity important enough to ban the product, service or activity in question? To avoid this uncertainty, it is useful to link in the regulation all different types of non-conformity with appropriately severe legal consequences. Legal consequences can e.g. be: rejection of the authorisation or certification, suspension of the authorisation or certification, prohibition to exert a certain activity, limitation of or conditions for exerting a certain activity, additional verification measures, additional procedural obligations (like partial re-authorisation or re-certification), or undergoing special training courses.

A good example can be found in Section 6.1.1.3 of the [Brazilian Portaria n.º 35](#) of 3 February 2009 “Requirements for conformity approvals for baby bottles and the teats for baby bottles”⁶². This regulatory act determines exactly the number of tests to be undertaken and how many of the tests must be negative to justify the rejection of a product.

The [Brazilian Portaria INMETRO / MDIC Number 247](#) of 26/05/2014 on the conformity assessment for the retreading of tires also contains, for example, an instruction on the number of tests to be conducted and what happens in case of negative test results. Furthermore, it highlights the relevance of doing the right sampling and determining the test setting:

“D.1.1 Definição dos ensaios a serem realizados

D.1.1.1 Os ensaios devem ser realizados em laboratório acreditado, de acordo com os requisitos estabelecidos pelo RTQ para o Serviço de Reforma de Pneus e de acordo com a respectiva família descrita no subitem 4.5 deste RAC.

D.1.1.2 Os ensaios devem ser realizados em uma amostra de prova. No caso de reprovação desta amostra, o ensaio deve ser repetido nas amostras de contraprova e testemunha, devendo ambas serem aprovadas.

D.1.2 Definição da amostragem

⁶² “Requisitos de avaliação da conformidade para mamadeiras e bicos de mamadeiras”.

A amostragem deve ser realizada por família de acordo com o subitem 4.5 deste RAC, composta por 01 (uma) unidade de prova, 01 (uma) unidade de contraprova e 01 (uma) unidade de testemunha.”

Amended machine translation:

“D.1.1 Definition of tests to be performed

D.1.1.1 The tests shall be conducted in an accredited laboratory in accordance with the requirements established by RTQ for Service Tyre Retreading and according to their families described in subsection 4.5 of this RAC.

D.1.1.2 The tests must be conducted with a test sample. In case of failure of this sample, the test must be repeated with a rebuttal and a witness sample, and both should be approved.

D.1.2 Definition of sampling

Sampling must be performed by family in accordance with subsection 4.5 of this RAC, consisting of 01 (one) unit test, 01 (one) unit of rebuttal and 01 (one) unit of witness.”

12.3 Discretionary powers and vague legal expressions / margins of appreciation

Discretionary powers and vague legal expressions are tools to allow for a fine-tuned implementation⁶³.

A discretionary power exists if an authority or another entity has the right to decide freely, provided that certain conditions are fulfilled. Discretionary powers are often expressed by the words “can” or “may” or by leaving a choice to the authority. Examples: “In case of infringement of the obligation to notify changes of the quality system, the authority may withdraw its authorisation ” and “In case of infringement of the obligation to notify changes of the quality system, the authority must withdraw its authorisation or impose additional conditions”. The empowerment of the authority is only given if certain conditions are fulfilled. These conditions can be precise or not.

⁶³ We address them here under the perspective of implementation, though they are evidently also part of the requirements.

Regulation often gives a certain discretionary power to authorities with a view to ensuring an implementation that is adapted to the local needs or the needs of a specific case. This can make sense if the regulator cannot precisely list all of the requirements for the authority or another entity to act or if the regulator considers that flexibility is needed to cover atypical cases. However, discretionary powers bring risks. The first is the risk of diverging administrative practice. The second is corruption which is linked to the third: limited judicial control. The risks can to a modest extent be reduced by indicating in the regulation to what purpose the discretionary power has been conveyed. The purpose can, subject to the jurisdiction, for instance be expressed in the recitals or in the rationale. In some jurisdictions, it is even possible to indicate the purpose of a discretionary power in the core text of the regulation.

The disadvantages stated for discretionary powers are also to be noted for vague legal expressions. Vague legal expressions may be used as part of the conditions (“In case of infringement of the obligation to notify substantial changes of the quality system, ...”) or as part of the enacting part of a sentence (“... , the authority must take appropriate measures.”). Vague legal expressions open up a margin of appreciation that is, according to the rules of the respective jurisdiction, subject to full or limited judicial control. However, whilst opening up a margin of appreciation, they may be used to limit a discretionary power; see e.g. the fragment “... , the authority may take proportionate measures.”. Without the word “proportionate” the authority could take all measures, not just proportionate ones. The word “proportionate” thus has a limiting effect. Thus, there are many ways to combine the two instruments.

Taking account the disadvantages of the two instruments, it is advisable to use them in a restricted way. To examine whether their use is really necessary, regulators might carefully check whether the cases intended to be covered cannot be better framed by more precise regulatory text.

12.4 Ensuring harmonised interpretation in general

Sometimes, questions of interpretation can even be clarified by simple definitions. To avoid diverging interpretations, regulation can also contain interpretation guidelines or provide for an empowerment to adopt interpretation guidelines later on.

[Commission Delegated Regulation EU/231/2013](#) of 19 December 2012 supplementing Directive 2011/61/EU of the European Parliament and of the Council with regard to exemptions, general operating conditions, depositaries, leverage, transparency and supervision (of alternative investment funds) contains, in its Article 56, an interpretation guideline:

“In the absence of specific interpretation given by ESMA or by the Joint Committee of the European Supervisory Authorities, the provisions of this Section shall be interpreted in a consistent manner with the corresponding provisions of Directive 2006/48/EC and with the Guidelines to Article 122a of the Capital Requirements Directive of 31 December 2010 issued by the Committee of European Banking Supervisors and their subsequent amendments.”

In some jurisdictions, it might be useful to establish as an “interpretative” or implementing rule that the law is to be applied in a strict way. See Section 18 of the [Graphic Health Warnings Law of the Philippines \(Act 10643\)](#):

“Section. 18. Strict Compliance and Inspections. – Absolutely no extensions of time to comply with the provisions of this Act shall be granted to tobacco manufacturers and importers or any other affected party.”

However, in some other jurisdictions, such a sentence could raise legal questions as to whether, in other cases, some leniency may be applied.

Sometimes the interpretation guidelines cannot be established in advance because it is, at the time of adoption of the regulation, not yet clear what questions will arise. In this case, it might be useful to provide for an empowerment to adopt interpretative measures. See as an example [Regulation \(EU\) No. 228/2013](#) of 13 March 2013 laying down specific measures for agriculture in the outermost regions of the Union and repealing Council Regulation (EC) No 247/2006. This Regulation contains, in its Article 12, an empowerment for the Commission to adopt regulatory acts necessary to ensure the uniform application by the Member States of a certain article. It is noteworthy that it does not contain any specific condition except that the act must be necessary:

“3. The Commission shall adopt implementing acts regarding the measures necessary to ensure the uniform application by the Member States of this Article, specifically relating to the introduction of the system of certificates and the commitment undertaken by operators at the time of registration. Those

implementing acts shall be adopted in accordance with the examination procedure referred to in Article 34(2).”

12.5 Ensuring the harmonised and stringent work of conformity assessment bodies

The designation, supervision and removal processes form the central point of leverage for influencing the conformity assessment bodies' work. The design of these processes also determines to what extent conformity assessment bodies are compliant with legal requirements and with instructions given by the authorities. There are many variables for the designation process:

- ◆ How many different authorities shall be involved? Subject to the degree of impartiality and to the competence of the main authority, it may make sense to involve more authorities.
- ◆ Shall there be a right to be designated once certain conditions are met or is the designation based on a discretionary decision which is not subject to full judicial control?
- ◆ Shall there be detailed documentation requirements for the application, e.g. in relation to the fulfilment of designation criteria?
- ◆ Shall there be an assessment in the premises of the conformity assessment body or in the premises of an economic operator being assessed by the conformity assessment body (so-called “observed audits”)?
- ◆ Shall the conformity assessment body be periodically assessed?
- ◆ Shall there be unannounced surveillance assessments?
- ◆ Shall the designation be based on accreditation or not? The weaker the authorities and the stronger the respective accreditation bodies, the more accreditation makes sense. However, accreditation is usually judged against standards, not against requirements set up by regulation. If there is a mismatch between the requirements in the standards and the requirements in the regulation, accreditation is not extremely useful.

Besides the designation mechanism, there is a wide variety of other measures that can be used to strengthen and harmonise the work of conformity assessment bodies (legal or paralegal control mechanisms, peer review, codes of conduct, informal co-ordination of decision making, etc.). The best example so far found in regulation: [Commission Implementing Regulation \(EU\) No 392/2013](#) of 29 April 2013 amending Regulation (EC) No 889/2008 as regards the control system for organic production. This Regulation contains a detailed programme for enforcement. The programme foresees assistance by entrusted private bodies, supervision of entrusted private bodies, exchange of information between the entrusted bodies and authorities, and risk management. The programme determines a minimum percentage of verifications and of unannounced verifications.

A comprehensive strategy on how the decision-making of conformity assessment bodies and authorities can be harmonised has been developed in [this article](#).

12.6 Ensuring a harmonised and stringent implementation by authorities

The implementation of regulation is often hampered by weak authorities. In order to ensure a minimum level of strength, regulators can set up various types of requirements, for example:

- ◆ Requirements on independence;
- ◆ Management requirements;
- ◆ Requirements on minimum resources (ideally with clear indication of minimum full-time equivalences, not just vague clauses like “appropriate number of staff” as the latter is difficult to enforce);
- ◆ Obligation to apply a quality system. The [Argentinian Decreto Nacional 38/13](#) of 22 January 2013 obliges, in its Article 13, obliges the National Genetic Data Bank to undergo an annual quality system ISO certification.

Authorities can furthermore be strengthened by clearly defining their tasks and by explicitly providing for necessary empowerments to act. Without explicit empowerments, authorities risk being helpless before unlawful operators or citizens. Examples of such clear empowerments have been presented in [Section 7.2](#).

A comprehensive strategy on how the decision-making of authorities and conformity assessment bodies can be harmonised has been developed in [this article](#).

12.7 Strengthening authorities through intra-organisational measures

The vast majority of intra-organisational measures for authorities do not depend on regulation or, if any at all, “just” financial regulation. Hence, they should not be a subject of this Handbook, which deals exclusively with regulation. However, subject to the jurisdiction, specific empowerments might exceptionally be needed for the following intra-organisational measures:

- ◆ (Re-)Assigning of human resources (in case of changing situation);
- ◆ (Re-)Assigning of financial resources (in case of changing situation);
- ◆ Assigning of and cooperation with external experts as advisors;
- ◆ Creating scientific or advisory bodies;
- ◆ Establishing procedures regarding scientific or other advisory bodies;
- ◆ Creating intra-organisational independence (e.g. for scientific or advisory bodies that must have independence to be credible);
- ◆ Establishing statutory intra-organisational reporting obligations;
- ◆ Establishing intra-organisational control mechanisms (e.g. mandatory review by superior instance for difficult or important decisions, periodic control review, right to instruct);
- ◆ Establishing intra-organisational disciplinary procedures; and
- ◆ Establishing whistle-blower protection mechanisms (a universe of its own, see [Subsection 11.4.3](#) and this [article](#)).

12.8 Implementation tasks: Centre, agency or geographic entities?

Four task assignment schemes are most frequently recommended:

- ◆ To centralise tasks with the Centre,

- ◆ To centralise tasks with a specialised agency, operating under control of the Centre but not necessarily located at the same place,
- ◆ To decentralise tasks to geographic entities, and
- ◆ To partly decentralise to geographic entities.

The advantages and disadvantages of these four task assignments can, from the perspective of the Centre, be summarised as follows:

Responsibility assigned to:	Advantages:	Disadvantages:
Centre	<ul style="list-style-type: none"> • Full control by the Centre, and • Harmonised practice across the jurisdiction. 	<ul style="list-style-type: none"> • Administrative burden for the Centre, • Little knowledge of the situation in geographic entities on the ground, and • Highest degree of responsibility for errors.
Agency	<ul style="list-style-type: none"> • High control by Centre, and • Harmonised practice across the jurisdiction. 	<ul style="list-style-type: none"> • Financial and organisational burden for the Centre, • Little knowledge with regard to the situation in the geographic entities, on the ground, and • High degree of responsibility for errors.
Full decentralisation	<ul style="list-style-type: none"> • No financial or organisational burden for Centre, • High level of knowledge of the situation in geographic entities on the ground, and • Low responsibility for errors. 	<ul style="list-style-type: none"> • Risk of diverging practice across the jurisdiction, and • Low control by the Centre.
Partial decentralisation	Subject to the degree of decentralisation: row 1 or 3.	<ul style="list-style-type: none"> • Subject to the degree of decentralisation: row 1 or 3, and • Risk of uncertainties with regard to the responsibilities.

There are alternatives to the classic assignment schemes based on decentralisation that have not yet been appropriately explored. The classic assignment schemes based on decentralisation contain an implicit assumption: all of the geographic entities have to do the same. But are all geographic entities identical? Do they really have the same capacities, strengths and weaknesses? Is it for instance

realistic to expect a geographic entity with less than 3 million inhabitants to create and maintain the technical competence for performing market surveillance in the entire range of products? If the answer is still “yes” today, starting from which degree of further technological sophistication or reduction of tax income must the Centre give up this expectation?

New options are needed. One way to identify new options is to do away with the assumption that all the geographic entities necessarily have to do the same. An asymmetric assignment of tasks is to be considered. Geographic entities with few inhabitants or resources thus could take over some specialised tasks for the entire jurisdiction, but would be assisted by other geographic entities for all other tasks in return. Tasks would be attributed in accordance with specific strengths and weaknesses, avoiding duplication of resources and striving for an increase of the overall output by intelligent task-sharing. If this type of co-operation works well in other spheres of life, be it research or industrial co-operation, it might well also work in inter-state co-operation, provided that it is based on a realistic assessment of strengths and weaknesses.

The asymmetric assignment of tasks can take place at two levels:

- ◆ Firstly, at the formal level of the legal act, and
- ◆ Secondly, informally once the geographic entities are made responsible by the legal act.

In both cases the participation with the asymmetric task assignment can also be kept optional. If a few rich geographic entities prefer to trust only their own staff, so be it. For the other geographic entities, the asymmetric task assignment can still provide for a better (market) surveillance per invested unit of staff or money.

As to the centralised assignment schemes, the following alternatives are sometimes worth examining. Firstly, tasks can be attributed via public tenders to public or private organisations that provide for the respective service. Secondly, if there are already organisations exerting the requested or a similar activity, grants might help to strengthen these organisations. Finally, the geographic entities and the Centre can also create a joint assignment of tasks to private operators whilst giving these operators the right to take fees for their services provided to third parties.

