Maturing Biological Risk Management for EU competitiveness and innovation in the life sciences

EBSA Position Paper on EU OMNIBUS Simplification Package

16 April, 2025

Executive summary

Founded in 1996, the European Biosafety Association (EBSA) is a professional organization that focuses on biosafety and biosecurity. It serves as a platform for professionals across Europe, and beyond, to share knowledge, collaborate, and promote best practices in the field. EBSA supports the responsible and sustainable development of Europe's life sciences and education sectors through risk-based management of potentially hazardous biological materials. Committed to collaborating with the European Commission, EBSA works to enhance biosafety and biosecurity standard practices while fostering innovation and competitiveness across biotechnology, and human, animal, and plant health sectors. EBSA welcomes the advancing collaboration with the European Commission to continuously uphold and strengthen biosafety and biosecurity standards, with a focus on the following aspects:

- **Simplification and harmonization** of the regulatory frameworks for **biological risk management** relating to the contained use of biological materials pathogenic to humans, animals, and/or plants or from biotechnology approaches.

- **Creation of one central register of biological agents** (i.e. human, animal and plant pathogens, as well as invertebrate pests) as the authoritative one-stop shop at the EU-level for the hazard classification and regulatory requirements for these biological agents.

- **Simplification of the Animal By-Products Regulations** (ABPR) through sector-specific exemptions or alternative means to comply (e.g. when the activity is already covered through other legislation).

- **Adaptation of the Biocidal Product Regulation** (BPR) to incentivize Producers to register or to exempt them if used under contained circumstances with safeguards for environmental protection.

EBSA is steadfast in its collaboration with the European Commission to uphold biosafety and biosecurity standards while driving innovation and competitiveness within the biotech sector. Our professional community remains fully available to engage further on any of the points outlined in this report.

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Introduction

Founded in 1996, the European Biosafety Association (EBSA) is a professional organization that focuses on biosafety and biosecurity. It serves as a platform for professionals across Europe and beyond to share knowledge, collaborate, and promote best practices in the field. Furthermore, EBSA is dedicated to promoting and disseminating best practices in biosafety and biosecurity among its members and in the greater professional, research and industrial communities. The association actively fosters dialogue on emerging challenges and plays an advisory role in shaping practices to mitigate risks associated with biological agents and materials. EBSA gathers more than 600 members from 45 countries and represents biosafety professionals from academic, clinical, governmental and industrial environments (1). As Europe's sole professional body for biosafety experts, EBSA drives scientific evidence-based biorisk management in various sectors.

Considering the aim of European Commission's Competitiveness Compass (2) to streamline legislation and enhance European competitiveness, EBSA welcomes the OMNIBUS simplification effort as a significant step towards reducing administrative burdens while maintaining high standards within EU legislation.

Of particular interest to the biosafety professional community, represented by EBSA, the EC's Competitiveness Compass also emphasizes "Putting Research & Innovation at the heart of our economy" (3) including the ambition to streamline and simplify processes to bring biotech from the laboratory to the market through a European Biotech Act (4).

Within the realm of biological science, whether it is for diagnostics, research and development, or industrial applications, EBSA has identified legislation that may benefit from simplification or improved harmonization to address the challenges faced by duty holders as well as regulators in the Member States. Examples include misaligned provisions in the legislation concerning Contained Use of Genetically Modified Microorganisms, Workers' Protection or Animal By-products. This paper aims to outline these challenges for EU biotechnology and pharmaceutical companies, labs, startups and academics in terms of regulatory complexity, which translates into increased costs, delays and loss of competitiveness. We share our reflections on how to simplify the current legislative framework and what the potential benefits could be.

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Biotechnology

Relevant legislation:
Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMM)
Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) into the environment
Regulation (EC) 1946/2003 on transboundary movements of GMOs

Challenge(s):
The GMO legislation regulates genome-edited organisms in which genetic alterations (mutations) have been introduced that exist in nature or can arise through conventional breeding. This leads to a situation where organisms with the same mutation – one made through genome editing and the other made using conventional methods – are treated differently. For plants, new NGT (New Genomic Techniques, also referred to as Genome-edited or GE) legislation is being negotiated that should be better fit for purpose, but for GE micro-organisms no alternative legislation has been proposed yet.

