

MODEL

LAW ON THE

PREVENTION OF PANDEMICS

The Regulatory Institute



Text of model law	Remarks
<p>1. Scope</p> <p>I. This law applies to the management of: - pandemics, - threats of pandemics, and - post-pandemic situations.</p> <p>II. This law applies also to the: - forecasting and prevention of pandemics, - preparation for pandemics, - assessment of factors influencing the preparedness, and - evaluation of past prevention of and preparation for pandemics, as well as of the past management of pandemics or past post-pandemic situations.</p> <p>III. It finally applies to research and technology development or production undertakings involving pathogens.</p>	<p>We have here the core of the scope of a pandemics law or regulation.</p> <p>But it is useful to clarify that these side aspects can be dealt with as well. These side aspects can influence how the next pandemic is dealt with.</p> <p>We recommend adopting a generic, independent law on research and technology risks, following our Model Law. But most jurisdictions do not have such a law on research and technology risks. And for all these jurisdictions, the risk of undertakings involving biological agents should be covered within the pandemics law, bearing in mind that agents spreading from labs or (e.g. vaccine) factories are one of the most important risk factors for pandemics. You see here the first and most important deviation and completion of the WHO Pandemics convention, as the latter deals only marginally with safety of laboratories and not at all with the safety of production facilities – a major flaw in the humble view of the Regulatory Institute.</p>
<p>IV. A pandemic within the meaning of this law is a pandemic that has been declared by the Secretary General of the World Health Organization or by the Government.</p> <p>V. A threat of a pandemic within the meaning of this law is given where such a declaration is likely OR not unlikely to happen within one [month] OR [three months] OR [six months] OR [one year].</p> <p>VI. A post-pandemic situation refers to when the consequences of a declared pandemic are still virulent.</p>	<p>Without an authoritative statement on whether there is a pandemic, scientists and policy makers will have diverging views on whether the provisions of this law will apply or not. In order to reach legal certainty, we find that an authoritative statement to trigger the applicability of this law is unavoidable.</p> <p>Alternatively, legal assumptions could be created: “A pandemic within the meaning of this law is to be assumed where ...”. We do not recommend replicating the definition of the WHO convention in Article 1, Point 1 (d)¹ as it is too imprecise for a</p>

¹ The definition of the WHO Pandemics convention is:
“(d) “pandemic” means the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality and causing social and economic disruptions, all of which require effective national and global collaboration

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	<p>directly applicable legal text, whilst it needs to be taken into account when deciding whether a pandemic is to be declared.</p> <p>Subject to the taste and the tradition of the drafters, the Subsections IV. To VI. Could also be reworded as definitions and thus placed into the following Section.</p>
2. Definitions	
<p>Pathogens: biological agents that can harm the health of humans and animals;</p> <p>Forecasting: all measures to identify and analyse risk of pandemics;</p> <p>Prevention: all measures aimed at limiting the occurrence of a pandemic or minimising the consequences of its occurrence;</p> <p>Preparation: all measures suitable to ensure that public and private entities and the population are ready to deal with an actual pandemic;</p> <p>Management: all measures that are taken when the pandemic actually occurs;</p> <p>Evaluation: the assessment of the quality of forecasting, prevention, preparation and management and of respective policies.</p> <p>Pandemic-related products: products that may be needed for pandemic prevention, preparedness, response and/or recovery, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;</p> <p>...</p> <p>- Research: Investigation of new possibilities in the field of natural science or engineering science;</p> <p>- Technology: application of possibilities offered by natural science or engineering science;²</p> <p>- Undertaking: organised activity, regardless of whether limited in time or space;</p> <p>- Operator: Natural or legal person [initiating,]³ organising or assuming the responsibility to the research or technology undertaking;</p>	<p>The definitions related to the scope on the left from here on are based on the WHO Pandemics convention text.</p> <p>Further definitions can be added depending on the need. See the text of the WHO Pandemics convention and the Terminology site of UNDRR for inspiration.</p> <p>These definitions stemming from our Model Law on Research and Technology Risks are only needed if you decide to cover the risks of undertakings involving biological agents. See the scope Subsection 1.III. above.</p>

and coordination for its control; ...

(f) "persons in vulnerable situations" means individuals, groups or communities with disproportionate increased risk of infection, severity or disease in the context of a pandemic;"

² The reference to "science" ensures that day-to-day activities following extremely simple engineering rules are excluded from the scope.

³ To include "initiating" ensures the inclusion of cases where a powerful legal body has the undertaking organised and executed by others without assuming responsibility. In particular if the undertaking is risky, big companies and research institutions might artificially create formally independent structures which organise and execute the undertaking so that the big companies or research institutions cannot be held liable or otherwise responsible.

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<ul style="list-style-type: none"> - Severity: Seriousness of harm without taking into consideration the duration / lasting; - Scope: Number of persons affected by harm; - Likelihood: probability of the harm occurring; - Lasting of harm: period during which the harm exists [or is psychologically perceived]; - Risk: likelihood of harm >0; - Death risk: likelihood of death >0; - Existential risk: likelihood of extinction of mankind >0; - Indirect risks: risks caused by a chain or several chains of events which are each linked by a causal relationship; - Causal relationship: relationship between two or more events according to which the second or subsequent events would not have happened at the very moment⁴ if the first had not happened;⁵ - Agency: (define or refer to the administration in charge of the application of this law). 	
<p>3. The pandemics agency</p>	
<p>The following authority is named “Agency” for purposes of this law: ... OR By virtue of this law, a pandemics agency (hereafter: “Agency”) has been created.</p>	<p>Subject to the situation in the respective jurisdiction, it may nominate an existing authority as the agency in charge. Alternatively, a new agency may be created. Criteria might include:</p> <ul style="list-style-type: none"> - Is there already an authority that has similar or even overlapping knowledge and tasks? - Is that authority already in a good position to implement the pandemics law? (Please check not only the staffing and equipment, but also its informal standing, reputation, acceptance by other administrations and the population.) - If not, how much money and effort would be needed to bring it into that position, when compared with the creation of a new agency? - Which frictions, coordination problems or other problems would emerge if a new agency is created?
<p>4. Support by research institutions and advisory board</p>	
<p>I. All state-funded universities or other research or technology institutes shall make their expertise available to the Agency. They shall accept invitations of the Agency to send a competent delegate to meetings or teleconference of the</p>	<p>Source: Model Law on Research and Technology Risks.</p>

⁴ The reference to the moment is crucial because otherwise no death risks would be covered as everybody dies sooner or later. The reference solves also the issue of alternative causality: a risk still needs to be taken into account even when there is an alternative causal chain leading later to the same result.

⁵ Application of the old Latin “condition sine qua non” formula and similar concepts in Asian philosophy.

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<p>scientific advisory board.</p> <p>II. The Agency may invite representatives of foreign institutes and universities and representatives of international organisations to become temporary observers or permanent members of the advisory board.</p> <p>III. Members and observers shall, two weeks before any meeting or teleconference, declare in writing whether they have potential conflicts of interest. The Agency shall decide on the temporary or permanent exclusion of the member or observer with full discretionary power.</p> <p>IV. The names and the roles of the members and observers of the advisory board [and their declarations of interests] shall [not] be public.</p>	
<p>5. Cooperation of public entities</p>	
<p>I. The following public entities are obliged to cooperate among themselves and with the Agency and to contribute [with all their available resources] to tackling the pandemic[, threat of a pandemic or post-pandemic situation]:</p> <ul style="list-style-type: none"> a. State research institutions in the field of medicine, veterinary medicine and biology; b. State medical or veterinary offices; Public hospitals; c. Intra-state regions; d. District administrations (hereafter: "districts"); ... <p>II. The Agency shall:</p> <ul style="list-style-type: none"> a. Settle conflicts of competence between different public entities; b. Promote the coordination between the Agency and public entities and coordination among public entities; c. Support public entities in the management of a pandemic; d. Substitute a public entity upon request of the Government where the public entity does not perform sufficiently well; e. Provide management and other methodological training to public entities; and f. Provide emergency command system guidelines for entities involved in the handling of pandemics. <p>III. The Agency may acquire goods or services on behalf of the public entities and may request refunding from them.</p>	<p>Source: Model Law on Emergency Management.</p> <p>It is recommended to list rather more than less authorities and public bodies.</p> <p>Where they exist.</p>
<p>6. Command at times of a pandemic</p>	