12.9 Ensuring that authorities decide in time

Many enforcement issues depend on timely decision-making by authorities. Likewise, operators or citizens who need an authorisation or certification depend on timely decision-making. For this reason it can be wise to establish deadlines for administrative decisions. On the other hand, the administrations cannot be made responsible for delays which are due to circumstances that are outside of their control. But it is possible to strike a balance between the legitimate interests of operators and citizens and the legitimate interests of authorities. See as an example the [Canadian Species at Risk Act - Permits Authorizing an Activity Affecting Listed Wildlife Species Regulations of 2013](#), which contains fine-tuned rules establishing deadlines for administrative decisions. These rules include various so-called “stop-the-clock-mechanisms”:

“90-day time limit

3. (1) *Subject to subsections (2) and (3), the competent minister must either issue a permit or notify the applicant of the refusal to issue a permit within 90 days after the date of the notice indicating that the application has been received.*

Application incomplete

(2) *The time limit set out in subsection (1) is suspended if the application is incomplete. The suspension begins on the day on which the competent minister notifies the applicant in writing that the information provided is insufficient to allow the competent minister to issue or refuse to issue a permit and ends on the day on which the competent minister receives all of the missing information.*

Non-application of time limit

(3) *The time limit set out in subsection (1) is not applicable in the following circumstances:*

(a) *additional consultations are necessary, including consultations held under subsections 73(4) and (5) of the Act;*

(b) *an Act of Parliament other than the Act or a land claims agreement requires that a decision be made before the competent minister issues or refuses to issue a permit under section 73 of the Act;*

- (c) the terms and conditions of a permit previously issued to the applicant under section 73 of the Act have not been met;*
- (d) the applicant requests or agrees that the time limit is not to apply;*
or
- (e) the activity described in the permit application is modified before the competent minister issues or refuses to issue a permit under section 73 of the Act.”*

12.10 Preventing corruption and other unlawful operations of authorities

The [Indian National Food Security Act](#) No. 20 of 2013, published on 10 September 2013, establishes, in its Chapter VII, a “Grievance Redress Mechanism” with a State Commission operating similarly to a court or to an arbitral tribunal:

“14. Every State Government shall put in place an internal grievance redressal mechanism which may include call centres, help lines, designation of nodal officers, or such other mechanism as may be prescribed. ...

20.

(1) The State Commission shall, while inquiring into any matter referred to in clauses (b) and (e) of sub-section (6) of section 16, have all the powers of a civil court while trying a suit under the Code of Civil Procedure, 1908, and, in particular, in respect of the following matters, namely:—

- (a) summoning and enforcing the attendance of any person and examining him on oath;*
- (b) discovery and production of any document;*
- (c) receiving evidence on affidavits;*
- (d) requisitioning any public record or copy thereof from any court or office; and*
- (e) issuing commissions for the examination of witnesses or documents.*

(2) The State Commission shall have the power to forward any case to a Magistrate having jurisdiction to try the same and the Magistrate to

whom any such case is forwarded shall proceed to hear the complaint against the accused as if the case has been forwarded to him under section 346 of the Code of Criminal Procedure, 1973.”

The [Indian National Food Security Act](#) No. 20 of 2013 provides also, in its Chapter XI, for transparency and accountability by obliging to publish records, to undertake social audits, and by establishing supervising committees:

“27. All Targeted Public Distribution System related records shall be placed in the public domain and kept open for inspection to the public, in such manner as may be prescribed by the State Government.

28.

(1) Every local authority, or any other authority or body, as may be authorised by the State Government, shall conduct or cause to be conducted, periodic social audits on the functioning of fair price shops, Targeted Public Distribution System and other welfare schemes, and cause to publicise its findings and take necessary action, in such manner as may be prescribed by the State Government.

(2) The Central Government may, if it considers necessary, conduct or cause to be conducted social audit through independent agencies having experience in conduct of such audits.

29.

(1) For ensuring transparency and proper functioning of the Targeted Public Distribution System and accountability of the functionaries in such system, every State Government shall set up Vigilance Committees as specified in the Public Distribution System (Control) Order, 2001, made under the Essential Commodities Act, 1955, as amended from time to time, at the State, District, Block and fair price shop levels consisting of such persons, as may be prescribed by the State Government giving due representation to the local authorities, the Scheduled Castes, the Scheduled Tribes, women and destitute persons or persons with disability.

(2) The Vigilance Committees shall perform the following functions, namely:—

(a) regularly supervise the implementation of all schemes under this Act;

- (b) inform the District Grievance Redressal Officer, in writing, of any violation of the provisions of this Act; and*
- (c) inform the District Grievance Redressal Officer, in writing, of any malpractice or misappropriation of funds found by it.”*

Finally, the [Indian National Food Security Act](#) No. 20 of 2013 establishes, in its Chapter XIII, a state liability for any non-fulfilment of rights accorded by the act:

“44. The Central Government, or as the case may be, the State Government, shall be liable for a claim by any person entitled under this Act, except in the case of war, flood, drought, fire, cyclone or earthquake affecting the regular supply of foodgrains or meals to such person under this Act: provided that the Central Government may, in consultation with the Planning Commission, declare whether or not any such situation affecting the regular supply of foodgrains or meals to such person has arisen or exists.”

A good deal of corruption and other unlawful operations can be observed in connection with contracts and public tenders. Besides specific rules on the attribution of contracts and on public tenders, it might help to prescribe by regulation how the contracts shall look. An example of this practice is to be found in the [Argentinian Decree 271/2014](#) of 6 March 2014 “Aprobación de Modelo de Contrato de Préstamo CAF a celebrarse con la Corporación Andina de Fomento destinado a financiar parcialmente el “Programa de Obras Básicas de Agua Potable 2012-2015 AySA - Fase I””.

Establishing rules on the liability of agents of the relevant authorities can also be a tool to promote good conduct. Section 34 of the [South African Border Management Authority Act 2 of 2020](#) exempts agents from liability only in case of absence of negligence and indirectly establishes liability for intentional or negligent unlawful action⁶⁴.

To dive deeper into this topic, see [this article](#), which describes how regulations can protect the impartiality of decisions and research in the public interest. See also the extremely detailed provisions of the French [ACT no. 2013-907](#) of 11 October 2013 on transparency in public life. This act obliges inter alia members of the government to declare the following:

⁶⁴ We would have recommended a positive wording instead of the exemption from the exclusion from liability.

- “1) Professional activities that give rise to remuneration or gratuities that are performed on the date of appointment*
- 2) Professional activities that have given rise to remuneration or gratuities that were performed during the last five years*
- 3) Activities in the capacity of consultant that are performed on the date of appointment and that were performed during the last five years*
- 4) Involvement in the managing bodies of a public or private organisation or of a corporation, company or partnership on the date of appointment or during the last five years*
- 5) Direct stakes in the capital of a corporation, company or partnership on the date of appointment*
- 6) Professional activities that are performed on the date of appointment by the spouse, partner by civil union or common law spouse [Provisions declared to be unconstitutional by Constitutional Council decision no. 2013-676 DC of 9 October 2013]*
- 7) Volunteer work that could give rise to a conflict of interest 8) [Provisions declared to be unconstitutional by Constitutional Council decision no. 2013-676 DC of 9 October 2013]*
- 9) Elective duties and offices performed and held on the date of appointment The declaration shall specify the amount of the remunerations, allowances or gratuities received by the member of the Government in respect of the items referred to in points 1) to 5) [Provisions declared to be unconstitutional by Constitutional Council decision no. 2013-676 DC of 9 October 2013] and point 9) of this sub-section III.”*

12.11 Co-operation amongst authorities

Most regulation contains little text on co-operation amongst authorities, as if it went without saying that authorities co-operate well. In practice, co-operation is not always sufficient. Partly this is due to a lack of willingness. Partly it can also be due to the fact that there are no clear and detailed obligations for co-operation, that there is no legal empowerment for the exchange of data foreseen in the regulation, or that there is no multi-lingual database for the exchange of detailed

information⁶⁵ (or that there is no other translation tool available). All this can be remedied by integrating issues of co-operation into the regulation.

Article 38 of [Directive 2009/72/EC](#) concerning common rules for the internal market in electricity contains a good example of relatively detailed rules on co-operation. It even creates an empowerment to create ever more detailed rules through regulatory acts:

“1. Regulatory authorities shall closely consult and cooperate with each other, and shall provide each other and the Agency with any information necessary for the fulfilment of their tasks under this Directive. In respect of the information exchanged, the receiving authority shall ensure the same level of confidentiality as that required of the originating authority.

2. Regulatory authorities shall cooperate at least at a regional level to:

(a) foster the creation of operational arrangements in order to enable an optimal management of the network, promote joint electricity exchanges and the allocation of cross-border capacity, and to enable an adequate level of interconnection capacity, including through new interconnection, within the region and between regions to allow for development of effective competition and improvement of security of supply, without discriminating between supply undertakings in different Member States;

(b) coordinate the development of all network codes for the relevant transmission system operators and other market actors; and

(c) coordinate the development of the rules governing the management of congestion.

3. National regulatory authorities shall have the right to enter into cooperative arrangements with each other to foster regulatory cooperation.

4. The actions referred to in paragraph 2 shall be carried out, as appropriate, in close consultation with other relevant national authorities and without prejudice to their specific competencies.

5. The Commission may adopt Guidelines on the extent of the duties of the regulatory authorities to cooperate with each other and with the Agency. Those

⁶⁵ See as an example the EU “[Internal Market Information System](#)” (IMI).

measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46(2).”

The [Canadian Proceeds of Crime \(Money Laundering\) and Terrorist Financing Act](#) (2000, Clause 17) contains a rather generic empowerment for the establishment of cooperation agreements with authorities inside and outside the state and even with persons or organisations in or outside the state:

“66 (1) The Centre may, for the purpose of exercising its 66 (1) powers or performing its duties and functions under this Part, enter into contracts, memoranda of understanding and other agreements with a department or an agency of the Government of Canada, with the government of a province, with the government of a foreign state and with any other person or organization, whether inside or outside Canada, in its own name or in the name of Her Majesty in right of Canada.

(2) Agreements relating to the Centre’s collection of information from databases referred to in paragraph 54(1)(b) must specify the nature of and limits with respect to the information that the Centre may collect from those databases.

(3) Despite subsection (1), only the Minister may enter into an agreement or arrangement referred to in subsection 56(1).”

The Uruguayan [Law No.19855](#) on the creation of a regulatory mark for the problematic consumption of alcoholic drinks of 23/12/2019 tries to achieve a better cooperation amongst authorities by creating, in Article 29, a coordination forum (“table”) to which the president’s office and various the ministries, some of them represented by specified agencies, participate. The law also decides on the presidency of the forum and provides, in Article 31, to its members a generic empowerment for the fulfilment of the tasks of this law.

Section 27 of the [South African Border Management Authority Act 2 of 2020](#) foresees the establishment of implementation protocols between in main authority in charge and its partners:

“(1) For the purpose of this section, “implementation protocol” means an implementation protocol concluded in accordance with section 35 of the Intergovernmental Relations Framework Act, 2005 (Act No. 13 of 2005).

(2) Where the implementation of a policy, the exercise of a statutory power, the performance of a statutory function or the provision of a service relating to border law enforcement functions by the Authority depends on the participation of other organs of state, the Authority and those organs of state must, within a reasonable time after the commencement of the Act, co-ordinate their respective functions in such a manner as may be appropriate or required in the circumstances by entering into an implementation protocol.

(3) The organs of state referred to in subsection (2) must, within a reasonable time after the commencement of the Act, enter into implementation protocols with the Authority to collaborate on and ensure the alignment of technological, electronic, information and communication systems and procedures necessary to ensure the efficient sharing of relevant information with the Authority.

(4) The Minister may initiate the process for the conclusion of implementation protocols contemplated in subsections (2) and (3) in the Inter-Ministerial Consultative Committee.

(5) (a) The Authority must, within six months after the commencement of this section, conclude implementation protocols with— ...” (list of authorities).”

See also the Section 12.13 on decision making by committees.

12.12 International cooperation

As business and private behaviours become more and more international, jurisdictions can no longer afford not to cooperate with other jurisdictions. Authorities are sometimes hindered from cooperating with authorities of other jurisdictions due to confidentiality rules or rules on data-protection. In some jurisdictions, the transfer of data regarding a natural or legal person as such requires a legal basis, regardless of rules on confidentiality and of rules on data-protection. Accordingly, regulation should contain precise empowerments for exchanging data with authorities in other jurisdictions. These empowerments can be made conditional upon the respect of rules of confidentiality and of data-protection rules by the other jurisdictions. When verifying the rules of other jurisdictions, special care should be applied to the question of whether rules on public access to documents

or other transparency rules do not counter confidentiality or data-protection in the other jurisdictions.

Whilst the exchange of information is the most relevant issue of international administrative cooperation, it is to be noted that international administrative co-operation can go further. See e.g. [Subsection 11.10.4](#) and [this OECD document](#) on international regulatory cooperation.

12.12.1 – Two paths of international cooperation

The full enforcement of obligations in cross-border internet trade and services will most likely require the cooperation of the majority of jurisdictions through international conventions. Such cooperation, which hardly exists today, might in the long run resemble current international cooperation in judicial matters. Like in that field, it will thus be extremely difficult to establish. Probably, it will only cover the severest cases of criminality and not ordinary infringements of law.

This perspective is admittedly not very attractive. The only alternative thereto is evolving very slowly here and there: several jurisdictions can establish, in their domestic legislation, empowerments for providing assistance to each other. If, at an (informal) administrative level, agreement on reciprocity has been reached amongst the administrations, cooperation can be initiated by regulatory acts other than legislation (adopted by the administration) or even by simple administrative acts in individual cases. This approach is not necessarily visible to the outside if it is triggered by an informal agreement. To the outside only the empowerments for unilateral recognition of foreign certificates appear. These are often used only once an informal agreement on reciprocity has been reached amongst the administrations concerned.

This approach brings with it the possibility of flexible mutual enforcement assistance. However, this might be legally problematic in quite a few jurisdictions. Classic international public law in the form of international conventions providing for such mutual assistance will probably remain the default solution. Sectors requiring full enforcement of obligations in cross-border internet trade and services and in other international contexts will also most likely require the cooperation of the majority of jurisdictions through international conventions.

12.12.2 – Empowering cooperation with other jurisdictions

Following the second approach described under 12.12.1, it is recommended to assess which of the national empowerments one can make available to other jurisdictions in return for assistance from those other jurisdictions. This assessment should be made even where no concrete cooperation partner is insight today: it is only a question of time when the need for international cooperation will arise. Furthermore, empowerments might be needed to allow another jurisdiction to work on one's own behalf or to operate on the ground of another jurisdiction with the agreement of the latter (e.g. common practice of food inspection authorities with regard to foreign slaughterhouses).

Though this list is not complete, we recommend verifying in particular the need for the following empowerments:

- ◆ Permitting foreign officers to take part in state operations;
- ◆ Disclosing confidential information to authorities of other jurisdictions;
- ◆ Establishing joint expert committees and data exchange needed for that purpose;
- ◆ Investigating or enforcing on the territory of the other jurisdiction;
- ◆ Empowering foreign authorities to investigate cases on one's own behalf on the territory of the other jurisdiction;
- ◆ Requesting foreign authorities to enforce on one's own behalf on the territory of the other jurisdiction;
- ◆ Enforcing on request of the foreign authority;
- ◆ Empowering foreign authorities to investigate cases on their own behalf on one's own territory;
- ◆ Requesting foreign authorities to enforce on their own behalf on one's own territory;
- ◆ Recognising foreign certificates or approvals;
- ◆ Extension of domestic investigational empowerments to cases committed outside the applicability of domestic law, but subject to the law of another jurisdiction where there is mutual assistance between the two jurisdictions (based on formal agreements or practical arrangements);

- ◆ Mutual legal assistance in general, including for court procedures, see Sections 106 onwards of the [Ugandan Anti Money Laundering Act 2013](#);
- ◆ Extradition of offenders for offences committed in other jurisdictions; and
- ◆ Transfer of witnesses in custody for court procedures in other jurisdictions.