Considerations for simplification:
With the upcoming Biotech Act, the European Union has the opportunity to create a streamlined and predictable product-based legislative environment taking into account the specifics of either classically genetically modified or genome-edited organisms. Specifically for genome-edited (GE) micro-organisms, a separate regulatory framework that treats these micro-organisms in the same way as wild-type micro-organisms should be created, thereby removing them from the scope of the GMO legislation (both the contained use and deliberate release legislation). It should be recognized that most of these micro-organisms or their products will be subject anyway to the applicable product legislation when before they can be placed on the market.
It could also be considered to harmonize various GMO definitions in light of the 2018 CJEU ruling (6) and the long-existing definition of Living Modified Organism (LMO) as described in the Cartagena Protocol on Biosafety (7).

Potential benefits:
With science-based and predictable legislative frameworks for GMO's and GE organisms, Europe can maintain its position in the front of the biotechnology race, whether it is for medicines, food and industrial processes. For both NGT plants and GE micro-organisms this would allow for reduced administrative effort while still maintaining the high product safety enshrined in Europe's core values.

Workers' Protection

Relevant legislation:
Directive 2000/54/EC on protection of workers from risks related to exposure to biological agents at work

Challenge(s):

- The directive widely overlaps in process with the processes required for other biological materials (GMM, animal, plant). This overlap/duplication results in an undue high administrative burden.

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- The risk assessment provision lacks structure and guidance to its implementation, and there is no alignment with the GMM Contained Use Directive. For instance, the Containment Tables in 2000/54/EC Annex V are not aligned with the requirements in 2009/41/EC Annex IV even though the Workers' Protection Directive is also applicable for GM-versions of human pathogens.
- Annex III (Community classification of biological agents) is restricted to "pathogens known to affect man".
- Annex III is too rigid and lacks frequent updates in line with Article 16. E.g. SARS-CoV-2 remains to be classified as risk group 3, while in practice the pathogen has evolved to a commonly circulating, well treatable risk group 2 agent.

Considerations for simplification:
Simplification could come from the ability to refer to already running processes under other regulatory frameworks. Hence, the different legislative frameworks could benefit from streamlining the approval processes and its timelines, as well as risk assessment requirements and containment requirements. In this effort, the draft instrument guidance from the International Labour Organization (ILO) on protection against biological hazards in the working environment should be considered as well (8).
In addition, there could be a much more frequent update to the classifications of biological agents based on a dynamic and purposeful implementation of the classification criteria.

Potential benefits:
It would allow duty holders to implement a more unified approach without the risk of being confronted with conflicting requirements between different regulators or differences in interpretation of how a risk assessment should be performed. More frequent updates, as are now urgently needed for SARS-CoV-2, would prevent the application of very strict and very expensive containment measures that are no longer warranted.

Biocides

Relevant legislation:
Regulation (EU) 528/2012 on Biocidal Products (Biocidal Products Regulation, BPR)

Challenge(s):
To safeguard workers and the environment, (potentially) biologically contaminated material (e.g. solid or liquid waste, surfaces) must be inactivated before reuse or disposal, so that exposure is avoided. Chemical disinfectants, falling under the definition of biocides, are used for this purpose. Such biocides include "disinfectants and algaecides not intended for direct application to humans or animals" (product type 2, PT2), and "products used for veterinary hygiene" (PT3). As a result of the implementation of the BPR some disinfectants, regularly used in research, manufacturing or diagnostic activities involving pathogens and/or GMOs, are taken off the market, although they are proven effective and have been validated (as required by the contained use legislation). For others, which are subject to the transitional regime, there is lingering uncertainty whether their registration will be continued due to high dossier costs.

Consequently, operators are confronted with a decreasing number of authorized disinfectants for validated inactivation of (micro)organisms. Some specific challenges are listed below:

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- BPR information is poorly coordinated between national authorities and the European Chemicals Agency ECHA. Users are often left with the very challenging task of identifying authorised products for specific applications and sometimes there are application gaps, for which there seems to be no process to obtain derogation in specific applications.
- Genetically modified eukaryotic cells, even though not infectious, fall within the scope of the contained use legislation and, as such, require validated inactivation before final disposal, e.g. using chemical disinfectants. It is unclear whether such disinfectants (which are used to protect humans, animals, materials or articles against harmful organisms) have to comply with the BPR as the BPR concerns the placing on the market and use of biocidal products.
- The removal of certain validated products from the market requires validation of similar/other products, which, especially in a GMP environment, is highly time-consuming and costly.

Research labs and biotech or pharmaceutical companies are end-users of biocides yet have to deal with the consequences if a proven disinfectant is pulled out from the biocides market. This can create worker safety and/or product quality issues. In addition, prescriptions for use may not cover all validated use cases, which can create compliance issues. Similarly, conflicting requirements have been identified between the BPR and other EU or national laws, such as the EU Foot and Mouth Disease (FMD) Minimum Standards (9).

