



EU-Legislators' Toolbox

The [Regulatory Institute](#) makes this initially internal document accessible to those working on new EU legislation because it is a unique instrument that can be used to improve EU legislation by drawing on tools that have already been tested in other regulatory sectors. The Tool Box avoids reinventing the wheel. Above all, it enables EU legislation to be made more complete, and therefore more efficient and less open to diverging interpretations. Using these tools ensures a more uniform, consistent and stringent application of the law. It indirectly creates or preserves a level playing field, and thus trust.

If you cannot find the appropriate tools in this Tool Box, we recommend our [Cross-sectoral Standard Provisions](#). The chapter titles in that document are similar to those in the Tool Box, enabling you to easily shift between the corresponding chapters. The Cross-sectoral Standard Provisions are largely based on EU legislation, but not exclusively. More recommendations can be found at the end of this document under "[Further Tools](#)".

For those readers who are particularly interested in the current hot topic "simplification", we have singled out [simplification tools](#). If you wish further topic-related subsets of this Tool Box or a sector-specific selection, please contact us.

Questions or suggestions? Please contact: manager@regulatoryinstitute.org

This document has been partially supplemented by Large Language Models. All parts supplemented by Large Language Models have been fully revised by humans, except for the Official Journal indications.

This document was conceived, developed and finalised by a former official of both the European Parliament and the European Commission who has worked on EU legislation for over two decades, drafting or substantially contributing to several dozen EU acts..

Attention: Most references relate to the initial permanent link to the Act to avoid the links breaking down later. To view the latest version of the Act, click on the top 'Consolidated version' link in the left-hand column of the EUR-Lex page.

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A. Interpretation (Rules)

EU Information System for Aligned Decision-Making (Authorities and Certification Bodies)

Regulatory Function:

Consistency in Interpretation and Implementation Across the Union

Problem:

Divergent national authorities or certification body practice creates market barriers and non-level playing fields.

Solution(s):

Establish a legally mandated, interoperable information system to share legal and interpretative decisions, case law, and authorisation / certification outcomes.

Reference(s):

Article 71(1)-(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 97, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178.

Note(s):

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National Information Systems for Interpretation and Guidance

Regulatory Function:

Consistency, Correct and Efficient Day-to-Day Compliance

Problem:

Operators, certification bodies and local authorities may misinterpret rules in the absence of a central source.

Solution(s):

Require Member States to create and maintain accessible national interpretative and guidance systems, linked to the EU platform (previous entry).

Reference(s):

Article 71(5)-(7), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Creates uniform guidance and continual feedback, ideal for fast-changing, technical or decentralised regulatory areas.

Product or Process Classification Procedures

Regulatory Function:

Classification Consistency and Predictability

Problem:

Conflicting or ambiguous classification impedes enforcement and market entry.

Solution(s):

Define detailed procedures, with Commission powers to clarify classification where needed.

Reference(s):

Article 4, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 84, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

The approach supports legal certainty and reduces friction between member state authorities and certification bodies.

Binding Interpretations by Implementing Acts

Regulatory Function:

Legal Clarity and Best Practice Support

Problem:

Operators need clear, up-to-date guidance to comply across languages and Member States.

Solution(s):

Right for the Commission to adopt binding interpretations by Implementing Acts, where guidance/FAQs, or other interpretative communications do not suffice.

Reference(s):

Article 30, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Also see the often overlooked instrument of Recommendations in accordance with Art. 292 [TFEU](#).

Empowerment for Guidance

Regulatory Function:

Legal Clarity and Best Practice Support

Problem:

Operators need clear, up-to-date guidance to comply across languages and Member States. However, it is sometimes argued that only the ECJ has the authority to set up interpretations.

Solution(s):

Explicit right for the Commission (services) to adopt guidance documents.

Reference(s):

Article 77, Regulation (EC) No [1107/2009](#) (Plant Protection Products), OJ L 309, 24.11.2009, p. 1–50.

Note(s):

See also the often overlooked instrument of Recommendations in accordance with Art. 292 [TFEU](#).

Reference to Commission, Agency or “Board/Body” for Binding Interpretation or Arbitration

Regulatory Function:

Conflict amongst Member States on Application / Interpretation

Problem:

Unresolved legal ambiguities lead to conflicts, delayed implementation and unequal enforcement.

Solution(s):

Allow national authorities to make “preliminary references” to the Commission or an EU agency or “board/body” with legal personality for official/binding interpretation.

Reference(s):

Regulation (EU) [2016/679](#), Art. 64 and 65 (Data Protection);
Article 59, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022,
p. 1–102;
Article 13, Regulation (EU) [2019/1149](#) (European Labour Authority), OJ L 186,
11.7.2019, p. 21-56.

Note(s):

Similar: New Legislative Framework product legislation contains so-called “safeguard clauses”, according to which measures taken by a Member State can be challenged by other Member States. The confirmatory decision or opinion of the Commission mostly needs to be transposed by all the Member States or is even directly applicable in all Member States. See “Coherent Handling of Risky or Non-compliant Products or Services across EU” in Chapter K.

Reference to Courts for Binding Interpretation

Regulatory Function:

Legal Uncertainty or Conflict amongst Member States on Application / Interpretation

Problem:

Unresolved legal ambiguities lead to conflicts, delayed implementation and unequal enforcement.

Solution(s):

Allow reference to a court in view of a “preliminary ruling”.

Reference(s):

Article [267 TFEU](#).

Note(s):

Can also be established by secondary legislation (to be checked). Similar mechanisms can be found in various constitutions or laws of the Member States.

Standards, International and Informal Document to guide Interpretation

Regulatory Function:

Clarity and Predictable Implementation

Problem:

Vague or ambiguous legal provisions risk inconsistent application.

Solution(s):

Refer to documents that can help to interpret a vague term or provision, without establishing a strict obligation to follow any of the documents. In the selected reference, the following documents are referred to:

“(a) European standards other than those the references of which have been published in the Official Journal of the European Union in accordance with Article 10(7) of Regulation (EU) No [1025/2012](#);

(b) international standards;

(c) international agreements;

(d) voluntary certification schemes or similar third-party conformity assessment frameworks, in particular those conceived to support Union law;

(e) Commission recommendations or guidelines on product safety assessment;

- (f) national standards drawn up in the Member State in which the product is made available;
- (g) the state of the art and technology, including the opinion of recognised scientific bodies and expert committees;
- (h) product safety codes of good practice in force in the sector concerned; ...”

Reference(s):

Article 8, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

Please note the subtle wording in Article 8: “... when assessing whether a product is safe, the following elements in particular shall be taken into account, when available: ...”. This wording does not bind the interpretation to any of the documents referred to. Binding the interpretation would be legally problematic.

Recitals to guide Interpretation

Regulatory Function:

Clarity and Predictable Implementation

Problem:

Vague or ambiguous legal provisions risk inconsistent application.

Solution(s):

Use detailed recitals with examples, interpretative principles and explicit guidance on intended meaning.

Reference(s):

Recitals 19, 26, 36, and 39, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

Some hold that recitals should only be used to justify the provisions. Even though recitals can often be formulated in a way that pursues both purposes.

B. Scope, Application and Harmonisation Approaches

Empowerment to clarify Applicability of an Act

Regulatory Function:

Legal Certainty, Scope and Applicability

Problem:

Uncertainty arises as to whether a legislative act applies in borderline or evolving scenarios.

Solution(s):

Empowerment for the Commission to clarify the applicability via binding acts.

Reference(s):

Article 4(1) and (2), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Helps ensure regulatory certainty and enforceability in fields with rapidly evolving products, services or other processes and social realities.

Member State to be exempted under Conditions

Regulatory Function:

Flexibility for Divergent National Situations and Interests

Problem:

Political goals can sometimes be better pursued with more flexibility regarding

the means. Whilst default means are needed, alternative paths can be more suitable in certain circumstances.

Solution(s):

Permit exemptions under certain conditions and with strict control by the Commission, expiry of exemption in case of non-fulfilment of obligations.

Reference(s):

Articles 50(5)-(7) and 52(2) and (3), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40.

Note(s):

Article 52 is unclear as to whether the Commission needs to exempt the Member States or whether the Member States may exempt themselves under certain conditions. Article 50 is preferable.

Member State “Opt-Out” from Marginal Scope

Regulatory Function:

Flexibility for Divergent National Interests

Problem:

A certain number of Member States need a regulatory element some others do not want.

Solution(s):

Permit Members to opt out of marginal areas of EU regulation, avoiding unnecessary blocking of wider harmonisation.

Reference(s):

Article 2(1), last sentence, Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

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Member State “Opt-ins”

Regulatory Function:

Flexibility for Divergent National Interests

Problem:

A certain number of Member States need a regulation or directive that others do not want.

Solution(s):

Permit Members to opt in, avoiding unnecessary blocking of wider harmonisation.

Reference(s):

The legal frameworks for the Schengen area and the single currency (Euro) are formally opt-out regimes, but new Member States can de facto decide on whether they wish to join—in which case they have to fulfil certain conditions—or not.

Note(s):

Argentina and Australia have developed easier to handle types of opt-ins: (1) Argentina – “ley convenio” technique (as recognised in constitutional [Article 75](#) and Senate analyses), where a federal law establishes a national regime in an area of shared or provincial competence and explicitly invites provinces to adhere by their own legislation. Provinces that do not adhere remain outside that regime, while the framework can still operate for adhering provinces. (2) Australia – [Mutual Recognition Act 1992](#) (Cth); Automatic Mutual Recognition ([AMR](#))

schemes for regulated professions have been adopted by some states and territories ([NSW](#), Victoria, ACT, Western Australia, ...), but not by all.

Member States to exempt Outermost Regions

Regulatory Function:

Tailoring Regulation for Non-Continental Markets

Problem:

EU rules may be misaligned or overly burdensome for distant territories (outermost regions).

Solution(s):

Permit Member States to exempt such regions or sectors, requiring notification and assurance that no market spill-over occurs.

Reference(s):

Article 2(3), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Exemptions in Case of “Public Interest Override”

Regulatory Function:

Balancing Rights and Interests

Problem:

Absolute rules may bar vital actions in cases of overriding public interest (e.g., national security, civil protection).

Solution(s):

Greater good exemptions defined and allowed through precise procedures, with transparency and accountability safeguards.

Reference(s):

Article 23, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 9, Directive (EU) [2016/943](#) (Trade Secrets), OJ L 157, 15.6.2016, p. 1–18.

Note(s):

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“Flexibility Clauses” – Adaptation to Local Contexts

Regulatory Function:

Subsidiarity/Proportionality

Problem:

One-size-fits-all regulation may not fit Member State circumstances.

Solution(s):

Legal flexibility for alternative methods or timings, subject to criteria and notification.

Reference(s):

Article 22, Directive [2008/50/EC](#) (Air Quality), OJ L 152, 11.6.2008, p. 1–44.

Note(s):

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Micro-Enterprise and De Minimis Exemptions

Regulatory Function:

Proportionality and Administrative Burden Reduction

Problem:

Full compliance burden may overwhelm micro-enterprises.

Solution(s):

Explicit exemption or simplified regime for micro-enterprises or activities below a quantitative threshold.

Reference(s):

Commission Recommendation [2003/361/EC](#) (SME), OJ L 124, 20.5.2003, p. 36–41;

Article 30(5), Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

-

Compatibility (“Coherence”) or Collision Clauses

Regulatory Function:

Legal Certainty and Avoidance of Conflict

Problem:

Potential inconsistencies if parallel sectoral legislation applies.

Solution(s):

Stipulate which provision or act prevails or define in another way the relationship between two acts.

Reference(s):

Article 1(2)(a), Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Articles 95 and 96, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 2(1), Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131;

Article 9, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151.

Note(s):

- Ensures a predictable legal order for both authorities and regulated actors. The classic collision rules (lex posterior derogat lex anterior; lex specialis derogat lex generalis) may lead to unclear results; therefore clear collision rules are preferable;

- The first reference contains the following quite unique rule on the relationship of two acts of secondary legislation: “2. This Regulation:

- (a) specifies and complements the rights laid down in Regulation (EU) [2016/679](#) ... “.

“Without Prejudice” Clauses

Regulatory Function:

Legal Clarity and Cross-Regime Compliance

Problem:

Regulators and operators face uncertainty when obligations overlap (e.g., competition, data protection, trade secrets).

Solution(s):

Explicit reference that provisions must be applied “without prejudice” to specific other laws (e.g., GDPR, trade secrets).

Reference(s):

Article 2(4), Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 2(4), Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

The meaning of “without prejudice” is not always clear. Please check whether more precise wordings can be found in your case.

Cross-Sectoral “Regulatory Alignment” Panels for Multi-Use Products/Services

Regulatory Function:

Clarifying Interlocking Legal Regimes

Problem:

Products and services may fall under multiple potentially conflicting sectoral rules.

Solution(s):

Panels to clarify alignment, publish common guides, resolve cross-sectoral issues.

Reference(s):

Article 4(4) and Annex IX, Sections 5.2 to 5.4, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Such panels have emerged as an administrative practice in the medical sector to cover borderline products and combined products. However, each potentially applicable legislation must have its own provisions.

Multi-Function Product/Service: Intended Use Declaration

Regulatory Function:

Legal Certainty for Complex Goods/Services and in Overlapping Sectors

Problem:

Products/services serving several markets risk being caught in legal conflict where different intended uses trigger diverging requirements. On the other hand, requirements are circumvented by denying that they have a certain intended use. Finally, products with different intended uses need to be in conformity with the requirements applicable to the various intended uses.

Solution(s):

Require a clear declaration of the intended use, as well as fulfilment of the various requirements applicable to the intended use(s) in question. The intended use must be respected and declared throughout the distribution chain to minimise the risk of products/services being used for unintended purposes.

Reference(s):

Article 31(1) and (2), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

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Extreme Variety of Products / Services / Situations

Regulatory Function:

Appropriate Coverage of Extreme Variety

Problem:

Some pieces of EU legislation aim to cover a large variety of products, services, situations or processes so that the appropriate requirements and other provisions cannot all be laid down in the regulation or directive.

Solution(s):

Shift the establishment of tailor-made requirements and other provisions to Delegated Acts.

Reference(s):

Articles 4-8, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1.

Note(s):

The Council / Member States often prefer Implementing Acts wherefore the Articles 290 and 291 [TFEU](#) are sometimes slightly squeezed or stretched. See also this [interinstitutional agreement](#).

Preventing “Gold Plating”, Distinguishing “Harmonised Sphere” and Aspects not covered

Regulatory Function:

Harmonising Implementation, Fairness, Level Playing Field

Problem:

Member States may add requirements beyond EU law (“gold plating”), fragmenting the single market. Partly, they regard aspects not or not appropriately covered by EU law.

Solution(s):

Clearly define which aspects are harmonised by EU law and which are not (define the 'harmonised sphere'). Directly prohibit or condition national additions, or require justification or notification. Set up a technical updating mechanism to cover any new or previously overlooked aspects.

Reference(s):

Article 11, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;
Articles 14 to 18, Directive [2006/123/EC](#) (Services Directive), OJ L 376,
27.12.2006, pp. 36–68.

Note(s):

In order to prevent the erosion of EU law, the ECJ legally presumes that EU law is exhaustive, i.e. that it covers all relevant aspects, even when this is not the case. This creates a discrepancy between law and reality that can give rise to safety, environmental and other policy issues. Therefore, it is preferable to clearly define the 'harmonised sphere'.

Maximum Harmonisation Clauses / Approach

Regulatory Function:

Free circulation of products, other items, services, capital and workforce

Problem:

Member States tend to add-on new requirements and sharpen common requirements, partly to protect their population, partly to protect their national economy.

Solution(s):

Establish upper limits of what Member States can request from operators, institutions or citizens.

Reference(s):

Article 4, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151.

Note(s):

- See also the previous entry. The solution proposed there mitigates the legal uncertainty arising from ambiguous wording such as that in Article 4.
- Article 4 of the referenced Machinery Regulation sets out the maximum that Member States can request. However, the Machinery Regulation also establishes minimum requirements, thereby adopting the so-called 'full harmonisation' approach. 'Full harmonisation', whereby upper and minimum limits are set for Member States at one precise level, is dominant in EU legislation today.
- Minimum and maximum harmonisation can also be combined to create a corridor of lawful action for Member States. In practice, however, the alternative approach of mandating a default approach and permitting exemptions under certain conditions is preferred. The alternative approach expresses better where the Union should head to, whilst providing enough flexibility.

Minimum Harmonisation Clauses / Approach

Regulatory Function:

Minimum Protection of Values or Policy Goals combined with Regulatory Flexibility upwards

Problem:

Member States require flexibility to introduce or maintain higher standards while ensuring a common EU minimum.

Solution(s):

Include explicit clauses allowing stricter national provisions beyond the EU minimum without (disproportionately) compromising internal market objectives.

Reference(s):

Article 16, Directive [2004/35/EC](#) (Environmental Liability), OJ L 143, 30.4.2004, p. 56–75;

Article 5, Directive (EU) [2022/2555](#) (Cyber Security), OJ L 333, 27.12.2022, p. 80–152;

Article 4, Directive (EU) [2024/1760](#) (Corporate Sustainability Due Diligence), OJ L, 2024/1760, 5.7.2024.

Note(s):

See the note of the previous entry regarding the combination of maximum and minimum harmonisation ('full harmonisation' or creation of a corridor of lawful action of Member States).

Equivalence/Mutual Recognition—Within EU

Regulatory Function:

Free circulation of products, other items, services, capital and workforce

Problem:

Differing national rules still cause barriers for goods/services/other processes/professional and other qualifications.

Solution(s):

Mandatory mutual recognition for goods, services or professional qualifications lawful in other Member States.

Reference(s):

Regulation (EU) [2019/515](#) (Mutual Recognition of Goods), OJ L 91, 29.3.2019, p. 1–29.

Note(s):

- Also widely adopted in (financial) services and vocational recognition provisions. But leading to disputes, uneven playing field and absorption of scarce enforcement capacities; thus only second best to harmonised rules.
- Accreditation can be set up as a precondition for mutual recognition.

Regulatory Sandboxes and Experimentation Clauses

Regulatory Function:

Innovation Facilitation

Problem:

Traditional frameworks may restrict the emergence of new technologies or business models.

Solution(s):

Allow temporary, controlled derogations or pilot regimes, with safeguards for experimenting with new concepts.

Reference(s):

Regulation (EU) [2022/858](#) (Distributed Ledger Technology Markets), OJ L 153, 3.6.2022, p. 46–84;

Article 57, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 12.7.2024, p. 1–225.

Note(s):

See also this [article](#) on the design of regulatory sandboxes.

Sunset Clauses and Review Triggers

Regulatory Function:

Time-Limited Regulation and Feedback

Problem:

Rules may outlive their suitability; periodic review is often neglected.

Solution(s):

Automatic expiry (sunset), or mandatory evaluation/review deadlines built in.

Reference(s):

Articles 16 and 17, Regulation (EU) [2021/953](#) (Digital COVID Certificate), OJ L 211, 15.6.2021, p. 1–22.

Note(s):

Incentivises regular legislative updating; but sunset clauses create unnecessary burden for Commission and legislators where continuity is necessary.

Rules for Direct Installation or Direct Use

Regulatory Function:

Clear Demarcation of Scope

Problem:

Some operators supply products for direct installation without ever “placing them on the market” in the usual sense. Others make the products available for use without “placing them on the market”.

Solution(s):

Define and separate the concepts of “placing on the market” and “direct installation” or “putting into service” and clarify obligations for each. Define “placing on the market” so as to include “making available for use”.

Reference(s):

Articles 3(5) and 5, Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final;

Article 1(1), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 2(2), Regulation (EU) [2016/424](#) (Cableways Installations), OJ L 81, 31.3.2016, p. 1–36.

Note(s):

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Products Offered as a Service

Regulatory Function:

Ensuring Full Regulatory Coverage for Service-Based Business Models

Problem:

If only products sold (not leased/offered as a service) are regulated, “as a service” business models could avoid compliance obligations.

Solution(s):

State that devices offered, for example as a service, are deemed “put into service” and hence subject to all regulatory obligations.

Reference(s):

Articles 1(1) and 3(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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C. Definitions and Connected Rules

Empowerment to Amend Legal Definitions

Regulatory Function:

Legal Clarity and Adaptation to Technical Progress

Problem:

Definitions may become inadequate over time as technology or practice evolves.

Solution(s):

Empower the European Commission to amend or update legal definitions via delegated acts.

Reference(s):

Article 3, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Indicative Lists and Exclusion Lists

Regulatory Function:

Legal Clarity and Alignment of Interpretation

Problem:

Definitions may be unclear if very abstract or unintendedly excluding important cases when drafted in a very concrete way.

Solution(s):

Use an “indicative list” of items or situations covered by a certain expression / term. Also use exclusion lists.

Reference(s):

Annex II, Tables 1 and 2, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Annex II, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151;

Article 7(2) and (3), Council Implementing Regulation (EU) No [282/2011](#), OJ L 77, 23.3.2011, pp. 1–22.

Note(s):

The last reference contains in paragraph (2) an indicative list and in paragraph (3) an exclusion list.

Dynamic Reference to other Acts for Definitions

Regulatory Function:

Alignment and dynamic Adaptation

Problem:

Definitions diverging between different acts create legal uncertainty. At the same time, some definitions need to be adapted over time.

Solution(s):

Create a dynamic reference to the definitions of other acts.

Reference(s):

Article 2 (at the end), Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1.

Note(s):

The reference to another EU act is by default dynamic. If you wish to avoid the dynamism, you need to refer to a precise version of the act referred to.

D. Authorisation/Licensing Procedures

Mandatory Pre-Market Notification

Regulatory Function:

Early Detection of Non-compliances, Risk Management

Problem:

Without advance notice, authorities may be unprepared for risks linked to new products/services.

Solution(s):

Obligate manufacturers or service providers to notify authorities before entering the market.

Reference(s):

Article 29, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Mandatory Electronic Application

Regulatory Function:

E-Government, Efficiency, and Accessibility

Problem:

Paper-based submission increases delay, error, and cost.

Solution(s):

Require or permit the use of online (secure) platforms for applications, reporting, notifications, and data sharing.

Reference(s):

Article 29, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 1(3), Commission Implementing Regulation (EU) No [1352/2013](#) as last amended.

Note(s):

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Mandatory Application Content / Form

Regulatory Function:

Efficiency and Fairness

Problem:

Non-standardised applications are more difficult to assess fairly. They often omit important information.