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<p>During a pandemic and in a situation of threat of pandemic, the Agency may:</p> <ul style="list-style-type: none"> - make decisions which will bind the other public entities, and - delegate certain tasks and corresponding empowerments to other public entities. 	<p>Source: Model Law on Emergency Management.</p> <p>A clear responsibility and command structure is paramount for the handling of pandemics. We recommend a clear supremacy structure so as to avoid conflicts. But this full power can only ensure full efficiency where it has the possibility to delegate tasks.</p>
<p>7. Infection prevention and control plans</p>	
<p>I. The Agency, in cooperation with ... (central authorities to be involved, subject to the content of the plan, e.g. veterinary, infrastructure and medical products authorities) [, intra-state regions and each district] shall[, for their respective geographic area] develop, implement, periodically review and update a multisectoral infection prevention and control plan. This plan shall at least cover the following:</p> <ul style="list-style-type: none"> a. measures to ensure access of all humans to safe water, sanitation and hygiene, namely access to periodically cleaned and emptied toilets, and the safe disposal of used waters and human or animal excrement; b. measures ensuring access to appropriate medical and veterinary services; c. establishment of appropriate public health laboratory and diagnostic capacities, especially with respect to the capacity to perform genomic sequencing, data science to assess the risks of detected pathogens and to safely handle samples containing pathogens, and the use of related digital tools; d. closing of public health laboratory and diagnostic capacities loopholes by national or international cooperation; e. periodic scrutinising of the health care institutions' infection prevention and control programmes; f. measures to ensure the sound management of wastes from health facilities, veterinary practices, live animal markets, and farms potentially contaminated by infectious pathogens; g. animal disease preventive measures, including, but not limited to: measures concerning farms, the transport of animals, live animal markets, trade in wild animals and 	<p>Transposition of the WHO Pandemics convention, with complementary elements.</p> <p>Consider attributing the task to a ministry or other top-level entity instead of the Agency, to provide more political or planning power. Downside: ministries are less technically competent than dedicated agencies. Please decide whether certain geographic entities, here referred to as “intra-state regions” and “districts” should also develop an infection prevention and control plan. It is possible to reduce the scope of their respective plans in Subsection II so that they do not become overburdened.</p> <p>The list here has been established by merging various sections of the WHO Pandemics convention. It contains therefore some of the redundancies of the WHO Pandemics convention itself. We have not eliminated the redundancies because legislators should first decide on what they want where various partly overlapping formulations exist.</p> <p>A few letters, like letters h. and i., have been added on our own initiative as we found some loopholes in the WHO Pandemics convention.</p>

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<p>veterinary practices for both food-producing and companion animals, taking into account the relevant international standards. Those measures include water and feed hygiene, safe disposal of waste waters, minimum distancing of animals of the same species, minimum distancing of animals of different species, farm sanitation, hygiene and biosecurity, and animal welfare support measures;</p> <p>h. measures aimed at hindering zoonotic pathogens from spreading to humans, like the obligation to wear masks and distancing rules for humans being in contact with animals, hygienic standards for and periodic screening of humans dealing with animals;</p> <p>i. the obligation to wear masks and distancing rules for humans in public spheres;</p> <p>j. measures establishing mobile multidisciplinary teams investigating and managing outbreaks, composed of medical and veterinary personnel, persons authorised to take police or other authority measures;</p> <p>k. other measures to ensure the implementation of the latest international standards and guidelines regarding infection prevention and control;</p> <p>l. measures aiming to reduce the use of antibiotics for humans and animals and other measures aiming to reduce the risk of pathogens that are resistant to antimicrobial agents;</p> <p>m. measures containing the spreading of pathogens that are resistant to antimicrobial agents, namely within healthcare and veterinary institutions;</p> <p>n. measures regarding the access to and stewardship of antimicrobials;</p> <p>o. measures harmonising the surveillance and management of environmental antimicrobial run-off;</p> <p>p. measures strengthening laboratory biosafety and biosecurity like training, good practice codes, peer review of laboratories, limiting and subjecting to conditions the access to sensitive locations, and strengthening transportation security;</p> <p>q. measures mandating OR inciting the application of standards and protocols for infection prevention and control, and for public health laboratory biosafety and biosecurity;</p> <p>r. measures inviting and enabling communities to contribute to the surveillance of identified zoonotic outbreaks and antimicrobial resistance at source;</p> <p>s. measures addressing the drivers of the emergence and re-emergence of disease at the human-animal-environment interface, including but not limited to [climate change,] land-use change, wildlife trade, desertification and antimicrobial resistance;</p> <p>t. measures establishing and strengthening public</p>	<p>We do not see the average agency to be in a good position to address climate change, even though climate change is listed in the WHO Pandemics convention.</p>

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<p>health emergency operational centres.</p> <p>u. measures assessing and increasing the medical treatment capacities during pandemics, including the establishment of stocks of pandemic goods;</p> <p>v. measures strengthening pandemic-related education and training of health and care workforce which include community health workers and volunteers;</p> <p>w. measures aimed at the physical and psychological protection of health and care workforce, including measures giving priority access to pandemic-related products during pandemics and measures protecting them from violence and intimidation whilst carrying out pandemic prevention, response and recovery;</p> <p>x. measures establishing and maintaining effective workforce planning systems to effectively and efficiently deploy trained health workers during pandemics;</p> <p>y. measures and plans kicking-in during a pandemic, aimed at the postponement of certain ordinary medical treatments to focus resources on the pandemic, subject to the relative importance of the pandemic disease versus the diseases to be treated ordinarily;</p> <p>z. measures preparing for a quick rehabilitation and recovery of the health system and its workforce after a pandemic;</p> <p>aa. measures creating a monitoring and evaluation system that periodically assesses the national pandemic prevention, preparedness and response, that shall also cover the supply chain management and risk assessment, through, among others, appropriate simulation or tabletop exercises, and intra- and after-action reviews.</p> <p>II. Letters ... do not apply to intra-state regions. Letters ... do not apply to districts.</p> <p>III. The Agency is empowered to adopt regulations in order to take measures in accordance with Letters ... [whilst respecting the legal boundaries set out in ...] AND/OR [whilst respecting the principle of proportionality].</p>	<p>Some of the planning obligations go too far for intra-state regions; some more might go over the heads of districts.</p> <p>Some minimal boundaries should be set up. It is of course also possible to give more detailed instructions about how the regulations should be cast.</p>
<p>8. Integrated surveillance</p>	
<p>I. The Agency, in cooperation with the public entities listed in Section 5, [the intra-state regions and the districts] shall[, for their respective geographic area] develop, strengthen and maintain the capacity to carry out integrated surveillance, including on:</p> <p>a. infectious diseases in humans;</p> <p>b. infectious diseases in animals that present significant risks for zoonotic, including vector-</p>	<p>Transposition of the WHO Pandemics convention, with complementary elements. To be decided: shall geographic entities also undertake integrated surveillance? Delegation is not necessarily meaningful where the geographic entities are weak and where they lack the means to fulfil the tasks.</p>

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<p>borne, spillover; and</p> <p>c. relevant samples taken from specific environmental settings for the purpose of preventing and controlling the spillover of potentially highly infectious pathogens, including antimicrobial resistant pathogens, across different animal species and between humans and animal populations.</p> <p>[The Agency shall develop benchmarks for the intra-state regions and districts, give training and advice to the intra-state regions and districts on how to fulfil the benchmarks, support the districts namely, by organising common purchase of laboratory and pandemic goods and supervise the performance of the intra-state regions and districts.]</p> <p>II. The Agency [, the intra-state regions and each district] shall collect and evaluate, also with the help of artificial intelligence, data on the phenomena of the human, animal, and environmental spheres that might influence the emergence and the dissemination of pathogens to develop a comprehensive and multidimensional assessment of risks and their spill-over between different species. These phenomena include societal behaviour, like travel and habits, that can contribute to the dissemination of pathogens. [The intra-state regions and the districts shall share their findings with their peers and with the Agency.]</p> <p>III. Based on these data, the Agency shall develop and continuously update a risk mapping. The Agency shall share its risk mapping and other findings internationally, with other government departments and with the intra-state regions and the districts.</p> <p>IV. The Agency [the intra-state regions and the districts] shall share its / their findings with the population where concrete recommendations can be given to reduce risks. Where needed and proportionate, it / they shall launch dedicated information campaigns in accordance with Section 10.</p> <p>V. The Agency shall, based on its hygienic and infection risk mapping and its human and veterinary infectious disease monitoring, undertake proactive targeted investigations including medical and veterinary control measures at sites and in situations where it deems risk to be the highest.</p> <p>VI. The Agency shall create and maintain an up-to-date universal and interconnected data and</p>	<p>Choice linked to the choice above.</p>

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<p>information exchange platform [and give districts appropriate access to it]. It may provide access to international organisations, foreign authorities and research institutions and to domestic or foreign private companies undertaking research.</p>	
<p>9. Integral clinical capacity planning</p>	
<p>The Agency, together with the districts and other authorities in charge of healthcare institutions, shall undertake an integral clinical capacity planning in view of pandemic prevention, preparedness, response and health systems recovery plans pre-, post- and inter-pandemic. This capacity planning shall at least:</p> <ul style="list-style-type: none"> a. identify populations to prioritise for access to pandemic-related products and health services; b. support the timely and scalable mobilisation of the multidisciplinary surge capacity of human and financial resources; c. facilitate the timely allocation of resources to the frontline pandemic response; d. review the status of stockpiles, the surge capacity of essential public health and clinical resources, and the surge capacity in production of pandemic-related products; e. facilitate the rapid and equitable restoration of public health capacities and routine health services following a pandemic; and f. promote collaboration with relevant stakeholders, including the private sector and civil society, namely to further increase the clinical capacity. 	<p>Transposition of the WHO Pandemics convention.</p>
<p>10. Public information and awareness</p>	
<p>I. The Agency [, the intra-state regions and the districts] shall:</p> <ul style="list-style-type: none"> a. promote and facilitate the development and implementation of risk communication, community engagement, information management, and educational and public awareness programmes on pandemics and their effects, in a way that is broadly accessible; b. conduct regular community outreach, social listening, and periodic analysis and consultations with civil society organisations and media outlets in order to identify the prevalence and profiles of misinformation, which will contribute to design communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust and promoting adherence to public health and social measures; c. promote communications on scientific, engineering and technological advances that are relevant to the development and implementation of 	<p>Transposition of the WHO Pandemics convention.</p> <p>The WHO convention uses the term “infodemic” instead of “information”.</p>