See as an example for rather generic provisions permitting cooperation with foreign authorities (and even persons or organisations) the [Canadian Proceeds of Crime \(Money Laundering\) and Terrorist Financing Act](#) (2000, c. 17):

“66 (1) The Centre may, for the purpose of exercising its 66 (1) powers or performing its duties and functions under this Part, enter into contracts, memoranda of understanding and other agreements with a department or an agency of the Government of Canada, with the government of a province, with the government of a foreign state and with any other person or organization, whether inside or outside Canada, in its own name or in the name of Her Majesty in right of Canada.

(2) Agreements relating to the Centre’s collection of information from databases referred to in paragraph 54(1)(b) must specify the nature of and limits with respect to the information that the Centre may collect from those databases.

(3) Despite subsection (1), only the Minister may enter into an agreement or arrangement referred to in subsection 56(1).”

But the same act also contains much more explicit provisions which reflect well some of the bullet points above:

“38

(1) The Minister, with the consent of the Minister designated for the purpose of section 42, may enter into an agreement or arrangement in writing with the government of a foreign state, or an institution or agency of that state, that has reporting requirements similar to those set out in this Part, whereby

a) information set out in reports made under subsection 12(1) in respect of currency or monetary instruments imported into Canada from that state will be provided to a department, institution or agency of that state that has powers and duties similar to those of the Canada Border Services Agency in respect

of the reporting of currency or monetary instruments;

(b) information contained in reports in respect of currency or monetary instruments imported into that state from Canada will be provided to the Canada Border Services Agency.

(2) When an agreement or arrangement referred to in subsection (1) is in effect with a foreign state or an institution or agency of that state and a person fulfils the reporting requirements of that state in respect of currency or monetary instruments that are imported into that state from Canada, the person is deemed to have fulfilled the requirements set out in section 12 in respect of the exportation of the currency or monetary instruments.

(3) The information received under an agreement or arrangement referred to in subsection (1) shall be sent to the Centre and, for the purposes of any provision of this Act dealing with the confidentiality of information or the collection or use of information by the Centre, is deemed to be information set out in a report made under section 12.

38.1 The Minister, with the consent of the Minister designated for the purpose of section 42, may enter into an agreement or arrangement in writing with the government of a foreign state, or an institution or agency of that state, that has powers and duties similar to those of the Canada Border Services Agency, whereby the Canada Border Services Agency may, if it has reasonable grounds to suspect that the information would be relevant to investigating or prosecuting a money laundering offence or a terrorist activity financing offence, provide information set out in a report made under section 20 to that government, institution or agency.”

Any state verification on the territory of another nation state needs of course to be authorised by an agreement under international public law. To foresee a state verification on the territory of another nation state without authorisation of the host state could amount to an infringement of international public law. Nonetheless, there are such mechanisms foreseen in the law of several jurisdictions. See as an example the [Canadian Customs Act / CCOFTA Verification of Origin Regulations](#).

Audits or inspections undertaken by (usually private) entrusted conformity assessment bodies are less problematic under aspects of international public law. If certain conformity assessment bodies are entrusted by different jurisdictions,

they can examine legal requirements of different jurisdictions on the same topic in one go, e.g. regarding the applicable quality management systems.

12.12.3 – Empowering cooperation with international organisations

Similar empowerments are needed where the intention is to authorise cooperation with international organisations. There are more and more international organisations that dispose of relevant information and thus can be targeted as cooperation partners.

12.13 Decision making by committees

It can make sense to attribute certain responsibilities to committees. Establishing a committee is not only important to harmonise views, but also for enlarging the knowledge basis for decision making. If so, the question arises of how the committee shall operate. In many jurisdictions, the internal rules are left to the committee to decide upon. However, this can lead to manipulation (for example by the chair) or to other unwanted results. As an alternative, regulators can consider setting up basic rules of operation themselves. This is done in the [Tunisian Decree No. 2014-2242 of 24 June 2014 fixing the amount and the procedures of allocation of pensions to resistants](#):

“Article 5 - Le président de la commission peut convoquer toute personne dont il juge la présence utile pour participer aux travaux de la commission sans prendre part au vote, et peut, le cas échéant, solliciter l’avis technique des organismes spécialisés. Les membres de la commission sont nommés par arrêté du chef du gouvernement, sur proposition des ministères et organismes concernés, pour une durée de trois ans renouvelable une seule fois.

Art. 6 - La commission se réunit sur convocation de son président quatre fois au moins par an et chaque fois que de besoin. Le Président établit l’ordre du jour de la commission et le transmet aux membres. La commission ne peut délibérer valablement qu’en présence de la moitié de ses membres au moins. Si le quorum n’est pas atteint lors de la première réunion, celle-ci est reportée à une date ultérieure. Une nouvelle convocation doit intervenir au moins une semaine avant la date de réunion. La deuxième réunion est réputée valable

quel que soit le nombre des membres présents.

Les avis de la commission sont rendus à la majorité des voix de ses membres présents et en cas d'égalité, celle du président est prépondérante.

Les réunions de la commission sont consignées dans des procès-verbaux et signés par son président et ses membres présents.

Art. 7 - Le secrétariat permanent de la commission est assuré par les services chargés des affaires sociales relevant de la Présidence du gouvernement.”

Amended machine translation:

“Article 5 - The Chairman of the Committee may summon any person whose attendance he considers useful to participate in the work of the Committee without taking part in the vote. He may, if necessary, seek technical advice from the specialist agencies. The members of the Committee are appointed by order of the Head of Government, on the proposal of departments and agencies, for a period of three years, renewable once.

Art. 6 - The Committee shall be convened by its chairman at least four times a year and whenever necessary. The President sets the agenda of the Committee and sends it to members. The Committee may only validly deliberate in the presence of at least half of its members. If the quorum is not reached at the first meeting, the meeting is postponed to a later date. A new notice must be made at least one week before the meeting date. The second meeting shall be deemed valid whatever the number of members present.

The opinions of the Committee are made by majority vote of its members present and in case of a tie, the Chairman has the casting vote.

Meetings of the Committee shall be recorded in the minutes and signed by its President and members present.

Art. 7 - Permanent Committee secretariat is provided by the departments responsible for social affairs under the Presidency of the Government.”

The Uruguayan [Law No.19855](#) on the creation of a regulatory mark for the problematic consumption of alcoholic drinks of 23/12/2019 tries to achieve better cooperation amongst authorities, but also aims for the development of a joint strategy by creating, in Article 29, a coordination forum (“table”) to which the president’s office and various ministries, some of them represented by specified agencies,

participate. The law also decides on the presidency of the forum and provides, in Article 31, its members with a generic empowerment for the fulfilment of the tasks of this law. The “table” is thus more than an ordinary committee.

12.14 Means for dispute resolution

Regulation often gives rise to disputes. Accordingly, it can be helpful to establish means for dispute resolution.

There are various mechanisms that can serve for purposes of dispute resolution:

- ◆ Arbitrator,
- ◆ Arbitrator Tribunals, or
- ◆ Special Committees.

An example of special Committees in charge of settling disputes can be found at the beginning of the previous section. An example of an Arbitrator Tribunal can be found in the law of Argentina. Article 46 of the [Argentinian Decreto 1.023/2013](#) of 29 July 2013 “Transparency of markets and protection of investors: Regulation of the Law on Capital Markets”⁶⁶ contains an empowerment and basic principles for the establishment of Arbitrator Tribunals:

“Los reglamentos para la creación y funcionamiento de los Tribunales Arbitrales dictados por los mercados, deberán ser aprobados por la COMISION NACIONAL DE VALORES, debiendo dicha reglamentación contener, como mínimo, los siguientes aspectos:

- a) Las condiciones de idoneidad, honorabilidad, integridad, experiencia, antecedentes académicos y profesionales que deben acreditar los miembros.*
- b) El Tribunal debe estar constituido por un número de miembros impar.*
- c) El contenido del laudo arbitral deberá ser exclusivamente de derecho.... “*

⁶⁶ “Transparencia de los mercados y protección de los inversores: Reglamentación de ley de Mercado de Capitales“

Amended machine translation:

“The regulations for the establishment and operation of Arbitrator Tribunals dictated by the markets must be approved by the National Securities Committee; such regulation must contain at least the following:

- a) The terms of suitability, honesty, integrity, experience, academic and professional background that the members have to demonstrate.*
- b) The Court must be composed of an odd number of members.*
- c) The content of the arbitrator’s award shall be exclusively legal. ...”*

The [Philippine “Lemon Law” on the protection of consumers buying motor vehicles \(Act 10642\)](#) provides for a sophisticated dispute settlement procedure to be managed by an ordinary administration:

“Section. 8. Remedies for Dispute Resolution. – The DTI shall exercise exclusive and original jurisdiction over disputes arising from the provisions of this Act. All disputes arising from the provisions of this Act shall be settled by the DTI in accordance with the following dispute resolution mechanisms:

(a) Mediation

(1) The principles of negotiation, conciliation and mediation towards amicable settlement between the manufacturer, distributor, authorized dealer or retailer and the consumer shall be strictly observed;

(2) In the course of its dispute resolution efforts, the DTI shall endeavor to independently establish the validity of the consumer’s outstanding complaint. The DTI shall likewise retain the services of other government agencies or qualified independent private entities in the ascertainment of the validity of the consumer’s complaint. Any cost incurred in establishing the validity of the consumer’s complaint shall be borne jointly by the consumer and the manufacturer, distributor, authorized dealer or retailer;

(3) The complaint shall be deemed valid if it is independently established that the motor vehicle does not conform to the standards or specifications set by the manufacturer, distributor, authorized dealer or retailer;

(4) Upon failure of the negotiation or mediation between the manufacturer, distributor, authorized dealer or retailer and the consumer, the parties shall execute a certificate attesting to such failure; and

(5) At any time during the dispute resolution period, the manufacturer, distributor, authorized dealer or retailer and the consumer shall be encouraged to settle amicably. All disputes that have been submitted for mediation shall be settled not later than ten (10) working days from the date of filing of the complaint with the DTI.

(b) Arbitration

In the event there is a failure to settle the complaint during the mediation proceedings, both parties may voluntarily decide to undertake arbitration proceedings.

(c) Adjudication

(1) In the event that both parties do not undertake arbitration proceedings, at least one of the parties may commence adjudication proceedings, administered by the DTI. The DTI shall rely on the qualified independent findings as to conformity to standards and specifications established herein. In no case shall adjudication proceedings exceed twenty (20) working days;

(2) In case a finding of nonconformity is arrived at, the DTI shall rule in favor of the consumer and direct the manufacturer, distributor, authorized dealer or retailer to grant either of the following remedies to the consumer:

(i) Replace the motor vehicle with a similar or comparable motor vehicle in terms of specifications and values, subject to availability; or

(ii) Accept the return of the motor vehicle and pay the consumer the purchase price plus the collateral charges. In case the consumer decides to purchase another vehicle with a higher value and specifications from the same manufacturer, distributor, authorized dealer or retailer, the consumer shall pay the difference in cost.

In both cases of replacement and repurchase, the reasonable allowance for use, as defined in this Act, shall be deducted in determining the value of the nonconforming motor vehicle; and (3) In case a nonconformity of the motor vehicle is not found by the DTI, it shall rule in favor of the manufacturer, distributor, authorized dealer or retailer, and direct the consumer to reimburse the manufacturer, distributor, authorized dealer or retailer the costs incurred by the latter in validating the consumer's complaints.

An appeal may be taken from a final judgment or order of the Adjudication Officer which completely disposes of the case within fifteen (15) days from receipt thereof. The appeal shall be taken by filing a Memorandum of Appeal with the Secretary of the DTI, with Notice of Appeal to the Adjudication Officer, and with a copy duly furnished the adverse party or parties on any of the following grounds:

- (i) Grave abuse of discretion;*
- (ii) The decision/order is in excess of jurisdiction or authority of the Adjudication Officer; and*
- (iii) The decision/order is not supported by the evidence or there is serious error in the findings of facts.*

The Secretary of the DTI shall decide on the appeal within thirty (30) days from receipt thereof. A party seeking further appeal from the decision of the Secretary of the DTI may file a case for certiorari to the Court of Appeals ...”

Taiwan (China) has, in Article 19 of its [Renewable Energy Development Act](#), established mediation as a means for dispute resolution. Mediation is obligatory before initiating legal proceedings.

12.15 De minimis clause

It is not necessarily helpful that authorities sue all non-conformities, above all if their enforcement capacity is rather limited. A “de minimis clause” sets a limit under which a certain consequence is not or not necessarily to be pursued. A “de minimis clause” can sometimes be found in final dispositions. At any rate, the “de minimis clause” is an item to be checked at the end of the drafting exercise. Is it

really worthwhile to apply all the mechanisms in the draft regulation in all cases covered by the scope? Is the necessary procedural effort still proportionate? If not, up to what limit can the application of the regulation be omitted? To raise this question helps to create better regulation.

See as an example of a “de minimis clause” [Council Regulation EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine, which sets such a limit at 50.000 hectolitres of yearly wine production per EU Member State:

“Article 105 - De minimis: This Chapter shall not apply in Member States where wine production does not exceed 50000 hectolitres per wine year. This production shall be calculated on the basis of the average production during the previous five wine years.”

12.16 Regularisation

Regularisation is a process that permits natural or legal persons to legalise a situation that is unlawful under the currently applicable law. Regularisation clauses can temporarily suspend certain legal obligations in order to create an incentive for regularisation (“No penalties to be paid for the past if you declare your fortune and pay taxes.”). Furthermore, they can set up conditions for regularisation, like the payment of a fee. See as an example [Council Regulation EC/479/2008](#) of 29 April 2008 on the common organisation of the market in wine:

“Article 86 - Obligatory regularisation of unlawful plantings planted before 1 September 1998

1. Producers shall, against the payment of a fee and not later than 31 December 2009, regularise areas planted with vines without a corresponding planting right, where applicable, before 1 September 1998.”

12.17 Rules on confidentiality

Law often needs to contain provisions on confidentiality. The provisions can oblige economic operators, professionals, authorities and conformity assessment bodies and their agents. Such provisions usually need to be adapted to the specific sector – general rules on data protection hardly match sector specific rules, but

can be referred to as a baseline. Rules on confidentiality must be strong enough to counter rules on public access to documents and other transparency rules.

Section 11 of the [Implementing Rules and Regulations of the Anti-Bullying Act of 2013 of the Philippines \(Act 10627\)](#) provides an example of precise confidentiality rules, namely rules on who is authorised to have access to sensitive information:

“Any information relating to the identity and personal circumstances of the bully, victim, or bystander shall be treated with utmost confidentiality by the Child Protection Committee and the school personnel, provided, that the names may only be available to the school head or administrator, teacher or guidance counselor designated by the school head, and parents or guardians of students who are or have been victims of bullying or retaliation.”

12.18 Algorithms and other data processing tools, usage, storage or destruction of data

Quite a few regulations need data processing tools to be implemented. Their number is constantly increasing.

In some jurisdictions, regulation must contain provisions on the data processing tools necessary for its implementation. In others, this is not mandatory. There are at least three reasons why it can be useful to mention the data processing tools in the regulation:

- ◆ In some jurisdictions the regulation must create the legal basis for the expenditures needed to create the data processing tools.
- ◆ In other jurisdictions, there is no need to create such a legal basis for the expenditures, but the administration in charge will have better chances to receive the funds if the data processing tools are mentioned in the regulation as being necessary for the implementation of the regulation. Mentioning the data processing tools will thus strengthen the position of the administration in budgetary negotiations.
- ◆ In some jurisdictions, the storage of data regarding natural or legal persons is only lawful when empowered by regulation.