Solution(s):

Ensure that all applications contain certain information and are in a specific order, or make a certain form mandatory.

Reference(s):

Annexes, Commission Implementing Regulation (EU) [2025/1126](#) (Authorisation to offer Asset-referenced Tokens), OJ L, 2025/1126.

Note(s):

This can be combined with an electronic application (see previous entry).

Uniform forms can sometimes also be used to harmonise the practice in the Member States where there is no proper EU competence, thereby achieving harmonisation via the backdoor of information standardisation.

“One Stop Shop” Registration/Notification Systems

Regulatory Function:

Administrative Simplification and Cost Reduction

Problem:

Multiple registrations and notifications across Member States or within the same Member State for different laws increase costs and complexity for businesses and authorities.

Solution(s):

Implement a single EU-wide “one stop shop” system for registration or notification (e.g., for data processing, VAT, chemicals, devices).

Implement “one stop shop” systems by which various types of authorisation or notification procedures to be submitted in the same jurisdiction are bundled.

Reference(s):

Articles 56 and 60, Regulation (EU) [2016/679](#) (Data Protection) – Single representative/registration for non-EU controllers, OJ L 119, 4.5.2016, p. 1–88 (for the first type of “one stop shop”);

Article 12, Regulation (EU) [2016/796](#) (Railways Agency), OJ L 138, 26.5.2016, pp. 1–43 (for the second type of “one stop shop”).

Note(s):

The two types of “one stop shop” systems can be combined, as implicitly done by Articles 12, 19, 20 and 21, Regulation (EU) [2016/796](#).

In advance Administrative Decisions (“Advance Rulings”)

Regulatory Function:

Legal Certainty, Reliability, Trust

Problem:

Actors sometimes need to know how administrations would decide under certain conditions (e.g. on a certain investment).

Solution(s):

Authorise in advance / hypothetical administrative decisions.

Reference(s):

Articles 33 and 34, Regulation (EU) No [952/2013](#) (Union Customs Code), OJ L 269, 10.10.2013, p. 1–101 (Binding Tariff Information and Binding Origin Information).

Note(s):

This technique stems from fiscal law and is still widely spread in fiscal law.

Deadlines for Decision-Making

Regulatory Function:

Predictable Administration

Problem:

Open-ended administrative procedures cause costly uncertainty.

Solution(s):

Legally prescribe maximum time periods within which authorities must issue decisions, approvals or refusals.

Reference(s):

Article 20(5), Regulation (EU) No [536/2014](#) (Clinical Trials), OJ L 158, 27.5.2014, p. 1–76.

Note(s):

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Silence = Automatic Consent

Regulatory Function:

Reducing Administrative Delay

Problem:

Administrative bottlenecks can unduly delay legal authorisation or product release.

Solution(s):

Allow authorisation if the competent authority does not refuse or comment within a set deadline.

Reference(s):

Article 20(8), Regulation (EU) No [536/2014](#) (Clinical Trials), OJ L 158, 27.5.2014, p. 1–76.

Note(s):

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Specification of Language of Application / Documentation

Regulatory Function:

Legal Certainty and Non-Discrimination

Problem:

Operators face cost or exclusion when required to use arbitrary languages.

Solution(s):

State explicitly the languages that may or must be used for official applications, certifications, or documents.

Reference(s):

Article 41, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

See also the elegant language regimes of:

- Article 37(3), Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327;
- Article 22(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Conditional and Provisional Authorisations

Regulatory Function:

Managing Uncertainty and Urgency

Problem:

Urgent societal needs (e.g., COVID-19 medicines) require provisional market access before full data is available.

Solution(s):

Permit time-limited or conditional authorisation subject to ongoing monitoring, obligations and withdrawal provisions.

Reference(s):

Articles 13(3), (8) and (14-a), Regulation (EC) No [726/2004](#) (EU Medicines Marketing Authorisation), OJ L 136, 30.4.2004, p. 1–33.

Note(s):

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Automatic Expiry of Non-Implemented Permits

Regulatory Function:

Administrative Clean-Up

Problem:

Unused authorisations or obsolete rules clutter legal systems and markets.

Solution(s):

Create “use it or lose it” provisions—if not acted upon within a set time, the permit or measure lapses.

Reference(s):

Article 14(4), Regulation (EC) No [726/2004](#) (EU Medicines Marketing Authorisation), OJ L 136, 30.4.2004, p. 1–33.

Note(s):

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Merging Assessment Procedures

Regulatory Function:

Simplification and Burden Reduction

Problem:

Conformity assessment bodies and economic operators often need to undergo various procedures under various EU acts. This leads to cumulative burden and unnecessary double assessments of certain aspects.

Solution(s):

Create an option to combine various procedures.

Reference(s):

Article 1 (10), Proposal for a Regulation amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), [COM\(2025\) 836](#) final.

Note(s):

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Integration of Parallel Legislation Requirements in Single Procedure

Regulatory Function:

Avoiding double procedures

Problem:

Various EU regulations and directives regulate different or overlapping aspects in parallel procedures, creating multiple procedural burdens.

Solution(s):

Integrate requirements of parallel legislation and exempt from obligation to undergo the procedure of the parallel legislation.

Reference(s):

Article 1(7) to (10), (12), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 18(6) and Recital 51, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1;

Articles 36(4), 25 and 27, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Article 148, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

- The exemption of medical devices from parallel procedures is set out in the relevant legislation (e.g. on pharmaceuticals and tissues). Conversely, Regulation (EU) [2017/745](#) exempts combination products where the medical device function is not primary.
- See, in particular, the fine-tuned suspension relationship between Regulations (EU) [2024/3110](#) (Construction products) and (EU) [2024/1781](#) (Eco-design for sustainable products). Construction products are not exempt from the scope of Regulation (EU) [2024/1781](#) per se, but its application is suspended for as long as Regulation (EU) [2024/3110](#) equally efficiently regulates environmental aspects. This mechanism incentivises the construction products system to match the level of environmental protection established by Regulation (EU) [2024/1781](#).
- The last reference is interesting in that it introduces requirements for another product group without amending its legislation.

Fulfilment of Obligations of other Acts as Fulfilment of own Act

Regulatory Function:

Avoiding double procedures

Problem:

Various EU regulations and directives regulate in parallel procedures, creating multiple procedural burdens. Sometimes they regulate similar aspects.

Solution(s):

Empower the Commission to determine, in Delegated Acts, the conditions under which the fulfilment of obligations under other Union law also fulfils certain obligations under the (own) act.

Reference(s):

Article 12, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

In particular useful where future Delegated or Implementing Acts make the fabric of obligations ever more dense.

Recognition of Previous Authorisation for Identical Substance or Item

Regulatory Function:

Assessment Efficiency and Avoidance of Redundancy

Problem:

Testing and authorisations may be unnecessarily repeated for substances or items already reliably tested.

Solution(s):

Allow manufacturers to rely on prior compatible test results and authorisations.

Reference(s):

Article 61(1), Regulation (EC) No [1107/2009](#) (Plant Protection Products), OJ L 309, 24.11.2009, p. 1–50.

Note(s):

Particularly useful where testing involves humans or animals.

Common Procedures for Identical Products or Services

Regulatory Function:

Efficient Parallel Processing

Problem:

Duplicated applications for identical products/services waste resources and foster divergent decisions. Product or service identity is determined by the identity of the economic actor. Where two actors offer the same product or service, two procedures are needed.

Solution(s):

Enable joint application channels and “single assessment to multiple decision” legal routes or recognise certificates/approvals issued for an identical product or service.

Reference(s):

Article 62, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Decentralised Manufacturing or Services

Regulatory Function:

Bundling various Authorisations / Licences / Certifications

Problem:

Procedures often depend on the location of manufacture or service. Accordingly, multiple procedures must be followed.

Solution(s):

Establish provisions, particular requirements and checks for decentralised manufacturing or decentralised provision of services.

Reference(s):

Article 26a, [Council Mandate for Negotiations](#) regarding the proposed Regulation on Medicinal Products for Human Use.

Note(s):

Decentralised manufacturing or services are implicitly authorised where there are no particular process requirements and where the manufacturing or service providing site is not subject to any conformity assessment.

Company Group Licensing or Recognition

Regulatory Function:

Efficiency for Multinational Operation

Problem:

Mergers and group operations complicate authorisation under divergent Member State rules.

Solution(s):

Introduce EU-wide or mutual group licensing or recognition of groups for specified sectors/activities.

Reference(s):

Article 37(2), Directive [2014/25/EU](#) (Utilities Procurement), OJ L 94, 28.3.2014, p. 243–374.

Note(s):

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“Forum Shopping” Avoidance Provisions

Regulatory Function:

Consistent Application Across Member States

Problem:

Operators may seek out countries with laxer enforcement or interpretation.

Solution(s):

Stipulate application of rules based on place of use/effect, or provide for centralised control.

Reference(s):

Article 56, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88 (single mandatory One-Stop-Shop).

Note(s):

A similar issue exists with regard to certification bodies. India avoids forum shopping by attributing certain bodies to certain economic operators.

Temporary “Safe Harbours” or “Sandboxes”

Regulatory Function:

Risk-Managed Pilots

Problem:

Legal uncertainty deters new business models and technologies.

Solution(s):

Designate safe harbour periods or regimes protecting participants from authorisation procedures contingent on compliance with basic process and reporting requirements.

Reference(s):

Article 57, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024.

Note(s):

See also this [article](#) on the design of regulatory sandboxes.

Approval and Oversight of Entrusted/Authorised Economic Operators

Regulatory Function:

Facilitating Secure and Compliant Trade

Problem:

Businesses with a strong compliance record should benefit from streamlined controls and lower administrative burdens.

Solution(s):

Establishment of Entrusted / Authorised Economic Operator status with formal approval, audits, and periodic review.

Reference(s):

Articles 38–39, Regulation (EU) No [952/2013](#) (Union Customs Code), OJ L 269, 10.10.2013, p. 1–101.

Note(s):

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Simplified Procedures for Custom or Heritage Products or Services

Regulatory Function:

Proportionality and Burden Reduction

Problem:

Complex standard compliance is excessive for minor or unique cases.

Solution(s):

Allow for “Specific Technical Documentation” as an alternative to full conformity assessment in justified cases.

Reference(s):

Article 14, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Fast-Track or Simplified Procedures for Minor Cases

Regulatory Function:

Administrative Efficiency and Flexibility

Problem:

Resource-intensive procedures hinder low-impact operations.

Solution(s):

Provision of fast-track or summary procedures (short deadlines, reduced documentation).

Reference(s):

Authorisation), OJ L 136, 30.4.2004, p. 1–33;

Articles 59 to 61, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Fast-Track or Simplified Procedures for Urgent Cases

Regulatory Function:

Administrative Efficiency and Flexibility

Problem:

Resource-intensive procedures hinder urgent operations.

Solution(s):

Provision of fast-track emergency or summary procedures (short deadlines, reduced documentation).

Reference(s):

Article 14(9), Regulation (EC) No [726/2004](#) (EU Medicines Marketing Authorisation), OJ L 136, 30.4.2004, p. 1–33.

Note(s):

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“Digital Green Channels” (Automated Regulatory Processing) for Low-Risk Activities

Regulatory Function:

Administrative Efficiency

Problem:

Low-risk operators face unnecessary procedural burdens.

Solution(s):

Permit digital fast-tracking or green channels with spot verification for low-risk cases.

Reference(s):

Article 22, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

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Authorisation for New Economic Operators

Regulatory Function:

Inclusion and Clarification

Problem:

Regulatory frameworks must keep pace with new business models or roles—e.g., 3D-printing service providers, digital-only intermediaries.

Solution(s):

Define in law the obligations and rights of novel actors and assign their treatment/obligations and authorisation procedure to one or several existing categories of actors or set up new obligations and procedures.

Reference(s):

Article 2(1)(a) and (b), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final;

Article 2(47) and (48), Articles 27 to 29, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 3(g), Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

Avoids regulatory “dark zones”.

Direct EU Agency or Commission Oversight for High-Risk Sectors/Services/Products

Regulatory Function:

Uniform High-Level Risk Control, Weak or Biased Member States

Problem:

Devolved enforcement may be inadequate in high-risk or critical areas.

Solution(s):

EU-level agencies or Commission given overriding or direct regulatory/supervisory powers for specific cases.

Reference(s):

Regulation (EU) [2019/1242](#) (CO2 Emissions/Heavy Duty Vehicles), OJ L 198, 25.7.2019, p. 202–240;

Article 1 (25)(c)(1c), p. 28, Proposal for a Regulation amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), [COM\(2025\) 836](#) final.

Note(s):

The second reference authorises the Commission to delegate tests to conformity assessment bodies - an interesting combination of state authorisation and certification approach that we can also observe in other jurisdictions like Canada.

Comparative Assessments in View of Goals

Regulatory Function:

Optimising Regulatory Goals

Problem:

Some policy goals merit being pursued in the best possible way. Setting a benchmark will mostly lag behind the optimal solution.

Solution(s):

Create a legal base for authorising only the best or least harmful products, substances, services, processes or actors.

Reference(s):

Article 23, Regulation (EU) No [528/2012](#) (Biocidal Products), OJ L 167 27.6.2012, p. 1.

Note(s):

This approach is particularly relevant for environmental and health aspects. The comparative assessment as a procedural step can be matched by an obligation to optimise, incumbent on actors; see e.g. the obligation to reduce risks as much as possible in Regulation (EU) [2017/745](#).

Voluntary Agreements as Compliance Tools

Regulatory Function:

Alternative Pathways to Compliance / (Partial) Replacement of Authorisation Procedures

Problem:

Not all regulatory objectives are efficiently achieved through classic mandatory rules to be examined in authorisation procedures.

Solution(s):

Allow voluntary agreements (e.g., self-regulation, codes of conduct) to be recognised as evidence of compliance if they meet set standards and are monitored. Recognise the fulfilment of the voluntary agreement as a (partial) replacement of an authorisation procedure.

Reference(s):

Articles 56 and 95, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L 2024/1689, 12.7.2024;

Article 9, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 17, Directive 2009/125/EC (Ecodesign), OJ L 285, 31.10.2009, p. 10–35;
Articles 40 and 41, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119,
4.5.2016, p. 1–88.

Note(s):

See also the labour law conventions elaborated and agreed by trade unions
which are thereafter generalised by EU directives.

Priority Procedure for Sustainable or Strategic Products or Services

Regulatory Function:

Innovation & Strategic Autonomy

Problem:

Critical or green innovations can be blocked by administrative delays.

Solution(s):

Fast-track or elevate priority for sustainable, strategic, or green applications in
administrative procedures.

Reference(s):

Article 15, Regulation (EU) [2024/1735](#) (Net-Zero Industry), OJ L 2024/1735,
29.6.2024;

Article 10, Regulation (EU) [2024/1252](#) (Critical Raw Materials), OJ L 2024/1252,
3.5.2024, p. 1–58.

Note(s):

-

Digital “Credential Wallets” for Operator/Staff Approval/Certification

Regulatory Function:

Streamlined Credential Verification

Problem:

Traditional paper or isolated digital certificates impede mobility and trust.

Solution(s):

Mandate or permit use of verifiable digital wallets for staff/operator qualifications.

Reference(s):

Regulation (EU) [910/2014](#) (Electronic Identification) OJ L 257, 28.8.2014, p. 73–114.

Note(s):

Also see India – Information Technology (Preservation and Retention of Information by Intermediaries Providing Digital Locker Facilities) [Rules 2016](#), with additional [Rule 9A](#) (notified February 8, 2017, G.S.R. 711(E)): deem issued documents in [DigiLocker system](#) to be at par with original physical documents, with Rule 9A(1) enabling issuers to issue and requesters to accept digitally signed certificates or documents shared from subscribers' Digital Locker accounts at par with physical documents, and Rule 9A(2) deeming documents issued by issuer and accessed by requester through URI as shared directly in electronic form, enabling digital storage of identity documents (Aadhaar, Driving License, PAN, Passport), academic credentials (degrees, diplomas), and professional certificates (professional certificates, skill certificates, employment documents) with regulatory recognition through Ministry of Finance PMLA Guidelines and RBI/SEBI Master KYC Circular accepting DigiLocker e-Docs as valid Officially Valid Documents, thereby establishing digital public infrastructure

credential wallet with legal equivalence to physical documents under Information Technology Act 2000 framework.

Also see the following Chapter E, which contains elements suitable for authorisation procedures.

E. Certification by Private Conformity Assessment Bodies

Also see the previous Chapter D, which contains elements suitable for certification by private conformity assessment bodies ('certification bodies').

Third-Party (Conformity) Assessment System

Regulatory Function:

Assurance of Independence and Credibility

Problem:

Self-certification may not engender trust or ensure safety.

Solution(s):

Require third-party conformity assessment by notified/accredited certification bodies for defined products or risks.

Reference(s):

Articles 42–58 and corresponding Annexes, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 35-50 and corresponding Annexes, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Other comprehensive third-party assessment systems can be found in the transportation sector and in the food and feed control area.

Stringency correlating to Risk Classes

Regulatory Function:

Proportionate Certification Intensity and Stringency

Problem:

Not all products or services merit the maximum intensity and stringency of verification.

Solution(s):

Define risk classes and link more or less intense and stringent conformity assessment procedures to these classes.

Reference(s):

Articles 51-55, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

-

Requirements for Designating Authorities— Separation of Functions

Regulatory Function:

Impartial Appointment and Oversight of Conformity Bodies

Problem:

Risk of bias if those who assess also notify/designate conformity assessment bodies.

Solution(s):

Designating authorities must be organised so that designation decisions are made independently from those performing assessments.

Reference(s):

Article 44, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

-

Separation of Certification Bodies' Tasks from other Tasks of the same Body

Regulatory Function:

Impartiality

Problem:

Lack of separation of functions may allow conflict of interest.

Solution(s):

Distinct documented procedures for assessments, walling off tasks as certification body vs. other business; ongoing monitoring of staff/subcontractor assignments.

Reference(s):

Annex VII Sections 1.2.2 and 1.2.6, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332;

Article 46(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

-

Impartiality and Remuneration Rules

Regulatory Function:

Avoiding Conflict of Interest in Certification

Problem:

Financial dependence on volume or assessment outcome creates risks to impartiality.

Solution(s):

Remuneration of top management/assessment staff not to depend on volume or results of assessments; explicit impartiality guarantees.

Reference(s):

Annex VII Section 1.2.5, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332;

Article 46(9), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Ownership Links between Bodies and Economic Operators

Regulatory Function:

Conflict of Interest Prevention

Problem:

Notified bodies with capital links to manufacturers or economic operators risk captured assessments.

Solution(s):

Direct prohibition on capital links between notified bodies and relevant market operators.

Reference(s):

Article 46(3), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Conflicts of Interest for Certification Bodies

Regulatory Function:

Independence and Market Confidence

Problem:

Certification bodies engaged in commercial activities may not act impartially.

Solution(s):

Statutory rules barring conflicts of interest and ensuring organisational, financial, and staff independence.

Reference(s):

Annex VII Sections 1.2.3 and 1.2.4, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332.

Note(s):

-

Quality Management System Requirements for Certification Bodies

Regulatory Function:

Stable Performance

Problem:

Assessment bodies may lack internally harmonised procedures and improvement loops.

Solution(s):

Legal requirement for a (certified) quality management system.

Reference(s):

Annex VII Sections 2, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332.

Note(s):

-

Limiting the Use of Subcontractors and External Staff by Bodies

Regulatory Function:

Transparency and clear Responsibility

Problem:

Uncontrolled outsourcing and use of external consultants may reduce accountability for certification bodies. Bodies tend to list as “staff” persons who

work also for various other bodies, without clear primary loyalty to the certification body. Both phenomena lead to the emergence of 'empty shell' bodies.

Solution(s):

Regulate, require disclosure/registration, and in some cases limit use of subcontractors. Reserve core and decision-making functions to staff employed under labour law.

Reference(s):

Articles 46(8) and 48, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Annex VII, Section 3.4, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Similar considerations apply to external laboratories and facilities, see the next entry.

External Testing Facilities

Regulatory Function:

Ensuring Quality and Reliability of Test Results

Problem:

Tests performed outside the certification body's own laboratory risk loss of traceability, comparability and result quality.

Solution(s):

External test facilities must have calibrated equipment; traceability and quality of measurements must be ensured.

Reference(s):

Article 49, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Accreditation for Certification Bodies or Laboratories

Regulatory Function:

Quality of Assessors

Problem:

Divergence in the reliability of notified bodies undermines outcomes. Member States' authorities are not necessarily good at checking the quality systems of bodies.

Solution(s):

All certification bodies should be accredited against harmonised EU requirements (not standards).

Reference(s):

Regulation (EC) No [765/2008](#) (Accreditation and Market Surveillance), OJ L 218, 13.8.2008, p. 30–47;

Article 50(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Accreditation is often based on standards rather than applicable legal requirements. Furthermore, accreditation usually relates to a group of legal entities rather than a specific body. Therefore, verification by the relevant authorities is also required. The highest quality of certification bodies is achieved through systems in which both accreditation bodies and authorities supervise

certification bodies. Accreditation bodies tend to be better at assessing quality systems, while authorities tend to be better at assessing compliance with sector-specific provisions.

Documentation for Application as Body

Regulatory Function:

Transparency in Body Notification

Problem:

Without full documentation relating to the precise applicant legal person, assessing notification eligibility is impossible.

Solution(s):

Application must include CVs, contracts, and accreditation documentation corresponding precisely to the legal person applying.

Reference(s):

Article 50(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 38(2) and Annex VII, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Promotes professionalisation and prevents 'empty shell' notifications.

Requirements for Permanent Technical Staff, Decision-Makers and Operational Staff

Regulatory Function:

Assuring Internal Expertise and Continuity

Problem:

Over-reliance on subcontractors/external experts risks loss of internal knowledge/control.

Solution(s):

Set minimum employed technical staff: at least one for every four non-employed staff/experts, all fully integrated at headquarters. At least one person for quality assessment and one for product or service category. Require documentation through CVs and employment contracts.

Reference(s):

Annex VII Section 3.3.2, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 46(8), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Best to be combined with a qualification matrix (see the next entry).

Qualification Matrices for Body Personnel

Regulatory Function:

Competence Assurance

Problem:

Opaque or insufficient qualifications in certification bodies risk poor quality assessments. Complex bodies and bodies recruiting from a large pool of external staff should demonstrate exactly who has what skills for which functions.