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<p>national and international rules and guidelines for pandemic prevention, preparedness, response and recovery of health systems, based on science and available evidence, when appropriate; and</p> <p>d. take effective measures to increase digital health literacy among the public and within the health sector, including with clinicians, health sector stakeholders and decision-makers, through education and meaningful engagement, to foster trust.</p> <p>II. The Agency shall, as appropriate, conduct research and form policies on factors that hinder adherence to public health and social measures in a pandemic, including confidence, the uptake of and demand for vaccines, the use of appropriate therapeutics, the use of non-pharmaceutical interventions, and trust in science and government institutions.</p> <p>III. The Agency shall promote [towards the intra-state regions, the districts and the health institutions] a science and evidence-informed approach to effective and timely risk assessment, mindful of the uncertainty and the evolving nature of data and evidence during a pandemic, when communicating such risks to the public.</p>	
<p>11. International cooperation</p>	
<p>I. The Agency and its supervising ministry are empowered to receive peer evaluators from international organisations and other states for the joint evaluation of policies and measures adopted in accordance with Sections 7 – 10.</p> <p>II. When calling for support of an international organisation or of other states in view of an upcoming or virulent pandemic, the Agency and its supervising ministry, both represented by the Ministry of Foreign Affairs, shall conclude arrangements to ensure that the command remains under national control. However, the command may be deliberately handed over to the international organisation or to another state where this is clearly advantageous in terms of managing the pandemic.</p> <p>III. Where an international organisation or another state assists in the pandemic emergency operations, the actions of the foreign agents shall be deemed to be actions of domestic agents. The foreign agents are exempted from civil and penal liability.</p>	<p>Transposition of the WHO Pandemics convention, but broader in scope.</p> <p>Calling for international support is often necessary to manage pandemics or other emergencies. States touched by emergencies frequently request help from others in case of emergency. Hence, it is useful to create a legal frame. It is, in particular, necessary to have a clear setting for who is in command.</p> <p>The action of the agents of the international organisation or of the foreign country should be regarded as the action of the national agents in relation to the persons concerned by the actions, whilst it is also appropriate to exempt these agents from civil and penal liability.</p>

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<p>IV. The empowerments of this law may not / may be used where an international organisation or another state has called for support in a pandemic emergency situation[, provided the Parliament has given its approval].</p>	<p>Evidently, other countries or international organisations might also need support. In order to establish a good basis of support for future pandemics within national borders or within the region, it is commendable to be positively disposed to requests for pandemic emergency assistance. To be prepared for this case, the legislator should clarify whether the empowerments of this law can also be used to support the international organisation or the other country.</p>
<p>12. Limitations to intellectual property rights</p>	
<p>I. The Agency may oblige private or public research institutions and their service providers to share the results of clinical trials, e.g. via open source publications.</p> <p>II. The Agency may request samples of pathogens or materials containing pathogens from private or public research institutions. The Agency may share these pathogens or materials containing pathogens nationally or internationally. The Agency may also request private or public research institutions to share samples of pathogens or materials containing pathogens nationally or internationally.</p> <p>III. Recipients of pathogens or of materials containing pathogens shall not claim any intellectual property or other rights with respect to the pathogens with pandemic potential, or their genomic sequences, components or related information. They are not allowed to further disseminate the pathogens or the materials containing pathogens without the consent of the intellectual property rights owner or of the Agency. In both cases, they shall convey these obligations to the further recipients; they are liable for the fulfilment of the obligation to convey these obligations to the further recipients. This Subsection also applies to recipients who received pathogens or materials containing pathogens from further recipients.</p> <p>IV. During a pandemic or immediately before [or after], the Agency may oblige intellectual property rights holders of pandemic-related products to provide a licence to one or several research institutions or economic actors. These research institutions and economic actors may not disseminate the pandemic-related products outside the national territory without the consent of the Agency or of the intellectual property rights</p>	<p>Transposition of the WHO Pandemics convention, with complementary elements.</p> <p>Moreover, to be considered for this Section: clarification rules on relationship with national law on intellectual property right; or modification thereof.</p> <p>Alternatively, the Agency could be empowered to issue itself a mandatory licence. Subject to the respective intellectual property right, one or the other way is more appropriate.</p>

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<p>holder.</p> <p>IV. During a pandemic or immediately before [or after], the Agency may oblige intellectual property rights holders of pandemic-related products to provide a licence to other states in need of these products, under condition that these states do not further merchandise the products.</p>	<p>Alternatively, the Agency could be empowered to issue itself a mandatory licence. Subject to the respective intellectual property right, one or the other way is more appropriate.</p>
<p>13. Purchase empowerment and liability regarding pandemic-related products</p>	
<p>I. The Agency is empowered to buy X % of the domestic production of pandemic-related products at an average price for domestic purposes or in view of sharing the products with other states in need.</p> <p>II. The Agency is empowered to reduce the liability risks of those economic actors who develop, manufacture, import or distribute innovative [pandemic-related products] OR [vaccines, <i>in vitro</i> diagnostic medical devices or medicines] at times of a pandemic [or immediately before or after]. The Agency shall, in this case, establish a national compensation fund that covers the risks excluded from liability in accordance with the previous sentence.</p> <p>III. The Agency shall make publicly available the information regarding any global, regional or national liability frameworks and vaccine compensation schemes that apply to the manufacture, distribution, administration or use of pandemic-related products [before,] during [or after] pandemic emergencies in its jurisdiction.</p>	<p>Transposition of the WHO Pandemics convention, with complementary elements.</p> <p>This is a nice incentive which can be applied either to all pandemic-related products or the most important medical ones.</p>
<p>14. Extraordinary admission of pandemic-related products</p>	
<p>I. The authority in charge of medicines, medical devices, <i>in vitro</i> diagnostic medical devices and other health products, including laboratory materials, may, during a pandemic, authorise the manufacturing, import, distribution and use of pandemic-related health products without the ordinary legal conditions therefore being fulfilled.</p> <p>II. The authority in charge of personal protective equipment and other pandemic-related non-health products may, during a pandemic, authorise the manufacturing, import, distribution and use of pandemic-related products other than health products without the ordinary legal conditions therefore being fulfilled.</p>	<p>Transposition of the WHO Pandemics convention, with complementary elements.</p> <p>Some products like masks and protective clothing fall, subject to the jurisdiction, under “medical devices” or “personal protective equipment”. To avoid a loophole with regard to innovative dual use devices, better cover both products with medical and non-medical purpose.</p>

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<p>III. Pandemic-related health products, personal protective equipment products and other pandemic-related products other than health products may, during a pandemic, be manufactured, imported, distributed and used where they fulfil the ordinary [or pandemic] marketing conditions of one of the following jurisdictions:</p> <p>...</p>	<p>Consider deleting “health products, personal protective equipment products and” where you wish to cover all pandemic-related products.</p>
<p>15. Other materials, equipment and services</p>	
<p>For each type of pandemic, the Agency shall assess which materials and which equipment would be needed to cope with the pandemic. It shall also assess the likelihood of various pandemic scenarios. It shall communicate both assessments to the state budget authority. [Pandemic prevention and preparation shall have a budget share of at least X % both at the level of the central Government and within geographic and other public entities.]</p> <p>The Agency shall plan together with other public entities likely to be involved in a potential pandemic, how best to distribute the materials and equipment and protect them against degradation or theft. The other public entities shall follow the instructions of the Agency in this regard.</p> <p>During the pandemic [and immediately before], the public entities may acquire materials and equipment or sign service contracts without respecting the following sections / provisions of law Y (on attribution of public contracts and on public tenders of public entities):</p> <p>...</p> <p>They shall however respect the following rules:</p> <p>...</p>	<p>Source: Model Law on Emergency Management.</p> <p>“Materials” is broader than “products”. Various types of pandemics, but certainly not all, can be better managed where certain materials, equipment and supportive services are available. We suggest to include here legal provisions in this regard although the respective planning could also be done without such provisions because the legal provisions strengthen the position of public entities towards the budgetary authority / authorities. In some jurisdictions, it might even be possible to obtain a minimum pandemic prevention budget, whilst in others, such a provision would be regarded as illegal for limiting the freedom of the parliament when deciding on the budget.</p> <p>The law applicable to acquisitions and public tenders of public entities is quite severe in many jurisdictions, establishing complex procedural requirements which cannot be easily managed, and even less so during an emergency where quick action is needed and where the overall management capacities of public entities is already under constraint.</p>
<p>16. Training</p>	
<p>I. Once a year, the Agency and each public entity referred to in this law shall undertake an pandemic emergency training exercise for at least one pandemic category described in Section 20, whilst each of the pandemic categories needs to be covered at least once every ... (3, 4, 5) years. The Agency shall involve at least three other public entities in its training exercise. The other entities called upon by the Agency shall actively support the training exercise.</p>	<p>Source: Model Law on Emergency Management.</p> <p>The capabilities of public entities to operate under emergency depends on their training, and the training of other entities with which they shall cooperate. Hence, it is appropriate to include a training programme. A training programme does not necessarily need to be laid down by law. However, laying it down by law creates a</p>