Regardless of whether the regulation must or should refer to the data processing tools, there is an important question to be checked prior to adopting new regulation: is the regulation easy to implement or at least implementable in terms of data processing?

The [Canadian Proceeds of Crime \(Money Laundering\) and Terrorist Financing Act](#) (2000, c. 17) contains an interesting set of provisions covering many of these aspects and even some more, like a public registry, access to information on request and pro-active feedback information for those persons who informed the authority on potential infringements and thus merit being rewarded by information on the follow-up given to their input:

“54 Destruction of certain information

(2) The Centre shall destroy any information contained in a document, whether in written form or in any other form, that it receives that purports to be a report made under section 7, 7.1, 9 or 12, made in accordance with a directive issued under Part 1.1, sent under subsection 14(5) or referred to in section 9.1, and that it determines, in the normal course of its activities, relates to a financial transaction or circumstance that is not required to be reported to the Centre under this Act, and shall destroy any information voluntarily provided to the Centre by the public that it determines, in the normal course of its activities, is not about suspicions of money laundering or the financing of terrorist activities. The Centre shall destroy the information within a reasonable time after the determination is made.

54.1 (1) The Centre is responsible for establishing and maintaining a registry of the prescribed information submitted under sections 11.12 to 11.3.

(2) The registry shall be organized in any manner and kept in any form that the Centre may determine.

(3) The Centre shall make available to the public the part of the information referred to in subsection (1) that is identifying information as defined in the regulations.

(4) The Centre may verify the information contained in any application for registration or any other information submitted under sections 11.12 to 11.3.

(5) The Centre may analyse and assess the information referred to in subsection (4) and, in that case, that analysis or assessment is deemed to be an analysis or assessment conducted under paragraph 54(1)(c).

(6) Subject to section 6 of the Privacy Act, the Centre shall retain information referred to in subsection (4) for 10 years beginning on the day on which the Centre denies the registration of an applicant, on which a registered person or entity notifies the Centre that they have ceased their activities, or on which a person or entity is no longer registered with the Centre.

55 *Disclosure by Centre prohibited*

(1) Subject to subsections (3) and (6.1), sections 52, 55.1, 56.1 and 56.2, subsection 58(1) and sections 65 to 65.1 and 68.1 of this Act and to subsection 12(1) of the Privacy Act, the Centre shall not disclose the following:

- (a) information set out in a report made under section 7;*
- (a.1) information set out in a report made under section 7.1;*
- (b) information set out in a report made under section 9;*
- (b.1) information set out in a report referred to in section 9.1;*
- (b.2) information provided under sections 11.12 to b.2) except for identifying information referred to in subsection 54.1(3);*
- (c) information set out in a report made under subsection 12(1), whether or not it is completed, or section 20;*
- (d) information voluntarily provided to the Centre about suspicions of money laundering or of the financing of terrorist activities;*
- (e) information prepared by the Centre from information referred to in paragraphs (a) to (d); or*
- (f) any other information, other than publicly available information, obtained in the administration or enforcement of this Part.*

56.2 *When the Centre receives information from an institution or agency under an agreement or arrangement referred to in subsection 56(1) or (2), the Centre may provide it with an evaluation of whether the information is useful to the Centre.*

57 *Use of information*

No person who obtained or who has or had access to 57 information referred to in subsection 55(1) in the course of exercising powers or performing duties and functions under this Part shall use the information for a purpose other than exercising those powers or performing those duties and functions.

58 (1) *Feedback, research and public education*

The Centre may

(a) inform persons and entities that have provided report under section 7, 7.1 or 9, or a report referred to in section 9.1, about measures that have been taken with respect to reports under those sections; ...”

The use of algorithms raises data protection issues of its own, linked to the power and capacities of algorithms. [New Zealand](#) is [said](#) to be the first jurisdiction reacting to this issue by adopting in 2020 an algorithm transparency and accountability charter. This charter is also extremely innovative in terms of defining the applicability or scope of its main obligations. It obliges authorities to undertake a risk assessment and subject to the result of the risk assessment either to apply or not to apply the obligations of the charter, whilst there is also an intermediate zone where the authority “should” apply these obligations:

RISK MATRIX	IMPACT	<i>Low</i> The impact of these decisions is isolated and/or their severity is not serious	<i>Moderate</i> The impact of these decisions reaches a moderate amount of people and/or their severity is moderate	<i>High</i> The impact of these decisions is widespread and/or their severity is serious.
	LIKELIHOOD			
Probable Likely to occur often during standard operations				
Occasional Likely to occur some time during standard operations				
Improbable Unlikely but possible to occur some time during standard operations				

RISK RATING: ■ **LOW** - The Algorithm Charter could be applied ■ **MODERATE** - The Algorithm Charter should be applied ■ **HIGH** - The Algorithm Charter must be applied

See also [Section 11.7](#) on registration systems as tools for enforcement.

12.19 Further collateral obligations

The implementation of a regulatory system depends mostly on the fulfilment of collateral obligations for citizens, operators or authorities that can be implicit or explicit. We have already dealt with quite some collateral duties so far, e.g.:

- ◆ keeping confidentiality,
- ◆ storing and processing information in a certain way,
- ◆ storing documents for a certain period of time,
- ◆ making available information on request or via the internet,
- ◆ informing authorities on own initiative or on request,
- ◆ undergoing training,
- ◆ providing training, and
- ◆ making available minimum (human or other) resources.

But there are more of these obligations on which a well-functioning system depends. E.g. citizens, operators or authorities should under certain circumstances:

- ◆ paying fees,
- ◆ providing a deposit,
- ◆ correcting any false statement or act;
- ◆ confirming on request the authenticity of a document they have issued or, invertedly, confirm that a certain document has not been issued by them or has been unlawfully modified⁶⁷;
- ◆ issuing duplicates of certain documents; and
- ◆ cooperating with a functional successor (e.g. a new internet service provider should receive some basic information from the outgoing internet

⁶⁷ See also [Section 13.4](#) on the authenticity of acts.

service provider and the outgoing conformity assessment body should be ready to transfer documents and samples to an incoming conformity assessment body).

The last example, the transfer from one conformity assessment body to the next, is particularly tricky. It requests either a good portion of good will or precise anticipative provisions, either at contractual level or in legal provisions. The question of the validity of certificates is only part of the picture. Furthermore, it merits to be thought of which body is responsible for the continuous obligations and collateral obligations of the body – when shall the responsibility shift?

We list these obligations as generic examples. Subject to the sector and the jurisdiction, other obligations should be laid down explicitly in regulation in order to avoid any later dispute. The situation is similar to the negotiation of a contract: it is better to think of potential difficulties in advance. For everything that can go wrong, sooner or later goes wrong (Murphy's law).

The question “What could go wrong?” is not only an excellent basis for identifying collateral obligations that merit being laid down in regulation, but also to double-check the completeness of a regulatory system.

12.20 Regulatory sandboxes

In particular for financial industries, some jurisdictions offer the possibility for economic operators to test how their respective product or activity fits into the regulatory system. The test can be “virtual”, meaning without real clients buying the product or service, or with a license limited in time and by other parameters. See for the second type of sandbox this website created by [Singapore](#), regarding financial services. The [Austrian](#) modifying law of 24 July 2020 to the law on the financial market surveillance authority establishes the possibility to participate in sandboxes either with or without a (limited) license. A description of different models of regulatory sandboxes in the energy sector can be found in this [article](#). See also this [conference debate](#), organised by the Florence School of Regulation, which also covers waivers, exemption procedures, and regulatory pilots where the authority is more in the driving seat than in the sandbox.

Regulatory sandboxes offer advantages to the economic operators in so far as they can reduce risks of non-compliance when they really start business in the relevant field. At the same time, the authorities can also take profit from checking business models early-on, avoiding cumbersome infringement procedures later on. However, these sandboxes also absorb quite some human resources on the side of the authorities.

13. MISCELLANEOUS



I have nothing but contempt for the kind of governor who is afraid, for whatever reason, to follow the course that he knows is best for the State.

Sophocles

13.1 Transitional provisions and phasing in

Each jurisdiction uses one or more standard formulations for determining the entry into application of regulation. Sometimes, these standard formulations are sufficient. Frequently, however, more questions should be reflected on:

- ◆ Shall the new law be introduced step by step for different parts of the scope or for all in one go? See e.g. the [Canadian Electricity and Gas Inspection Act - Regulations Amending the Electricity and Gas Inspection Regulations](#).
- ◆ For which stage in a process shall the new regulation be applied as from date X and for which other stage from date Y? [For products, the stages can be determined with the help of the following questions: Is the relevant product already approved / certified? Has the product been created? Has it been sold to customers (placed on the market)? Has the product been handed over to the customer? Is the product already in use?] [For services, the stages can be determined with the help of the following questions: Has the service been approved / certified? Has the service been offered? Has the service been subject to a contract? Has the service been provided?] Regulation may also refer to different stages in one single provision. E.g., the [Tunisian Decree of the Minister of Health of 20 May 2014](#) amending the Decree of 24 February 1999 laying down the procedures for listing particulars which must be displayed on the outer cover of packets and packages containing tobacco products

refers both to the time of manufacturing and to the time of order:

“Article 8 (nouveau) - Les paquets et les emballages destinés aux produits de tabac qui sont fabriqués ou commandés avant l’entrée en vigueur du présent arrêté, peuvent être utilisés jusqu’au 30 avril 2015.”

Amended machine translation:

“Article 8 (new) - Packages and packaging for tobacco products that are manufactured or ordered before the entry into force of this Order may be used until 30 April 2015.”

- ◆ Shall there be a period in which citizens / operators can choose between the old and the new law? The anticipation of new law is, generally speaking, in the interest of the jurisdiction, as the new law is usually more advanced. However, it can create difficulties for the administration of enforcement. They have to distinguish between the products or services that are already fulfilling the new requirements and those that are not.
- ◆ Should geographic entities have the option of keeping the old law applicable for a period of time? Normally, previously applied law shall cease to apply by a certain date. However, there might be a need to give geographic entities the possibility of maintaining the law, for a certain time at least.
- ◆ Is there a need to redirect references? If a legal act is repealed, there might be a need to ascertain whether references to the repealed act are redirected / transferred to the new act.
- ◆ Is there a need to repeal (parts of) other legal acts that have become obsolete with the repeal of the major act?
- ◆ Is there a need to stipulate the provisional application of certain parts of the measure?

Regulation needs to determine the date of its application. However, there can be, in exceptional cases, a need to leave the date of application open for a certain time and to determine it later.

At the time of adoption, it is not necessarily clear (a) when the act will be published and (b) when the administration will be ready to apply the act. Accordingly, it can be advisable to empower the administration to determine the entering into force of the regulation within a certain period of time.

The [Indian right to fair compensation and transparency in land acquisition, re-settlement and rehabilitation act of 2013](#), provides in its Chapter I, Article 1 Paragraph 3 that the act shall enter into force once the Government has so decided, provided that the decision is taken within three months after the act being agreed to by the president. Canada too uses this technique, and does so even for specific sections of a regulation; see for example the [Order Fixing February 13, 2014 as the Day on which Sections 178 and 185 of the Act come into Force](#) (i.e. of the Canada Marine Act).

The entry into force or application date of a regulatory act may be linked to the entry into force or application date of another regulatory act; see e.g. the [Canadian Electricity and Gas Inspection Act - Regulations Amending the Electricity and Gas Inspection Regulations](#):

“8. These Regulations come into force on the day on which section 6 of the Fairness at the Pumps Act, chapter 3 of the Statutes of Canada, 2011, comes into force, but if they are registered after that day, they come into force on the day on which they are registered.”

Normally, regulation should not come into force prior to its publication. However, there might be special reasons to foresee a limited retroactivity (e.g. to avoid manipulations in the transition phase). The [Indian National Food Security Act No. 20 of 2013](#), published on 10 September 2013, stipulates in Chapter I Section 1.(3) that it shall be deemed to have come into force prior to its publication:

“(3) Save as otherwise provided, it shall be deemed to have come into force on the 5th day of July, 2013.”

The [Senegalese law No. 2014-01](#) of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) also provides for an entry into force and supposedly of an application date earlier than the date of adoption:

“Art. 23. - La présente loi entre en vigueur le 1er janvier 2014.”

[...]

Fait à Dakar, le 6 janvier 2014”

“Art. 23 -. This Act comes into force on 1 January 2014.

[...]

Made in Dakar, January 6, 2014”

13.2 Validity of decisions, legal acts and certificates based on the previous law

Something that is sometimes forgotten when preparing new regulation is the question of whether decisions, legal acts and certificates taken or issued under the old law shall remain valid, and if so under which conditions and for how long. Forgetting this question causes a lot of legal uncertainty or difficulties, or both, in the transition.

Evidently, there is a conflict between the economic operators' wish to maintain their legal position for as long as possible and the regulator's interest in introducing the obligations of the new regulation as fast as possible.

13.3 Applicability of other regulation

There is a wide variety of clauses dealing with the applicability of other regulation:

- ◆ Repeal provisions;
- ◆ Provisions stipulating that other regulations remain unaltered;
- ◆ Provisions stipulating that other regulations prevail;
- ◆ Provisions stipulating that the new regulation prevails over other regulations;
- ◆ Provisions stipulating that no other regulations apply.

Repeal provisions can be specific, targeting one or several regulatory acts, or general. Section 20 of the [Graphic Health Warnings Law of the Philippines \(Act 10643\)](#) repeals not just a specific regulatory act or part thereof, but stipulates, in addition, in general terms: *“all other laws, decrees, executive orders and other administrative issuances and parts thereof which are inconsistent with the provisions of this Act are hereby modified, superseded or repealed accordingly.”*

The [Senegalese Law No. 2014-01](#) of January 6, 2014 relating to the treatment of dormant accounts in the books of financial institutions of the Member States of the West African Monetary Union (WAMU) also provides for repeal of “contrary previous provisions”, and this is even combined with an application date earlier than the adoption date:

“Art. 23. - La présente loi entre en vigueur le 1er janvier 2014.

Sont abrogées, à compter de cette date, toutes dispositions antérieures contraires.”

Amended machine translation:

“Art. 23 -. This Act comes into force on 1 January 2014.

All previous contrary provisions are repealed with effect from that date.”

It is sometimes useful to clarify that other regulation should remain unaltered; see as an example [Council Regulation EC/428/2009](#) setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items:

“Article 26 - This Regulation does not affect:

- the application of Article 296 of the Treaty establishing the European Community,

- the application of the Treaty establishing the European Atomic Energy Community.”

However, the most common place for such kind of clearance is rather at the beginning of the legislative measure. Section 21 of the same [Graphic Health Warnings Law of the Philippines \(Act 16043\)](#) clarifies that the international obligations prevail over the new legislation:

“Section. 21. Compliance with Existing International Conventions. – Nothing in this Act shall modify the measures adopted to give effect to the obligations of the Philippines under international conventions existing at the time of the enactment of this Act.”

Such a clarification is not necessary in jurisdictions where international law automatically prevails over domestic regulation.

An explicit statement that no other legal acts apply is contained in Section 3.(2) of the [Canadian Food and Drugs Act, Blood Regulations, P.C. 2013-1065 October 9, 2013](#):

“(2) Except for section A.01.045 of the Food and Drug Regulations, no other regulation made under the Act applies to blood that is the subject of these Regulations.”

We deal in this Section with simple statements on the applicability or non-applicability of other regulation. References to or integration of other regulation is dealt with in [Section 2.8](#). See also [Section 6.7](#) on issues relating to overlap in scope between different regulations.