Solution(s):

Require certification bodies to maintain and submit a qualification matrix matching person, status, task, competence, and product family.

Reference(s):

Annex VII Section 3.3.2, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 50(6)(b), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

The requested model matrix should be made available by the Commission.

On-Site Audits of Bodies and Economic Operators

Regulatory Function:

Depth in Oversight Procedures

Problem:

Paper assessments may not reveal real operational quality.

Solution(s):

Commission/Member States can require on-site audits of certification bodies, including subsidiaries and subcontractors, and of economic operators.

Reference(s):

Article 55(3), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110, for the on-site assessment of manufacturers by notified bodies;

Article 39(3), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175, for the on-site assessment of certification bodies by designating/notifying authorities;

Article 32(2), Directive (EU) [2022/2555](#) (Cyber Security), OJ L 333, 27.12.2022, p. 80–152, for audits of other operators, even outside certification.

Note(s):

Regulation (EU) [2017/745](#) takes it a step further by mandating so-called 'observed audits', in which notified bodies assess manufacturers under the supervision of the designating/notifying authorities.

Notification Procedure—EU Commission as Final Arbiter in Case of Member States' Objection

Regulatory Function:

Ultimate Quality Control of Notified Bodies

Problem:

Disputes between Member States risk stalling authorisations or letting problematic bodies operate.

Solution(s):

Commission decides—by implementing act—on contested notifications, after investigation; decisions published.

Reference(s):

Article 54, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also Article 51(5) thereof: valid designation/notification only where there is no objection by the Commission or another Member State. This is a smart rule that hinders unqualified bodies from being designated/notified in the first place.

Periodic Reassessment of Bodies

Regulatory Function:

Quality Assurance of Conformity/Assessment Bodies

Problem:

Bodies may lose competence or impartiality over time.

Solution(s):

Mandatory periodic review, re-accreditation or re-designation of certification bodies.

Reference(s):

Article 44, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Consider mandating onsite-audits as part of the reassessment. Consider giving the Commission the possibility to attend onsite-audits.

Ongoing Monitoring and For-Cause-Audits of Bodies

Regulatory Function:

Quality Assurance of Conformity/Assessment Bodies

Problem:

Bodies may lose competence or impartiality over time.

Solution(s):

Mandate ongoing monitoring and For-Cause-Audits, based on:

- Market surveillance data;

- Sampling and scrutiny of certificates for the same category of products / services / processes;
- Information on non-compliance of bodies, or economic actors operating under control of the bodies.

Reference(s):

Article 44, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Should be combined with provisions on periodic reassessment.

Mandatory Coordination Group for Bodies

Regulatory Function:

Inter-Body Alignment, Dissemination of Best Practices

Problem:

Fragmentation of assessment approaches/staff skills over time.

Solution(s):

Bodies subjected to mandatory participation in a coordination group.

Reference(s):

Article 58, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Alignment of Bodies' Practices

Regulatory Function:

Inter-Body Alignment, Dissemination of Best Practices

Problem:

Fragmentation of assessment approaches/staff skills over time.

Solution(s):

Clear catalogue of obligations, precise conformity assessment tasks.

Reference(s):

Inter alia Article 52 and Annexes IX to XI, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Inter alia Articles 55–56 and Annex IX, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Further tasks can be found in other provisions of the two regulations referred to.

Peer Reviews of Bodies

Regulatory Function:

Inter-Body Alignment, Dissemination of Best Practices

Problem:

Fragmentation of assessment approaches/staff skills over time.

Solution(s):

Bodies subjected to peer review by other bodies, or coordinated EU-level peer review procedures.

Reference(s):

Article 10, Regulation (EC) No [765/2008](#) (Accreditation and Market

Surveillance), OJ L 218, 13.8.2008, p. 30–47 (for accreditation bodies);
European Cooperation for Accreditation (EA) [Peer Evaluation Rulebook](#).

Note(s):

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Peer Reviews of Notifying/Designating Authorities

Regulatory Function:

Inter-authority Alignment, Dissemination of Best Practices

Problem:

Fragmentation of assessment approaches/staff skills over time.

Solution(s):

Designating/notifying authorities subjected to peer review by other authorities, or coordinated EU-level peer review procedures.

Reference(s):

Article 48, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Rules for “De-Designation”

Regulatory Function:

Quality Assurance

Problem:

Non-performing bodies must be removed to guarantee credibility. Where bodies stop their activities for whatever reason, the validity of certificates and the take-over of continuous monitoring tasks of the body have to be regulated

Solution(s):

Lay out notification, appeal, and enforcement mechanisms for withdrawing designation. Set out consequences, including for certification and continuous monitoring tasks of notified bodies. Give preference to agreements between the parties, but set up fall-back solutions by intervention of authorities.

Reference(s):

Articles 46-47, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1-175;

Articles 53-54, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also the next entry which is connected to this.

Transfer and Continuity of Certificates when Bodies' stop Activity

Regulatory Function:

Legal Continuity and Supply Chain Integrity

Problem:

Certifications might be lost when a business is transferred to a new legal entity or simply phased out. At the same time, there can be safety / monitoring loopholes.

Solution(s):

If 100% control passed to another legal person, certificates and test reports remain valid; if not, six-month validity after de-notification.

Reference(s):

Article 58, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Articles 53(2) and 55(7), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Please contact us for detailed advice on this ultra-complex issue. The references do not provide the full range of measures needed to ensure business continuity and safety.

Publication of Certification/Assessment Results

Regulatory Function:

Public Trust

Problem:

Hidden or proprietary assessment results can undermine confidence and impede cross-border supervision.

Solution(s):

Require the publication of (non-confidential) results of certification body activities, including certificates and withdrawal/suspension status.

Reference(s):

Article 47(1), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Confidentiality and Data Handling by Bodies

Regulatory Function:

Protection of Commercial Confidentiality

Problem:

Sensitive business data must be protected without obstructing regulatory clarity.

Solution(s):

Enshrine confidentiality as a rule, with dedicated transparency provisions (see previous and next entry) as exceptions.

Reference(s):

Article 46(4), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Reporting Requirements for Bodies

Regulatory Function:

Transparency and Compliance

Problem:

Authorities need timely, full information to ensure oversight and compliance.

Solution(s):

Notified bodies must report refusals, suspensions, key changes, and respond to all information requests by authorities.

Reference(s):

Article 58, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Includes documentation and confidential information sharing for supervision.

Recognition of Previous Tests, Certification or Authorisation in Modular Assessment

Regulatory Function:

Assessment Efficiency and Avoidance of Redundancy

Problem:

Testing may be unnecessarily repeated for products/modules already reliably tested.

Solution(s):

Allow manufacturers to rely on prior compatible test results for essential components, interim products, characteristics or modules, under specific conditions.

Reference(s):

Article 62, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 22, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151;

Article 61(1), Regulation (EC) No [1107/2009](#) (Plant Protection Products), OJ L 309, 24.11.2009, p. 1–50.

Note(s):

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F. International Matters

“Extraterritorial” Scope Covering Companies abroad Targeting the EU Market

Regulatory Function:

Enforcement in the Digital Age

Problem:

Foreign providers can evade regulation despite substantial EU impact.

Solution(s):

Explicitly extend law to non-EU actors offering services or selling in the EU.

Reference(s):

Article 3, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 1(2), Regulation (EU) [2022/1925](#) (Digital Markets), OJ L 265, 12.10.2022, p. 1–66;

Article 4, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51.

Note(s):

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Inspections and Enforcement outside the EU

Regulatory Function:

Global Supply Chain Control

Problem:

Product ingredients, parts, or data processed outside the EU require direct oversight for safety and compliance.

Solution(s):

Grant EU bodies or authorities explicit legal powers to audit or inspect facilities/information outside the Union.

Reference(s):

Articles 120 to 123, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

Under international public law, the activities of states on the territory of another state need to be authorised by the latter. The same applies to the Union.

Reporting Duties for Third-Country Operators

Regulatory Function:

Level Playing Field Across Borders

Problem:

Non-EU actors otherwise evade reporting requirements by operating solely abroad.

Solution(s):

Mandate third-country operators addressing the EU market to appoint EU-based representatives for reporting/communication.

Reference(s):

Article 27, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 23, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Third Country Access to EU Databases

Regulatory Function:

International Regulatory Engagement

Problem:

Trusted third country partners may need access to facilitate mutual regulatory oversight.

Solution(s):

Grant conditional access to regulatory information systems, with strict safeguards (confidentiality, data protection, engagement).

Reference(s):

Article 14(7), Regulation (EU) [2022/2371](#) (Health Threats), OJ L 320, 22.12.2022, p. 1–86;

Article 75(5), Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Article 45, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

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International Data Sharing (General)

Regulatory Function:

Global Data Collaboration

Problem:

Lack of framework for data sharing with third countries damages public policy and cross-border users.

Solution(s):

Legal basis for sharing data internationally, allowing access.

Reference(s):

Articles 88-91, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Note(s):

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Enforcement and Implementation Data Sharing

Regulatory Function:

Global Regulatory Collaboration

Problem:

Lack of framework for data exchange necessary for enforcement and implementation with third countries damages public policy and cross-border users.

Solution(s):

Legal basis for sharing data with foreign authorities, allowing access to EU information (systems).

Reference(s):

Article 81, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Enforcement on behalf of Third Countries

Regulatory Function:

Mutual Enforcement and Regulatory Diplomacy, indirect Support of Own Enforcement abroad

Problem:

Enforcement synergies with aligned third countries are hampered by lack of legal basis.

Solution(s):

Legally permit authorities to support third countries or even to use their

enforcement powers on behalf of third countries, contingent on mutual support agreements or de facto reciprocity. Consider establishing rule of law requirements.

Reference(s):

Article 124, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Article 82(5), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final;

Article 48, Directive [2013/36/EU](#) (CRD IV - Capital Requirements), OJ L 176, 27.6.2013, p. 338–436;

Article 93(11), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Articles 77 and 78, Regulation (EU) [2021/23](#) (Recovery and Resolution of Central Counterparties), OJ L 22, 22.1.2021, pp. 1–102;

Articles 89 and 90, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Articles 76 and 77, Directive (EU) [2025/1](#) (Recovery and Resolution of Insurances), OJ L, 2025/1, 8.1.2025.

Note(s):

See in particular the last three references covering foreign administrative decisions and judgments.

Risk Classification of Third Countries

Regulatory Function:

Unequal Non-compliance Risks

Problem:

Third countries and their actors are not equally performing and equally able to apply EU law correctly.

Solution(s):

Classify third countries in a dialogue procedure.

Reference(s):

Article 29, Regulation (EU) [2023/1115](#) (Deforestation), OJ L 150, 9.6.2023, p. 206–247.

Note(s):

-

Dialogue with Non-Government Actors in Third Countries

Regulatory Function:

Global Regulatory Collaboration and Convergence

Problem:

The application of EU law in third countries sometimes requires the involvement of actors other than the governments of the third countries.

Solution(s):

Establish an open dialogue with business associations and other private / non-governmental actors.

Reference(s):

Article 30, Regulation (EU) [2023/1115](#) (Deforestation), OJ L 150, 9.6.2023, p. 206–247.

Note(s):

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Information-Sharing, Training, and Staff Exchange Access for Third Countries

Regulatory Function:

Global Regulatory Collaboration and Convergence

Problem:

International partners voluntarily recognise/apply EU law but receive no formal recognition or benefit.

Solution(s):

Allow entry of such third countries into information sharing, training, and regulatory staff exchange mechanisms.

Reference(s):

Article 40, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51.

Note(s):

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Regulatory International Alignment

Regulatory Function:

Global Regulatory Alignment

Problem:

Isolated EU standards may impede participation in the global economy.

Solution(s):

Obligation to consult, inform, or align with international bodies (e.g., WHO, Codex, ISO, UNECE) or informal alignment bodies (e.g. International Medical Devices Regulatory Forum).

Reference(s):

Articles 4(7), 5(5) and 13(1), Regulation (EU) [2022/2371](#) (Health Threats), OJ L 320, 22.12.2022, p. 1–86;

Article 50(6), Regulation (EC) No [178/2002](#) (General Food Law), OJ L 31, 1.2.2002, p. 1–24;

Article 1 (90), Proposal for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden ... , [COM\(2025\) 1023](#) final.

Note(s):

See also the many empowerments to adapt requirements in view of international alignment in the last reference, e.g. in Article 1 (5), (9), (28), (41), (43), (44) and (52).

Member States' International Cooperation Agreements

Regulatory Function:

Legal Certainty, Subsidiarity

Problem:

In particular where there are detailed provisions on international cooperation of the Union, it is often questionable to what extent Member States may themselves

establish international cooperation agreements with third countries or international organisations. Such agreements may conflict with the Union's own international cooperation.

Solution(s):

Establish conditions for international cooperation agreements of Member States.

Reference(s):

Article 75(1), Directive (EU) [2025/1](#) (Recovery and Resolution of Insurances), OJ L, 2025/1, 8.1.2025.

Note(s):

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Recognition of International Test Reports, Certificates or Approvals

Regulatory Function:

Burden Reduction, Cheaper Production / Services

Problem:

Industry produces for the world market, but is burdened by test reports, certificate and approval requirements of many different jurisdictions. Products and services become more expensive than necessary.

Solution(s):

Recognition of test reports, certificates or approvals where these are issued in accordance to international agreements or even informal international cooperation that the EU has adhered to (e.g. UNECE or OECD).

Reference(s):

Articles 49 and 50, Regulation (EU) No [167/2013](#) (Agricultural Vehicles), OJ L 60, 2.3.2013, p. 1–51;

Article 2(6), Regulation (EU) No [528/2012](#) (Biocidal Products), OJ L 167 27.6.2012, p. 1;

Article 1 (90), Proposal for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden ... , [COM\(2025\) 1023](#) final.

Note(s):

See also the following entry.

Adequacy or Equivalence Decisions

Regulatory Function:

International Data/Service/Goods Transfer

Problem:

Other jurisdictions often recognise EU approvals or certificates if their own are recognised. De facto mutual recognition - outside cumbersome international agreements - is in the interest of both sides. Furthermore, certain third countries should be smoothly integrated into the EU system.

Solution(s):

Empower the European Commission to issue adequacy/equivalence decisions for cross-border flows of products, services and data or foreign authorities assessing products, services and data. Allow formal assessment of foreign regimes for equivalence, often leading to simplified procedures for compliant imports.

Reference(s):

Article 45, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 129, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142;

Articles 46 to 48, Regulation (EU) [2018/848](#) (Organic Production), OJ L 150, 14.6.2018, p. 1–92;

Article 47, Regulation (EU) No [600/2014](#) (Financial Markets), OJ L 173, 12.6.2014, p. 84–148.

Note(s):

Ensures trusted cross-border flows while upholding EU standards. Easier to manage than international agreements, whilst de facto reciprocity can be requested as precondition. Also suitable to integrate third countries voluntarily applying EU law.

“Passport” as Means for Cross-Border Activities

Regulatory Function:

Fostering the Internal Market

Problem:

Duplicative national licences obstruct the cross-border supply of products and services.

Solution(s):

Ensure operators authorised in one Member State can operate in other Member States and in third countries on strength of a single registration or approval (“passport” regime).

Reference(s):

Articles 9-15, Regulation (EU) [2024/1781](#) (Ecodesign for Sustainable Products), OJ L1781, 28.6.2024;

Articles 75-81, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 34-35, Directive [2014/65/EU](#) (Financial Instruments), OJ L 173, 12.6.2014, p. 349–496.

Note(s):

Can also be used among Member States. The last reference (MiFID II Directive) is, historically, referred to as (one of the) first passport regimes, whilst resembling more to a classic mutual recognition regime.

See also “Enforcement Assistance among Member States” in Section J which could be used for international cooperation as well.

G. Obligations of (Economic) Actors

See also the last entry of the previous Section F.

“State of the Art” or “Best Available Technique” as Legal Benchmark

Regulatory Function:

Ensuring Up-to-Date Performance and Safety

Problem:

Legal standards can become outdated or may not reflect the latest technological or safety advances.

Solution(s):

Define “state of the art” or “best available technique” as a substantive legal benchmark, with guidance on how this is to be regularly assessed and referenced.

Reference(s):

Article 3(28), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 2(10), Directive [2010/75/EU](#) (Industrial Emissions), OJ L 334, 17.12.2010, p. 17–119.

Note(s):

“Best available techniques” is more stringent than “state of the art”. See for more details our [Handbook ‘How to Regulate?’](#), Sections 3.3.1, 8.13 and 8.14.

Power to Adapt Technical / Legal Requirements

Regulatory Function:

Technical Detail and Adaptive Implementation

Problem:

Primary law cannot anticipate all future details or change.

Solution(s):

Explicit empowerment in accordance with Articles 290/291 [TFEU](#) to adopt delegated (policy-detailed) or implementing (technical) acts.

Reference(s):

Articles 290–291, Treaty on the Functioning of the European Union ([TFEU](#)), OJ C 202, 7.6.2016, p. 47-199;

Articles 7(8) and 89, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

The Council often prefers Implementing Acts, since Member States have a stronger say in the 'examination' procedures of the Committee. However, Delegated Acts are legally safer.

Dynamic Link/Reference to Future Innovations

Regulatory Function:

Automated Future-Proofing

Problem:

Statutory reference to technical standards or protocols is quickly outdated.

Solution(s):

Allow “dynamic referencing” so that references always point to the latest version of a standard or protocol adopted under defined EU or international schemes.

Reference(s):

Regulation (EU) [2018/858](#) (Motor Vehicles), OJ L 151, 14.6.2018, pp. 1–218, Annex II Part II “List of UN Regulations recognised as an alternative to the Directives or Regulations referred to in Part” ... “Any further amendment to the UN Regulations listed in the following table ([15](#)) shall also be deemed to be equivalent to an EU type-approval, subject to the Decision referred to in Article 4(2) of Decision 97/836/EC.” - “(15) For subsequent amendments, see UNECE TRANS/WP.29/343.”

Note(s):

Distinct from static reference clauses. Legally only permitted where the acts referred to (or the accession thereto) are under legal control by EU institutions empowered to regulate.

“Retirement” of Outdated Technical Norms

Regulatory Function:

Regulatory Hygiene and Simplification

Problem:

Obsolete or excessively complex norms create hidden barriers.

Solution(s):

Mandate periodic review, sunset or simplification, and open procedure for “retiring” old standards.

Reference(s):

Articles 5(9), 8(6) and 34(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

The references only empower updates; they do not mandate them.

Reference/Alignment with International Standards

Regulatory Function:

International Interoperability and Best Practice

Problem:

Unnecessary divergence from widely-accepted international standards increases barriers and costs.

Solution(s):

Mandate or facilitate the use of international standards where compatible (e.g., ISO, IEC).

Reference(s):

Articles 3 and 13, Regulation (EU) [1025/2012](#) (European Standardisation), OJ L 316, 14.11.2012, p. 12–33.

Note(s):

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COM to Assess Standards for Legal Compliance

Regulatory Function:

Pre-Emptive Legal Review and Legal Certainty

Problem:

Whatever use is made of standards, there is a potential for harmonised standards to conflict with primary law, secondary law or general principles of law.

Solution(s):

Require the Commission to check legal conformity (including with regard to the act in question, fundamental rights and general principles of law or other Union law) before publication of standard references in the OJ.

Reference(s):

Articles 5(7) and 34(1), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 34(4) and Article 38(4), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

Necessary in view of ECJ case law (e.g. James Elliott ruling [C-613/14](#)) regarding harmonised standards as part of the EU law. Moreover, the Commission should be empowered to reject standards which:

- are not compatible with the relevant standardisation requests, including its basic principles and reference points (Article 5(8), Regulation (EU) [2024/3110](#));
- are not compatible with other harmonised standards cited in the Official Journal,
- provide an unjustified advantage to certain manufacturers or are discriminatory to certain types of economic operators and namely SME,
- are technically inaccurate, or
- establish requirements that are not needed for the fulfilment of legal requirements.

Instead of rejecting, the Commission should have the possibility to limit in scope or overrule the respective standards for purposes of legal effects under the act in question, see the next entry.

COM to Substitute or Correct Standards

Regulatory Function:

Standardisation, Rule of Law and Legal Certainty

Problem:

Incomplete, erroneous or outdated standards can impede legal compliance and market innovation. Standards developed by European Standardisation Bodies are often (legally) deficient and cannot be referred to for that reason, whilst their correction would take time and is sometimes even impossible, namely where the standards are based on ISO/IEC standards. See also the deficiencies referred to in the “Note” to the previous entry. Finally, the participants to technical committees of the standardisation organisations sometimes simply fail to agree.

Solution(s):

Empower the Commission to:

- a) Issue EU technical specifications in the absence of—or to override—harmonised standards;
- b) Specify that only the legal effects of a standard—not its content—are overridden;
- c) Publish references to standards only “with restrictions”.

Reference(s):

Article 6, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; Articles 4(3) and 34(4), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final;

Article 9, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

First invented for medical devices, this approach is now broadly accepted across product sectors and even rolled-out via a so-called “Omnibus” amendment.

COM to make Standards Mandatory

Regulatory Function:

Standardisation and Equal Application of Requirements

Problem:

It is difficult to establish regulation for all technical details. At the same time, the application of generic law varies widely.

Solution(s):

One way to strike a balance is to make standards mandatory. This can be achieved through a reference to a specific version of a standard in secondary legislation. However, this approach requires the secondary legislation to be updated periodically, which is inconvenient due to the immense administrative burden it entails. An alternative is to empower the Commission to make standards mandatory through Delegated or Implementing Acts.

Reference(s):

Article 5(8), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110 (for the Implementing Acts approach);

Annex of Commission Implementing Regulation (EU) [2025/1533](#) (Marine Equipment), OJ L, 2025/1533, 14.8.2025 (for the Implementing Acts approach);

Article 4(1), Directive [2014/40/EU](#) (Tobacco Products), OJ L 127, 29.4.2014, pp. 1–38 (for the secondary legislation approach).

Note(s):

Should be combined with the approach described in the previous entry. It is not commendable to rely on standardisation organisations without a fall-back solution, as they sometimes fail to deliver standards that can be referred to, see the problem description of the previous entry.

Presumption of Conformity for Standards and COM Specifications

Regulatory Function:

Standardisation, Legal Certainty and Equal Application of Requirements

Problem:

It is difficult to establish regulation for all technical details. At the same time, the application of generic law creates legal uncertainty and varies widely. Operators need legal certainty on how they can be on the safe side with regard to compliance.