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<p>II. Each public entity may call upon volunteers to undergo training. Trained volunteers shall be registered and kept periodically informed of preparations for emergencies. The same applies to former staff of public entities involved in the management of pandemics.</p> <p>III. Trained and registered volunteers and former staff have the right to undergo a one day refresher training every year whilst maintaining their usual salary or other compensation for those that may be retired or do not draw a salary.</p>	<p>legal obligation and thereby is an indirect means to provide for the necessary funding.</p> <p>Many pandemics require the help of more persons than those employed by the entities in charge of pandemics. Hence, volunteers are needed. The quality of the work of volunteers depends among other things on their training. Former staff constitutes another source for support in case of a pandemic.</p>
<p>17. Obligations of private and public health care institutions and of its staff</p>	
<p>I. Health care institutions shall establish infection prevention and control programmes and shall submit them for scrutiny to the Agency.</p> <p>II. Health care institutions shall report the presence of pathogens able to trigger a pandemic to the Agency [and to their district administration] and shall subsequently periodically update this reporting.</p> <p>III. Where a staff of a health care institution has doubts as to the fulfilment of this reporting obligation, it may OR shall report the same to the Agency [and to the district administration].</p> <p>IV. During a pandemic, the right to collective action of employees is limited to forms that do not reduce the ability of health care institutions to provide services.</p>	<p>Transposition of the WHO Pandemics convention, with complementary elements.</p>
<p>18. Obligations of non-active medical personnel</p>	
<p>I. Non-active medical personnel are obliged to serve in healthcare institutions if requested by the Agency [or the district of their place of residence]. To enforce this obligation, the Agency [and the responsible district] may impose sanctions of up to 3 months income of the non-active medical personnel.</p> <p>II. Personnel requested to serve shall receive from the requesting entity, during their time of service, the salary that:</p> <ul style="list-style-type: none"> a. they would have otherwise gained; or b. which is commonly paid to those providing the medical service they are qualified to provide; or c. which is commonly paid to those providing the 	<p>Transposition of the WHO Pandemics convention, with complementary elements.</p>

Text of model law	Remarks
<p>medical service that they provide in reality; whatever of the three is highest.</p> <p>III. Personnel requested to serve shall receive ordinary social benefits and are insured in accordance with common rules.</p>	
<p>19. Supervision of Agency during pandemic</p>	
<p>During a pandemic, the Agency [is still] OR [is not] under the supervision of its usual supervisory authority.</p> <p>The Agency may / shall, where time is available, seek confirmation of its far-reaching or questionable decisions from the supervisory authority.</p>	<p>Source: Model Law on Emergency Management.</p> <p>It might be useful to clarify whether the Agency is, during the pandemic, still subject or not to the usual supervision by the supervisory authority. On one hand, this supervision seems logical in terms of political responsibility. On the other hand, meddling by a supervisory authority may complicate and delay coordinated action. An intermediate solution could consist in giving the Agency the possibility to obtain confirmation for far-reaching or questionable decisions or to oblige the Agency to go for such confirmation.</p>
<p>20. Categories of pandemics and corresponding empowerments</p>	
<p>I. Subject to the severity of pandemics, different categories of empowerments are attributed to the Agency[, intra-state regions and districts]. The types of pandemics and their corresponding categories of empowerments are defined as follows:</p> <p>a. Category I: Empowerments for ordinary pandemics affecting humans:</p> <ul style="list-style-type: none"> • Requesting information which is not confidential, • Ordering other public entities to contribute, • Creating incentives for blood or tissue donations, • Communicating acute warnings and recommendations to the population. <p>b. Category II: Empowerments for pandemics causing casualties:</p> <ul style="list-style-type: none"> • Empowerments of Category I, • Requesting confidential information, • Use of artificial intelligence, also with regard to confidential information, • Calling for volunteers to help, • Banning the use of objects, • Steering public traffic, • Ordering media and internet service 	<p>Source: Model Law on Emergency Management.</p> <p>The attribution of empowerments to the Agency and to geographic entities is easier when using empowerment categories. However, it is also conceivable to attribute all the empowerments in an undifferentiated way or, on the contrary, to attribute empowerments individually in a big matrix crossing the geographic entities with the categories of pandemics and empowerments.</p> <p>The categories as defined on the left side should be regarded as mere inspiration. Categories can also be merged or individual empowerments can be shifted to another category.</p> <p>For jurisdictions wishing to set up more detailed empowerments, we recommend reading Sections 6 to 10 of the Jersey Emergency Powers and Planning law 1990.</p>

Text of model law	Remarks
<p>providers to communicate warnings and recommendations,</p> <ul style="list-style-type: none"> • Use of public stocks, • Obliging public entities to shelter persons, • Requesting support from international organisations or other states via the Ministry of Foreign Affairs. <p>c. Category III: Empowerments for pandemics having the potential to extinguish 3% or more of the population:</p> <ul style="list-style-type: none"> • Empowerments of Category I and II, • Targeted dissemination of confidential information, • Drawing qualified professionals, • Requesting the military to intervene, • Imposing mandatory vaccination, • Requesting the population to stay at home, • Ordering the population to leave certain places, • Confiscation and use of vehicles, objects, funds and property, • Obliging service providers to provide services, • Obliging manufacturers to produce certain items, • Obliging private persons to shelter other persons, • Controlling the production of goods and services or taking over the management of the production, • Limiting, banning or putting under price or other conditions the selling and the consumption of [food, water, fuel, gas, electricity and other goods of daily necessity] goods and services, • Limiting, banning or putting under price or other conditions the import and export of goods and of services, • Limiting, banning or putting under price or other conditions the transport of goods, • Limiting, banning or putting under price or other conditions any form of travel of persons. <p>d. Category IV: Empowerments for pandemics having the potential to extinguish 10% of the entire population:</p> <ul style="list-style-type: none"> • Empowerments of Categories I to III, • Publication of confidential information, • Drawing of all civilians, • Forcible evacuation, • Assigning places for civilians to go to, • Destroying of objects and property, • Deciding on the processing of corpses, 	<p>Please consider merging Categories III to V or at least Categories IV and V. In terms of life savings, it is better to give as many empowerments as are legally possible for the lower degrees of severity. On the other hand, the principle of proportionality and the protection of fundamental rights need to be protected as well, subject to the legal setting of the respective jurisdiction. The balancing cannot be done here for all the various jurisdictions.</p>

Text of model law	Remarks
<ul style="list-style-type: none"> • Temporarily extending the scope or issuing of professional licenses,⁶ • Ordering or executing triage decisions,⁷ • Sanctioning of persons hindering the emergency operations other than by detention, • Sanctioning persons refusing to contribute to the emergency operations, • Ordering media and internet service providers not to report and not to forward information where this might trigger panic or other behaviours putting lives at risk. <p>e. Category V: Empowerments for pandemics about to extinguish 20% of the population:</p> <ul style="list-style-type: none"> • Empowerments of Categories I to IV, • Detaining persons hindering the emergency operations as sanction and as a means to prevent repetition, • Exerting pressure to trigger blood or tissue donations, • Other decisions that lead to the death of persons (e.g. on attribution of life-saving resources to one place or the other where persons at both places are in urgent need), • Interrupting or fully controlling telephone, media and internet services to avoid panic or other behaviour that puts persons at risk. <p>II. The Government is empowered to complement the list of empowerments, namely to close regulatory loopholes and to ensure the coverage of new and emerging needs. The empowerments introduced shall be attributed into the category where there are the most similar empowerments, thus respecting the proportionality principle.</p> <p>III. The Government shall state the applicable category by decree and shall make the decree known by media, together with a link to this law.</p>	
21. Involvement of military	
<p>Where the military is involved in pandemics operations, it is under the command of the Agency. The military may / may not use its military empowerments in addition to the empowerments provided by this law.</p>	<p>Source: Model Law on Emergency Management. It might be useful to state the same for (special) police forces.</p>
22. Triage and other decisions implying the	

⁶ So that, e.g.: persons with a normal driving license are authorised to drive trucks; nurses, advanced medical students or medical trainees are authorised to work as doctors.

⁷ These are decisions on who gets life-saving medical treatment where capacity limits are reached. Where this empowerment is not given or not used, the medical professionals on the spot will decide. This is not necessarily worse an approach.