13.4 Authenticity of acts

Many regulations foresee declarations or other acts of authorities, operators or citizens that trigger legal effects. If they do, the question arises as to how and whether the authenticity of these acts is to be proven. The acts can consist of:

- ◆ oral statements, to be made in front of an empowered official in a precise form and with appropriate minutes, and
- ◆ written statements.

For written statements, the first question that arises is that of the signature: is it to be authenticated by an official?

Can the signature be replaced by an electronic signature? If so, what are the requirements for authenticity? Regulation should establish these requirements. It should be noted that electronic signatures are under threat from hackers. Therefore, the range of valid signatures must be established in a dynamic way. Apparently, this issue is becoming a business of its own. Canada has even set up regulation establishing criteria for the regulator when determining requirements for electronic signatures, thus setting up a kind of horizontal meta-requirements. The [Canadian Department of Employment and Social Development Act - Electronic Documents and Electronic Information Regulations](#) provides:

“8. The standard of reliability required with respect to any electronic signature must be established taking into account the following factors, including

- (a) the purpose for which the electronic signature is required;*
- (b) a secure electronic signature, which has the same meaning as in subsection 31(1) of the Personal Information Protection and Electronic Documents Act; or*

(c) a signature that results from the application of any technology or process that is determined by the Minister or the Commission as able to provide the same level of security as a secure electronic signature.”

For written statements, the second question that arises is that of transmission. Transmission by classic letter, sent through the mail, is certainly the standard. But may transmission be made by e-mail or by fax? Or is it, on the contrary, necessary to request the letter to be sent as a “registered letter” or by bailiff?

All these questions can evidently arise both for acts of the authority and for acts of private persons.

13.5 Applicability of general administrative or civil law

The topic of authenticity brings us to the more general topic of applicability of general administrative or civil law in the respective sector, as a kind of underlying layer. Sector specific acts can hardly regulate in detail all issues like:

- ◆ validity of a declaration in case of error,
- ◆ validity of a declaration of a person which is not necessarily knowing what s/he does,
- ◆ prescription of rights and obligations,
- ◆ the rights and duties of one side where these depend on the fulfilment of an obligation of another entity (natural or legal person or authority)⁶⁸,
- ◆ impossibility to perform⁶⁹,
- ◆ representation, or
- ◆ means of proof,

to name but a few. Even where explicitly or implicitly generic provisions of the respective jurisdiction are applicable, it makes sense to check whether these

⁶⁸ For example, an obligation of an economic operator to register electronically cannot be fulfilled where the authority has not established the means to register. Moreover, it is sometimes unfair to maintain an obligation where “the other side” has not fulfilled its own. These so-called synallagmatic relationships exist not only in civil law, but also in public law.

⁶⁹ See the example of the previous footnote.

generic provisions are also appropriate in the respective sector or whether there is a need for adaptation, e.g. with regard to the minimum age as a condition for valid consent. Furthermore, where law is created at a higher level than the law of the underlying administrative or civil law, it has to be assessed whether the underlying administrative or civil law needs to be harmonised in the same process, in order to avoid discrepancies.

As inspiration for further investigation, we recommend this translation of a part of the good old French Civil Code: [The law of contract, the general regime of obligations, and proof of obligations, the new provisions of the Code civil created by Ordonnance n° 2016-131 of 10 February 2016](#). Whilst these provisions relate to the civil law, the issues are mostly transposable to administrative law as well.

13.6 Separability clause

Contracts often contain a clause stating that, if parts of the contract are invalid, the rest is deemed to remain valid. We found a similar clause applied to regulation in the [Graphic Health Warnings Law of the Philippines \(Act 16043\)](#):

“Section. 19. Separability Clause. – If any clause, provision, paragraph or part thereof shall be declared unconstitutional or invalid, such judgment shall not affect, invalidate or impair any other part hereof but such judgment shall be merely confined to the clause, provision, paragraph or part directly involved in the controversy in which such judgment has been rendered.”

13.7 Sunset clause

The sunset clause consists of fixing a date of cessation of applicability for a certain regulation. The sunset clause came out of fashion in some jurisdictions when it was discovered that problems do not necessarily disappear when a regulation ceases to be applicable. A full new legislative procedure became necessary in some of the cases for which no renewal was foreseen. The sunset clause was a measure to minimise bureaucratisation, however it became the cause of additional procedures. Nevertheless, the sunset clause still constitutes a good tool if there really is only a temporary measure to be taken.

The sunset clause can also be used for parts of legal acts. E.g., the [Canadian Motor Vehicle Safety Act - Regulations amending the Motor Vehicle Safety Regulations](#) contains section specific sunset clauses.

13.8 Review clause

Sometimes it is useful to foresee a review of the regulation at a certain point in time or even at regular intervals. An obligation to review a set up by the regulator can enter into conflict with the right of initiative of another institution, if, according to law of higher order, only the other institution is authorised to develop drafts. However, this is a rather exceptional situation.

Practically speaking, a review clause can be both useful and detrimental. It is useful if a review is necessary and would not take place without the review clause. It is detrimental if the institution in charge of initiating the review would at any rate act within a reasonable space of time. In that case, a stiff time-setting for review can hinder the institution in initiating the review at the most appropriate point in time. The most appropriate point in time may be subject to the maturity of preparatory investigations, experiences made, and developments of the respective sector or of neighbouring sectors or of the law of higher order.

The [Energy Efficiency Act of Canada](#) creates even a regulatory improvement automatism. Every three years the Minister shall demonstrate the extent to which the energy efficiency standards prescribed under this law are as stringent as comparable standards established by any Canadian province, the United Mexican States, the United States of America (USA) or any state of the USA.

14. WORKING METHODS AND ETHICS



*Achieve results,
Because this is the natural way.
Achieve results,
But not through violence.
Force is followed by loss of strength.*
Lao Tse

14.1 Elaboration methods

The old-fashioned approach of elaborating regulation can be described as follows: The ministry / administration works behind closed doors on a proposal or the draft measure and consults some stakeholders as much as this cannot be avoided.

- ◆ A more modern approach consists of:
- ◆ sharing the basic analysis and ideas,
- ◆ describing a range of possible measures,
- ◆ consulting the stakeholders extensively by surveys and in open debates,
- ◆ letting working groups draft various items, and
- ◆ coming up with a proposal or draft measure that does not catch anyone by surprise.

A third approach has not yet been practised yet, but is looming on the horizon: Letting administration staff and stakeholders work on the draft in an open

peer-to-peer process⁷⁰. Especially if the open issues to be regulated are extremely numerous or complex, the peer-to-peer process might lead to better results (more aspects covered, a wider range of solutions etc.). This is no surprise as well arranged collective intelligence tends to be superior to the intelligence of a few individuals. On the other hand, the administration would have to make sure that lobbying in the peer-to-peer process does not block the development of good options.

Contrary to what many think, the peer-to-peer method does not reduce the number of options and the “influence” of those formally responsible, but increases them. More people tend to develop more thoughts and more options amongst which the formally responsible service can choose. Peer-to-peer work lessens not the right to decide, but the right to ignore (alternatives).

Identifying the basic strengths of the more open working methods does not mean that the old-fashioned method cannot be the best in some cases. If the administration has good reason to take a certain political line opposing lobby interests, to work behind closed doors is sometimes the only way to defend the political line. Furthermore, it reduces the credibility of the administration’s participatory processes altogether to suggest that a certain question is debatable for the administration whereas, in reality, it is not. Therefore the open methods should only be used to the extent that the administration really is open and can afford to be.

The more open the working method, the more the result will be influenced by the strongest lobbies. Naturally, those on whom legal measures impose a burden will try to avoid them. They will try to influence both the initial legislative process and any implementation afterwards. They often have more resources than the administration and more stable personnel. Therefore it is important to introduce checks and balances, perhaps anticipating third-party review at regular intervals from the start or enforcing publication of results etc. in order to restore some balance.

14.1.1 - Advanced electronic tools for the elaboration process

Nowadays, everybody uses text editing software for the elaboration process. However, there are also software systems which are made for the development and

⁷⁰ More on the peer-to-peer processes to be found on www.p2pfoundation.net; see also the mostly American scientific debate on “E-Rulemaking”.

the management of legislations. See as introduction into this topic this [article](#).

14.2 Negotiating regulation

We have observed a wide range of attitudes taken by officials when negotiating. The most frequent attitude is to take a position and to defend it, be it alone or be it in an alliance with others. This is the easy game which often leads to a power struggle, not necessarily to the benefit of the common cause. Other officials try to understand the reasons behind a certain view of their interlocutor. They think more in terms of interests. Thinking in terms of interests instead of positions is paramount for finding a consensus. Only on the basis of a good understanding of the interests of all sides can a good or at least acceptable solution be found. Some officials even feel responsible for the negotiation process without being the chair. These officials often have methodological knowledge on process steering and negotiations. These officials are able to intervene when there is a deadlock in the elaboration or negotiation process. They can even prevent problematic situations upstream. They know when more collaborative work forms need to be applied, when a break-out session is necessary or when, on the contrary, more classic streamlining is required to get to a result. They are able to co-steer or even to steer the negotiation process, regardless of who is formally chairing the process.

Sooner or later officials are confronted with difficult situations in which no progress seems to be possible. In such situations, it is helpful to take a step back or to look at the situation from above. The following questions might help you to overcome the deadlock through new ideas. These questions might also be used to establish a controlling process during negotiations even when there is no deadlock:

- ◆ What is the issue to be regulated?
- ◆ Why is this issue to be regulated?
- ◆ What are my major goals?
- ◆ How shall my major goals be weighed against one another?
- ◆ Who is best placed to regulate the issue? Who is second best placed?
- ◆ What major regulation parameters are there?

- ◆ Which are the most appropriate incentives?
- ◆ What are the stakeholders' preferences with regard to these parameters?
- ◆ What are the stakeholders' negotiation positions?
- ◆ What are their interests behind the positions?
- ◆ By which solutions can these interests (not positions) best be accommodated?
- ◆ Which solutions have been found in parallel sectors of the same field or even in other regulatory fields?
- ◆ Which solutions could be imported from completely different contexts, e.g. from private business, engineering, or science?

Often the devil is in the detail, for instance in the detailed requirements. If there is a dispute on detailed requirements, it is useful to be familiar with a basic typology of requirements as laid down above ([Section 5.3](#)). Knowledge of this typology permits the development of new options that might be accepted as a compromise.

Sometimes negotiation deadlocks can be overcome by promising a review process after one to five years. However, such a review process binds important resources and creates uncertainty for stakeholders. In this respect, it is similar to dynamic conditions.

14.3 The ethical values as a means to find consensus

In courses on negotiation techniques, one learns that talking about interests is more fruitful than talking about positions. In negotiations about regulation, this approach can be complemented by discussing ethical values, especially if the negotiations are stuck. Explicitly expressed ethical values can help to understand the position of others. Ethical values can also become a basis for a good regulatory solution based on mutual understanding and fairness. In the extreme case, discussing ethical values can trigger new solutions, new requirements, and even new measures.

Ethical values can refer to the overall process of developing regulation or to the content of regulation. Ethical values may give new perspectives on the goals or objectives to be pursued, on the requirements to be set up, on the incentives

to be used, or on the administrative principles to be applied, e.g. with regard to enforcement.

14.4 Creative solution finding

We constantly miss occasions to find better solutions. We do so partly because we are not willing to invest in solution finding and partly because we think that things cannot become better anyway.

The range of possible solutions we find to legislative problems is limited by basic assumptions, be they explicit or implicit. To put aside a basic assumption can help us to find new solutions.

To identify and put aside basic assumptions is one way of finding creative solutions. There are many more ways to find creative solutions:

- ◆ Reflect on your issue while imagining that the opposite of a basic assumption was true. If you find a solution with the opposite basic assumption, think about how the opposite basic assumption could become real by measures that you can trigger.
- ◆ Put all the elements of your systems on cards and arrange them in a way that best describes your system. Play around with the cards to express a potential alternative system. You do not need to use all of the cards.
- ◆ Check what element of your system is not really needed. Arrange the cards without that element.
- ◆ Look at the ideal output of the system. Think backwards from the ideal result: what is really needed to get the ideal result? What is the shortest way to this result?
- ◆ Look at how things are done in other fields. What could you copy or adapt to your system?
- ◆ Look at processes in nature. What could you copy or adapt to your system?
- ◆ Talk to managers, scientists or other people with a completely different background. Note their questions and hints, and do not immediately judge them. Though they do not know your system, they might indicate which assumption is questionable or where you could learn from.

- ◆ Stretch: how is the issue to be defined on a larger scale and how would it be approached at that scale?
- ◆ Squeeze: divide into sub-problems. How else can you approach them?
- ◆ List the components, functionalities, mechanisms etc.: Are they needed? Can they be broken down further?
- ◆ How else could functionalities and mechanisms be ensured? What would be the most natural, fluid way of ensuring these functionalities?
- ◆ Try to put the components, functionalities and mechanisms to other use.
- ◆ Combine the components, functionalities and mechanisms.
- ◆ List attributes for components, functionalities and mechanisms: ask how you could change or improve them. Could you cut them into components and find solutions for the components?
- ◆ Whichever of the previously listed ways you use: separate the idea finding phase from the idea evaluation. Reserve a second day for the latter. On a different day, you will have a clearer view.

More hints and techniques are to be found in: Michael Michalko, [Thinkertoys](#), Ten Speed Press, Berkeley (California), 1st edition 1991.

Another possibility for solution finding consists of involving the stakeholders in a special, creativity fostering setting. Frequently, the joint creative work not only increases acceptance, but also increases the number of options and insights.

However, these methods are not a panacea. They do the job, but they are no guarantee for the ideal solution. Why? Those who operate in a system (the “experts”) are not necessarily those who can best analyse and repair it. They also are not necessarily those who have the most creative potential. Furthermore, the experts need to forget their preconceptions and expertise for the purpose of the idea finding exercise. Not all experts are able or ready to do so. To involve outsiders with a particularly strong analytical capacity for systems and who have a high creative potential is therefore equally important. A combination of the two is ideal.

14.5 Finding the optimal path

Once the goal has been identified, some time and energy should be invested in identifying the optimal path towards achieving the goal. The following simple statements might help you to find the best path:

- ◆ The shortest path is not necessarily the fastest.
- ◆ The fastest path is not necessarily the path which brings about the most sustainable result.
- ◆ Neither of these three is necessarily the safest.
- ◆ All four might require efforts that go beyond the available energy.
- ◆ The steering must be continuously adapted to follow the path chosen, whatever it may be.

Change management knowledge or methodology can help to find a viable path and way of implementation. Change management is dealing with questions of transitions to a goal which is deemed worthy. Regulators are often unaware of the need for conscious change management. Accordingly, many initiatives unnecessarily fail.

14.6 Managing regulatory work

The answer to the following questions might influence not only the way of dealing with regulatory issues, but also the decision on what is to be dealt with by regulations and by other means. Conscious reflection and a subsequent choice are especially needed if human resources are limited.

- ◆ For whom do we work? In whose interests do we work?
- ◆ For whom do we want to work? In whose interests do we want to work?
- ◆ How do we balance the different interests?
- ◆ What is really the core issue in the sector I have to deal with? How can I best tackle it? What are the other issues? How do all these issues interrelate?
- ◆ Do I know the ideal scenario to deal with these issues?
- ◆ If not, what is the best way to find out and trigger a process going in the right

direction? In which style do I want to steer the process, how narrowly shall it be steered? Do I have the necessary skills in-house? Who else could help me to steer the process?