Solution(s):

Empower the Commission to:

- a) Issue detailed mandates to Standardisation Organisations, setting out the basic principles, but also the technical reference points;
- b) Control and correct submitted standards (see separate entry);
- c) Provide a presumption of conformity with certain, precisely defined legal requirements by means of citation of the standards in the Official Journal on the basis of an Implementing Act;
- d) Adopt own technical specifications by Implementing Acts in case that the Standardisation Organisations do not provide citable standards.

Reference(s):

Articles 36 and 37, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Articles 7 and 8, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 9(2), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Common practice for the letters a) and c), but commendable also for the letters b) and d). The voluntary character of the standard gives operators some leeway, in particular for atypical products, services or processes. However, Certification Bodies often unlawfully request operators to apply standards even if they are voluntary. Take precautionary measures in that regard.

Standards or COM Specifications to be Followed by Default

Regulatory Function:

Standardisation, Legal Certainty and Equal Application of Requirements

Problem:

It is difficult to establish regulation for all technical details. At the same time, the application of generic law creates legal uncertainty and varies widely. In some areas, technical specifications should be followed except in atypical cases.

Solution(s):

Empower the Commission to:

a) Issue detailed mandates to Standardisation Organisations, setting out the

basic principles, but also the technical reference points;

- b) Control and correct submitted standards (see separate entry);
- c) Render the standards mandatory by default, but permitting exceptions for atypical cases or when justified by the operator;
- d) Adopt own technical specifications by Implementing Acts in case that the Standardisation Organisations do not provide citable standards, and render them applicable by default whilst permitting exceptions for atypical cases or when justified by the operator.

Reference(s):

Article 9(3), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

This approach can be combined with the presumption of conformity described in the previous entry. Of course, it is also possible to provide only for standards or only for Commission specifications. However, the combination suggested here provides the utmost flexibility.

To avoid disputes over whether the Standardisation Organisations have failed to deliver citable standards, it would be better to formulate the empowerment in letter d) more generically. In any case, the COM will prioritise the development of standards over its own technical specifications wherever possible, since standards are less burdensome.

Obligations Tiered by Risk / Value / Volume

Regulatory Function:

Proportionate Burden and Risk Management

Problem:

Uniform due diligence or other obligations can impose excessive burdens.

Solution(s):

Structure requirements with intensity/complexity fitting the scale of risk or the operator's market volume.

Reference(s):

Article 4(4) and (5) and Article 13, Regulation (EU) [2023/1115](#) (Deforestation), OJ L 150, 9.6.2023, p. 206–247;

Article 1, Directive (EU) [2025/2](#), inserting Article 29a onwards into Directive [2009/138/EC](#) (Insurances Solvency), OJ L, 2025/2, 8.1.2025;

Article 3, Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355.

Note(s):

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Catalogue of Detailed Obligations for Economic Operators

Regulatory Function:

Role-Specific Clarity and Responsibility

Problem:

Legal uncertainty can result when roles in the supply chain are ill-defined. Moreover, Member States' enforcement is not sufficient in many instances if there is no support by economic operators with regard to compliance.

Solution(s):

All relevant economic operator categories' obligations and relations are precisely detailed. This should include mutual control of and by economic operators for certain formal compliance aspects.

Reference(s):

Articles 20–30, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 10–23, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Helps guarantee traceability and compliance throughout the chain.

Outsourcing of Obligations: Limits and Conditions

Regulatory Function:

Compliance

Problem:

Some actors outsource compliance tasks and thereby lose control.

Solution(s):

Establish limits and conditions for the outsourcing of compliance obligations.

Reference(s):

Article 73, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178;

Article 22, Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355.

Note(s):

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Responsibility Organisations of Economic Actors

Regulatory Function:

Compliance

Problem:

It is sometimes difficult for a single economic operator to fulfil certain legal obligations alone, on its own.

Solution(s):

Permit or mandate the creation of “responsibility organisations” that take over the obligations of a pool of economic operators.

Reference(s):

Article 46, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40.

Note(s):

See also the following entry.

Guarantee for Fulfilment of Obligations

Regulatory Function:

Compliance

Problem:

Some functions are systemically important. Failure to fulfil obligations, e.g. following insolvency, might cause important damage.

Solution(s):

Require a performance guarantee, including in case of insolvency, e.g. as part of an authorisation or certification.

Reference(s):

Article 47(6), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40.

Note(s):

See also the previous entry which constitutes a case where such a guarantee might be suitable.

Withdrawal, Recall, and Corrective Action

Regulatory Function:

Public Safety and Market Order

Problem:

Non-compliant or dangerous products or services must be rapidly controlled, removed or corrected.

Solution(s):

Obligation for rapid market withdrawal, recall, or other corrective measures—triggered by defined risks.

Reference(s):

Articles 14 and 16, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Articles 65–67, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also our "[List of Powers and Obligations](#)" with several hundred empowerments useful for enforcement.

Obligations for Brokers and Platform Operators

Regulatory Function:

Adapting Rules to the Digital/Supply Chain Shift

Problem:

Platforms, brokers or other intermediaries exploit loopholes as neither conventional retailers nor manufacturers. Classic economic operators can hide behind platforms, brokers or other intermediaries so that authorities cannot get hold of them.

Solution(s):

Explicitly define duties and liability of intermediaries, “marketplaces” and online service providers.

Reference(s):

Chapter III, Sections 3 to 5, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102;

Article 22, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51;

Article 28, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also our model law on [Cross-border internet activities and virtual worlds](#).

E-Commerce and Digital Market-Specific Provisions

Regulatory Function:

Digital-Readiness and Effective Enforcement

Problem:

Online market structures evade enforcement under traditionally formulated laws.

Solution(s):

Set obligations and liabilities specifically tailored for online marketplaces, interfaces, and digital intermediaries.

Reference(s):

Articles 19-21, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51;

Article 29, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 6 and 6a, Directive [2011/83/EU](#) (Consumer Rights), OJ L 304, 22.11.2011, p. 64–88;

Chapter III, Sections 3 to 5, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

Should be combined with international cooperation so as to ensure enforcement abroad. See also our model law on [Cross-border internet activities and virtual worlds](#).

Coverage of New / Atypical Economic Operators

Regulatory Function:

Adapting Regulation to new Forms of Operation

Problem:

The markets produce ever new forms of economic operators. Legislation often lags behind.

Solution(s):

Try to learn from other sectors and jurisdictions and also integrate types of economic operators that have emerged in other sectors or jurisdictions. Moreover, establish a set of basic obligations for “economic operators” whilst

defining this term in an open way, not just by referencing the currently known types of actors.

Reference(s):

Articles 20 and 26-29, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; (for the definition of “economic operators”, better see the next reference)

Articles 3(9), 19 and 26-30, Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

Since the late 1990s, 'fulfilment service providers' have emerged in one sector after another, leaving the relevant authorities unable to cope. Even today, some sector legislation does not cover them. And ever new roles have emerged since.

Coverage of 3D-Printing or Blue Print Selling

Regulatory Function:

Adapting Regulation to new Forms of Operation and Closing Safety Loopholes

Problem:

The obligations of manufacturers and the many safety guarantees linked to that role are not applicable when one party simply provides the dataset or blueprint, another party manufactures and sells the 3D-printing material, and a third party provides the 3D printer.

Solution(s):

Assign the following responsibilities to the three types of actors:

- Responsibility for design (as quasi-manufacturer) to the first type of actor.
- Responsibility for the appropriateness of the printing material to the second type of actor.

- Responsibility for compatibility to both types of actor.
- Responsibility for indicating legal requirements to the commercial provider of the 3D printer.

Together, these responsibilities ensure a minimum level of product safety.

Reference(s):

Recitals 9 and 52, Articles 2(1)(a) and (b), 2(4), 3(9), (10), (11) and (13), 10(1), 28, and 90(2)(m), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

See also [this article](#).

Permalinks for Electronic Documentation

Regulatory Function:

Digital Simplification and Traceability

Problem:

Paper documentation is hard to access and keep up-to-date in cross-border trade.

Solution(s):

Allow/require use of secure digital links or electronic documentation as the official record.

Reference(s):

Articles 16(2)(f) and 18(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Reporting/Information on Alignment with Standards

Regulatory Function:

Transparency and Quality Control

Problem:

Users lack information if a certain product or service meets certain standards (e.g. green taxonomy).

Solution(s):

Oblige companies to disclose to what extent they align with certain standards (e.g. EU Green Taxonomy).

Reference(s):

Articles 3-8, Regulation (EU) [2020/852](#) (Taxonomy), OJ L 198, 22.6.2020, p. 13–43;

Article 7, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1;

Article 22(1) and (2) and Annex V, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Quality Management Systems

Regulatory Function:

Internal Quality Control by Manufacturers or Service Providers

Problem:

Manufacturers' and service providers' processes require reliable internal systems to assure constant compliance.

Solution(s):

Mandate the use of a comprehensive quality management system, be it tailor-made, be it based on an international standard.

Reference(s):

Article 17, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L 2024/1689, 12.7.2024;

Article 10(9), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Factory Production or Service Control Requirements

Regulatory Function:

Internal Quality Control by Manufacturers or Service Providers

Problem:

Manufacturers' and service providers' processes require reliable internal systems to assure constant compliance.

Solution(s):

Legal obligation for documented, continuous 'factory production control' (FPC) or 'services control' procedures.

Reference(s):

Annex IX Section 3 "System 2+", Regulation (EU) [2024/3110](#) (Construction

Products), OJ L 2024/3110;

Annex XI, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332;

Annex II, Modules A, C, D and H, Decision No [768/2008/EC](#) (New Legislative Framework), OJ L 218, pp. 82–128.

Note(s):

Decision No [768/2008/EC](#) has been replicated and adapted in many directives and regulations.

Periodic Sample Testing Obligation

Regulatory Function:

Active Post-Market Surveillance

Problem:

Product failures may emerge only after placement on the market.

Solution(s):

Manufacturers (and sometimes importers/distributors) should be required to perform regular sample testing of products on the market.

Reference(s):

Article 22(4) and Annex IX, Sections 1, 2, 3 and 6, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 52(14), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Compliance Checks by Digital Twins or Simulations

Regulatory Function:

Innovation in Testing and Approval

Problem:

Physical testing can be costly, slow, and environmentally burdensome.

Solution(s):

Allow digital twins/simulation data in compliance, provided quality criteria are met.

Reference(s):

Permitted by Annex IV, Part A, Section (g) “reports and/or results of the design calculations”, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151.

Note(s):

Better to refer precisely to digital twins or simulations.

“Technical Dossiers” of Service Providers

Regulatory Function:

Traceability and Legal Accountability

Problem:

Service operations can be as safety-critical as goods, but lack equal traceability.

Solution(s):

Service providers maintain full technical records, parallel to manufacturers.

Reference(s):

Article 7(2) and (3), Directive [2014/33/EU](#) (Lifts), OJ L 96, 29.3.2014, p. 251–308.

Note(s):

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Technical Documentation and Event Records Keeping

Regulatory Function:

Traceability, Evidence, and Ex-Post Controls

Problem:

Verification and incident response require robust documentation both on the technical characteristics and particular events.

Solution(s):

Obligation for economic operators to keep specified technical documentation, typically for at least 10 years. Obligation to keep records on usage for a certain time.

Reference(s):

Article 10(8), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175

Article 26(6) Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024;

Article 30, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

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Reduced Technical Documentation for Individually Manufactured or Non-Series Products

Regulatory Function:

Proportionality in Assessment Methods

Problem:

Full systematic conformity assessment is excessive for custom or single-use products.

Solution(s):

Allow assessment via Specific Technical Documentation equivalent to formal harmonised requirements.

Reference(s):

Article 14, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Traceability Requirements

Regulatory Function:

Tracking for Safety, Market Order, and Effective Recalls

Problem:

Inadequate traceability hinders rapid response to safety or compliance concerns.

Solution(s):

Impose traceability duties (batch/serial numbers, supply chain linkage, data requirements; customer, supplier and service provider recording). Impose “know-your-customer” rules.

Reference(s):

Annex I Chapter III Section 23(2)(g) and Annex VI, Part C, Section 3.5, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175; Article 22, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40; Articles 20(3) and 22(5), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; Article 19, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151.

Note(s):

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Digital Identification / Know-Your-Customers Rules

Regulatory Function:

Secure Digital Access and Fraud Prevention

Problem:

Growing fraud, non-compliance and money laundering risk, plus the need for cross-border digital trust.

Solution(s):

Mandate or enable the use of secure digital identity (eID) and harmonised Know-Your-Customers procedures.

Reference(s):

Regulation (EU) [910/2014](#) (Electronic Identification) OJ L 257, 28.8.2014, p. 73–114;

Regulation (EU) [2023/1113](#) (Information on Transfers of Funds and Crypto-assets), OJ L 150, 9.6.2023, p. 1–37;

Article 20(3), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Internet Platforms and Brokers to cooperate with Authorities

Regulatory Function:

Supply Chain Traceability and Enforcement

Problem:

Enforcement is weak regarding economic operators offering products and services via internet platforms or brokers.

Solution(s):

Specific cooperation obligations of internet platforms and other brokers.

Reference(s):

Article 22, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51.

Note(s):

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Electronic and Bundled Declaration of Conformity

Regulatory Function:

Burden Reduction

Problem:

Accompanying each individual product with a paper declaration of conformity is cumbersome.

Solution(s):

Permit electronic declarations of conformity under certain conditions. Permit that only one paper copy is handed out where the same client acquires several identical products.

Reference(s):

Article 16, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Detailed Declaration of Conformity and Performance

Regulatory Function:

Consumer / User Information and Market Transparency

Problem:

Inconsistent or absent declarations obstruct rational choices.

Solution(s):

Require clear, standardised declarations of conformity and performance.

Reference(s):

Article 15 and Annexes II, IV and V, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

In the context of construction products, performance characteristics have a specific function. However, certain characteristics merit being declared for virtually all other products. See also the second entry below.

Declarations of conformity and performance also have an important compliance function. Economic operators are obliged to work through the points listed in the declaration model. The declaration model thus serves as a compliance checklist.

Labels for Product Information

Regulatory Function:

Consumer / User Information and Market Transparency

Problem:

Inconsistent or absent labelling obstructs sustainable choices, safety choices and product traceability.

Solution(s):

Require clear, standardised labels showing sustainability, performance, or regulatory status.

Reference(s):

Article 22(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Mandatory “Key Characteristics” Indication

Regulatory Function:

User-Friendly Regulatory Disclosure

Problem:

Complex documentation obscures the most important facts.

Solution(s):

Require standardised summary tables of “key characteristics” in technical and user documentation.

Reference(s):

Article 22(6) and Annexes II, IV and V, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Right to Information for Customers / Consumers / End-Users

Regulatory Function:

Transparency, Consumer Choice, Safety

Problem:

Customers / consumers / end users cannot make informed decisions without access to accurate compliance and safety information.

Solution(s):

Right to request, receive and access all prescribed information, including online.

Reference(s):

Articles 5–8, Directive [2011/83/EU](#) (Consumer Rights), OJ L 304, 22.11.2011, p. 64–88.

Note(s):

Extends to both pre- and post-purchase, and to complex services. Particularly important: information on the limitation of the product or service to professional users, see Article 22(5), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Precontractual Information Obligations

Regulatory Function:

Transparency, Consumer Choice, Safety

Problem:

Customers / consumers / end users cannot make informed decisions without access to accurate compliance and safety information.

Solution(s):

Detail mandatory, easy-to-understand pre-contractual information requirements.

Reference(s):

Articles 5–6a, Directive [2011/83/EU](#) (Consumer Rights), OJ L 304, 22.11.2011, p. 64–88;

Article 22(5) last sentence, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Information Accessibility for End Users

Regulatory Function:

Safety

Problem:

End users may not have access to accurate, up-to-date compliance or safety data.

Solution(s):

Obligation for free, user-friendly access to compliance documentation and product status.

Reference(s):

Article 22(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 10(11), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Article 22(5) last sentence of Regulation (EU) [2024/3110](#) contains the complementary obligation to provide precontractual information.

Plain Language and Accessibility of Information

Regulatory Function:

Public Usability and Inclusion

Problem:

Complex legal and technical documents exclude non-specialists or people with disabilities.

Solution(s):

Oblige that notices, forms, and digital content conform to plain language and accessibility requirements.

Reference(s):

Directive (EU) [2016/2102](#) (Accessibility of Public Bodies' Websites), OJ L 327, 2.12.2016, p. 1–15;

Chapter III, Regulation (EU) [2018/1724](#) (Single Digital Gateway), OJ L 295, 21.11.2018, p. 1–38.

Note(s):

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Mandatory Language Requirements

Regulatory Function:

Accessibility for All EU Users

Problem:

Users, authorities, and operators must be able to understand legal and technical information.

Solution(s):

Make translations into required official languages obligatory for all key materials.

Reference(s):

Article 22(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 41, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Essential, but always to be balanced with SME capabilities. Recommended compromise: “language commonly understood”.

Parallel Trade / Dissemination of Products Beyond Intended Member State(s) with Language/Packaging Adaptation

Regulatory Function:

Ensuring Internal Market and Product Access Regardless of Manufacturer's Plans

Problem:

Manufacturers may attempt to block cross-border trade through restrictive distribution or packaging/language policies.

Solution(s):

Permit economic operators, under certain safeguards, to change or translate packaging/instructions for use to serve new markets, even without manufacturer consent.

Reference(s):

Article 53, Regulation (EU) No [528/2012](#) (Biocidal Products), OJ L 167 27.6.2012, p. 1;

Article 26(3)-(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Codifies the European Court of Justice parallel trade approach in all sectors.

Conformity Marking Systems (e.g. CE)

Regulatory Function:

Market Access and User Assurance

Problem:

Lack of clear badges of conformity impedes free movement and user confidence.

Solution(s):

Institute mandatory labelling/markings (such as CE) for compliant products.

Reference(s):

Articles 17 and 18, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

To be distinguished from quality marks. "CE" stands for conformité européenne = European conformity.

Detailed CE Marking Information

Regulatory Function:

Consumer / User Information and Market Transparency

Problem:

CE marking is often lacking essential information and thus does not provide crucial information to customers. Inconsistent or absent declarations obstruct rational choices.

Solution(s):

Require clear, standardised information linked to the CE marking.

Reference(s):

Article 18, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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No Mimicking and Interfering Markings

Regulatory Function:

Clarity of Markings

Problem:

Non-EU marks can obscure, mislead, or dilute the impact of EU conformity marks. Unofficial or lookalike markings can confuse consumers and undermine trust in certification systems.

Solution(s):

Explicitly ban all markings that interfere, cause confusion, or are placed too close to Union marks; stipulate required minimum distance on products.

Reference(s):

Article 19, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Key for technical, digital, food/label-heavy sectors.

“Batch” and Serial Number Marking

Regulatory Function:

Traceability and Recall Effectiveness

Problem:

Lack of batch/serial numbers makes targeted withdrawal impossible.

Solution(s):

Mandate legible and durable batch, lot or item-level labelling.

Reference(s):

Article 15(5), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Article 22(5), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also the entry “Traceability Requirements” above.

Statutory “Claims Rules”

Regulatory Function:

Fair Comparison and Credibility

Problem:

Unregulated claims mislead consumers.

Solution(s):

Define category-specific rules for e.g. product footprint, eco-labelling, and environmental claims.

Reference(s):

Article 28, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Article 14, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Regulation (EU) [2017/1369](#) (Energy Labelling), OJ L 198, 28.7.2017, p. 1–23.

Note(s):

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Ban on Misleading Claims and Marketing Practices

Regulatory Function:

Consumer/Market Protection and Safety

Problem:

Misleading environmental, safety or compliance claims distort competition and lower the average level of safety.

Solution(s):

Statutory ban on misleading claims; clarification of permitted/unpermitted terms and verification requirements.

Reference(s):

Article 7, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Articles 5–7, Directive [2005/29/EC](#) (Unfair Commercial Practices), OJ L 149, 11.6.2005, p. 22–39.

Note(s):

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Obligation to Provide Samples or to Grant Access

Regulatory Function:

Facilitating Oversight and Safety Checks

Problem:

Lack of access to products and services or their documentation hinders investigation and enforcement.

Solution(s):

Operators must provide samples or grant access to products or services upon request by competent authorities, for free or at cost.

Reference(s):

Article 10(14), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 21(2), Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024.

Note(s):

First reference for samples, second for access.

Suppliers / Service Providers to Cooperate for Compliance

Regulatory Function:

Compliance

Problem:

A main economic actor cannot always fulfil its compliance obligations without cooperation of upstream economic actors.

Solution(s):

Give economic actors and certification bodies the right to request cooperation.

Reference(s):

Article 21, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024.

Note(s):

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Contact Details for Accidents/Incidents/Safety Issues

Regulatory Function:

Rapid Risk Detection and Stakeholder Engagement

Problem:

Authorities and other users/affected persons lack a simple channel to report safety problems.

Solution(s):

Mandatory 24/7 contact interface (e.g., hotline or portal) for the public and authorities to report safety incidents and complaints.

Reference(s):

Article 15(6), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Article 20(5), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Transparency on Rules and Procedures

Regulatory Function:

Compliance and Protection of the Interests of Clients

Problem:

The operations of economic operators are often opaque.

Solution(s):

Impose a duty to publish internal rules and procedures.

Reference(s):

Article 27, Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355.

Note(s):

The reference encompasses the obligation to publish key market data.

Complaints Handling and Recording

Regulatory Function:

Responsiveness to Market Information, Safety, Compliance

Problem:

Complaints may be ignored or inadequately processed, risking persistent harms.

Solution(s):

All relevant economic operators must have explicit systems to receive, evaluate, and document complaints, including obligations to act where necessary.

Reference(s):

Articles 31 and 71, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178;

Article 20, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102;

Chapter VII, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Cyber Incident or Security Breach Notification

Regulatory Function:

Resilience and Prevention

Problem:

Authorities, users and market actors must be able to respond quickly to security failures.

Solution(s):

Mandatory notification of incidents/breaches within specified timeframes.

Reference(s):

Article 23, Directive (EU) [2022/2555](#) (Cyber Security), OJ L 333, 27.12.2022, p. 80–152;

Articles 33 and 34, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

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Information and Audit Obligations proportionate to Operator Size and Risk

Regulatory Function:

Avoiding Unnecessary Burden

Problem:

Uniform obligations may disproportionately hurt smaller operators and low-risk sectors.