Text of model law	Remarks
<p data-bbox="134 188 411 221">potential loss of lives</p> <p data-bbox="134 253 783 353">I. Triage or other decisions implying the potential loss of lives shall be taken in view of the following principles:</p> <p data-bbox="134 353 738 421">a. Highest priority is the saving of lives OR life years;</p> <p data-bbox="134 421 751 488">b. Second highest priority is the prolongation of lives⁸ OR the reduction of suffering.</p> <p data-bbox="134 488 791 589">c. Third highest priority is the prolongation of lives OR the reduction of suffering (choose the one you have not chosen under the second indent).</p> <p data-bbox="134 620 799 891">II. Deviations from this priority list are [in particular] justified where a life saved would be a life in a vegetative state / without consciousness whilst several other persons could obtain a prolonged life or have their suffering reduced if the resources needed for the lifesaving were available. Extreme economic consequences shall not / may influence decision making.</p>	<p data-bbox="831 253 1286 320">Source: Model Law on Emergency Management.</p> <p data-bbox="831 353 1409 757">Triage decisions and a few other situations can present difficult ethical choices. The legislator can either refrain from regulating, leaving the difficult ethical questions to the front-line practitioners, or set up basic principles to provide leeway or discretion. Medical personnel are often trained to make triage decisions; leaving decisions entirely to them is, therefore, possible. But for other situations presenting similar difficult ethical choices, decision-makers might be less prepared.</p> <p data-bbox="831 790 1409 1395">Here is an example for such difficult decisions, taken from the realm of ordinary emergencies (not pandemics): imagine that a decision-maker has enough staff either to evacuate a home with 40 elderlies (65 years or above) or 300 ordinary inhabitants (average age: 30) in an area that is threatened by flooding. The decision-maker is sure that none of the elderly would survive without evacuation assistance, whilst, according to his estimation, 9/10 of the ordinary inhabitants (thus 270) would survive without evacuation assistance. When deciding in view of the number of lives that can be saved, he has to evacuate the elderly. When deciding in view of the number of life years saved, he would need to go for the ordinary inhabitants.</p>
<p data-bbox="134 1431 708 1464">23. Parliamentary control of empowerments</p>	<p data-bbox="831 1498 1286 1565">Source: Model Law on Emergency Management.</p> <p data-bbox="831 1568 1401 2000">This law provides quite some broad empowerments to the Government and to the Agency so as to enable them to react quickly and comprehensively. However, this approach is risky in terms of protecting democratic and citizens' rights. Emergencies have been abused by some governments to restrict rights of citizens, and the same risk exists for the emergency sub-type pandemic. Clear rules on the parliamentary control can protect the rights of citizens and the democracy. It might be useful to establish a hurdle</p>

Text of model law	Remarks
	(quorum) which is higher than usual for the parliament to withdraw empowerments. However, it needs to be verified whether it is compatible with the constitution to establish such a higher hurdle. In a number of jurisdictions, only the constitution itself can establish or modify the quorum.
24. Government decrees	
<p>I. The Government may issue decrees setting out details on the execution of the empowerments and on the management of pandemics. [Where there is no urgency, it shall give the parliament one-month notice prior to adoption and shall take account of the reaction of the parliament.]</p> <p>II. The decrees may / may not further restrain data protection law and the protection of confidential information.</p> <p>III. The decrees may / may not further limit other rights of legal and natural persons.</p>	<p>Source: Model Law on Emergency Management.</p> <p>Decrees, subordinate legislation or similar regulatory tools of the government can complement the law appropriately. However, given the very sensitive character of the matter, it might also be deemed appropriate to give the parliament the possibility to informally react to a decree project. This is also helpful where, as suggested below, the parliament can formally revoke a decree. The informal reaction at an earlier stage can help avoid a later conflict which would let the parliament revoke the decree.</p>
25. Parliamentary control of government decrees	
<p>The parliament may revoke, suspend or modify the decrees adopted by the government by ordinary majority decision.</p>	<p>Source: Model Law on Emergency Management.</p> <p>As stated above, the rights-sensitive character of the matter might be regarded as justifying a tight control of the government by the parliament.</p>
26. Cost coverage, damage compensation and income losses	
<p>I. All persons involved in the handling of a declared pandemic, including OR with the exemption of volunteers who have not been registered, shall obtain coverage of their costs caused by accidents from ... (either state insurance or state administration).</p> <p>II. They shall obtain coverage of other costs or compensation for damages from ... (responsible state administration).</p> <p>III. Volunteers who have been [registered following a call for volunteering or] drawn shall, in addition, obtain compensation of their income loss. Where their employer has continued to pay them during their volunteering, the right to receive compensation is transferred to the employer.</p>	<p>Source: Model Law on Emergency Management.</p> <p>Hardly any emergency is manageable without causing damages, even by the emergency operations themselves, and pandemics are no exemption to the rule. In states where there are no generic provisions on cost coverage, damage compensation and income loss of volunteers, we would recommend developing at least basic provisions.</p>
27. Other compensations	

Text of model law	Remarks
<p>I. Natural or legal persons whose goods were confiscated, who had to manufacture goods or who had to provide services or who have suffered a damage or loss in connection with the emergency operations shall have a right to compensation, to be addressed by the Agency [in the following cases: ...].</p> <p>II. Where their claim has been rejected, they may apply for compensation to the national emergency compensation fund which shall deal with their claims as a priority.</p>	<p>Source: Model Law on Emergency Management.</p> <p>We have suggested a broad range of empowerments in view of enabling the entities to take all appropriate measures, even where they do not dispose themselves of the necessary means. However, it is not fair to use private resources for pandemics or other emergencies without compensation. The existence of a compensation mechanism might also increase the readiness of private rights holders to cooperate in the emergency. Therefore, generous rules on compensation are in the interest of all sides.</p>
<p>28. Liability of the state and its agents</p>	
<p>During a pandemic, ordinary provisions on the liability of the state and its agents do not apply. Liability is excluded.</p> <p>OR</p> <p>During a pandemic, liability for [gross] negligence is excluded. Agents targeted by lawsuits have the right to get reimbursed for their expenses.</p>	<p>Source: Model Law on Emergency Management.</p> <p>Emergencies trigger the need to make many decisions in a short time. Applying ordinary liability provisions might be regarded as unfair, at least when an individual state agent is attacked by a lawsuit. At least, the liability stringency should be reduced, and protection be provided to the individual agent.</p>
<p>29. Data protection</p>	
<p>The following sections / provisions of law Y (on data protection) do not apply during a pandemic: ...</p>	<p>Source: Model Law on Emergency Management.</p> <p>During a pandemic, like during any other grave emergency, it might be necessary to have access to medical data of patients in order to take the best possible decision. See also the Category II empowerment in Section 18 which permits to obtain confidential information.</p>
<p>30. Legal remedies and judicial review</p>	
<p>Legal remedies and judicial review are excluded during a declared pandemic.</p> <p>OR</p> <p>Where a pandemic of Category ... (e.g. III to V) has been declared, legal remedies, including judicial remedies do not have any suspensive effect. [However, the responsible court may reinstate the suspensive effect or take provisional decisions protecting the interests of natural [and legal] persons.]</p>	<p>Source: Model Law on Emergency Management.</p> <p>The simplest solution to not waste scarce energy and attention on legal remedies is to ban them during the pandemic. However, legal remedies can also have a warning function. Where many natural or legal persons launch legal remedies, something is very likely to go wrong. For this reason, we recommend rather still to permit legal remedies, but to suspend, if any there is, the suspensive effect of these legal</p>

Text of model law	Remarks
<p>Where the pandemic has been declared to be over, all measures taken during the pandemic are subject to ordinary judicial review[, with the exception of ...] .</p>	<p>remedies to ensure that the measures taken shall be executed. In jurisdictions with a strong position of the judiciary in the constitution, a blunt restriction of the control by courts would be unconstitutional, however it should be possible for the courts to reinstate the suspensive effect or to take provisional decisions.</p> <p>At any rate, once the pandemic is over, it should be possible for natural and legal persons to trigger ordinary judicial review. Judicial review is not only important as a first step for compensation. It is also important for the future. The time after an emergency is also the time before another emergency still to come.</p>
<p>31. Registry</p>	
<p>I. The Agency shall establish a registry for research and technology undertakings dealing with pathogens [or potential pathogens]. The registry shall at least cover the following parameters:</p> <ul style="list-style-type: none"> a. Legal identity of the operators; b. Identity of the legal representatives of the operators; c. Identity of the persons in charge of the undertaking; d. Contact means for the above; e. Start and end of the undertaking; f. Subject of the undertaking in key words; g. Short description of the undertaking; h. List of major risks identified; i. Date of submission to registry; j. Date and administrative code of authorisation, if any; [k. Risk assessment; l) Full scientific and technical documentation.] <p>II. [The parameters a. and e. to j. shall be publicly accessible and researchable.]⁹</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>Transparency creates an additional level of control by the general public.</p>
<p>32. Risk assessment, risk management and acceptability of risks</p>	
<p>I. Operators shall assess risks prior to starting their undertaking and repeat their risk assessment periodically, at least once per year, and when there are facts indicating a [potential] need for revision. To assess risks, operators shall apply ISO standard 35001 “<i>Biorisk management of laboratories and other related organisations</i>” or a more severe</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>We cannot assess the suitability of this standard. But even if it was not very stringent,¹⁶ it would be good to refer to it as</p>

⁹ Transparency creates an additional level of control by the general public.