- ◆ If yes, what would the ideal scenario be in five, ten or fifteen years? Which is the time horizon I am mainly interested in?
- ◆ What is the easiest way to reach the ideal scenario?
- ◆ What is the fastest, what is the safest way?
- ◆ Who might oppose it? Why and how?
- ◆ How can opponents be convinced?
- ◆ What other uncertainties are there?
- ◆ What type of steering is needed to get to the ideal scenario? Linear, cybernetic or multi-dimensional and complex steering? Do I have the necessary skills for this type of steering?
- ◆ What time frame is needed as a minimum? Does a more generous time frame lead to a better result? What are the consequences of a slower preparation for the addressees of the measure and for the jurisdiction? If more time leads to a better result, does the additional win in quality outweigh the slower entry into application of the measure?
- ◆ Where resources are limited: What can I achieve together with my colleagues in one year if we work jointly on new regulation? What can we achieve jointly if we work on regulatory measures other than regulation? Where can we achieve most utility? For what kind of measures will we receive how many staff? (System maintenance and implementation might be less rewarded in terms of staffing than a system renewal whilst not necessarily being less important.)

Sometimes, the answers to these questions depend on the time frame for which the answer is to be given. The answers may be different in a three-year perspective when compared to a five-year perspective.

14.7 Attitudes towards regulatory work

There is a wide variety of attitudes towards regulatory work to be observed.

Sometimes officials shift from one attitude to the other or combine two of them. Some examples:

- ◆ I develop regulatory measures only if it is advantageous for me or for my unit in terms of visibility;
- ◆ I develop regulatory measures if I am asked by my line-managers or if it is in the interest of my line-managers;
- ◆ I develop regulatory measures if powerful interest groups ask me to do so;
- ◆ I develop regulatory measures if I am completely sure that it is the right step or if it is less risky to take the measure than not to take it;
- ◆ I develop regulatory measures if it is the best way to solve the issues in the sector;
- ◆ I try to optimise the output I can reach with my staff in order to develop the legal system as well as possible in the years to come;
- ◆ I try to optimise the output I can reach with my staff in order to develop the legal system as well as possible in the years to come but also in the longer term.

In these attitudes, we can identify various goals:

- ◆ Improve reputation;
- ◆ Avoid nuisance from inside the institution - serving those who legitimately represent the institution;
- ◆ Avoid nuisance from outside the institution - serving clients;
- ◆ Risk avoidance;
- ◆ Optimisation of the result for one specific issue;
- ◆ Optimisation of the short term overall result for the system;
- ◆ Optimisation of the long term overall result for the system.

14.8 Ethical considerations in regulatory work

When undertaking regulatory work, it is of the utmost importance to identify the constituency for which one is working. Is it a local constituency, a regional, a nation-state constituency or even a multi-national constituency? Is the constituency the entire population or only a certain part of it? Is the constituency more precisely defined in terms of societal characteristics or economic functions? Once the constituency has been identified, one needs to further define to what extent the defence of the interests of the constituency should prevail over the interests of other people affected by the regulatory work. Defending the interests of citizens of a rich and powerful nation-state in terms of product safety will have effects on the economic chances of operators in poor parts of the world outside this nation-state and the people who depend on these operators for employment. International treaties may exceptionally contain limits to a strong unilateral imposition of rules on operators across the world, but mostly there are not such limits. At best some basic ethical principles in respect to this are contained in the national constitution. But even in these cases there is room for ethical considerations which can help to fill any loopholes. Ethical considerations should of course be based on an analysis of the impacts of a considered regulatory measure.

Another loophole contained in most legal systems relates to future generations, human beings not yet born. Research, economic and other activities today may have tremendous effects on future generations; see e.g. the multi-faceted issue of waste or today's research on synthetic biology which can threaten, according to a symposium of the University of Oxford in 2014, the entirety of humankind (whilst there are also undoubtedly benefits thereof). See generally the work of the [2014 oxford symposium](#) on the many threats to humanity's future. Very few legal systems provides for protection of future generations, although these human beings do not necessarily merit being protected less than those living today. Hence it is ethically worthwhile to think of the trans-generational effects of what takes place in society and the regulation thereof.

A further topic for ethics is animals. Roughly every week there is new research published on the similarities of processes that take place in certain animals and in human beings, be they related to intelligence or to feelings. There are animals which can express joy after meeting a childhood friend after 30 years, as there are animals which mourn or even bury their mates. Even altruistic behaviour is not limited to humankind. Hence it might well be that, with further research

completing the picture, future humankind will regard the lack of protection of the interests of animals as similar to the lack of protection of human beings held in slavery. We may remember that the shift of the majority view as to the ethical correctness of slavery took place only about a hundred years ago. As regulators, do we wish to be regarded, let us say in 50 years, in a similar way as the defenders of slavery in 1900 are regarded by us today?

We have added into the Chapter on Quality Verification ([Chapter 15](#)) a few ethical questions that can help to take account of these ethical aspects even if these ethical aspects are not (yet) laid down in the respective constitution.

14.9 Temporality of regulatory measures

Some laws survive across thousands of years. The principle “eye for eye, tooth for tooth”, presumably first laid down in the penal code of the ancient empire of Babylon and aimed at limiting vengeance, has been transmitted via the Bible and the Quran to numerous legal systems. It is still a basis of penal law in some jurisdictions today. However, this degree of endurance is rather an exception. Normally, regulation is appropriate in a certain societal context only. The Babylonian principle, though progressive at times of adoption, is now regarded as outdated by most of the jurisdictions which can afford to run prisons. As societies change, it is a question of time as to when a certain piece of regulation becomes inappropriate.

There are two consequences to be drawn from this statement:

- ◆ Regulators should provide for updating mechanisms.
- ◆ Regulators should cast regulation in such a way that it can easily be updated – e.g. by a modular approach. Another technique for ensuring endurance of regulation is to limit regulation to basic principles⁷¹. Some of these basic principles, namely those of civil law, can be traced back to Roman times.

⁷¹ The French Code Civil, initially also called Code Napoléon, could survive during two centuries in several European states because it is based on essential principles that are not very much subject to changing societal views.

Thus there are ways to prepare regulation for the future. However, even if we were to respect this advice, we still need to bear in mind that everything that is built falls down sooner or later⁷², and so do regulatory systems. Again we might think of Babylon and its famous tower, today only visible by satellite as mere lines on the ground.

⁷² “Time crumbles things; everything grows old under the power of Time and is forgotten through the lapse of Time.”
(Aristotle)

15. INTEGRAL QUALITY VERIFICATION



Laws are like sausages. It is better not to see them being made.
Unknown author, sometimes attributed to Otto von Bismarck

It is dangerous to be right in matters where established men are wrong.
Voltaire

15.1 The need for integral quality verification

Is it already time to think in terms of integral quality verification for regulatory measures? The idea might be regarded as sacrilege or at least provoke substantial resistance. However, its time has come for different reasons:

- ◆ More and more regulation worldwide requires the application of a full quality system from economic operators, which is much more than simple quality verification. It is a question of consistency and credibility to apply the same principles, to whatever extent possible, to one's own activity as well.
- ◆ Quality verification as a first step towards quality systems is nowadays used in most of the product- and service-providing industry and also in more and more processes of public authorities. The reasons for this trend are simple: quality verification leads to a better use of resources, less liability risks, a better reputation, and less risk of public criticism. Why should these reasons not also apply to regulatory measures?
- ◆ Feasibility is no longer a hindrance. The classic negative reaction "Quality verification is not possible for us!" has been observed in so many other fields but has been overcome in most of them. With the experience from other societal activities, it is possible today to describe the process of regulating, to

name the points that are relevant for the elaboration of regulatory measures and to list the items to be verified at the end of the process.

- ◆ The complexity of societal processes continues to increase tremendously. Regulatory measures, if well-conceived, respond to this complexity – and thus become ever more complex themselves! Due to this complexity, mistakes and unconscious omissions become unavoidable. Quality verification (and a systematic approach in the elaboration of regulatory measures as suggested by this Handbook) could become a means to reduce the likelihood of these mistakes and omissions.

Are impact assessments not doing the job of integral quality verification? Impact assessments can only be regarded as a subset of what is called quality verification here. Subject to the design of the impact assessments in the respective jurisdiction, impact assessments go more or less into detail. However, impact assessments cover less than one fourth of the topics dealt with in the Handbook. Mostly, impact assessment methods limit themselves to much less. Furthermore, impact assessments do not / cannot go far enough into details. It is, for example, usually not the task of impact assessments to verify whether transitional provisions respond to the sector's needs for a smooth transition from the old to the new legal regime or whether all necessary enforcement provisions have been integrated. Finally, impact assessments have to be limited to a few scenarios whilst developing regulation consists of selecting one of several solutions for several dozen parameters and arranging them in a harmonious way. Even if there were only 10 parameters, we would end-up with one million possible combinations. Calculating impacts for one million possible combinations is not feasible. Inversely, analysing impacts for a handful scenarios falls short of capturing what is open to debate and legitimising the many choices already implicitly made when developing the scenarios.

All this does of course not mean that impact assessments have no merit. Impact assessments can prompt certain verification, and often they do so for the most important questions. Historically the concept of impact assessment has the merit of being a very first big step towards quality verification of regulatory measures. But this does not mean that jurisdictions should stay at that level for ever. Evolution is going on, and maybe our views on how regulatory measures should be conceived and controlled should evolve as well.

In some jurisdictions, there are efforts to verify the quality of regulatory measures with regard to particular aspects, for example:

- ◆ administrative burden,
- ◆ citizen-friendliness,
- ◆ business-friendliness,
- ◆ rules of legal drafting, and
- ◆ leaving the utmost liberty to geographic entities / regulating only what is strictly necessary at the level of the Centre.

However, all these efforts do not cover more than a fringe of the aspects which need to be borne in mind by the officials selecting and preparing regulatory measures. Accordingly, even all of these efforts together do not reach more than partial quality verification. Integral quality verification would go much further.

15.2 Suggested elements for an integral quality verification

Quality verification needs to be adapted to the regulatory system under which it is applied. It is thus clear that the following list of questions is not an ideal fit for any jurisdiction because it is not adapted to it. However, readers might take it as a starting point for setting up their respective quality verification system or simply get inspired by the questions for the revision of the regulation they are responsible for. Finally, officials who wish to improve their regulatory practice might also find the list to be helpful. To suit the latter, the questions are presented in an order that mirrors as much as possible the structure of the Handbook. It goes without saying that the questions could be regrouped in many other ways⁷³.

⁷³ E.g. the questions could be attributed to the following categories: 1. Impacts, efficacy and own policy; 2. Relationship with / consistency with other acts and policies; 3. Internal consistency; 4. Conformity control and enforcement; 5. Other implementation questions; 6. Regulatory policies and drafting rules; 7. Process

15.2.1 – Questions regarding all regulatory measures15.2.1.1 – Process (Sections [5.5](#) and [14.1](#))

Has the regulatory measure been subject to a mandatory public consultation?

Has the mandatory public consultation provided enough results to identify the needs and the characteristics of the sector?

If not, have the necessary further consultations been initiated?

Have all the mentioned consultations been appropriately considered?

Did the stakeholders have enough opportunities to comment and to provide input, including input on the draft measure?

Did the geographic entities have enough occasions to comment and to provide input, including input on the draft measure?

Did the international partners (other jurisdictions and international organisations) have enough occasions to comment and to provide input, including input on the draft measure?

Did other ministries / departments or advisory institutions (e.g. Court of Auditors, Ombudsmen) provide for sufficient input?

*Has the regulation of other sectors been studied for comparison and inspiration?
Has experience from other sectors been appropriately used?*

*Has regulation of other jurisdictions been studied for comparison and inspiration?
Has experience from other jurisdictions been appropriately used?*

If there were different elaboration tracks: have all results of the different elaboration tracks been appropriately integrated? See ([Subsection 5.5.1](#))

15.2.1.2 – Overall substance ([Sections 5.1 to 5.4](#))

Have the real needs of the sector been identified?

Do(es) the regulatory measure(s) selected fully respond to the identified sector needs?

Should the selected measure(s) be complemented by other measures to cover the sector's needs? Check against [Section 5.3](#). Check also against information and enforcement needs in [Chapters 10](#) and [11](#).

Do(es) the selected measure(s) bring the sector closer and close enough to its ideal state?

Do(es) the selected measure(s) tackle the issues which had been identified by the sector analysis?

Do(es) the selected measure(s) fit with future developments? Check against [5.1.1.1](#).

Will the top five problems of the sector be solved by the measure(s)?

Could some of the non-top-five-problems be elegantly solved in addition?

Will the top three development potentials for the sector be used?

Will the selected measure(s) ensure that the predetermined or set policy goals are reached?

Will the measure(s) ensure that the set objectives are reached?

Have all appropriate requirements been set? Check against the typology in [Chapter 3](#) and against the requirements of similar sectors and of other jurisdictions.

Have all appropriate incentives been used? Check against the typology in [Section 4.1](#).

Is it necessary to ensure that the regulatory measure(s) become(s) known? Have all appropriate information tools been used or foreseen?

Given the state of the sector, is it realistic that the citizens, operators and geographic entities can reasonably use or transpose the selected measure(s)?

Do(es) the selected measure(s) lead to an optimised use of available resources at the level of the Centre and in geographic entities? Do we reach the best we can with the available resources?

15.2.1.3 – Ethics (Sections [14.9](#) and [8.17](#))

Are/is the measure(s) positive / optimised for the constituency?

Do(es) the measures strike a fair balance between the interests of those persons (within the constituency) who take profit from it and the interests of those who bear the direct or indirect costs or negative effects?

Are/is the measure(s) ethically acceptable with a view of persons not belonging to the constituency?

Do(es) the measure(s) strike a fair balance between the positive effects for the constituency and the effects on persons not belonging to the constituency?

Are/is the measure(s) ethically acceptable with a view to future generations?

Are/is the measure(s) ethically acceptable with a view to animals?

15.2.1.4 – Formal aspects and consistency (only some elements covered in Chapters [2](#) and [9](#))

Does the regulatory measure follow the applicable editing policy?

Is the regulatory measure correctly structured?

Are the sections and subsections correctly numbered?

Are the references correct?

Is the terminology of the regulatory measure coherent with the terminology of other regulatory measures and above all with the terminology of the empowering regulation?

Is the terminology consistently applied in the regulatory measure, including its annexes?

Does the terminology correspond to the common language in the sector?

Is the terminology and the syntax understandable for the targeted citizens or operators?

Is the regulatory measure altogether understandable for the targeted citizens or operators?

Do have citizens and operators a fair chance to fulfil the requirements set by the regulatory measure?

Is the regulatory measure fair in terms of predictability (= not too surprising)?

Is the regulatory measure fair in terms of equality?

Is the average depth / the average level of detail appropriate?

Are there important deviations from the average depth / the average level of detail? If so, are they justified?

Are the Recitals / the rationale detailed enough?

Are the Recitals / the rationale in line with the content?

Does the regulatory measure follow the applicable regulatory policies (e.g. on “Better regulation”, “Smart regulation”, “Business friendliness”)?

15.2.2 – Questions regarding regulation only

15.2.2.1 – Basic legal choices for regulation (Chapters [2](#), [6](#), [7](#) and [9](#))

Does the regulation cover all that it needs to cover? Check against regulation of other sectors, of other jurisdictions, against the typology of scopes presented in [Chapter 6](#) and the particular checklists for products and for services at the end of this Section ([15.2.4](#) and [15.2.5](#)).