Solution(s):

Legally scale requirements by risk profile and size, with published thresholds.

Reference(s):

Article 30(5), Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Articles 11(1), 43, 55, 57(9)(g), and Chapters III and IV in general, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024.

Note(s):

The AI Act is complicated, but particularly instructive as it crosses size and risk parameters.

Annual Reporting of Operators

Regulatory Function:

Compliance and Transparency

Problem:

Authorities cannot easily know to what extent operators ensure compliance or fulfil policy goals.

Solution(s):

Establish an annual reporting obligation.

Reference(s):

Article 31, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40.

Note(s):

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“Benchmarking” and “League Table” Publication

Regulatory Function:

Driving Performance and Transparency

Problem:

Without comparative data, users and regulators cannot assess market or regulatory outcomes.

Solution(s):

Obligation for benchmarking and regular “league table” publication of regulated operator or authority performance.

Reference(s):

Article 14, Directive (EU) [2019/944](#) (Electricity Market), OJ L 158, 14.6.2019, p. 125–199.

Note(s):

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Importer/Distributor to Verify and Inform

Regulatory Function:

Ensuring Compliance Throughout the Supply Chain

Problem:

Distributors and importers are often closest to the market but may not ensure products comply with EU requirements.

Solution(s):

Importers and distributors must verify key aspects of product compliance before placing on the market and must inform authorities of known non-compliances.

Reference(s):

Articles 17-19, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Articles 32 and 33, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Articles 24, 25 and 27 Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 13, 14, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Responsible Person for Regulatory Compliance

Regulatory Function:

Enhancing Compliance, Individual Accountability

Problem:

Anonymous corporate actors make enforcement and compliance culture difficult.

Solution(s):

Require the appointment of a named natural person responsible for conformity and regulatory compliance.

Reference(s):

Article 15, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

See also the next entry.

Regulatory Compliance Department with High-level Head

Regulatory Function:

Enhancing Compliance

Problem:

Those in charge of compliance do not always have the standing to enforce compliance necessities.

Solution(s):

Mandate the creation of a regulatory compliance department with a high-level head (“compliance function”).

Reference(s):

Article 41, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

See also the previous entry.

Governance Requirements for Compliance

Regulatory Function:

Enhancing Compliance

Problem:

Governance structures are not always appropriate to ensure compliance and to address risks.

Solution(s):

Set up governance requirements that ensure compliance and ability to address risks. See the reference for illustration of how such requirements can be cast.

Reference(s):

Article 9, Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355.

Note(s):

See also the previous entry.

Authorised/Legal Representatives: Detailed Obligations, Tasks, and Liability

Regulatory Function:

Accountability in Indirect Representation

Problem:

Manufacturers based outside the EU often operate through authorised representatives, potentially leading to gaps in liability or unclear roles.

Solution(s):

Define in law the detailed obligations, tasks, and liability of authorised representatives, making them jointly and severally liable alongside the manufacturer for non-compliance.

Reference(s):

Article 31, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025;

Article 11, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 23, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Change of Authorised/Legal Representative

Regulatory Function:

Continuity of Representation and Market Oversight

Problem:

Changing authorised representatives can interrupt regulatory oversight or documentation availability.

Solution(s):

Require notification to authorities and explicit processes to ensure seamless transfer of obligations and records to the new representative, with clear liability overlap during transition.

Reference(s):

Article 12, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Authorised/Legal Representatives: Right of Action Against Non-compliant Manufacturers/Service Providers

Regulatory Function:

Empowering Effective Compliance Enforcement

Problem:

Representatives may be blocked by manufacturers or service providers from fulfilling compliance obligations.

Solution(s):

Grant authorised representatives explicit rights in dealings with their clients (manufacturers or service providers) where compliance is at stake, including right to withhold services or report non-compliance.

Reference(s):

Article 17(2)(e), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40;

Article 11(3)(h) and (6), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Duties where Product/Service is Modified or Intended Purpose Changed

Regulatory Function:

Continuous Product Compliance

Problem:

Products can lose compliance after market placement if modified or their intended purpose changes post-sale.

Solution(s):

Legally require manufacturers' or service provider's obligations to re-apply when products or services are significantly altered or their use changes, reactivating conformity duties.

Reference(s):

Article 16(1), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 26(1), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Economic Operators to be Identified by Labels

Regulatory Function:

Clarity and Traceability in the Supply Chain

Problem:

Authorities and users need to identify responsible parties quickly.

Solution(s):

Legal obligation for labels to include clear data on manufacturer, importer, and relevant compliance contact.

Reference(s):

Article 24(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 13(3), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Supply Chain Operators to Cooperate for Conformity Assessment Procedures

Regulatory Function:

Compliance

Problem:

Main economic operators often cannot ensure compliance without cooperation of suppliers or upstream service providers.

Solution(s):

Supplier to cooperate in conformity assessment, at least by providing information.

Reference(s):

Article 17, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40.

Note(s):

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Use of Previous Test Results / Certificates

Regulatory Function:

Efficiency and Resource Use

Problem:

Duplicate testing is wasteful and can slow market access.

Solution(s):

Allow prior test results to be used in conformity/compliance assessment, under clear criteria.

Reference(s):

Article 62, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Necessary to ensure that the 2nd assessment body is informed when the 1st assessment body withdraws or limits the certificate or test report.

Modular or System-Based Conformity Assessment

Regulatory Function:

Reflecting Industry Practice/Flexibility

Problem:

Rigid, item-by-item approaches do not fit “systems” or kits.

Solution(s):

Enable conformity assessment on a modular or system basis.

Reference(s):

All automotive industry legislation (whole-vehicle type approval based on type-approval of parts), e.g. Regulation (EU) [2018/858](#) (Motor Vehicles), OJ L 151, 14.6.2018, pp. 1–218.

Note(s):

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Non-discrimination and Equal Access Clauses

Regulatory Function:

Market Fairness/Integrity

Problem:

Favouritism or exclusion based on nationality, location, or other grounds undermines the Single Market.

Solution(s):

Mandate non-discrimination, equal access and proportionality in regulatory measures.

Reference(s):

Article 5, Regulation (EU) [2018/302](#) (Geo-blocking), OJ L 601, 16.3.2018, p. 1–15;

Articles 5–7, Regulation (EU) [2022/1925](#) (Digital Markets Act), OJ L 265, 12.10.2022, p. 1–66.

Note(s):

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Open API / Third-Party Access in Digital Services

Regulatory Function:

Technical Interoperability and Competition

Problem:

Closed digital environments hinder innovation and competition.

Solution(s):

Statutory obligation for open API (application programming interfaces) and secure third-party access for defined markets.

Reference(s):

Article 6(10), Regulation (EU) [2022/1925](#) (Digital Markets), OJ L 265, 12.10.2022, p. 1–66.

Note(s):

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“Clean Break” Transfers Following Service or Supplier Change

Regulatory Function:

User Control and Market Switching

Problem:

Technical or contractual lock-in stifles competition and user choice.

Solution(s):

Mandate clear procedures for smooth, transparent transfer or porting of data, funds, or services, with deadlines and non-blocking covenants.

Reference(s):

Article 20, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

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Minimum Training Requirement

Regulatory Function:

Baseline Competence/EU-Wide Standards

Problem:

Inconsistent training undermines outcomes and hinders mobility.

Solution(s):

EU harmonised basic safety/competence training requirements and mutual recognition.

Reference(s):

Article 15(1), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Custom or Heritage Product Regimes

Regulatory Function:

Proportional Regulation

Problem:

Generic rules cannot be applied to unique, heritage, or custom-made products without undue burden.

Solution(s):

Tailor requirements or allow derogations for individually manufactured, custom, or historic products.

Reference(s):

Article 14, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Surplus or Non-Installed Products

Regulatory Function:

Resource Efficiency and Market Flexibility

Problem:

Surplus or unused products should be re-marketable, subject to safety/proof conditions. The same applies to remanufactured products

Solution(s):

Define procedures for surplus/non-installed product validation and re-launch.

Reference(s):

Article 11(7) and (8), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Remanufactured and Used Products

Regulatory Function:

Circular Economy, Re-use, and Product Life-Cycle Extension

Problem:

Legal uncertainty can impede the legitimate placement of remanufactured or previously used products back on the market.

Solution(s):

Define tailored rules for remanufactured and used products, specifying when and how these products may be marketed or declared conformant.

Reference(s):

Articles 2(20) and (25), 21(3) and 26(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also, as example for a simple coverage of used products, Article 2(3), Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.-

Producer Responsibility Schemes

Regulatory Function:

Waste Management/Circularity

Problem:

End-of-life management falls on the public sector unless producers retain responsibility.

Solution(s):

Impose extended producer responsibility (EPR) obligations for collection, recycling, or take-back.

Reference(s):

Articles 8 and 8a, Directive [2008/98/EC](#) (Waste), OJ L 312, 22.11.2008, p. 3–30.

Note(s):

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Product or Service “Passports”

Regulatory Function:

Traceability and Transparency

Problem:

Regulatory and market actors need reliable, transferable data on the product's characteristics and compliance history.

Solution(s):

Mandate provision of digital product passports/database entries, accessible to authorities and market operators.

Reference(s):

Articles 9-15, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1;

Articles 75-80, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 77 and 78, Regulation (EU) [2023/1542](#) (Batteries), OJ L 191, 28.7.2023, p. 1–131.

Note(s):

The third reference was the pioneer for the first two references.

Transparency Registers for Market Actors

Regulatory Function:

Market Integrity and Public Confidence

Problem:

Opaque market participants may obscure true interests or relationships.

Solution(s):

Dedicated open registers listing actors, roles and beneficial owners in regulated sectors.

Reference(s):

Articles 30–31, Directive (EU) [2015/849](#) (Anti-Money Laundering), OJ L 141, 5.6.2015, p. 73–117.

Note(s):

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Voluntary Certification/Approval of Parts

Regulatory Function:

Reducing Reporting and Compliance Burden

Problem:

Parts should often be checked as well. Full duplicate testing/approval for assemblies using already-certified parts is wasteful.

Solution(s):

Enable voluntary certification of parts, ideally with a legal mechanism for products to “build-on” that certificate when seeking product-level approval.

Reference(s):

Articles 2(1)(e), 67, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Automotive industry legislation, e.g. Regulation (EU) No [167/2013](#) (Agricultural Vehicles), OJ L 60, 2.3.2013, p. 1–51.

Note(s):

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Mandatory Certification/Approval of Key Parts or Ingredients

Regulatory Function:

Ensuring Safety and Environmental Performance at the Subsystem Level

Problem:

Critical component failures may cause systemic hazards.

Solution(s):

Designate “key parts” requiring mandatory certification/approval prior to use in end products.

Reference(s):

Article 2(1)(d), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Automotive industry legislation, e.g. Regulation (EU) No [167/2013](#) (Agricultural Vehicles), OJ L 60, 2.3.2013, p. 1–51;

Article 7, Regulation (EU) [2023/1230](#) (Machinery), OJ L 165, 14.6.2023, p. 1–151;

Article 1(3) and Section II, [Council Mandate for Negotiations](#) regarding the proposed Regulation on Medicinal Products for Human Use.

Note(s):

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Obligations for Parts and Components Distinct from Accessories

Regulatory Function:

Safety and Functional Integrity of Products

Problem:

Replacement parts, consumables, or components used for repair may bypass regulatory controls.

Solution(s):

Define and regulate “parts” and “components” as distinct categories, with clear legal obligations for conformity and traceability.

Reference(s):

Article 23, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Articles 2(1) and 17(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Require full new certification or approval where the parts lead to substantial change.

Imported Used Products Checked as New Products

Regulatory Function:

Closing Compliance Loopholes on Imports

Problem:

Used imports may never have met EU standards, posing risks to safety/environment.

Solution(s):

Explicit rule that imported used products must fulfil the same regulatory requirements as new products.

Reference(s):

Articles 2(1), 11(1) and 26(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

This is a partial and fine-tuning codification of the so-called “[Blue Guide](#)”, the main guidance document for EU product legislation.

Voluntary Conformity Assessment for Used Products Not Subject to Mandatory Assessment

Regulatory Function:

Enhancing Market Acceptance for Safe Used Products

Problem:

Lack of conformity assessment options blocks legitimate used goods from being re-placed on the market where the market requires up-to-date certification.

Solution(s):

Permit voluntary full or “reduced” conformity assessment for used products, tailored to reduced or different intended use.

Reference(s):

Article 12 (in particular paragraph (6)), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

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Re-labelled, Re-purposed, or Misdeclared and “Pseudo” Products

Regulatory Function:

Combatting Regulatory Evasion by Misleading Declaration

Problem:

Products may be falsely declared for another use to avoid regulation.

Solution(s):

Explicit legal duties for economic operators handling ambiguous or “pseudo” products; authorities empowered to reclassify as regulated products.

Reference(s):

Article 31, Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

-

Manufacturer to Define/Certify Precise Product Type

Regulatory Function:

Clear Targeting for Market Surveillance and Certification

Problem:

Ambiguous declarations enable evasion and confusion across operators.

Solution(s):

Manufacturers must define a precise “product type” and not use over-broad or fuzzy labels; notified bodies must verify this determination.

Reference(s):

Article 22(1) and Annex V (testing and certification procedures), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Foundation for precision in market recalls and enforcement.

Detailed and Logically-Ordered Declaration of Conformity

Regulatory Function:

Enhanced Legal Certainty and Market Clarity

Problem:

Confusing, incomplete, or ill-ordered declarations hinder enforcement and market function.

Solution(s):

Set clear steps: compliance check, then declaration of conformity, then CE marking, then market placement.

Reference(s):

Articles 13–18, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Guides best practice online, for digital/AI, green and safety declarations.

Life Cycle Assessment (LCA) of Effects

Regulatory Function:

Holistic Longterm Policy

Problem:

Environmental and other impacts can be “offshored” or hidden unless the whole value and use chain is considered.

Solution(s):

Legal requirement for full life-cycle assessment (LCA), e.g. for environmental product declarations or labelling.

Reference(s):

Annex II, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; Annexes I to III, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1.

Note(s):

Best practice for construction, chemicals, batteries, finance, and more.

Labelling Schemes

Regulatory Function:

Consumer Information and Green Marketing

Problem:

Consumers and professionals lack reliable information e.g. on environmental or social attributes of products/services.

Solution(s):

Establish, regulate, or mandate the use of harmonised environmental/social labelling.

Reference(s):

Regulation (EC) No [66/2010](#) (EU Ecolabel), OJ L 27, 30.1.2010, p. 1–19.

Note(s):

-

Discontinuity Notification

Regulatory Function:

Access to Crucial Products or Services

Problem:

Economic operators sometimes stop their activities from one day to the next and thereby cause the collapse of a certain market. In some cases, crucial products or services cannot be accessed anymore. In others, prices jump.

Solution(s):

Oblige economic operators to notify their intention to discontinue their activity in advance so that authorities can react.

Reference(s):

Article 10a, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

-

Obligation to offer Repairs and Spares

Regulatory Function:

Consumer Protection and Circular Economy

Problem:

Lack of timely approval or access to repair information locks product users into new purchases.

Solution(s):

Impose duties for timely registration/approval of replacement parts and access to repair manuals or even repair.

Reference(s):

Article 22(2), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 14, Directive (EU) [2019/771](#) (Sale of Goods), OJ L 136, 22.5.2019, p. 28–50.

Note(s):

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Requirements for Supply Chain Due Diligence

Regulatory Function:

Responsible Trade and Upstream Control

Problem:

Lax control allows risks and abuses deep in the supply chain.

Solution(s):

Impose detailed due diligence obligations extending to sub-suppliers and service providers.

Reference(s):

Article 4, Regulation (EU) [2023/1115](#) (Deforestation), OJ L 150, 9.6.2023, p. 206–247;

Articles 5-12, Directive (EU) [2024/1760](#) (Corporate Sustainability Due Diligence), OJ L, 2024/1760, 5.7.2024.

Note(s):

-

End-of-Life “Product Stewardship”

Regulatory Function:

Life-Cycle Environmental Protection

Problem:

Products can cause harm at the end of life if not managed by those best placed to mitigate risks.

Solution(s):

Statutory duty for producers/importers to manage product collection, recycling, or disposal.

Reference(s):

Chapter VIII, Regulation (EU) [2023/1542](#) (Batteries), OJ L 191, 28.7.2023, p. 1–131.

Note(s):

-

“Do No Significant Harm” Clauses

Regulatory Function:

Mainstreaming Sustainability

Problem:

A sector’s advances may undermine environmental/social goals elsewhere.

Solution(s):

Prohibit actions likely to cause significant harm to defined social or environmental interests, as assessed against official DNSH criteria.

Reference(s):

Article 3(b), Regulation (EU) [2020/852](#) (Taxonomy), OJ L 198, 22.6.2020, p. 13–43.

Note(s):

-

Pre-Market Risk Assessment in High-Risk Sectors

Regulatory Function:

Precaution and Responsible Innovation

Problem:

Some products/services are placed on the market without prior assessment of broader impacts.

Solution(s):

Compulsory ex ante (e.g. environmental/social/health/safety/rights) risk assessment for certain categories.

Reference(s):

Articles 4–8, Directive [2011/92/EU](#) (Environmental Impact Assessment), OJ L 26, 28.1.2012, p. 1–21;

Article 27, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L 2024/1689, 12.7.2024.

Note(s):

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H. Liability of Actors

Liability for Defective Products or Services

Regulatory Function:

Accountability and Consumer Protection

Problem:

Injuries and losses occur when services or products are defective; ambiguity about who is liable slows compensation and undermines trust.

Solution(s):

Explicit provision on the liability of service providers and of manufacturers (and, if relevant, importers or even distributors) for harm caused by defective products.

Reference(s):

Article 5, Directive (EU) [2024/2853](#) (Product Liability), OJ L, 2024/2853, 18.11.2024.

Note(s):

Consider also mandatory liability insurance.

Liability for Conformity or Compliance (not just Responsibility)

Regulatory Function:

Closing Loopholes on Payment/Compensation, incentivising for compliance

Problem:

The term “responsibility” generates legal ambiguity, especially in cross-border cases.

Solution(s):

Use “liability” to refer to all economic operators and other actors, subjecting them to full national and EU civil law consequences.

Reference(s):

Article 6, Directive (EU) [2024/1203](#) (Environmental Crime), OJ L, 2024/1203, 30.4.2024;

Articles 13(2), 17(3) and 20(7), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Consider also mandatory liability insurance.

Liability for Correctness of Information

Regulatory Function:

Consumer and User Protection, Safety

Problem:

Actors do not always stick to the truth in their communication. This can trick consumers and other clients into purchasing a product or service. This can also trigger sub-optimal safety choices.

Solution(s):

Establish a liability for the correctness, completeness and fairness of information provided.

Reference(s):

Articles 15 and 26, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178.

Note(s):

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Liability of Authorised/Legal Representative

Regulatory Function:

Increasing Compliance by Liability and ensuring Liability

Problem:

Manufacturers and Service Providers are difficult to sue.

Solution(s):

Making authorised representatives jointly and commonly liable, together with the manufacturer or service provider.

Reference(s):

Article 11(5), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Consider also mandatory liability insurance.

Liability Insurance for Certification Services

Regulatory Function:

Accountability and User Protection

Problem:

Member States law on liability applies to Certification Bodies and other certification services. However, some bodies might not be able to cover large damages. Assessment/certification errors may cause substantial harm.

Solution(s):

Mandatory liability insurance for certification services, unless the state takes over liability.

Reference(s):

Article 31(9), Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024;

Article 46(10), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Multiple Liable Persons

Regulatory Function:

Legal Clarity, Effective Protection of Victims

Problem:

The law of Member States varies as to the question who is liable when different persons have contributed to a damage.

Solution(s):

Establish joint and common/several liability and recourse rules.

Reference(s):

Article 12, Directive (EU) [2024/2853](#) (Product Liability), OJ L, 2024/2853, 18.11.2024.

Note(s):

See also Article 13 of the referenced directive.

I. Risk Management and Technology Ethics

See also the last entry of Section G.

Risk-Based Supervision/Control Requirements

Regulatory Function:

Efficient Oversight and Prioritisation

Problem:

Resources of authorities are too scarce to cover all products, services or processes.

Solution(s):

Impose a duty to apply “risk-based” principles not only for approvals and certification, but also for surveillance, inspections, and supervision.

Reference(s):

Article 11, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Title II Chapter II, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142.

Note(s):

Establishment of a concrete risk is very cumbersome whilst formal non-compliance may indicate inaccurate work methods and thus risks. Hence it is often preferable to start with formal checks of high risk products, services or processes.

Risk Management System Requirements

Regulatory Function:

Efficient Oversight and Risk Reduction

Problem:

Without a systemic approach to risks, actors cannot identify and reduce risks in the best possible way.

Solution(s):

Impose a duty to apply a risk management system or framework, be it tailor-made or be it based on an international risk management standard.

Reference(s):

Articles 10, 11, 13 and 18-21, Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355;

Article 9, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L 2024/1689, 12.7.2024;

Article 10(2) and Annex I Section 3, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Joint or Centralised Technology Assessment

Regulatory Function:

Joint Assessment and Avoidance of Fragmentation

Problem:

Member State fragmentation in assessing new products, services or technologies delays market entry and burdens applicants.

Solution(s):

Establish EU-level or multi-country joint assessment mechanisms, coordinated by nominated bodies, EU agencies or the Commission.

Reference(s):

Regulation (EU) [2021/2282](#) (Health Technology Assessment), OJ L 458, 22.12.2021, p. 1–76;

Articles 54 and 55, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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Ethics Panels or Committees

Regulatory Function:

Upholding Societal Values in Novel/Emerging Fields

Problem:

Technical or automated rules may lack sufficient protection for ethics or fundamental rights.

Solution(s):

Set up independent ethics panels for AI, biomedical, or data processing proposals.

Reference(s):

Article 62(3), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175, for national ethics committees.

Note(s):

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Notification and Scrutiny for Emerging Risks

Regulatory Function:

Proactive and Adaptive Regulation

Problem:

Conventional provisions may miss new or rapidly evolving risks (e.g., AI, nanotechnology, gene-editing).

Solution(s):

Develop/adapt “watching” or notification mechanisms for emerging risks and scrutiny mechanisms or panels.

Reference(s):

Articles 45(5), 87-92, 105 and 106, Annex XIV, Part B, 6.1(c), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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COM as Risk Assessment Arbiter

Regulatory Function:

Alignment of Member States in risk matters

Problem:

Member States may have diverging views on the assessment of a specific risk.