¹⁶ Quite some standards are not very stringent due to a strong influence of industry in the standardisation process.

Text of model law	Remarks
<p>standard.</p>	<p>a minimum benchmark.</p>
<p>II. When assessing risks, operators shall take account of the severity (seriousness), the scope (the number of affected persons), the likelihood and the lasting of harm. These factors are to be multiplied. The risk assessment shall take into account all conditions influencing these factors, including those which derive from the outside such as the environment at the specific location of the undertaking.</p>	
<p>III. Indirect risks shall be taken into account.</p>	
<p>IV. In case of risk of multiple harms for the same victims, such as the risk of suffering followed by the risk of death, it is appropriate to evaluate both risks and to assess and classify risks separately.</p>	
<p>V. A particularly thorough risk assessment shall be undertaken when pathogens might lead to the extinction of mankind (“existential risk”).¹⁰</p>	<p>It would be more straightforward to say “... have an existential risk“ because the term “existential risk“ has already been defined. However, it is more user friendly to make the reader again familiar with the rather uncommon meaning of “existential risk“. Both solutions are viable.</p>
<p>VI. In case of uncertainty, operators shall apply a safety margin proportionate to the uncertainty and at least of [100%] OR [1000%].¹¹</p>	<p>In some jurisdictions, the safety factor is mandatory due to the application of the so-called “precautionary principle“.</p>
<p>VII. Operators shall reduce risks to the extent that the risk reduction does not disproportionately endanger the utility of the undertaking. To that end, they shall assess how they can improve the conditions influencing the risks, the location of the undertaking being itself one of the conditions. They shall refrain from reducing a certain risk when this risk reduction would disproportionately increase another risk. To reduce risks, operators shall cooperate with the concerned natural or legal persons. Operators shall inform the concerned persons on risks that cannot be further reduced.¹²</p>	<p>To inform the concerned persons permits them to decide whether they wish to stay in the risky perimeter.</p>
<p>VIII. Operators shall apply ISO standard 35001 “<i>Biorisk management of laboratories and other related organisations</i>” [or a more severe standard] to manage and control risks.</p>	
<p>IX. Operators shall refrain from undertakings for which, after risk reduction, the possible benefit,</p>	<p>This derogation is justified in view of the high moral value of remedying an existential</p>

¹⁰ It would be more straightforward to say “... have an existential risk” because the term “existential risk” has already been defined. However, it is more user-friendly to make the reader again familiar with the rather uncommon meaning of “existential risk.” Hence, both solutions should be deemed defensible.

¹¹ In some jurisdictions, the safety factor is mandatory due to the application of the so-called “precautionary principle.”

¹² To inform the concerned persons permits them to decide whether they wish to stay in the risky perimeter.

Text of model law	Remarks
<p>multiplied with the likelihood of the benefit, does not outweigh the various risks. [However, they may launch such a research or technology undertaking if the undertaking might help to remedy an existential risk, unless it also triggers another existential risk with a higher likelihood.]¹³</p> <p>X. Operators shall refrain from undertakings for which the benefit is not to be weighed much higher than the risks when the risks are borne by other natural or legal persons than those who take profit from the undertaking.¹⁴</p> <p>XI. Undertakings bearing an existential risk are only acceptable when they remedy another existential risk with higher likelihood.¹⁵</p> <p>XII. The final decision on whether the undertaking shall be conducted despite the risks shall be taken by the natural persons legally representing the operator. These persons shall decide on the basis of the risk documentation which shall include documentation on risk assessment, risk management and acceptability of risks.</p>	<p>risk (defined as existential risk for mankind).</p> <p>This high value is to be explained by the extremely high number of humans expected to live for the next thousands or millions of years. The extinction of mankind would stop the potential not only of billions, but trillions, or even quadrillions of humans who could live over the next millions of years.</p> <p>Risks almost always affect (also) other people than those who profit from an undertaking. Hence it would go too far to oblige to refrain from an undertaking whenever risks are borne by others than those who profit from the undertaking. The expression “much higher“ is evidently very vague. However, experience shows that legislators are often opposing precise quantification. If your legislator is different, it is worth trying a quantified criterion (50%, 100% ...).</p> <p>Because of the high number of human beings and the definitive character of extinction of mankind, an existential risk, as small as it might be, can only be justified when the undertaking leads with a certain likelihood to the remedying of another existential risk for mankind with higher likelihood, if at all.</p>
<p>33. Risk classification</p>	
<p>I. Research or technology undertakings are classified in Risk Classes I to V according to the following method: ...</p> <p>II. The risk classification for certain currently known research and technology undertakings dealing with pathogens is laid down in Annex I to this law.¹⁷</p>	<p>Develop method, e.g. in accordance with one of the risk classification models presented here. We recommend Model A for jurisdictions which only wish to manage a simple method and Model D for those which prefer a complex, fine-tuned method.</p> <p>The classes here are not identical and do not</p>

¹³ This derogation is justified in view of the high moral value of remedying an existential risk (defined as existential risk for mankind). This high value is to be explained by the extremely high number of humans expected to live for the next thousands or millions of years. The extinction of mankind would stop the potential not only of billions, but trillions or even quadrillions of humans who could live over the next millions of years. For further reflection on this aspect, we recommend the writings of the existential risk pioneer Nick Bostrom and in particular his article Existential Risk Prevention as Global Priority.

¹⁴ Risks almost always affect (also) people other than those who profit from an undertaking. Hence it would go too far to oblige to refrain from an undertaking whenever risks are borne by other than those who profit from the undertaking. The expression “much higher“ is evidently very vague. However, experience shows that legislators are often opposing precise quantification. If your legislator is different, it is worth trying a quantified criterion (50%, 100% ...).

¹⁵ Because of the high number of human beings and the definitive character of extinction of mankind, an existential risk, as small as it might be, can only be justified when the undertaking leads with a certain likelihood to the remedying of another existential risk for mankind with higher likelihood, if at all.

¹⁷ In principle, the legislator could just lay down a method and leave the rest to the administration. But the legislator would then lose control. The regulator could also try to classify the risks altogether without leaving any role to the

Text of model law	Remarks
<p>III. The Agency may [inter alia] modify and complement Annex I by administrative regulation to cover new types of research or technology undertakings.¹⁸ [It shall report to the parliament immediately [before and] after adopting such modification or completion.] [The parliament may revoke or modify the administrative regulation at any moment in accordance with the procedure set-out in]¹⁹</p>	<p>necessarily match with the categories for pandemics set out in Section 20, though it would be elegant to obtain such a match. We are not knowledgeable enough to assess whether such a match is possible and wishful.</p> <p>In principle, the legislator could just lay-down a method and leave the rest to the administration. However, the legislator would lose control. The regulator could also try to classify the risks altogether without leaving any role to the administration, but would, as a consequence, need to adapt its classification very frequently. We recommended here a mixture of the two approaches. The legislator should determine the method but also apply the method to provide concrete instruction. To apply the method on some already known research and technology undertakings has a positive secondary effect: the users of the method (the administration or the regulator at a future point in time) would see from the examples how the legislator has thought that his method needs to be applied. Most jurisdictions we know have at least two levels of regulation: one decided upon by the parliament (here also called “legislator”) and one decided upon by the government or another administration. The latter is referred to as “administrative regulation“. These two sentences would ensure better control by the legislator.</p>
<p>34. Procedural obligations of operators by risk class</p>	
<p>I. Class I: (a) Operators planning a research or technology undertaking falling in Class I shall: - fulfil the obligations set out in Articles 31 and 39, and - shall register their undertaking in the public database set-up by the Agency in accordance with Article 30. (b) Before changing their undertaking in a way that might affect risks, and at least every six months,</p>	<p>Source: Model Law on Research and Technology Risks.</p>

administration, but would as a consequence need to adapt its classification very frequently. We recommended here a mixture of the two approaches. The legislator should determine the method but also apply the method to provide concrete instruction. To apply the method on some already known research and technology undertakings has a positive secondary effect: the users of the method (the administration or the regulator at a future point in time) would see from the examples how the legislator has thought that his method needs to be applied.

¹⁸ in most jurisdictions, there are at least two levels of regulation: one decided upon by the parliament (here also called “legislator”) and one decided upon by the government or another administration. The latter is referred to as “administrative regulation“.

¹⁹ These two sentences would ensure better control by the legislator.