Are the subject matter or purpose and the scope of the future regulation rightly defined (i.e. pretending to cover something which is not covered in reality and vice versa)?

Are the subject matter or purpose and the scope of the future regulation consistent with one another and with the content of the regulation?

Has the right legal basis been chosen? Meaning: Does the legal basis cover the type of regulation to be adopted? Do the goals of the regulation fit with the legal basis? Does the content of the regulation fit with the legal basis?

How does the future regulation fit into the overall regulatory architecture? See the basic models of architecture in [Section 2.2](#).

Are overlaps with other regulation reasonably dealt with?

Is other regulation meaningfully referred to?

Has the right legal instrument (amongst those authorised by the legal basis) been chosen?

Mainly for international regulation: has the most appropriate harmonisation approach been chosen?

Does the regulation have the right degree of density?

Is the regulatory measure consistent with other, similar measures of the same level? If not, are the deviations justified?

Is the regulatory measure consistent with regulatory measures of a higher order (e.g. the Constitution)?

Is the regulatory measure compatible with international law?

Is the content of the articles rightly placed in the articles?

Is the content of the annexes rightly placed in the annexes? See [Sections 2.5 to 2.7](#).

Has the right balance been struck between the various conflicting legislative and constitutional goals?

Have the limits for the empowerment of agencies and subordinate bodies been respected?

Does the regulatory measure include all necessary references? See the typology provided in [Section 9.1](#).

Was it right to refer / not refer to standards?

Should certain standards be referred to in addition?

Was it right to refer / not to refer to non-legal documents other than standards?

Should certain other non-legal documents be referred to in addition?

Has a conscious choice been made between the use of static or dynamic references and have the consequences of this choice been taken into account? [See Subsection 9.1.2.](#)

15.2.2.2 – Risks and performance in requirements and measures ([Chapter 8](#))

Have the different types of risks been identified and covered by the measure? Check against Sections [8.1](#) and [8.18](#).

Was it right to establish fixed, stable risk limits or would a risk-benefit analysis be more appropriate?

Have basic risk management principles been imposed on operators?

Have different types of risks been appropriately valued against one another?

Have multi-dimensional impacts (including impacts going beyond the sector regulated) been appropriately evaluated?

Have trade-offs between different quantifiable requirements been consciously and, to the extent possible, rationally weighed and addressed? See the example outlined in [Section 8.9](#).

Was it right to apply / not to apply the precautionary principle?

Was it right to apply / not to apply a safety margin?

Has the proportionality principle (if applicable) been respected?

Has adaptation to technical progress been ensured?

Was it the right to establish static / dynamic risk and performance requirements?

Was it right to establish quantitative / qualitative risk and performance requirements?

Have high risk products and processes been appropriately covered?

Is a fair balance struck between the interests of those who bear the risks and the interests of those who cause them?

Has the right reference time or stage been fixed for assessing whether the requirements are fulfilled?

15.2.2.3 – Conformity verification and enforcement (Chapters [10](#) and [11](#) and [Section 12.4 to 12.8](#))

Have operators and citizens been informed of their obligations?

Is the regulation precise enough to be enforced?

Is the regulation precise as to the verification and enforcement obligations contained therein?

Is the regulation precise as to the what shall be the subject of verification (i.e. the end product or the production process)?

Has the right balance between ex ante and ex post verification been found? Check against the considerations presented in [Section 10.4](#).

Has the right balance between the involvement of state authorities and private conformity assessment bodies in ex ante verification been found?

Should accredited reference laboratories be used?

Have potential third parties to be involved in ex ante verifications been identified (e.g. insurers)?

*Does the relevant ex ante verification procedure (see typology in [Subsection 10.6.1](#)):
take into account the parameters listed in [10.6.2](#) and [10.6.4.2](#)?*

include rules on renewal or transfer of authorisations / certificates?

include rules on the recognition of foreign authorisations / certificates ?

clearly specify the potential result of the procedure?

specify the conditions that can be imposed on authorisations / certificates?

take account of potential synergy with other sectors' verification and supervision?

Do the rules on ex post verification:

specify the content and density of enforcement activities to an appropriate extent?

take into account the parameters presented in [Section 11.3](#)?

provide for the potential mandatory or voluntarily involvement of third parties? See option outlined in [Section 11.4](#).

Does the regulation provide the authorities or entrusted private bodies with the necessary enforcement powers? See more specifically the checklist provided in [Section 15.4](#) below.

Have the necessary means been provided for to ensure the harmonised work of conformity assessment bodies?

Does the regulation foresee minimum resource equipment for enforcement authorities, be they at the Centre or in the geographic entities?

Are the resources necessary for enforcement available in reality in the Centre and in the geographic entities?

If not, can they be built up over time? Is there something that can be laid down in the regulation to build them up?

Is there a need to build a new agency or shall an existing agency be entrusted with new tasks?

If yes, is the necessary budget available?

Do the entrusted private bodies possess enough staff, equipment and money to efficiently execute their verification and supervision function?

If not, does the regulation foresee minimum resource equipment for such entrusted bodies?

Does the regulation contain all the necessary provisions to ensure good cooperation between authorities and different levels of the relevant jurisdiction? See also [15.4.15](#).

Should the Centre take over the role of enforcement supervisor?

Is the verification and supervision of compliance of geographic entities (with regard to verification and enforcement tasks) intense enough?

Have possibilities for “enhanced enforcement” been used or, for good reason, disregarded? Check against the basic programme presented in [Section 11.6](#) (or the more detailed description of potential empowerments in [Section 11.5](#)) and more specifically the checklist provided in [Section 15.4](#) below.

Should there be reimbursement of verification costs?

Has own-brand-labelling been limited to acceptable practices?

Have the possibilities of rogue operators been reduced?

Have rights for indemnities, administrative sanctions (including confiscation) and penal provisions been introduced or, for good reason, disregarded?

Are indemnities, administrative and penal sanctions high enough to deter?

Has the responsibility of associated companies been dealt with?

Have the special verification and enforcement needs of e-commerce and private imports been dealt with?

Have the special verification and enforcement needs of deconstructed products been dealt with?

Have the special verification and enforcement needs of services and products originating from zones without state control been dealt with?

Is there a need to attribute responsibilities to courts or administrations? Has this need been covered?

15.2.2.4 – Other implementation questions ([Chapter 12](#))

Are the consequences of non-conformities or negative test results clearly spelled out?

Is the regulation clear as to burden, means and degree of proof?

Is there a need to provide authorities with the right to issue provisional orders to avoid imminent danger?

Does the regulation provide enough, but not too much discretionary power?

Is the use of vague legal expressions justified / not excessive?

Are interpretation guidelines within the regulation or an empowerment for the adoption of interpretation guidelines needed?

Are more definitions needed to avoid interpretative questions?

Are the existing definitions precise?

Are the requirements clear as to the legal persons to whom they apply? What about branches, subsidiaries (daughter companies), mother companies, joint-ventures?

Are special rules needed for branches, subsidiaries (daughter companies), mother companies, joint-ventures?

Have the necessary means been provided for to ensure that the authorities decide in time?

Have the necessary means been provided for to ensure that the authorities are strengthened?

Have the necessary means been provided for to prevent corruption or other unlawful operations of authorities?

Does the regulation contain the provisions necessary to allow for effective international cooperation?

Have means for dispute resolution been provided for?

Should certain decisions be taken by committees? If yes, have the necessary committees been set up in the regulation or do they exist already? Do the committees have the appropriate means and internal rules?

Should certain situations of minor importance be exempted from certain requirements or even from the scope by a “de minimis clause”?

Should the possibility of regularisation be offered?

Should, for certain items, one authority of the geographic entities coordinate the work of their peers in other geographic entities?

Does the regulation contain all the necessary provisions to empower international data-exchange and cooperation?

Does the regulation contain all the necessary provisions to ensure confidentiality?

Does the regulation contain all the necessary provisions to ensure that verification can take place on the territory of other jurisdictions?

Is it clearly stipulated which regulatory measures geographic entities may take in the regulated sector, e.g. to further implement the regulation?

Does the regulation contain the necessary provisions to set up the data processing tools needed for its implementation?

Is the regulation easy to implement or at least implementable in terms of data processing?

Does the regulation contain all necessary collateral obligations? Check against the list in [Section 12.19](#).

15.2.2.5 – Miscellaneous ([Chapter 13](#))

Are the transitional provisions sufficient? Check against the questions in [Section 13.1](#).

Are the provisions on the validity of decisions, legal acts and certificates based on the so-far applicable law sufficient?

Does the regulation contain the necessary provisions of the following types:

Repeal provisions;

Provisions stipulating that other regulations remain unaltered;

Provisions stipulating that other regulations prevail;

Provisions stipulating that the new regulation prevails over other regulations; and

Provisions stipulating that no other regulations apply?

Does the regulation contain what is necessary to determine which acts are authentic?

Would it be useful to insert a “separability clause” in case of partial invalidity of the regulation?

Would it be useful to insert a sunset clause (limiting the applicability of the regulation in time)?

Has a review clause or another updating mechanism been foreseen or, for good reasons, disregarded?

Is the regulation easy to update, e.g. by its modular construction?

15.2.3 – Questions regarding regulatory acts only

Can all the content be regulated by a regulatory act (regulation adopted by the administration) or does it fall under the prerogatives of the legislator?

Is the scope within the boundaries of the empowering legislation?

Are the goals pursued covered by the empowerment contained in the legislation and/or by the legal basis of the first-level empowerment (e.g. in the Constitution)?

Are the definitions in line with the definitions used in the empowering act?

Are the obligations in line with the obligations contained in the empowering act?

Are the obligations covered by the empowerment?

15.2.4 – Particular checklist for regulation on products (also partly applicable to materials)

Check whether you also need to regulate with regard to the following elements:

- ◆ *Product components, replacement parts;*
- ◆ *Services used in the production process;*

- ◆ *Services with regard to products once they are placed on the market⁷⁴;*
- ◆ *Services with the products (offered to final users, consumers etc.);*
- ◆ *Long-distance sales (e.g. via Internet), with special focus on salespersons outside the jurisdiction;*
- ◆ *Advertisement;*
- ◆ *Distribution modalities;*
- ◆ *Parallel trade;*
- ◆ *Reprocessing;*
- ◆ *Manufacturing as an activity;*
- ◆ *Professional activities linked to the products and their distribution;*
- ◆ *Fees for conformity assessment activities;*
- ◆ *Fees for enforcement / market surveillance activities;*
- ◆ *Fees for the application of conformity assessment bodies as conformity assessment bodies.*

Check whether all of the following risks, if relevant, have been covered:

- ◆ *Mechanical risks (e.g. failing of brakes, failing of steering, squeezing mechanisms, cutting mechanisms),*
- ◆ *Software failure risks,*
- ◆ *Risks of software manipulation,*
- ◆ *Risks of electric failure,*
- ◆ *Risks linked to electricity,*
- ◆ *Risks of incompatibility of devices, connectors, chemical substances etc.*

⁷⁴ In some product legislation sectors, manufacturers try to make profit via expensive authorised repair services, blocking competition by cheaper “free” repair service providers. [Regulation 168/2013/EU](#) of 15 January 2013 on the approval and market surveillance of two- or three-wheel vehicles and quadricycles counters this tendency by its Articles 55 to 60. These provisions guarantee access to information and technical documentation for all repair service providers.

- ◆ *Risks linked to electro-magnetic radiation (risk of interference with devices, risks for ultra-sensitive persons),*
- ◆ *Risk of radioactivity,*
- ◆ *Risk of other tissue destructing radiation (e.g. by protons or other parts of atoms),*
- ◆ *Risk of optical disturbance by beams and other light(s),*
- ◆ *Risk of too high or too low temperature,*
- ◆ *Risk of fire,*
- ◆ *Risk of spreading disease by use of human, animal or synthetic tissues,*
- ◆ *Risk of uncontrolled proliferation of living tissues or beings,*
- ◆ *Risks of bio-compatibility of chemicals,*
- ◆ *Risk of too high pressure (e.g. in case of explosion),*
- ◆ *Risk of not performing sufficiently / as intended (e.g. medicine),*
- ◆ *Risk of misunderstanding instructions for use,*
- ◆ *Risk of unintended inappropriate use,*
- ◆ *Risk of intended inappropriate use (“off-label use”).*

Check whether the right risk management principles have been applied to each of these risks.

Check whether you need specifically regulate on steps before the final product leaving the manufacturer, e.g. with regard to:

- ◆ *Risks of research (e.g. the research on synthetic biology might already constitute a risk),*
- ◆ *Development of intermediate products (like synthetic biology tissues intended to be used for various types of final products falling under different legislation),*
- ◆ *Making available of intermediate products (like synthetic biology tissues that could be used for various types of final products falling under different legislation),*

- ◆ *Development of final products (thus not the risk of the final product itself, but the risks of developing final products).*

15.2.5 – Particular checklist for regulation on services (also partly applicable to materials)

Check whether you also need to regulate with regard to the following elements:

- ◆ *Intermediate services;*
- ◆ *Services used to provide the services;*
- ◆ *Products used to provide the services;*
- ◆ *Remedying deficient services;*
- ◆ *Long-distance services (e.g. via Internet), with special focus on service providers outside the jurisdiction;*
- ◆ *Advertisement;*
- ◆ *Distribution modalities;*
- ◆ *Professional activities linked to the services or linked to the distribution;*
- ◆ *Service providing as a professional activity;*
- ◆ *Fees for conformity assessment activities;*
- ◆ *Fees for enforcement activities;*
- ◆ *Fees for the application of conformity assessment bodies as conformity assessment bodies.*

Final note: *If, during the revision process, substantial amendments have been introduced, it is recommended to apply the checklist a second time in view of these amendments. E.g. the amendments might go beyond the legal empowerment.*

15.3 A further possible element of quality verification: the analysis of affected interests

Once the regulatory measures have been developed, it might be suitable to analyse how the various elements or parts thereof or even particular requirements affect the interests of the targeted population. Such an analysis can be part of an official “impact assessment” or be undertaken separately. The analysis should establish, for each of the elements or parts:

- ◆ which interests are affected,
- ◆ to what extent the various interests are affected,
- ◆ to what extent the affected interests are legitimate and merit being protected,
- ◆ whether the improvements reached by the measure(s) justify going against the legitimate interests, and
- ◆ what can be done to accommodate legitimate interests without disproportionately endangering the improvements.

The analysis might lead to the conclusion that some legitimate interests should be re-formulated as an additional regulatory goal or objective. Such conclusions might invite the officials to re-visit their measures, requirements and incentives in a second step. Once again, we see that a looping-back from quality verification to initial basic steps of planning can increase the overall quality of the regulatory measures.

15.4 A final quality check perspective: completeness of empowerments

Hardly anything is more annoying for the engaged official than being confronted with a situation where s/he should act but is not empowered to act, whilst the next revision of the regulation is too far away. At the same time, it is the empowerments perspective that can easily detect many operational deficiencies of draft regulation in one strike. Thus we recommend an empowerments check-up in particular to all those regulators who have no time to verify more.⁷⁵ The following list

⁷⁵ Therefore, we reprint here extracts of a dedicated article on empowerments: [”Empowerments \(Part II\): The empowerment checklist”](#) which was preceded by [“Empowerments \(Part I\): typology”](#). For a complete understanding of the issue, we recommend reading the full two articles.

of empowerments should be used to verify whether all necessary empowerments have been integrated into the draft regulation under development:

15.4.1 – Determining non-financial rights

Empowerments might be needed for:

- ◆ Authorising undertakings/activities;
- ◆ Subjecting authorisations to conditions (from the beginning or even later);
- ◆ Renewing an authorisation;
- ◆ Suspending authorisations;
- ◆ Withdrawing authorisations (with effect from the time when the conditions were not met anymore);
- ◆ Repealing/revoking authorisations (in case conditions were not met from the beginning and thus with effect from the beginning); and
- ◆ Stating that a certain right exists by virtue of the law.