Solution(s):

Give the Commission the right to decide in case of diverging views.

Reference(s):

Article 29, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51.

Note(s):

Similar to classic safeguard procedures in product legislation. Creates an incentive for Member States to find a compromise among themselves.

Incentives for Risk Reduction

Regulatory Function:

Risk Reduction

Problem:

Without incentives, actors do not necessarily reduce risks.

Solution(s):

Impose a duty to create risk reduction incentives or create them in the regulation.

Reference(s):

Article 10(3), Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355.

Note(s):

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Risk Communication and Public Information

Regulatory Function:

Risk Governance and Trust

Problem:

Failure to inform the public weakens risk prevention and can cause panic or mistrust.

Solution(s):

Impose duties for timely, comprehensible, and proportionate public information when risks are detected.

Reference(s):

Articles 14 and 34, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Chapter VIII, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

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Risk Assessment Methodology

Regulatory Function:

Complexity of Risk Assessment, Harmonisation of Practices

Problem:

Risk assessment is extremely complex. Authorities are not necessarily familiar with respective methodologies.

Solution(s):

Mandate or recommend a common risk assessment methodology.

Reference(s):

Section “Risk Assessment Guidelines for Consumer Products” in Implementing Decision (EU) [2019/417](#) (RAPEX), OJ L 73, 15.3.2019, p. 121-187;

Annex II, Commission Delegated Regulation (EU) [2024/3173](#) (Safety Gate Rapid Alert System), OJ L, 2024/3173, 13.12.2024..

Note(s):

The first reference has been superseded by the second, but is partly more detailed. See also Chapter 8 of our [Handbook 'How to Regulate?'](#)

See also the entry “Coherent Handling of Risky or Non-compliant Products or Services across EU” in Chapter K.

J. Public Ensurance of Compliance / Implementation

Confidential Two-Way Digital Communication Channels

Regulatory Function:

Responsive, Transparent Administration

Problem:

Unidirectional communication leads to missed information, misunderstanding, delays.

Solution(s):

Mandate digital, secure two-way communication platforms for regulatory filings, notifications, alerts and appeals.

Reference(s):

Article 67, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016;
Article 51, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;
Chapter III, Directive (EU) [2019/1937](#) (Whistleblowing), OJ L 305, 26.11.2019, p. 17–56.

Note(s):

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Authentication of Signatures and Documents

Regulatory Function:

Legal Security in E-Administration

Problem:

Disputes about authenticity/acceptance of electronic documents.

Solution(s):

Explicitly require/refer to qualified electronic signatures or mandates under eIDAS and national law.

Reference(s):

Section 4, Regulation (EU) [910/2014](#) (Electronic Identification), OJ L 257, 28.8.2014, p. 73–114.

Note(s):

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Implementation Coordination Group

Regulatory Function:

Mutual Checks of Commission and Member States

Problem:

Implementation by Commission needs checks and national input, implementation by Member States needs supervision and support by Commission.

Solution(s):

Coordination Group with co-ownership of Member States and Commission measures and clear rules on its functioning.

Reference(s):

Articles 65 and 66 Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024;

Article 103, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Complements the classic “Comitology”; no duplication or substitution thereof if correctly established and managed.

EU Enforcement Information System

Regulatory Function:

Strengthening Enforcement in Member States

Problem:

When uncoordinated, Member States enforce in an inconsistent and inefficient way.

Solution(s):

EU Enforcement Information System, collecting all relevant data, from individual cases to comprehensive national strategies.

Reference(s):

Article 34, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 100, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Such systems are mostly implemented by databases.

Peer Review of Enforcement Authorities

Regulatory Function:

Benchmarking and Progressive Improvement of Enforcement

Problem:

Enforcement / Implementation quality assessment is biased when conducted by own staff.

Solution(s):

Establish periodic peer review by authorities of other Member States.

Reference(s):

Article 12, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

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Annual Public Enforcement Reporting

Regulatory Function:

Benchmarking and Progressive Improvement

Problem:

Enforcement quality is unmeasurable without transparent reporting.

Solution(s):

Oblige authorities to publish annual statistics and analysis on enforcement actions, risks, and trends, best in accordance with a predetermined format to ensure comparability.

Reference(s):

Article 113, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142;

Article 59, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 34(4), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

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Public Access to Enforcement Data

Regulatory Function:

Market Trust and Deterrence

Problem:

Enforcement outcomes are opaque; operators may underestimate compliance risks.

Solution(s):

Publish data on inspection, enforcement, compliance, and penalties with privacy exclusions.

Reference(s):

Article 114, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142.

Note(s):

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Compliance Visualisation (“Heat Maps”)

Regulatory Function:

Transparency, Market Intelligence, and Risk Prevention

Problem:

Operators, consumers, and authorities cannot easily integrate non-compliance or incident patterns.

Solution(s):

Mandate visual presentation of compliance patterns.

Reference(s):

Article 34, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131;

Implementing Decision (EU) [2019/417](#) (RAPEX), OJ L 73, 15.3.2019, p. 121-187.

Note(s):

The references permit the publication of compliance information in general terms, but do not refer to a specific visualisation.

Multi-annual National Control Plans

Regulatory Function:

Harmonised and Strengthened Enforcement

Problem:

Inconsistent national surveillance leads to gaps in consumer and market protection.

Solution(s):

Mandate multi-annual national control plans, compare and evaluate them.

Reference(s):

Title V (Articles 109 to 115), Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Article 13, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

Control plans like this can also help to balance uneven enforcement across Member States, especially in federal Member States.

Enforcement Database

Regulatory Function:

Coordination of Enforcement

Problem:

Lack of accessible data on which enforcement actions have happened and the results thereof; unnecessary double controls.

Solution(s):

Create an EU-wide database for enforcement actions.

Reference(s):

Article 100, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175

Articles 131 to 134, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

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EU-Wide Registers

Regulatory Function:

Transparency, Oversight, and Enforcement

Problem:

Lack of accessible data for compliance, enforcement, and cross-border operations.

Solution(s):

Mandate creation and/or participation in EU-wide registers/databases for regulated products, service providers or activities.

Reference(s):

Article 33, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

Consider “Digital Passports” as an alternative.

Standardised Procedures for Surveillance and Inspections

Regulatory Function:

Harmonised Enforcement

Problem:

Inconsistent national surveillance leads to gaps in consumer and market protection.

Solution(s):

Define inspections, sampling, and reporting procedures, with EU-level consolidation of results.

Reference(s):

Many Articles and Sections (e.g. Articles 65-70), Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Chapter VII, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

Regulation (EU) [2017/625](#) is most granular.

Border Control of Products

Regulatory Function:

Compliance Verification

Problem:

Once products are inside the EU, they are difficult to control. At the same time, products originating from third countries have a much higher non-compliance rate than EU products.

Solution(s):

Set up a precise border control system, with dedicated own human resources.

Reference(s):

Title II Chapter V Sections II and III, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Article 25, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

Relying on generic border control by customs authorities does not result in the frequent detection of non-compliant products. The first reference is exemplary in that it covers many aspects of border control, including organisational requirements, frequency, and procedures.

Continuous Improvement Obligation

Regulatory Function:

Better Pursuit of Objectives

Problem:

State actors tend to become complacent.

Solution(s):

Oblige them to continuously improve.

Reference(s):

Article 6(10) last subparagraph, Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40, 22.1.2025.

Note(s):

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Minimum Frequency/Number of Checks

Regulatory Function:

Ensuring Effective Enforcement

Problem:

Under-resourced or infrequent checks enable persistent non-compliance.

Solution(s):

Set binding minimum frequency/number of enforcement checks per product group per period.

Reference(s):

Article 54, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Article 11(4), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

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Minimum Enforcement Resources

Regulatory Function:

Ensuring Effective Enforcement

Problem:

Under-resourced or infrequent checks enable persistent non-compliance.
Understaffing is often the root cause thereof.

Solution(s):

Set binding minimum full-time equivalences for enforcement authorities or empower the Commission to set them.

Reference(s):

Article 64(4) (in relation to (3)(a)), Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Article 73(1), Proposal for a Regulation on the marketing of construction products, [COM\(2022\) 144](#) final.

Note(s):

Abstract wording like “sufficient resources” do not suffice in practice as they create too much legal uncertainty. Parameters for setting up minimum resources requirements (full-time equivalents) may include: population of Member States; number of economic actors active towards clients of the Member State or active on its territory; number of product or service types; number of products or service interactions; complexity of the products or services; complexity of the respective legislation; dynamic of technology and markets. Minimum resources requirements should be set up in such a way that staff attributed to a certain task have no other responsibilities.

Enforcement Delegation within Member States

Regulatory Function:

Ensuring Effective Enforcement

Problem:

Under-resourced authorities cannot enforce alone.

Solution(s):

Set rules on delegation of enforcement activities.

Reference(s):

Title II, Chapter III, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

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Artificial Intelligence to Detect Diverging Practice or Infringements

Regulatory Function:

Data-Driven Oversight and Harmonisation

Problem:

Without systematic monitoring, divergences in regulatory/certification practice and infringements go undetected.

Solution(s):

Empower and/or require national authorities, EU agencies or bodies and the Commission to use AI/machine learning to detect interpretive or procedural divergences across Member States and bodies and to detect infringements.

Reference(s):

Article 14(5), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

We did not find any explicit empowerment. However, the reference may be understood as covering the use of artificial intelligence.

Testing Infrastructure (Physical, Artificial Intelligence or other Software)

Regulatory Function:

Enhancing Compliance, facilitating Enforcement

Problem:

Products and processes can be extremely cumbersome or difficult to test, both for operators and authorities.

Solution(s):

Empower EU agencies or bodies and the Commission to develop a testing infrastructure.

Reference(s):

Article 40, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Article 84, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024.

Note(s):

Consider mandating the use of the testing infrastructure.

Mandatory Software, Software Component(s) or Datasets

Regulatory Function:

Enhancing Compliance, facilitating Enforcement, Interoperability, Comparability

Problem:

Compliance, comparability of products or services, interoperability and easy enforcements are often hampered by the use of a variety of software or, in particular in the case of artificial intelligence, of datasets.

Solution(s):

Mandate the use of a certain software, software component or dataset.

Reference(s):

Article 25, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Note(s):

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Notification of Draft National Measures/Deviations

Regulatory Function:

Legal Certainty, Single Market Control

Problem:

Unannounced national deviations fragment the Single Market.

Solution(s):

Require Member States to notify draft measures to the Commission and other Member States prior to adoption.

Reference(s):

Directive (EU) [2015/1535](#) (Information on Technical Regulations), OJ L 241, 17.9.2015, p. 1–15.

Note(s):

“TRIS” system for technical barriers; is also used for digital, environmental, and consumer protection fields.

COM as Arbiter in case of Member States Dissent

Regulatory Function:

Alignment of Member States

Problem:

Member States may have diverging views on concrete matters relevant for various Member States.

Solution(s):

Give the Commission the right to decide in case of diverging views.

Reference(s):

Article 29, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

It is similar to the classic safeguard procedures found in product legislation. It creates an incentive for Member States to reach a compromise among themselves.

National Focal Points and Coordinating Authorities

Regulatory Function:

Efficient Regulatory Management

Problem:

Information flow is inefficient or blocked where roles are unclear at national level.

Solution(s):

Member States must nominate and maintain clear focal points for liaison.

Reference(s):

Article 64, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Particularly important for Federal States.

EU-Wide Rapid Alert Systems

Regulatory Function:

Consumer & Market Protection

Problem:

Delayed risk communication increases harm and market distortion.

Solution(s):

Establish rapid alert IT systems for safety or compliance failures (e.g., SAFETY GATE / RAPEX).

Reference(s):

Article 34, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 34, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131;

Commission Delegated Regulation (EU) [2024/3173](#) (Safety Gate Rapid Alert System), OJ L, 2024/3173, 13.12.2024.

Note(s):

See also the [Rapid Alert System for Food and Feed](#).

EU Joint Investigation Teams

Regulatory Function:

Cross-Border Enforcement

Problem:

Fraud, cheating or risks often cross Member States' borders.

Solution(s):

Empower the creation of joint investigation teams by the EU or with Member States' authorities, with harmonised procedures.

Reference(s):

Article 13, Regulation (EU) [2017/1939](#) (European Public Prosecutor's Office), OJ L 283, 31.10.2017, p. 1–71.

Note(s):

-

Shared Roles and Joint Decision-Making of Authorities Cross-Border

Regulatory Function:

Efficient and Specialised Cross-Member State Regulation

Problem:

Some Member States lack capacity or expertise for specialised sectors.

Solution(s):

Allow authorities of different Member States to share regulatory roles—enabling specialisation and efficiency.

Reference(s):

Article 74, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; Articles 5 and 6, Regulation (EU) [2025/38](#) (Cyber Threats), OJ L, 2025/38, 15.1.2025.

Note(s):

This is useful for any sector requiring pooled expertise. Legalises Malta–Italy, Luxembourg–France and Cyprus–Greece (supposedly slightly parenting)

cooperation, as well as the cooperation of Scandinavian Member States in certain sectors.

Multi-Country Enforcement Operations

Regulatory Function:

Coordinated Crisis Response

Problem:

Fragmented, asynchronised enforcement leaves market gaps.

Solution(s):

EU coordination of planned multi-country investigations, checks or “sweeps”—including reporting and publication.

Reference(s):

Article 32(2)(c), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 30(3)(b) and (d), and Article 32, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

See also the first entry of Chapter P: “Imposing Regional Cooperation”.

Enforcement Assistance among Member States

Regulatory Function:

Pan-EU Enforcement Power

Problem:

Member States do not necessarily enforce in the interest of other Member States.

Solution(s):

Establish procedure and obligation for mutual assistance of enforcement authorities, including the obligation to alert each other.

Reference(s):

Articles 28 to 36, Directive [2006/123/EC](#) (Services Directive), OJ L 376, 27.12.2006, pp. 36–68;

Articles 102 to 108, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Articles 22 to 24, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44. 23;

Article 95, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178.

Note(s):

Could also be used for international cooperation.

Control of Entities active in different Member States

Regulatory Function:

Pan-EU Enforcement Power

Problem:

Some companies and other actors are active in different Member States.

Solution(s):

Establish information sharing and cooperation procedures.

Reference(s):

Annex, Section ARGH.OVS.330, Commission Implementing Regulation (EU) [2025/23](#) (Ground Handling Services Oversight), OJ L, 2025/23.

Note(s):

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Responsibility Collision Rules

Regulatory Function:

Ensuring Effective Enforcement

Problem:

Several Member States might feel responsible or no Member State might feel responsible, namely where an operator is based in a third country.

Solution(s):

Set rules on who is responsible.

Reference(s):

Article 26, Directive (EU) [2022/2555](#) (Cyber Security), OJ L 333, 27.12.2022, p. 80–152.

Note(s):

Other legislation obliges third country operators to nominate an authorised representative from the outset and link the responsibility to its place of business; see Chapter G. But this technique does not close the loophole for EU operators present and active in various Member States and those operators of third countries that do not nominate an authorised representative.

Coordination/Consultation Procedures with Supervisory or Regulatory Agencies

Regulatory Function:

Holistic and Informed Decision-Making

Problem:

Overlapping mandates can cause conflicting directives or gaps in supervision.

Solution(s):

Statutory requirements for coordination and consultation between relevant agencies (at EU or national level) and arbitration mechanisms.

Reference(s):

Article 65, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;
Articles 19 and 20, Regulation (EU) [1093/2010](#) (Banking Authority), OJ L 331,
15.12.2010, p. 12–47.

Note(s):

-

Legal Personality and Independence for Regulatory Agencies

Regulatory Function:

Robust and Impartial Enforcement

Problem:

Bodies tasked with supervision may lack formal legal personality or operational independence. This can create a bottle-neck at the level of the Commission.

Solution(s):

Statute-based grant of legal personality and functional independence.

Reference(s):

Article 1, Regulation (EU) [1093/2010](#) (Banking Authority), OJ L 331, 15.12.2010, p. 12–47.

Note(s):

The opposite issue is even more difficult to handle: Agencies and bodies becoming so powerful that the Commission loses control over them. This is particularly problematic when the agency or body has the power to set rules.

Direct Control and Enforcement by COM

Regulatory Function:

Pan-EU Enforcement Power

Problem:

Member States are not necessarily very performing in terms of control and enforcement.

Solution(s):

Establish a supplementary Commission competence for control and enforcement.

Reference(s):

Articles 116 to 119, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

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Disruption in a Member State's Control System

Regulatory Function:

Regulatory Quality and Efficiency

Problem:

Authorities in Member States lacking human resources or will to enforce EU law.

Solution(s):

Empower the Commission to take compensation or mitigation measures.

Reference(s):

Article 141, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142.

Note(s):

Might also be relevant in the context of emergencies. Consider also the attribution of tasks of the Member State affected by disruption to another Member State, e.g. regarding notified bodies.

Training and Capacity-Building for Authorities

Regulatory Function:

Regulatory Quality and Efficiency

Problem:

Authorities' competence may lag behind policy or market developments.

Solution(s):

Impose continuing training and capacity-building obligations, including for coordinated pan-EU implementation.

Reference(s):

Article 73, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; Inter alia Articles 49(5) and 130, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142, but many more references to “training” spread in the text.

Note(s):

-

Exchanges and “Twinning” Among Member State Authorities

Regulatory Function:

Exchange of Best Practice and Consistency

Problem:

Fragmented national approaches slow down harmonisation.

Solution(s):

Mandate, fund, or encourage structured exchanges and “twinning.”

Reference(s):

Article 130(5), Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017.

Note(s):

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Compliance Cooperation with Other Actors

Regulatory Function:

Compliance and Information

Problem:

Authorities in charge are often too weak to ensure compliance alone.

Solution(s):

Empower or mandate cooperation with public and private institutions, associations etc.

Reference(s):

Article 9, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

-

Sampling of Produced Items or Provided Services

Regulatory Function:

Compliance Verification

Problem:

Even if the technical documentation and the certified or approved type or service are compliant, the items produced or services provided may still be non-compliant.

Solution(s):

Set rules for the systematic and documented sampling of produced items or provided services.

Reference(s):

Annex IX, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 48(13), 88(1), 100(2) and (5), Annex VII Sections 2.3, 3.2, 3.4, 3.5, 3.7, 4.12, 4.13, Annex X Sections 1 and 2, Annex XI Section 5, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332; Title II Chapter IV, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

-

Early Regulatory Dialogue / “Pre-Notification” of Measures

Regulatory Function:

Anticipatory Implementation

Problem:

Operators can be surprised by enforcement measures and might be ready to comply with obligations once informed of the authority’s concerns.

Solution(s):

Duty on authorities to pre-notify compliance concerns prior to taking enforcement measures.

Reference(s):

Article 18(3), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 65, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

-

Serious Incidents / Corrective Actions to Be Notified

Regulatory Function:

Central Learning and Prevention

Problem:

Repeated mistakes or hazards go undetected unless reported and evaluated centrally.

Solution(s):

Obligation of economic operators and certification bodies to notify the authorities of serious incidents and recalls.

Reference(s):

Articles 87-89 and 92, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 20(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

-

Certification Bodies to Report on Infringements

Regulatory Function:

Better Information of Authorities

Problem:

Authorities are not necessarily aware of infringements committed by operators.

Solution(s):

Mandate certification bodies to report on infringements they happen to observe.

Reference(s):

Article 56(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

-

Model Forms, Templates, and IT Tools

Regulatory Function:

Uniformity and Efficiency

Problem:

Variation in reporting or documentation increases burden and confusion.

Solution(s):

Mandatory use or EU-level endorsement of forms, templates or digital tools for reporting and declaration.

Reference(s):

Article 34(7) and (8), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Annex V, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Aids interoperability, multilingualism, and data quality.

Enforcement Funding and Cost Recovery

Regulatory Function:

Resourcing Enforcement

Problem:

Underfunded authorities cannot carry out effective enforcement or surveillance. Understaffing is to be observed in many small Member States, but not only in small Member States.

Solution(s):

Rules on how costs may be recovered from non-compliant actors, market fees, or earmarked public funding. Minimum human resources requirements to be set up by the Commission.

Reference(s):

Article 69, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; and Articles 73(2) and 75 of its proposal [COM\(2022\) 144](#) final;

Article 43, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102;

Articles 79 to 84, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

Can also be used to finance EU institutions or bodies, see the second reference.

Definition of Technical Protocols and Test Methods

Regulatory Function:

Adaptive and Future-Proof Norms

Problem:

Technical methods/protocols need to evolve with science and practice.

Solution(s):

Empower Commission (or agencies) to specify protocols and standards via delegated/implementing acts, regularly updated.

Reference(s):

Articles 5(3) and 39, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1.

Note(s):

-

Prevention of Test Cheating

Regulatory Function:

Legal Certainty, Fairness and Enforcement

Problem:

Operators tend to interpret provisions on testing in their own, not necessarily intended way. Operators sometimes try to cheat.

Solution(s):

Ban certain behaviours or measures related to tests.

Reference(s):

Article 40, Regulation (EU) [2024/1781](#) (Eco-design for Sustainable Products), OJ L 1781, 28.6.2024, p. 1.

Note(s):

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Testing Laboratories' Equipment and Procedures

Regulatory Function:

Reliability and Comparability of Test Results

Problem:

Inadequately equipped or biased labs can undermine regulatory confidence.

Solution(s):

Set minimum technical requirements and quality assurance/traceability for test laboratories.

Reference(s):

Article 100(4) and (8), Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332.

Note(s):

Consider reference to EN ISO 17065.

European Reference Laboratories

Regulatory Function:

Benchmarking and Consistency of Testing

Problem:

Fragmented or inconsistent testing undermines market confidence and fairness. The more laboratories are active in a certain sector, the more methodological divergence can be observed. Moreover, the knowledge and expertise is fragmented where there are many laboratories.

Solution(s):

Designate a limited number of European Reference Laboratories to provide highest-level comparative testing and arbitration.

Reference(s):

Article 100, Regulation (EU) [2017/746](#) (In Vitro Diagnostic Medical Devices), OJ L 117, 5.5.2017, p. 176–332.

Note(s):

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Contact Points/Digital Gateways

Regulatory Function:

Market Access Assistance and Support

Problem:

SMEs and cross-border operators struggle to obtain reliable information on national provisions.

Solution(s):

Member States provide fully accessible product contact points and digital “one-stop-shops”.