Text of model law	Remarks
<p>they shall update their database entries.</p> <p>(2) Class II: (a) Operators planning a research or technology undertaking falling in Class II shall: - fulfil the obligations set out in Articles 31 and 39, - apply a quality management system covering the fulfilment of the obligations contained in these Articles, and - register their undertaking in the public database set-up by the Agency in accordance with Article 30. (b) Before changing their undertaking in a way that might affect risks and at least every six months, they shall update their database entries.</p> <p>(3) Class III: (a) Operators planning a research or technology undertaking falling in Class III shall: - fulfil the obligations set out in Articles 31 and 39, - apply a quality management system covering the fulfilment of the obligations contained in these Articles, - have their quality management system certified by a conformity assessment body [entrusted by the Agency] [and] [accredited by ...], and - register their undertaking in the public database set-up by the Agency in accordance with Article 30. (b) Before changing their undertaking in a way that might affect risks and at least every six months, they shall update their database entries and inform the conformity assessment body thereof.</p> <p>(4) Classes IV and V: (a) Operators planning a research or technology undertaking falling in Classes IV or V shall: - fulfil the obligations set out in Articles 31 and 39, - apply a quality management system covering the fulfilment of the obligations contained in these Articles, - have their quality management system certified by a conformity assessment body [entrusted by the Agency] [and] [accredited by ...], - register their undertaking in the public database set-up by the Agency in accordance with Article 30, and - apply for authorisation with the Agency by submitting [the quality management system,] the risk documentation and all available scientific or engineering literature dealing directly or indirectly with risks of similar undertakings, regardless of whether this literature is in their favour or not. (b) Before changing their undertaking in a way that might affect risks, and at least every six months, they shall update their database entries and inform the conformity assessment body and the Agency thereof.</p>	

Text of model law	Remarks
<p>(5) Voluntary choice of a more stringent conformity assessment procedure: Operators may opt for a more stringent conformity assessment procedure than the one foreseen for the respective risk class.²⁰</p> <p>(6) Upclassification of ongoing undertakings: Whenever new facts or a corrected evaluation of previously known facts lead to the conclusion that the undertaking falls in a higher Risk Class than initially assumed, the operator shall immediately initiate the conformity assessment procedure for the higher Risk Class.</p>	<p>To opt for a more stringent conformity assessment procedure makes sense for operators who cannot exclude that their undertaking falls now or will later fall in another Risk Class than assumed. It might also make sense for those operators who wish to be particularly prudent or who aim for a lower liability insurance premium.</p>
<p>35. Authorisations</p>	
<p>(1) The Agency shall provide authorisations where the application is complete and the conditions set-out in Articles 31, 33 and 39 are fulfilled. In case of non-fulfilment of ... (list certain of the General Obligations), authorisations may still be provided if the research or technology undertaking might help remedy an existential risk, unless it triggers another existential risk with higher likelihood.²¹</p> <p>(2) Applications are deemed authorised if the Agency does not react within three months. [In cases of particular difficulty, the Agency may prolong the deadline for its decision up to an additional three months by notifying this prolongation to the applicant.]</p> <p>(3) For authorisations of undertakings falling in Class IV, the Agency shall consult a panel of national experts (or reference to an existing panel). (Further provisions on the composition, the setting-up and the functioning of the panel, if necessary.)</p> <p>(4) For authorisations of undertakings falling in Class V, the Agency shall consult a panel of international experts (or reference to an existing panel). (Further provisions on the composition, the setting-up and the functioning of the panel, if necessary.)</p> <p>(5) Authorisations may be limited in time or be subject to conditions.</p> <p>(6) The Agency may consult other jurisdictions, whether affected or not, prior to or after issuing authorisations. It shall inform other jurisdictions</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>For example, it might be inappropriate to require a quality management system and its certification when there is an urgent existential risk. To apply a quality management system requires at least some weeks or months of investment. To obtain certification thereof takes several months.</p>

²⁰ To opt for a more stringent conformity assessment procedure makes sense for operators who cannot exclude that their undertaking falls now or will later fall in another Risk Class than assumed. It might also make sense for those operators who wish to be particularly prudent or who aim for a lower liability insurance prime.

²¹ For example, it might be inappropriate to require a quality management system and its certification when there is an urgent existential risk. To apply a quality management system requires at least some weeks or months of investment. To obtain certification thereof takes several months.

Text of model law	Remarks
<p>which might possibly affected on its authorisations.</p> <p>(7) Authorisations may be prolonged in the same procedure as for initial applications. [However, the Agency may abstain from a new panel consultation if ... (no new facts / no new insights to be expected ...).]</p> <p>(8) Authorisations may be revoked with effect from the beginning in the following cases:</p> <ul style="list-style-type: none"> - The operator knew of facts that would have hindered the authorisation from the beginning, but did not refer to these facts in his application. - The operator exerted pressure or used illegal means to obtain the authorisation. - The operator infringed the penal code in connection with the undertaking and the infringement is directly or indirectly linked to the risk of the undertaking or the authorisation procedure. <p>(9) Authorisations may be revoked with effect from the date of [the revoking decision] [the revoking decision becoming effective] in the following cases:</p> <ul style="list-style-type: none"> - New scientific findings create the need to re-assess the risks linked to the undertakings in question. - The Agency comes to know of facts that would have hindered the Agency to authorise the undertaking if the Agency had known them prior to the authorisation. 	
<p>36. Protection of [animals] [and] [of nature] / Respect of other applicable law</p>	
<p>(1) In order to protect [animals] [and] [the nature], the Agency may refuse to authorise or ban individual research or technology undertakings by administrative decision. It may, for the same reason, also generally ban certain types of research or technology undertakings in the procedure set-out in ... (procedure for administrative regulation).²²</p> <p>(2) The Agency may also refuse to authorise or ban individual research or technology undertakings when there are reasons to believe that the undertakings infringe other applicable law.²³</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>This article distinguishes between individual and general decisions. In jurisdictions where such a distinction is not necessary, the simpler text of the article might be used.</p> <p>This is the interface permitting to assess the compliance with other applicable law, such as law on research on embryos, animal testing etc.</p> <p>The interface permits to reach a higher degree of compliance with other applicable law and thereby increases the overall</p>

²² The wording of this article distinguishes between individual and general decisions. In jurisdictions where such a distinction is not necessary, the simpler wording might be used.

²³ This is the interface permitting to assess the compliance with other applicable law, such as law on research on embryos, animal testing etc. The interface permits reaching a higher degree of compliance with other applicable law and thereby increases the overall consistency of state action.

Text of model law	Remarks
	consistency of state action.
37. Temporary ban of undertakings awaiting classification ²⁴	
<p>Pending the classification of new types of research or technology undertakings, the Agency may temporarily refuse to authorise or ban these undertakings or subject them to conditions or time-limitations.</p>	<p>Source: Model Law on Research and Technology Risks. In jurisdictions where a distinction is made between the individual and the general decisions of an administration, the wording of the previous article might be more appropriate.</p>
38. General empowerments of the Agency regarding activities of operators	
<p>(1) The Agency has the following empowerments: a) to request information and all types of internal documents, including commercial documents, from operators or natural or legal persons supposed to be operators;²⁵ b) to cooperate with their peers and scientific institutions inside or outside of ... (jurisdiction) and to exchange information and documents on the operators and their undertakings if they can formally or informally ensure confidential treatment; c) to temporarily stop an undertaking or subject it to conditions in view of further investigating the related risks; d) to definitively or temporarily stop an undertaking or subject it to conditions or time-limitations, if any of the generally applicable obligations set-out in this law are not fulfilled; e) to enforce temporary or definitive stops or other measures mentioned in c) and d) by any measures including the sealing of facilities, confiscation or destruction of data or objects;²⁶ f) [in cases of extremely high risks,]²⁷ to supervise electronic and telecommunication of operators; g) [in cases of extremely high risks or in cases of conscious or of evident non-compliance with obligations set-out in this law or in cases of criminal activities] to confiscate or transfer patent rights linked to the undertaking and to request the registration of these rights in view of subsequently confiscating or transferring them; h) to take measures similar to those permitted by</p>	<p>Source: Model Law on Research and Technology Risks. This formulation gives some leeway to the Authority in cases where the real operator, initiating the undertaking, hides behind another operator and tries to conceal his responsibility. In jurisdictions which require extremely precise and delimited empowerments, regulators might appreciate studying as reference or inspiration the Singapore Air Navigation (Amendment) Act 2014 which contains comprehensive empowerment in its Section 4.</p>

²⁴ In jurisdictions where a distinction is made between the individual and the general decisions of an administrations, the wording of the previous article might be more appropriate.

²⁵ This formulation gives some leeway to the Agency in cases where the real operator, initiating the undertaking, hides behind another operator and tries to conceal his responsibility.

²⁶ In jurisdictions which require extremely precise and delimited empowerments, regulators might appreciate studying as reference or inspiration the Singapore [Air Navigation \(Amendment\) Act 2014](#) which contains comprehensive empowerment in its Section 4.

²⁷ Principle of proportionality, applied at constitutional level in quite some jurisdictions.