15.4.2 – Determining non-financial obligations of natural and legal persons

This section can hardly be illustrated by concrete empowerments without taking the specific context of the respective sector into account. [Chapter 3](#) describes the building blocks of requirements as well as a range of different requirements and thus, indirectly, obligations and might serve as an illustration of what needs to be considered. However, two types of obligations and corresponding empowerments are often forgotten and thus merit being mentioned explicitly from the beginning:

- ◆ Imposing injunctions, e.g. aiming at non-interference, toleration of action of the state or third parties; and
- ◆ Imposing interim obligations (obligations pending a final decision).

15.4.3 – Determining financial rights and obligations of natural and legal persons

Empowerments might be needed for:

- ◆ Providing subsidies;
- ◆ Subjecting grants to conditions (from the beginning or at a later point in time);
- ◆ Renewing grants;
- ◆ Withdrawing grants (with effect from the time when the conditions were not met anymore);
- ◆ Repealing/revoking grants (in case conditions were not met from the beginning and thus with effect from the beginning);
- ◆ Making financial contributions other than grants (e.g. joint investment);
- ◆ Stating that a certain right exists by virtue of the law;
- ◆ Obliging to compensate damages;
- ◆ Compensating damages;
- ◆ Recovering compensation or other payments given to some persons from others;
- ◆ Recovering payments (which were not due from the beginning or which had to be returned for reasons arising later); and
- ◆ Recovering costs for state action, e.g. for investigations triggered by infringements.

15.4.4 – Imposing costs on natural or legal persons

Empowerments might be needed for:

- ◆ Imposing enforcement costs;
- ◆ Taking fees for state action (e.g. for authorisation procedures);
- ◆ Requesting securities (as guarantee for the fulfilment of financial obligations); and

- ◆ For all financial obligations and financial sanctions or penalties: levying extra fees and interests for delayed payment.

15.4.5 – Sanctions and penalties

Empowerments might be needed for:

- ◆ Penalties for natural persons;
- ◆ Financial sanctions for legal persons: direct sanctions and indirect sanctions like banning from receiving subsidies;
- ◆ Exclusions from public tenders;
- ◆ Imposing a ban from participating in certain activities other than tenders;
- ◆ Imposing a ban from receiving grants;
- ◆ Public naming and shaming;
- ◆ Withdrawing titles and rewards;
- ◆ Withdrawing membership;
- ◆ Extending sanctions to mother or sister companies and their agents, at least in cases where a company has been set-up as a shield for illegal activities⁷⁶;
- ◆ Extending sanctions to partner companies and their agents where they contributed to illegal activities;
- ◆ Confiscating illegal objects or property used in or in connection with the illegal activity or obtained in return or in connection with the illegal activity (“tainted property” according to the terminology used in the [Ugandan Anti Money Laundering Act 2013](#), see for details the Sections 61 onwards thereof);
- ◆ Restraining orders against objects (see Sections 71 onwards of the [Ugandan Anti Money Laundering Act 2013](#)); and
- ◆ Restraining orders against persons (obligation to stay in a certain perimeter).

⁷⁶ See [Subsection 11.5.3.10](#).

15.4.6 – Additional empowerments for all financial obligations and financial sanctions or penalties

One might need an empowerment to enforce financial obligation or sanction through confiscation of objects, rights or money or via lawsuits or generic state enforcement procedures. This should in particular include “tainted property”, meaning property used in or in connection with the illegal activity or obtained in return or in connection with the illegal activity; see Sections 61 onwards of the [Ugandan Anti Money Laundering Act 2013](#).

15.4.7 – Enforcement with the help of non-designated third parties

Empowerments might be needed for:

- ◆ Establishing complaints, alert or whistle-blowing portals or specific communication channels;
- ◆ Communication campaigns aimed at introducing or giving information about the whistle-blowing portals or communication channels; and
- ◆ Communicating with third parties to obtain further evidence and details.

15.4.8 – Enforcement via regional authorities, geographic entities or designated third parties

We distinguish here between regional authorities and geographic entities, because regional authorities can also be those that belong formally to the federal state though being just responsible for a region.

Empowerments might be needed for:

- ◆ Establishing minimum resource requirements or a list of parameters for determining how many full-time equivalents (FTE) are needed for enforcement

at the level of geographic entities or designated third parties⁷⁷.

- ◆ Benchmark designated third parties, regional authorities or geographic entities, applying the naming and shaming principle;
- ◆ Creating the legal possibility of steering grants away from authorities not willing to enhance enforcement to those which are strongly engaged;
- ◆ Creating incentives for highly performing third parties, regional authorities or geographic entities⁷⁸;
- ◆ Obliging to undertake certain enforcement activities (in some jurisdictions: to be specified);
- ◆ Obliging to inform about enforcement activities;
- ◆ Obliging to inform about certain critical events, incidents, problems, obstacles;
- ◆ Obliging to ensure qualification of staff by minimum recruitment requirements and training requirements;
- ◆ Obliging to participate in certain training or information or coordination events;
- ◆ Obliging to undergo accreditation (by independent accreditation bodies, see [IAF](#));
- ◆ Obliging to participate to peer-review;
- ◆ Delegating investigation tasks (by means of public or private law);
- ◆ Therein in particular: Delegating the collection and investigation of complaints;
- ◆ Delegating enforcement tasks (by means of public or private law);

⁷⁷ Parameters could include population, number of operators to be verified, or number of administrative districts. Quantified minimum resources could be, for example: 10 FTE per region and 1 FTE per million population at the central level for the overall management of enforcement (with no other tasks of course). 2 FTE per district and 1 per 100,000 inhabitants in each district.

⁷⁸ We heard that Bulgarian customs authorities obtain, when being particularly successful, financial rewards that they can use to improve their office facilities.

- ◆ Giving regional authorities or geographic entities the right to delegate investigation or enforcement tasks; and
- ◆ Designating the lead regional authority, geographic entity or lead third party in cases where different regional authorities, geographic entities or third parties are involved and coordination is necessary.

15.4.9 – Designation and supervision of public or private organisations entrusted to play a special role in the application of regulation

Empowerments might be needed for:

- ◆ Preselecting potential cooperating organisations in cases of high number of potential candidates;
- ◆ Establishing selection criteria;
- ◆ Selecting members of panels attributing subsidies, functions or other advantages;
- ◆ Taking discretionary decisions regarding the attribution of subsidies, functions or other advantages (which can exclude full legal control); and
- ◆ Taking into account previous assessments of the candidate organisation (by the same authority, by others, by foreign jurisdictions or by third bodies like accreditation bodies).

15.4.10 – Investigations and data

Empowerments might be needed for:

- ◆ Conducting, or cooperating with persons conducting research, development, tests, demonstrations and studies and publishing this research or test results;
- ◆ Imposing obligations to cooperate, without remuneration, with the authority and in particular to permit samples to be taken or provide samples on request, provide information, and to grant access to documentation and premises;

- ◆ Arrest (and financial sanctions) in case these obligations are not fulfilled;
- ◆ Visiting and inspecting offices, factories, warehouses, wholesaling establishments, retailing establishments, laboratories, research institutions and other premises in which products are produced or kept, or where services provided);
- ◆ Entering and inspecting any vehicle used to transport or hold products or to provide services;
- ◆ Investigate alleged violations of laws and regulations
- ◆ Taking samples of the products covered by the regulation in question;
- ◆ Ordering anonymously or via proxy products or services in view of assessing their conformity;
- ◆ Seizing and taking possession of all articles which are in non-conformity, be they placed with the person responsible for the infringement or other persons;
- ◆ Seizing and taking possession of all documents, data and objects which might serve as means of proof for stating the non-conformity;
- ◆ Compelling the attendance of witnesses and the production by third parties of evidence via a subpoena, when there are reasons to believe or first evidence for assuming that any infringement there is;
- ◆ Compelling the production or delivery of data or documents of any kind, including on property or other rights related to objects and rights, issuing document search warrants and further empowerments needed to search and confiscate documents (see the excellent Sections 44 and onwards of the [Ugandan Anti Money Laundering Act 2013](#));
- ◆ An empowerment to request data from internet or telecommunication service providers;
- ◆ Supervising the internet communication or telecommunication (meta-data or even content) in a personalised or generic way;
- ◆ Acquiring data and documents from third parties, including against payment or providing advantages;
- ◆ Processing data;

- ◆ Exchanging data with other authorities, courts, natural or legal persons or other jurisdictions and adopting agreements in this regard⁷⁹; and
- ◆ Personal supervision of persons / monitoring orders (see as example Sections 56 onwards of the [Ugandan Anti Money Laundering Act 2013](#)).

15.4.11 – Enforcement in general

Empowerments might be needed for:

- ◆ Requesting from internet or telecommunication service provider blocking of certain content;
- ◆ Blocking certain internet content by own means;
- ◆ Issuing notices of non-compliance and set an appropriate deadline for rectification of the situation;
- ◆ Confiscating and destroying illegal products or means to produce them or means to provide illegal services;
- ◆ Forbidding the use of premises or establishments;
- ◆ Closing plants and other premises;
- ◆ Retaining shipments (in particular for customs authorities);
- ◆ Requesting securities (as guarantee for the fulfilment of non-financial obligations);
- ◆ Publishing evaluations on own compliance statistics, compliance reporting by regional authorities and third parties (naming and shaming);
- ◆ Publishing individual infringements;
- ◆ Obligating regional or local authorities to publish stated infringements of operators (“naming and shaming”);
- ◆ Creating a label for those operators who, over a longer period, have not been reported to infringe the law;

⁷⁹ For these aspects, please have a look at Sections 37 and onwards and 46 and onwards of the [Ugandan Anti Money Laundering Act 2013](#).

- ◆ Creating a label for those operators who undergo a voluntary compliance verification program managed by the chambers of commerce or similar semi-public organisations or by conformity assessment bodies engaged by them (entrusted certification).
- ◆ Obliging economic operators to display information on the conformity assessment of regulated products or services, e.g. by web link;
- ◆ Obliging operators to disclose (better online, but at least to the authorities) the major components and substances/materials used;
- ◆ Obliging operators to disclose (better online, but at least to the authorities) the supply chain for major components or service providers and for substances/materials used, ensuring traceability;
- ◆ Obliging operators to inform their clients of their rights in case of illicit practice; and
- ◆ Imposing immediate, temporary obligations by provisional order (e.g. for reasons of imminent danger).

15.4.12 – Information

Empowerments might be needed for:

- ◆ Information dissemination to media, with or without data concerning natural or legal persons;
- ◆ Information campaigns for the general public or specific target groups;
- ◆ Blocking illegal information or information which endorses illegal activities;
- ◆ Informing the clients of non-compliant operators of their rights; and
- ◆ Informing the clients of non-compliant operators of the legal requirements applicable for the product in question, inviting them to verify compliance and to report.

15.4.13 – Cooperation, including exchange of data with other jurisdictions

It is recommended to assess which of the national empowerments one can make available to other jurisdictions in return for assistance from these other jurisdictions. Furthermore, empowerments might be needed to make the other jurisdiction work on one's own behalf or to operate on the ground of another jurisdiction with the agreement of the latter (e.g. common practice of food inspection authorities with regard to foreign slaughter houses).

Whilst the following list is not complete, we recommend verifying in particular the need for the following empowerments:

- ◆ Permitting foreign officers to take part in state operations;
- ◆ Disclosing confidential information to authorities of other jurisdictions;
- ◆ Establishing joint expert committees and data exchange needed for that purpose;
- ◆ Investigating or enforcing on the territory of the other jurisdiction;
- ◆ Empowering foreign authorities to investigate cases on one's own behalf on the territory of the other jurisdiction;
- ◆ Requesting foreign authorities to enforce on one's own behalf on the territory of the other jurisdiction;
- ◆ Enforcing on request of the foreign authority;
- ◆ Empowering foreign authorities to investigate cases on their own behalf on one's own territory;
- ◆ Requesting foreign authorities to enforce on their own behalf on one's own territory;
- ◆ Recognising foreign certificates or approvals;
- ◆ Extension of domestic investigational empowerments to cases committed outside the applicability of domestic law, but subject to the law of another jurisdiction where there is mutual assistance between the two jurisdictions (based on formal agreements or practical arrangements).

- ◆ Mutual legal assistance in general, including for court procedures, see Sections 106 and onwards of the [Ugandan Anti Money Laundering Act 2013](#);
- ◆ Extradition of offenders for offences committed in other jurisdictions; and
- ◆ Transfer of witnesses in custody for court procedures in other jurisdictions.

15.4.14 – Cooperation, including exchange of data with international organisations

Similar to the previous, except that some items might not be relevant.

15.4.15 – Intra-organisational measures

Empowerments might be needed for:

- ◆ (Re-)Assigning of human resources (in case of changing situation);
- ◆ (Re-)Assigning of financial resources (in case of changing situation);
- ◆ Assigning of and cooperation with external experts as advisors;
- ◆ Creating scientific or advisory bodies;
- ◆ Establishing procedures regarding scientific or other advisory bodies;
- ◆ Creating intra-organisational independence (e.g. for scientific or advisory bodies that must have independence to be credible);
- ◆ Intra-organisational reporting obligations;
- ◆ Intra-organisational control mechanisms (e.g. mandatory review by superior instance for difficult or important decisions, periodic control review, right to instruct);
- ◆ Intra-organisational disciplinary procedures; and
- ◆ Whistle-blower protection mechanisms (a universe of its own, see this [article](#)).

ANNEX I: LITERATURE AND TOOLS

The Australian Government

Guide to Regulation

<https://www.cuttingredtape.gov.au/handbook/australian-government-guide-regulation>

“Victorian Guide to Regulation”

(elaborated by the Australian province of Victoria):

<http://www.dtf.vic.gov.au/Publications/Victoria-Economy-publications/Victorian-guide-to-regulation>

OECD: Regulatory Policy and Behavioural Economics

(DOI:10.1787/9789264207851-en):

http://www.oecd-ilibrary.org/governance/regulatory-policy-and-behavioural-economics_9789264207851-en

OECD: International Regulatory Co-operation

- Addressing Global Challenges

(DOI:10.1787/9789264200463-en):

http://www.oecd-ilibrary.org/governance/international-regulatory-co-operation_9789264200463-en

Alan IRWIN et al,

“[Regulatory Science – Towards a sociological Framework](#)”,

in: Futures, Vol. 29 No. 1 pp 17-33, Elsevier Science Limited,

Amsterdam 1997

Fiona HAINES, [The Paradox of Regulation](#),

Edward Elgar Publishing, Cheltenham (UK) 2012

Jacqueline PEEL, [Science and Risk Regulation in International Law](#),

Cambridge (UK) 2013

Jaap SPIER, [Shaping the Law for Global Crises](#),

Eleven International Publishing, The Hague 2012

More relevant books, including handbooks can be found at this site of the [International Association for Legislation](#) and the website of the [Commonwealth Association of Legislative Counsels](#) that publishes also a periodic review with articles relevant for practitioners, named “[Loopholes](#)”. Rather scientific articles on law-making can be found in the [review](#) “The Theory and Practice of Legislation”.