Reference(s):

Article 72, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110; Regulation (EU) [2018/1724](#) (Single Digital Gateway), OJ L 295, 21.11.2018, p. 1–38.

Note(s):

-

Social Partners in Regulatory Committees

Regulatory Function:

Inclusive and Balanced Governance

Problem:

Labour, employer and civil society interests need structured voices alongside technical authority.

Solution(s):

Mandate participation rights for social partners in formal and advisory committees.

Reference(s):

Articles 152, 154 and 155, Treaty on the Functioning of the European Union ([TFEU](#)), OJ C 202, 7.6.2016, p. 47-199;

Council Decision [2003/C 218/01](#) (Advisory Committee on Safety and Health at Work), OJ C 218, 13.9.2003, p. 1-4;

Article 17(1)(d), Regulation (EU) [2019/1149](#) (European Labour Authority), OJ L 186, 11.7.2019, p. 21-56.

Note(s):

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Information-Sharing among Certification Bodies and Authorities (Obligations and Empowerments)

Regulatory Function:

Cross-Border Consistency and Quality Control

Problem:

Certification done in isolation increases duplication and non-uniformity.

Solution(s):

Impose and empower detailed information-sharing mechanisms among certification bodies and authorities at EU and national level.

Reference(s):

Articles 56 and 65(1) last subpara, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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EU-Wide Training / Learning for Practitioners

Regulatory Function:

Institutional Learning and Upkeep

Problem:

Diverse administrative cultures and knowledge levels can lead to uneven enforcement and misinterpretation.

Solution(s):

Impose a legal obligation for the Commission and/or national competent authorities to organise regular training, joint learning opportunities, and practitioner exchanges targeting consistent, high-quality implementation.

Reference(s):

Article 73, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;
Article 130, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142.

Note(s):

Can be extended to reference laboratories.

Mandating Good Administrative Practices

Regulatory Function:

Fairness, Efficiency and Compliance

Problem:

Administrations do not always behave in a fair and efficient way.

Solution(s):

Mandate the respect of good administrative practice (codes).

Reference(s):

Article 99, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

-

Capping of Compliance Costs

Regulatory Function:

Market Fairness and Access

Problem:

High prices for compliance procedures, standards or technical documents act as barriers to compliance.

Solution(s):

Set legal maximum prices for essential procedures or standards/documents to ensure all actors can comply.

Reference(s):

Articles 3 and 4, Regulation (EU) [2015/751](#) (Card-based Payments), OJ L 123, 19.5.2015, pp. 1–15.

Note(s):

See also the obligation to make notified bodies' fees transparent in Article 50 Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Incentives/Prizes for Voluntary Over-Compliance, Innovation, or Social Good

Regulatory Function:

Promoting Exceedance of Minimum Standards

Problem:

Minimum compliance does not reward extra effort or innovator-early adopters.

Solution(s):

Recognition schemes, simplified procedures, or reduced audits for documented superior performance.

Reference(s):

Article 50(11), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40 (exemption of Annex X where the 90% goal is reached before deadline);

Article 82, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 43, Regulation (EU) [2021/695](#) (Horizon Europe), OJ L 170, 12.5.2021, p. 1–68.

Note(s):

See also the Section on incentives in our [Handbook “How to regulate?”](#).

See also the first two entries of Section P and the first three entries of the following Section K.

K. Enforcement Powers

Proactive Surveillance and Own-Initiative Audits

Regulatory Function:

Risk Detection and Preventive Action

Problem:

Authorities previously acted almost solely on complaints or “signals”.

Solution(s):

Legal basis for authorities to conduct surveillance or audits without exogenous triggers.

Reference(s):

Article 11(3), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 32(2), Directive (EU) [2022/2555](#) (Cyber Security), OJ L 333, 27.12.2022, p. 80–152.

Note(s):

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“Stress Tests” and Real-Time Audits

Regulatory Function:

Risk Detection and Preventive Action

Problem:

Paper compliance may miss vulnerabilities; only real-world tests expose failures.

Solution(s):

Empower/require authorities to commission or perform stress tests and real-time (“live”) audits.

Reference(s):

Article 76, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024;

Article 44(5), Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 18, Directive (EU) [2022/2557](#) (Resilience of Critical Entities), OJ L 333, 27.12.2022, p. 164–197.

Note(s):

-

Authority to Test as Client (e.g. Mystery Shopping)

Regulatory Function:

Real-World Compliance Checks

Problem:

Manufacturers or sellers might present compliant samples to authorities while offering different (non-compliant) products on the market. Services and other processes might be executed with less care when no inspection is expected.

Solution(s):

Grant explicit power to authorities to carry out tests as clients—including covert or “mystery shopping”—to verify real-world compliance.

Reference(s):

Article 14(4)(j), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

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Proportional/Graduated Enforcement Toolkit / Comprehensive Empowerment Catalogue

Regulatory Function:

Proportional Enforcement and Deterrence

Problem:

Rigid enforcement can be unfair or unworkable. Effective enforcement depends on having powers to act appropriately in all situations of non-compliance.

Solution(s):

Legally set out a range of enforcement actions—from warnings to fines, recalls and withdrawals—matched to risk/gravity. Establish a comprehensive catalogue of empowerments.

Reference(s):

Articles 94, 103 and 104, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178;

Articles 65-68 and 138, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142;

Articles 57 and 58, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Articles 14 and 16, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44;

Article 74, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024;

Article 22(4) and (5), Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

See also our “[List of Powers and Obligations](#)” with several hundred empowerments useful for enforcement.

Layered Administrative, Civil, Criminal Enforcement

Regulatory Function:

Proportionate and Effective Enforcement

Problem:

One channel of enforcement may be too weak or inflexible.

Solution(s):

Enable various pathways (administrative, civil, criminal) for different levels of breach, defined by law.

Reference(s):

Article 6 for civil liability, other articles for penal responsibility, Directive (EU) [2024/1203](#) (Environmental Crime), OJ L, 2024/1203, 30.4.2024;

See the references of the previous entry for administrative measures.

Note(s):

See also our “[List of Powers and Obligations](#)” with several hundred empowerments useful for enforcement and the parallel “[List of Sanctions and Collateral Measures](#)”.

Targeted Information Interventions by Authorities

Regulatory Function:

Tailored Risk Communication

Problem:

Generic warnings are ignored or misunderstood.

Solution(s):

Allow for special, sectoral, or real-time targeted warnings issued via regulatory platforms or media.

Reference(s):

Article 33(1), Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

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“Blacklisting” and “Shaming” of Persons or Businesses

Regulatory Function:

Effective Sanctions, Prevention of future Non-compliance

Problem:

Ordinary sanctions might not suffice to deter effectively.

Solution(s):

Explicit exclusion mechanisms or “blacklisting” or “shaming” in public databases.

Reference(s):

Article 83, Regulation (EU) [2021/23](#) (Recovery and Resolution of Central Counterparties), OJ L 22, 22.1.2021, pp. 1–102;

Article 59(2)(a), Directive (EU) [2015/849](#) (Terrorism and Money-Laundering), OJ L 141, 5.6.2015, S. 73-117;

Articles 135-137, Regulation (EU, Euratom) [2018/1046](#) (Financial Regulations), OJ L 193, 30.7.2018, S. 1-222;

Articles 84 and 85, Directive (EU) [2025/1](#) (Recovery and Resolution of Insurances), OJ L, 2025/1, 8.1.2025.

Note(s):

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Blocking Access to Non-Compliant Products or Services

Regulatory Function:

Effectiveness in the Digital Economy

Problem:

Authorities lack the ability to block access to illegal products or services online.

Solution(s):

Give powers for temporary or permanent digital blocking, subject to proportional safeguards.

Reference(s):

Article 9, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

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Market Withdrawal Notification to Users/Consumers

Regulatory Function:

Cross-Border Consumer Protection

Problem:

Limited language coverage and variable formats can lead to missed or misunderstood safety recalls.

Solution(s):

Procedural, language and format requirement for multilingual recall/withdrawal notifications.

Reference(s):

Articles 35 and 36, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

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Coordinated Market Withdrawal or Remediation Measures (“Union Safeguard Procedure”)

Regulatory Function:

Pan-EU Protective Action

Problem:

Ineffective or uncoordinated actions can leave risks in the market or duplicate removal efforts.

Solution(s):

Enshrine a Union-wide notification, consultation, and decision procedure for serious safety or compliance risk responses, with automatic extension to the Union in case of non-objection by Member States.

Reference(s):

Article 65-67, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

See also the next entry which contains further refinements.

Coherent Handling of Risky or Non-compliant Products or Services across EU

Regulatory Function:

Enhancing Compliance, Countering Risks

Problem:

Measures taken in one Member State need to be replicated, if justified, in other Member States. The distinction between products/services presenting a risk and those being non-compliant can be tricky. The burden of proof is on the side of the authorities wherefore they often do not dare to act.

Solution(s):

To reduce the difficulty of proof, extend the procedure for risky products/services to products/services for which there was a serious incident. Align the procedures

for the two cases so that risk and non-compliance can be processed in the same procedure or two totally parallel procedures.

Reference(s):

Articles 44-46, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Note(s):

The reference is better than any other we found, but does not make the last step: merger of the two procedures into one. Please contact us if you are interested in obtaining a draft for a merged procedure.

See also Article 102, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178. This Article deals only with the coordination of two Member States, but also reduces the burden of proof in its first paragraph (“suspecting”).

Authorities to Inform Bodies of Non-Compliant or Risky Products

Regulatory Function:

Feedback Loops for Certification Improvement

Problem:

Certification bodies may not be alerted to recurring or systemic non-conformities or risks in their certified products.

Solution(s):

Where non-compliance/risk is found, market surveillance authorities must inform relevant certification bodies.

Reference(s):

Article 65(1), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Powers for “Recall” of Digital Content or Correction of Published Errors

Regulatory Function:

Digital Era Consumer/Market Protection

Problem:

Unlawful, misleading, or dangerous digital content can spread rapidly with lasting damage.

Solution(s):

Statute-based power for authorities to order removal or correction of digital content or services.

Reference(s):

Article 9, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

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Power to Impose Corrective Advertising / Publication

Regulatory Function:

Remedying the Effects of Misleading Actions

Problem:

Consumers or businesses may have been misled or harmed by non-compliant marketing or claims.

Solution(s):

Express power for authorities to require corrective advertising or notices to reach affected audiences.

Reference(s):

Article 11(2) last subpara, Directive [2005/29/EC](#) (Unfair Commercial Practices), OJ L 149, 11.6.2005, p. 22–39.

Note(s):

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Economic Powers Catalogue

Regulatory Function:

Enforcement Ensurance in Complex or Difficult Business Settings and (Threat of) Insolvency

Problem:

Enforcement is difficult or impossible where the targeted operator is in a complex or difficult business setting or even under threat of insolvency.

Solution(s):

Select some of the powers from the reference.

Reference(s):

Chapter IV, Regulation (EU) [2021/23](#) (Recovery and Resolution of Central Counterparties), OJ L 22, 22.1.2021, pp. 1–102;

Article 15(5) and Title III (in particular Chapter IV), Directive (EU) [2025/1](#) (Recovery and Resolution of Insurances), OJ L, 2025/1, 8.1.2025.

Note(s):

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Fees, Charges, Cost-Sharing for Regulatory Services

Regulatory Function:

Fair and Effective Resourcing

Problem:

Regulation is hampered if costs fall solely on the public purse or are distributed unfairly.

Solution(s):

Set transparent rules for levying fees for approvals, surveillance, or market controls.

Reference(s):

Title II Chapter VI and Article 138(4), Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, p. 1–142;

Article 111, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 15, Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

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Measures targeting Company Groups

Regulatory Function:

Efficiency of Enforcement, Risk Reduction

Problem:

Deficiencies and risks are often spreading over several companies belonging to the same group (covering at least all mother, daughter or sister companies).

Solution(s):

Introduce empowerments to act against an entire company group on the basis of a presumed non-compliance or risk.

Reference(s):

Articles 10, 11, 14, 16 and 17 and Title IV, Directive (EU) [2025/1](#) (Recovery and Resolution of Insurances), OJ L, 2025/1, 8.1.2025.

Note(s):

If there was a full proof of non-compliance or risk, this specific empowerment would not be needed. See in particular the complex joint decision-making mechanism in Title IV.

Precise Delegation for Enforcement Powers

Regulatory Function:

Strengthening Enforcement and institutional balancing

Problem:

Vague or excessive delegation may bypass checks and balances.

Solution(s):

Explicitly define what may / may not be delegated, with limits and procedures for subdelegation.

Reference(s):

Articles 15(6), 18(10), 19(4), 20(4), 21(7), 22(4), 24(5), 26(1) and (4) and Title II Chapter III, Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

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Criteria for Selection of Enforcement or Sanctions

Regulatory Function:

Fairness and Effectiveness of Enforcement and Sanctions

Problem:

Authorities do not necessarily select fair and effective enforcement measures or sanctions.

Solution(s):

List criteria for the selection of measures.

Reference(s):

Article 32(7), Directive (EU) [2022/2555](#) (Cyber Security), OJ L 333, 27.12.2022, p. 80–152.

Note(s):

See also the entry “Penalty Regime with Proportionality and Discretion” below.

Sanctions for Failure to Cooperate with Authorities

Regulatory Function:

Enforcement and Deterrence

Problem:

Operators concerned, but also their partners, clients and employees may simply refuse to cooperate with market surveillance or investigation.

Solution(s):

Express penalties for non-cooperation, especially where information or access is legally required.

Reference(s):

Article 59(1)(b), Directive (EU) [2015/849](#) (Terrorism and Money-Laundering), OJ L 141, 5.6.2015, S. 73-117;

Article 23(1)(a), Council Regulation (EC) [No 1/2003](#) (Rules on Competition), OJ L 1, 4.1.2003, S. 1-25.

Note(s):

-

Power to Define Methods for Calculating Fines

Regulatory Function:

Legal Certainty and Predictability for Penalties

Problem:

Arbitrary or excessive fines undermine legitimacy and may be challenged.

Solution(s):

Entrust Commission (or national bodies) with establishing harmonised fine-calculation methods.

Reference(s):

Article 83, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

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Complete Penal System— including Whistleblower and Witness Protection

Regulatory Function:

Enhancing enforcement, harmonising too diverging penal practices

Problem:

The current default wording in EU law regarding sanctions leads to a wide variety of national provisions and an even more diverse practice. The deterring effect of sanctions is undermined by the possibility of operating from more lenient Member States.

Solution(s):

Establish a complete system of penal and other sanctions, as well as protection, support and rewards for whistle-blowers and witnesses.

Reference(s):

Directive (EU) [2024/1203](#) (Environmental Crime), OJ L, 2024/1203, 30.4.2024 and its Proposal [COM/2021/851 final](#).

Note(s):

Recent DG JUST proposals follow this excellent example. See also our "[List of Sanctions and Collateral Measures](#)". Regarding the protection of whistle-blowers and witnesses: Directive (EU) [2019/1937](#) contains loopholes. See our

“[Cross-sectoral Standard Provisions](#)”, Sections 68 to 70, and our [articles on whistleblower protection](#).

Administrative and Collateral Sanction Package

Regulatory Function:

Enhancing enforcement, harmonising too diverging penal practices

Problem:

The current default wording in EU law regarding sanctions does not really target legal persons.

Solution(s):

Establish a complete system of administrative and collateral sanctions that includes, inter alia, the following: public statements on infringements; administrative fines of at least twice the profit made or loss avoided; maximum administrative fines of at least X % of the annual turn-over, including the turn-over of mother or daughter companies; disgorgement of the profits gained or losses avoided due to the infringement; withdrawal or suspension of the authorisations; temporary ban preventing any member of the management body of the crypto-asset service provider, or any other natural person who is held responsible for the infringement, from exercising management functions.

Reference(s):

Article 111, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178.

Note(s):

See also our much more complete “[List of Sanctions and Collateral Measures](#)”.

Penalty Regime with Proportionality and Discretion

Regulatory Function:

Effective Deterrence

Problem:

Unreasonably harsh or fixed penalties can discourage compliance or distort competition.

Solution(s):

Set criteria for the proportionality of fines/sanctions, possibly with escalation scales.

Reference(s):

Directive (EU) [2024/1203](#) (Environmental Crime), OJ L, 2024/1203, 30.4.2024; Article 83, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

-

Precise Catalog of Infringements

Regulatory Function:

Legal Certainty and Fairness

Problem:

In practice, it is often disputed whether a certain behaviour constitutes an infringement or not.

Solution(s):

Precise catalog defining infringements.

Reference(s):

Annex X, Proposal for a European Space Act, [COM\(2025\) 335](#) final.

Note(s):

-

Ban on Double Penalties by different Member States

Regulatory Function:

Legal Certainty and Fairness

Problem:

Operators risk cumulative sanctions in multiple Member States for the same factual breach.

Solution(s):

Legal protection against double sanctions (“ne bis in idem”) for single-subject enforcement.

Reference(s):

Article 50, [Charter of Fundamental Rights of the EU](#), OJ C 326, 26.10.2012, p. 391–407;

Article 56, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88 (One-Stop-Shop, applies also to sanctions);

Article 25(2)(c), [Regulation \(EU\) No 596/2014](#) (Market Abuse), OJ L 173, 12.6.2014, S. 1-61.

Note(s):

None of the references is a perfect match. The second comes closest.

See also our “[List of Powers and Obligations](#)” with several hundred empowerments useful for enforcement and the parallel “[List of Sanctions and Collateral Measures](#)”.

L. Third-Party Enforcement Assistance

Right to Comment in Procedures and Public Registers

Regulatory Function:

Transparency and Broad Information Base

Problem:

Public procedures and public registers may have a sub-optimal information base.

Solution(s):

Right to comment, reply, annotate, or supply evidence to procedures and entries in official registers.

Reference(s):

Articles 9 to 12, Regulation [1367/2006](#) (Aarhus Convention), OJ L 264, 25.9.2006, S. 13-19;

Article 34, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, pp. 1–51;

Have-your-say-portal of the European Commission.

Note(s):

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Public Complaint and Whistleblower Mechanisms

Regulatory Function:

Integrity of Enforcement and Compliance

Problem:

Regulators may miss breaches without inside or third-party reporting systems.

Solution(s):

Impose robust complaint procedures and protect/reporting structures (including whistleblower protection).

Reference(s):

Chapter III, Directive (EU) [2019/1937](#) (Whistleblowing Directive), OJ L 305, 26.11.2019, p. 17–56;

Article 67, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016;

Article 63, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

Directive (EU) [2019/1937](#) contains loopholes. See our "[Cross-sectoral Standard Provisions](#)", Sections 68 to 70, and our [articles on whistleblower protection](#).

Protection of Informants / Whistleblowers /

Witnesses

Regulatory Function:

Integrity and Detection

Problem:

Potential informants and witnesses fear retribution, limiting the detection of wrongdoing.

Solution(s):

Comprehensive sectoral and cross-sectoral whistleblower and witness protection statutes.

Reference(s):

Directive (EU) [2019/1937](#) (Whistleblower Protection), OJ L 305, 26.11.2019, p. 17–56.

Note(s):

Directive (EU) [2019/1937](#) contains loopholes. See our “[Cross-sectoral Standard Provisions](#)”, Sections 68 to 70, and our [articles on whistleblower protection](#).

EU Complaint Portal with Re-routing

Regulatory Function:

Streamlined Market Intelligence and Redress

Problem:

Fragmented complaints handling creates blind spots for enforcement.

Solution(s):

Establish an EU-level portal for complaints, with automated routing to responsible national authorities—except when the complaint concerns that authority.

Reference(s):

Article 63, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Right—and Obligation (in Serious Risk)—to Inform Authorities of Infringements by Others

Regulatory Function:

Peer-Controlled Market Supervision

Problem:

Operators may have knowledge of competitor wrongdoing, but no route or obligation to notify.

Solution(s):

Right for operators to inform authorities about presumed infringements by others, and mandatory duty to do so when serious risks are identified.

Reference(s):

Article 20(6), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Actors to Inform on Suspected Criminal Acts

Regulatory Function:

Preventing and Countering Criminality

Problem:

Authorities rarely become aware of criminal acts.

Solution(s):

Oblige (economic) actors to report on suspected criminal acts.

Reference(s):

Article 18, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

Can be extended to severe non-conformities. However, when extended to all non-conformities, the authorities might obtain too many notices.

Trusted Flaggers to Inform on Suspected Non-conformities / Filtering Non-compliance Notices

Regulatory Function:

Preventing and Countering Non-conformities

Problem:

Authorities rarely become aware of non-conformities, but risk becoming flooded with low-quality notices if anybody was to report.

Solution(s):

Establish a Trusted Flaggers system in which the Trusted Flaggers filter the notices coming from non-experts.

Reference(s):

Article 22, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

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Third-Party Rights (Standing) in Regulatory Appeals

Regulatory Function:

Access to Justice and better enforcement

Problem:

Only directly regulated companies often have formal standing in regulatory challenges and at court, whilst authorities do not have the administrative capacities to address all non-compliances.

Solution(s):

Legally enable broader third-party participation (competitors, NGOs, affected parties) in appeals and reviews. Authorise third-parties to sue non-compliant actors at court for injunction, repair and compensation.

Reference(s):

Article 11, Directive [2011/92/EU](#) (Environmental Impact Assessment), OJ L 26, 28.1.2012, p. 1–21;

Article 80, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016.

Note(s):

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Invalidity Clauses for Contravening Private Acts

Regulatory Function:

Opens access to private law courts, indirectly supporting enforcement

Problem:

Rules/decisions adopted in breach of the applicable Regulation/Directive could otherwise cause confusion.

Solution(s):

Legal provision annulling actions taken in breach (e.g., without procedure or out-of-scope).

Reference(s):

Article 25, Directive [2011/83/EU](#) (Consumer Rights), OJ L 304, 22.11.2011, S. 64-88.

Note(s):

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See also the first entry of the next Section M.

M. Dispute Resolution and Appeals

Third Party Standing and Representation Rules

Regulatory Function:

Access to Justice, Access to Procedures

Problem:

Public authorities lack resources for enforcement. Individuals may be unable to enforce rights where collective action is essential.

Solution(s):

Define which organisations/groups can represent the public interest or claimants collectively in court or administrative procedures. Permit and encourage private natural and legal persons to use administrative and court procedures to counter infringements of the law.