Text of model law	Remarks
<p>letters a) to g) above against planned undertakings when there is either complete uncertainty regarding the risks triggered by the research project or if, based on <i>prima facie</i> evidence or findings regarding similar research projects, it is not completely unlikely that the undertaking will trigger [major] risks;</p> <p>i) to communicate its decisions to peers, to third parties and, if useful / necessary to prevent further risks or damage, to the general public, all in or outside of ... (jurisdiction).²⁸</p> <p>(2) All the empowerments shall be used with full respect of the principle of proportionality.</p> <p>(3) Decisions shall be reasoned and the legal remedies shall be pointed out.</p>	<p>This is necessary because nothing is gained if the risky undertaking is just relocated to another jurisdiction, possibly next door just behind the border. Publication of measures to peers might also stop a competition spiral downwards in terms of control intensity.</p> <p>Principle of proportionality, applied at constitutional level in quite some jurisdictions.</p>
<p>39. General obligations of the Agency regarding operators</p>	
<p>The Agency shall:</p> <ul style="list-style-type: none"> - investigate potentially risky undertakings;²⁹ - make available at least ... full-time equivalences for the investigation and authorisation of undertakings;³⁰ - ensure by internal procedures that each staff is independent and has no conflict of interest with the undertakings for which s/he is in charge; - refuse all financial or other support from operators in charge of undertakings falling under this law or legal entities which are mother, daughter or sister entities of operators; - refuse instructions from others except from the ministry for ...; - launch information campaigns to inform operators and potential future operators on the obligations set-out in this law. 	<p>Source: Model Law on Research and Technology Risks.</p> <p>Such a legal obligation might help the authority defend its interests when it comes to the annual budgeting exercise. In many jurisdictions, mandatory tasks can be easier defended against budget cuts.</p> <p>A precise indication of minimum staffing for the actual tasks avoids a disproportionate administrative overhead and may protect the financial interests of the Agency.</p>
<p>40. Obligations of operators towards staff, contractors and their staff³¹</p>	
<p>(1) Operators shall inform all their staff working on the undertaking on the obligations incumbent on the operators, on sanctions applicable to the operators and their staff and on the provisions on whistleblowing protection set-out in this law. [They shall</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>Should there be a need, this Section could be complemented by further obligations of operators and labeled “General obligations</p>

²⁸ This is necessary because nothing is gained if risky research is just relocated to another jurisdiction, possibly next door just behind the border. Publication of measures to peers might also stop a competition spiral downwards in terms of control intensity.

²⁹ Such a legal obligation might help the authority to defend its interests when it comes to the annual budgeting exercise. In many jurisdictions, mandatory tasks can be easier defended against budget cuts.

³⁰ A precise indication of minimum staffing for the actual tasks avoids a disproportionate administrative overhead and may protect the financial interests of the Agency.

³¹ If needed, this Article could be complemented by further obligations of operators and labelled “General obligations of operators”.

Text of model law	Remarks
<p>prove the fulfilment of these obligations by sending to the Agency the signed declarations of the staff according to which they have been informed about all this.]</p> <p>(2) Operators shall train their staff on all the legal obligations set-out in this law.</p> <p>(3) If the operators refer to contractors, the same obligations shall apply with regard to contractors and the staff of contractors.</p>	<p>of operators“.</p>
<p>41. Administrative sanctions against operators and persons working for the operators</p>	
<p>I. The Agency may impose on operators administrative sanctions of up to three times their annual budget in case of non-fulfilment of obligations set-out in this law.</p> <p>II. Persons steering or co-steering undertakings covered by this law, regardless of whether they are employees or contractors or staff of contractors, are subject to a penal sanction of up to ... years of imprisonment or a fine of up to triple their annual net salary in cases of wilful non-fulfilment of obligations incumbent on the operators. They are subject to a penal sanction of up to ... years imprisonment or a fine of up to one annual net salary in cases of negligence with regard to the obligations incumbent on the operators.</p>	<p>Source: Model Law on Research and Technology Risks.</p>
<p>42. Bio-safety alerts</p>	
<p>The Agency shall create a central alert portal which permits the uploading of information on possibly problematic undertakings dealing with pathogens [or potential pathogens] anonymously. It shall also provide a hot-line via which any person may inform the Agency orally.</p>	<p>Source: Model Law on Research and Technology Risks.</p>
<p>43. Whistle-blower protection</p>	
<p>(1) Employees or other persons working for operators, contractors of operators and staff working for contractors of operators are exempted of their confidentiality obligations under labour or contractual law and any other legal provisions or contracts obliging them to keep information of the undertaking or its operator confidential provided that they act in good faith when disclosing information on possible infringement of legal obligations set-out in this law.</p> <p>(2) Statement of whistle-blowers shall be recorded in presence of ... (e.g. a judge) and can be used in</p>	<p>Source: Model Law on Research and Technology Risks.</p>

Text of model law	Remarks
<p>all state procedures, including criminal and civil law procedures.</p> <p>(3) The Agency may compensate whistle-blowers for damage, advise them, and organise the change of identity with the help of the authorities ... (in charge of identity documentation).</p>	
44. Confidentiality	
<p>The Agency shall keep all information confidential, unless the sharing of information is explicitly foreseen in this law or other laws or regulation. The Agency [keeps] OR [may keep] information obtained from a whistle-blower confidential even where there is an obligation to share this information set-up by other laws or regulation. The Agency [may not] OR [may] share information obtained from whistle-blowers with other jurisdictions unless the whistle-blower agrees thereto.</p>	<p>Source: Model Law on Research and Technology Risks.</p>
45. Liability of research and technology operators	
<p>I. [Regardless of whether they neglected their duty of care.] Operators of research and technology undertakings dealing with pathogens [or potential pathogens] are liable towards those natural or legal persons who were affected by a harm [most] probably caused by the undertaking. Causality is also proven in cases where the harm is caused by a chain of events which are each linked by a causal relationship.</p> <p>II. [Where the damaged person has proven the harm and provided first evidence for the causality between the undertaking and the harm, e.g. by reference to generally recognised causal chains, causality shall be assumed unless the operator proves that there is no causality given.]</p> <p>III. [Research and] Technology undertakings dealing with pathogens [or potential pathogens] that might cause harm to more than [1.000 / 1.000.000] persons or harm(s) worth more than 1.000.000 [\$, €, ¥, ... or] shall be covered by liability insurance of an insurer with place of business in one of the following jurisdictions: ... [The liability insurance must accept direct claims from damaged persons.]</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>Best to specify the likelihood benchmark, preferably by indicating a quantified likelihood.</p> <p>Another fair solution is to give the victim the benefit of the doubt where the victim can provide <i>prima facie</i> (first sight) evidence.</p> <p>The insurance obligation ensures the ability to compensate harm.</p> <p>But legal bodies in charge of undertakings can disappear entirely, e.g. following insolvency. For these cases, it is useful to give a direct right to claim compensation from the insurance.</p>
46. Financial incentives and involvement in funding procedures	

Text of model law	Remarks
<p>(1) The Agency may subsidise within the limits of its budget:</p> <ul style="list-style-type: none"> - The development of best-practice guidance for research and technology undertakings; - Voluntary compliance programs referring to the legal obligations or the best-practice guidance established by organisations which are representative of the research or technology sector in question. - Voluntary mutual control by analysis of research and technology projects by an expert panel set-up by a roof organisation. <p>(2) Within this range, Agency shall give priority to ...</p> <p>(3) The Agency is to be invited to participate all research and technology funding procedures. It may veto the attribution of funds in case of non-compliance with this law [or best-practice guides established by recognised research or technology organisations].³²</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>For research, public funds are the most important financial source. Hence it should be possible for authorities to establish a link between the fulfillment of legal obligations and public funding. A similar mechanism could be created to favour the application of best-practice codes.</p>
<p>47. International cooperation with regard to operators</p>	
<p>I. The Agency may conclude formal and informal cooperation agreements with other jurisdictions and international organisations on information exchange, mutual advice, and cooperation on enforcement with regard to operators.</p> <p>II. The Agency may use its general empowerments provided in Article 37 to enforce administrative measures of the other jurisdiction [provided that reciprocity is ensured at least on the basis of an administrative arrangement].</p>	<p>Source: Model Law on Research and Technology Risks.</p> <p>As operators sometimes act in various jurisdictions, it is important to obtain possibilities to enforce on the territory of other jurisdictions. These other jurisdictions will hardly be ready to cooperate if they do not obtain reciprocity. Hence it is useful to have, in one's own jurisdiction, the possibility to assist authorities of other jurisdictions</p>
<p>48. International sanctions against non-cooperative states in case of extinction risk</p>	
<p>I. The Government may suspend any international cooperation, including cooperation mandatory under international agreements, where a state does not react appropriately during a pandemic, before an upcoming pandemic or with regard to operators dealing inappropriately with pathogens, provided that the pandemic or the pathogens threaten the existence of the entire mankind.</p> <p>II. The Government may under the same condition</p>	

³² For research, public funds are the most important financial source. Hence it should be possible for authorities to establish a link between the fulfilment of legal obligations and the public funding. A similar mechanism could be created to favour the application of best-practice codes.

Text of model law	Remarks
sanction the responsible state. III. The Government may under the same condition use its secret services [and its military] on the territory of the responsible state to reduce the risk of extinction of mankind.	

Annex 1 – Risk classification for currently known research and technology undertakings dealing with pathogens

(To be developed by scientists.)