Reference(s):

Articles 9 to 12, Regulation [1367/2006](#) (Aarhus Convention), OJ L 264, 25.9.2006, S. 13-19;

Article 4, Directive (EU) 2020/1828 (Collective Interests of Consumers), OJ L 409, 4.12.2020, p. 1–27.

Note(s):

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Transparency regarding Appeals

Regulatory Function:

Access to Justice

Problem:

Individuals and NGOs cannot contribute to appeals when they are not aware of them.

Solution(s):

Institutions and bodies to publish all requests for internal reviews or appeals, and final decisions online.

Reference(s):

Article 11a, Regulation [1367/2006](#) (Aarhus Convention), OJ L 264, 25.9.2006, S. 13-19.

Note(s):

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Right to be Heard prior to Adverse Decisions

Regulatory Function:

Procedural Rights and Good Administration

Problem:

Operators should be able to present their case and defend themselves before sanctions or adverse decisions.

Solution(s):

Oblige authorities to hear affected parties and provide reasons for decisions.

Reference(s):

Article 41, [Charter of Fundamental Rights of the European Union](#), OJ C 326, 26.10.2012, p. 391–407;

Article 18(3), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

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Central Oversight or Appeals Bodies

Regulatory Function:

Consistency and Judicial Review

Problem:

Decisions by notified/accredited bodies or national authorities may be inconsistent or challenged as arbitrary.

Solution(s):

Set up EU-level or cross-country appeals/oversight bodies.

Reference(s):

The "[Board of Appeal](#)", a joint body of the European Banking Authority (EBA), the European Insurance and Occupational Pensions Authority (EIOPA) and the European Securities and Markets Authority (ESMA), collectively known as the three European Supervisory Authorities (ESAs).

Note(s):

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Ex ante Judicial Approval

Regulatory Function:

Legal Protection, Reliability and Stability of Decisions

Problem:

Administrative decisions are often reversed by later judicial decisions. This creates important damage and reduces trust in the state's action.

Solution(s):

Permit or mandate ex ante judicial approval.

Reference(s):

Article 67(1), Directive (EU) [2025/1](#) (Recovery and Resolution of Insurances), OJ L, 2025/1, 8.1.2025.

Note(s):

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Reverse Burden of Proof

Regulatory Function:

Effective Redress

Problem:

Injured parties struggle to prove complex or hidden harms.

Solution(s):

Statutory presumption of liability/reversing burden where required for justice (e.g., product liability).

Reference(s):

Article 10, Directive (EU) [2024/2853](#) (Product Liability), OJ L, 2024/2853, 18.11.2024.

Note(s):

-

Victim/Complainant Assistance Provisions

Regulatory Function:

Access to Redress

Problem:

Users, consumers, or affected parties struggle to pursue claims or protections in complex sectors.

Solution(s):

Require authorities or market actors to provide independent helpdesks, legal support, or compensation schemes.

Reference(s):

Article 14, Directive [2013/11/EU](#) (Alternative Dispute Resolution for Consumers), OJ L 165, 18.6.2013, p. 63–79;

Articles 10 and 12, Directive (EU) [2020/1828](#) (Collective Redress), OJ L 409, 4.12.2020, p. 1–27.

Note(s):

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Representation of Victims/Claimants by NGOs

Regulatory Function:

Protection of Rights

Problem:

Individuals have difficulties in defending their rights, whilst lawyers are expensive.

Solution(s):

Allow legal representation by non-profit organisations.

Reference(s):

Article 101, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Note(s):

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Alternative Dispute Resolution (ADR) Pathways

Regulatory Function:

Efficient Resolution of Market and Consumer Disputes

Problem:

Judicial litigation is lengthy and costly for SMEs and end users.

Solution(s):

Commission or Member States mandate, facilitate, or operate ADR/mediation as an option or obligation prior to judicial litigation.

Reference(s):

Directive [2013/11/EU](#) (Alternative Dispute Resolution for Consumers), OJ L 165,

18.6.2013, p. 63–79;

Regulation (EU) [524/2013](#) (Online Dispute Resolution for Consumers), OJ L 165, 18.6.2013, p. 1–12;

Article 21, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

-

N. Data, Information and Artificial Intelligence

Access to Own File within Administration

Regulatory Function:

Transparency and Fairness

Problem:

During investigations and the preparation of authority measures, persons concerned are mostly left in the dark. Hence they cannot properly defend themselves. Moreover, they cannot provide crucial information that would probably even stop the investigation or the preparation of authority measures. This leads to a waste of resources on the side of the authority.

Solution(s):

Mandatory release of investigative files on request, with protection of the identity of informants.

Reference(s):

Article 5, Regulation (EU) [2025/1355](#) (Systemically Important Payment Systems), OJ L, 2025/1355.

Note(s):

Not appropriate for all sectors or matters. Beware of the repercussions on the informants.

Open Data and Access to Public Sector Information

Regulatory Function:

Transparency and Reusability

Problem:

Restrictive or paywalled access to public data stifles innovation and accountability.

Solution(s):

Mandatory proactive release of public sector data and digital accessibility under open licences.

Reference(s):

Directive (EU) [2019/1024](#) (Open Data), OJ L 172, 26.6.2019, p. 56–83.

Note(s):

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Retention and Deletion of Data

Regulatory Function:

Privacy and Data Protection

Problem:

Unrestricted retention increases risks to privacy and unnecessary regulatory burden.

Solution(s):

Specify strict rules for the periods for which data may/must be retained and when it must be deleted.

Reference(s):

Articles 5(1)(b) and (e) and 17, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 20(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Right to Correct Data in Official Databases

Regulatory Function:

Accuracy, Correction, and Fairness

Problem:

Inaccurate database entries can cause market exclusion or legal issues.

Solution(s):

Statutory right of concerned operators to correct or contest official regulatory database entries.

Reference(s):

Articles 5(1)(c) and (d) and 16, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88.

Note(s):

For further rights of individuals regarding data, see Chapter II Section 1, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Data Portability and Interoperability

Regulatory Function:

Switching, Competition, and User Rights in Digital Markets

Problem:

Closed systems lock users into providers and hamper competition.

Solution(s):

Legal right to receive and transfer data between systems, and mandates for technical interoperability.

Reference(s):

Article 20, Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Articles 4 and 6, Regulation (EU) [2018/1807](#) (Free Flow of Non-personal Data), OJ L 303, 28.11.2018, p. 59–68.

Note(s):

For further rights of individuals regarding data, see Chapter II Section 1, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Transparency Requirements for Algorithmic Systems

Regulatory Function:

Accountability in Automated Decision-Making

Problem:

Algorithms create risks of bias, error, or unfairness whilst the use of algorithms is often even not known.

Solution(s):

Mandate clear disclosure of (1) use of automated systems and (2) automated systems' logic, criteria, and operation, especially where affecting rights or access to services.

Reference(s):

Articles 13(2)(f), 14(2)(g), Regulation (EU) [2016/679](#) (Data Protection), OJ L 119, 4.5.2016, p. 1–88;

Article 13, Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 12.7.2024, p. 1–225.

Note(s):

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Right to Human Review of Automated Decisions

Regulatory Function:

Redress for Individuals

Problem:

Automated rejection or profiling can harm individuals without transparency or recourse.

Solution(s):

Require clear explanation and avenue for human review of significant automated decisions.

Reference(s):

Article 14, in particular (4)(d), Regulation (EU) [2024/1689](#) (Artificial Intelligence), OJ L, 2024/1689, 12.7.2024.

Note(s):

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Prohibition of “Dark Patterns” in Digital Interfaces

Regulatory Function:

Upholding Fairness in Digital Markets

Problem:

Manipulative digital design tricks (“dark patterns”) undermine user autonomy and trust.

Solution(s):

Statutory prohibition and definition, with monitoring duties for platforms.

Reference(s):

Articles 25-27, Regulation (EU) [2022/2065](#) (Digital Services), OJ L 277, 27.10.2022, p. 1–102.

Note(s):

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Protection of “Know-How” and Trade Secrets

Regulatory Function:

Commercial Confidentiality

Problem:

Assessment procedures may force companies to reveal confidential innovation or trade secrets.

Solution(s):

Mandatory protections and secure handling arrangements for confidential business information during regulatory assessment and publication.

Reference(s):

Article 32(2)(b), Annex VI Section 1, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Directive (EU) [2016/943](#) (Trade Secrets), OJ L 157, 15.6.2016, p. 1–18.

Note(s):

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For other aspects regarding data, please check the quite progressive and comprehensive Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

O. Emergencies

Power for Emergency/Provisional Measures

Regulatory Function:

Risk Management and Crisis Response

Problem:

Standard procedures are too slow for urgent threats, and powers not necessarily sufficient.

Solution(s):

Allow the European Commission and/or other authorities to set emergency, time-limited measures, also with regard to legal requirements.

Reference(s):

Articles 85 to 88, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Rapid Regulatory Adaptation via Emergency / Temporary Delegated Acts

Regulatory Function:

Short-term, Targeted Crisis Response

Problem:

Full legislative revision is too slow to address fast-moving emergencies or innovation shocks.

Solution(s):

Commission empowered to adopt temporary or emergency delegated acts subject to review/expiry.

Reference(s):

Article 13, Regulation (EU) [2021/953](#) (Digital COVID Certificate), OJ L 211, 15.6.2021, p. 1–22.

Note(s):

-

Periodic Disaster Risk Assessment, Exercise or Audit

Regulatory Function:

Preparedness and Resilience

Problem:

Crisis laws are untested until a real event, risking failure.

Solution(s):

Require risk assessments, simulation exercises or external audits of emergency regulatory and coordination procedures.

Reference(s):

Article 12, Directive (EU) [2022/2557](#) (Resilience of Critical Entities), OJ L 333, 27.12.2022, p. 164–197;

Article 8, Regulation (EU) [2022/2371](#) (Health Threats), OJ L 320, 22.12.2022, p. 1–86.

Note(s):

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Temporary Legal Derogation During Crisis

Regulatory Function:

Flexible Market Stability Management

Problem:

Sudden supply chain or health crises require extraordinary regulatory steps.

Solution(s):

Time-limited derogations for essential goods/services, subject to reporting and review.

Reference(s):

Articles 12 and 25, Regulation (EU) [2022/2371](#) (Health Threats), OJ L 320, 22.12.2022, p. 1–86.

Article 1a, [Council Mandate for Negotiations](#) regarding the proposed Regulation on Medicinal Products for Human Use.

Note(s):

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Safeguard Regimes for “Critical” Infrastructure, Institutions, Enterprises or other Actors

Regulatory Function:

Resilience and Special Risk Mitigation

Problem:

Generic rules may not address risks/vulnerabilities for critical infrastructure.

Solution(s):

Dedicated safeguard regimes, with enhanced obligations, oversight, and reporting.

Reference(s):

Directive (EU) [2022/2557](#) (Resilience of Critical Entities), OJ L 333, 27.12.2022, p. 164–197.

Note(s):

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P. Financial Implementation and General Planning

Imposing Regional Cooperation

Regulatory Function:

Increasing Efficiency

Problem:

Member States planning on their own without consulting their neighbors miss efficiency opportunities.

Solution(s):

Mandate regional cooperation of Member States.

Reference(s):

Article 12, Regulation (EU) [2018/1999](#) (Energy Union Governance), OJ L 328, 21.12.2018, p. 1–77.

Note(s):

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Multiannual Programming/Planning Obligations (e.g., in Funding or Implementation)

Regulatory Function:

Stability and Predictability

Problem:

Stop-start annual planning undermines longer-term regulatory, funding, or supply stability.

Solution(s):

Mandate multiannual implementation and funding plans, with review/update requirements.

Reference(s):

Article 3, Regulation (EU) [2018/1999](#) (Energy Union Governance), OJ L 328, 21.12.2018, p. 1–77;

Title V (Articles 109 to 115), Regulation (EU) [2017/625](#) (Food and Feed Controls), OJ L 95, 7.4.2017, pp. 1–142.

Note(s):

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Mandatory Financing by Commission

Regulatory Function:

Ensuring Efficiency of the Law, namely with regard to Implementation

Problem:

Financial resources are scarce. The implementation of regulation suffers from insufficient financial means on the side of the Commission.

Solution(s):

Mandate the financing of certain activities.

Reference(s):

Article 41(1), Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131;

Article 36 (1), (3) and (4), Regulation (EU) [2019/1020](#) (Market Surveillance), OJ L 169, 25.6.2019, p. 1–44.

Note(s):

Reinforces the position of the respective Commission Directorate General in the annual budget negotiations. Might be legally problematic to the extent that it aims at binding the future budget legislator.

Combination of Funding: Compatibility and Collision

Regulatory Function:

Legal Certainty and Efficiency

Problem:

Various funding sources, including EU funding sources, might be suitable for the same activity.

Solution(s):

Set out compatibility or collision rules and rules avoiding the double coverage of identical costs.

Reference(s):

Article 15, Regulation (EU) [2021/695](#) (Horizon Europe), OJ L 170, 12.5.2021, p. 1–68.

Note(s):

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Joint Procurement or Buying Schemes

Regulatory Function:

Leveraging Scale, Reducing Prices and Ensuring Availability

Problem:

Crisis or specialised markets benefit from aggregated purchasing power.

Solution(s):

Enable EU/joint Member State procurement, including legal structure and allocation of goods/services.

Reference(s):

Article 12, Regulation (EU) [2022/2371](#) (Health Threats), OJ L 320, 22.12.2022, p. 1–86.

Note(s):

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Procurement Rules Integrating Product Compliance

Regulatory Function:

Compliance

Problem:

Non-compliant products could be purchased with public money if procurement rules don't check regulatory compliance.

Solution(s):

Procurement authorities must verify and ensure that only compliant products (and economic operators) are considered.

Reference(s):

Article 83, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;
Article 85, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L,
2025/327, 5.3.2025.

Note(s):

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Procurement Rules Furthering Political Goals

Regulatory Function:

Making Procurement a Political Means

Problem:

Non-compliant products could be purchased with public money if procurement rules don't check regulatory compliance.

Solution(s):

Permit or mandate that sector specific procurement rules require a higher level than the legal minimum.

Reference(s):

Article 50(5)-(7), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40.

Note(s):

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For other aspects regarding the financial implementation of EU law and also as reference for regulations setting out financing programs, we recommend Regulation (EU) [2021/695](#) (Horizon Europe), OJ L 170, 12.5.2021, p. 1–68; of course to be read with the generic Financial

Regulations: Regulation (EU, Euratom) [2018/1046](#), OJ L 193, 30.7.2018, S. 1-222. Regulation (EU) [2021/695](#) (Horizon Europe) contains a rich variety of inspiring tools.

Q. Final Provisions / Miscellaneous

Gradual Phase-in of Regulatory Obligations

Regulatory Function:

Supporting SMEs and Sectors Undergoing Transition

Problem:

Sudden full entry into force may overwhelm some market actors.

Solution(s):

Stepwise or staged application dates for different categories of actor/product/type.

Reference(s):

Articles 95 and 96, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Articles 120 and 123, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175.

Note(s):

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COM to decide on Application Date / Fulfilment of Conditions Necessary for Application

Regulatory Function:

Application dates adapted to reality

Problem:

The application of certain provisions might be subject to certain conditions that are not yet fulfilled at the time of adoption of the act adopted by the legislators.

Solution(s):

Let the Commission decide on whether and when the necessary conditions are fulfilled by a Commission act that triggers the application of the legislators' act.

Reference(s):

Article 1 (31)(a), p. 30, Proposal for a Regulation amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), [COM\(2025\) 836](#) final.

Note(s):

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Member States' Postponement Option

Regulatory Function:

Balance between Ambitious Goals and Feasibility / Flexibility

Problem:

The same deadlines might not be suitable in all Member States.

Solution(s):

Give Member States a postponement option under control of the Commission, to avoid abuse.

Reference(s):

Article 52(2) and (3), Regulation (EU) [2025/40](#) (Packaging and Packaging Waste), OJ L, 2025/40, 22.1.2025.

Note(s):

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Transitional Product / Service Approval or “Grandfathering” of Existing Approvals

Regulatory Function:

Transition Management

Problem:

Existing/legacy products, processes, or certifications may require a transition path to the new regime.

Solution(s):

Explicit “grandfathering” clauses for licences, certificates, or products lawfully authorised under prior rules.

Reference(s):

Article 120, Regulation (EU) [2017/745](#) (Medical Devices), OJ L 117, 5.5.2017, p. 1–175;

Article 95, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Remedies for Overregulation or Regulatory Overlap

Regulatory Function:

Regulatory Simplification

Problem:

Layered or competing requirements create legal uncertainty and cost.

Solution(s):

Petition or appeal rights for operators or citizens where cumulative or conflicting requirements exist.

Reference(s):

Practiced by the European Commission in the framework of its "[REFIT](#)" program.

Note(s):

Could also be laid down in legislation, with more specific procedures namely for Implementing and Delegated Acts exempting from cumulative or conflicting provisions.

Expert Consultation

Regulatory Function:

Expertise for Technically or Legally complicated Regulation

Problem:

Rules adopted without expert knowledge may falter in practice.

Solution(s):

Consultation with defined stakeholder groups or experts before adoption of rules or delegated acts.

Reference(s):

Article 42, Regulation (EU) [2018/1725](#) (Union Data Processing), OJ L 295, 21.11.2018, p. 39–98;

Article 89(4), Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110;

Article 36(5) and (6), Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Note(s):

The last reference mandates the consultation of expert groups established under other regulations.

Whole Society Consultation

Regulatory Function:

Increasing the Knowledge Base, enhancing Engagement

Problem:

Important change processes require the involvement of the whole society, not just of administrations and certain stakeholders.

Solution(s):

Consultation mechanism covering the entire society.

Reference(s):

Articles 10 and 11, Regulation (EU) [2018/1999](#) (Energy Union Governance), OJ L 328, 21.12.2018, p. 1–77;

Article 9, Regulation (EU) [2021/1119](#) (European Climate Law), OJ L 243, 9.7.2021, p. 1–17.

Note(s):

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Stakeholder Forum

Regulatory Function:

Increasing the Knowledge Base, enhancing Engagement

Problem:

Important change processes and good implementation require the involvement of stakeholders.

Solution(s):

Create a forum for stakeholders.

Reference(s):

Article 93, Regulation (EU) [2025/327](#) (European Health Data Space), OJ L, 2025/327, 5.3.2025.

Note(s):

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Impact and Progress Assessment or Reporting

Regulatory Function:

Evidence-Based and Sustainable Law Making and Implementation

Problem:

Lack of robust analysis can yield counterproductive or unsustainable regulation or other measures.

Solution(s):

Require integrated progress reports and impact assessments (including social, environmental, digital, and fundamental rights dimensions) by secondary law.

Reference(s):

Article 18, Directive (EU) [2019/1024](#) (Open Data), OJ L 172, 26.6.2019, p. 56–83;

Articles 140-142, Regulation (EU) [2023/1114](#) (Crypto Assets), OJ L 150, 9.6.2023, p. 40–178;

Article 29, Regulation (EU) [2018/1999](#) (Energy Union Governance), OJ L 328, 21.12.2018, p. 1–77.

Note(s):

High administrative burden, absorbing scarce human resources. Preferable with precise metrics / performance indicators.

Joint Programming and Co-Regulatory Roadmapping with Stakeholders / Industry

Regulatory Function:

Forward-Looking Policy Coordination

Problem:

Regulators and industry often work on different time-frames and with misaligned expectations.

Solution(s):

Mandate public joint programming/roadmapping exercises on mid- and long-term regulatory needs.

Reference(s):

Article 10 and, to some extent, Article 6(6), Regulation (EU) [2021/695](#) (Horizon Europe), OJ L 170, 12.5.2021, p. 1–68;

Article 4, Regulation (EU) [2024/3110](#) (Construction Products), OJ L 2024/3110.

Note(s):

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Binding Sectoral Roadmaps/Action Plans

Regulatory Function:

Structured Forward-Looking Policymaking

Problem:

Sectoral reform intentions may not bind unless legally formalised.

Solution(s):

Mandate public, revisable, and enforceable sectoral roadmaps with clear reporting.

Reference(s):

Article 4, Regulation (EU) [2021/1119](#) (European Climate Law), OJ L 243, 9.7.2021, p. 1–17.

Note(s):

Climate, energy, and digital transition sectors currently leading.

Voluntary Agreements on Top of Law

Regulatory Function:

Furthering Policy Goals

Problem:

Pursuing all policy goals by legislation is not always possible or appropriate.

Solution(s):

Establish a two-tiered system, with one tier laid down in legislation and a second pursued by voluntary agreements.

Reference(s):

Article 38, Regulation (EU) [2023/988](#) (General Product Safety), OJ L 135, 23.5.2023, p. 1–131.

Note(s):

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Regulatory Correction Following CJEU/ECJ Rulings

Regulatory Function:

Alignment with EU Law

Problem:

Declared invalid or misapplied rules may linger and be enforced contrary to Court rulings.

Solution(s):

Statutory obligations to withdraw, amend, or invalidate rules post-judgment automatically.

Reference(s):

Article 266 Treaty on the Functioning of the European Union ([TFEU](#)), OJ C 202, 7.6.2016, p. 47-199.

Note(s):

Rules in secondary legislation should not duplicate Article 266 [TFEU](#). However, not all provisions affected by CJEU/ECJ rulings are covered by Article 266 TFEU. Moreover, rules in secondary legislation may help to create legal certainty where the applicability of Article 266 TFEU is not ascertained.

Table of Contents

Regulatory Function:

Better Information of Users, Clarity

Problem:

EU Regulations and Directives are often long and difficult to understand, structure-wise.

Solution(s):

Create a table of contents, to be placed after the Recitals and before the enacting terms.

Reference(s):

Council Directive [2006/112/EC](#) (Value Added Tax), OJ L 347, 11.12.2006, p. 1–118.

Note(s):

Unfortunately rarely used in the EU, whilst common place in many jurisdictions around the world.

Further Tools

If you haven't found what you were looking for or if you wish further inspiration, please check our [Cross-sectoral Standard Provisions](#), our "[List of Powers and Obligations](#)", our "[List of Sanctions and Collateral Measures](#)" and our sector model provisions which also contain many generic provisions: [Protection of vulnerable persons and persons with special needs](#); [Food and drinks legislation](#).

For methodological questions regarding the conception of legislation, including quality control, see our [Handbook 'How to Regulate?'](#) and our introductory [Training Video 'How to Regulate?'](#).

Training and Advice

For all other questions or issues, advice or custom-made training, please contact: manager@regulatoryinstitute.org.