Considerations for simplification:
Disinfectants are a relatively small market, so producers should be incentivized to register disinfectants and include multiple uses. Additionally, validation studies should be accepted by ECHA or national authorities to augment ECHA registrations. Alternatively, if the active substance is used under contained facilities, under e.g. Contained Use or Workers' Protection permit restrictions, i.e. preventing environmental release, there should be no need for additional regulation.
None of the PT2 registered products mention in their authorization certificates the inactivation of liquids as an authorized application, whereas this is commonly applied in laboratory practice.

Potential impact:
The proposed approach will decrease the risk of market disruption as well as offer better protection of human, animal and plant health.

Animal By-Products

Relevant legislation:
Regulation (EC) 1069/2009 on animal by-products and derived products not intended for human consumption (Animal By-Products Regulation, ABPR) and its Implementing Regulation (EC) 142/2011

Challenge(s):
The ABPR was introduced in response to the Bovine spongiform encephalopathy (BSE) crisis yet evolved to a central regulatory framework that covers all areas of life science, the food-chain and feed-chain industry. This wide remit combined with the rigidity of the framework creates unnecessary regulatory burden, especially for life science research organisations, while in other sectors like slaughterhouses tailored approaches have been developed to limit the burden.

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As a result, research organizations are confronted with very strict obligations for activities with substances that do not pose a risk of re-introduction of these substances into the food or feed chain. Concrete examples include small scale research activities with antibodies, animal serum, commercially available Fetal Calf Serum (FCS) and Bovine Serum Albumin (BSA) etc.

Considerations for simplification:
The research sector should be recognized as a sector that poses negligible risk of re-introducing hazardous ABPs into the food and feed chain. Materials are generally inactivated and disposed of in a way that prevents these materials from entering the food or feed chain. This should allow for more categorical exemptions for the research and education sectors, thereby eliminating requirements such as import permits.
We would like to draw attention to a potential approach on a national level that was taken, i.e. the regulatory framework related to animal by-products in Belgium. Based on the EU Regulation (EC) 1069/2009 and the Implementing Regulation (EC) 142/2011, national legislation has been implemented specifically focusing on the use of animal by-products in the context of R&D and education (10). Alternatively, an option to qualify certain ABPs in a manner that releases them from the ABPR controls should be considered beyond the pharmaceutical sector, where this is already applied.

Potential benefits:
Avoidance of unnecessary administrative burden and improvement of compliance.

Plant Health

Relevant legislation:
Regulation (EU) 2016/2031 on protective measures against plant pests (Plant Health Law, PHL), with corresponding set of implementing and delegated acts.

Challenge(s):
Seeds, plants and fresh plant materials (e.g. plant cell lines, immature seeds, leaf samples) that are either imported from third countries or shipped within the EU, with the sole purpose of being handled or grown in contained facilities for research purposes, and therefore not entering any field, are being subjected to the same phytosanitary requirements (e.g. phytosanitary certificates, plant passports) as seeds or plants intended for planting that are either released into the environment or transported for commercial purposes. Since these materials are only handled in contained facilities the phytosanitary risks for the EU are considerably lower than those of commercial materials.

- Because all these materials are considered living plant materials, a phytosanitary import inspection is needed at the first point of entry into the EU, following a prior notification via TRACES-NT and the creation of a CHED-PP, with a physical check to be performed on 1% of the consignments. As a result, research or diagnostic institutions wanting to import such materials need to revert to expensive specialty courier services and are confronted with delays or even loss of their samples in case of perishable materials.
- Similarly, intra-EU plant passports, implemented to ensure traceability and absence of quarantine and RNQP pests, are now required for all plants for planting (incl. seeds), with only limited exemptions for certain seeds and purposes, leading to considerable administrative efforts for research institutes.

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In addition, for materials that are not grown inside contained facilities but directly processed in a destructive (often molecular) analysis, the risk of (re-)introduction of plant pathogens into the environment or food production chain is nonexistent.

While exemptions "for official testing, scientific or educational purposes, trials, varietal selections, or breeding" can be requested under Delegated Regulation (EU) 2019/829, this requires the establishment of an authorized "confinement facility", and an official Letter of Authority (LoA) for import that needs to be officially endorsed by the EU MS or 3rd country of origin, a process which is cumbersome and not feasible for many smaller research organisations.

Considerations for simplification:
Several measures could be implemented in the short term to improve the EU's Plant Health framework without the need for new legislation or reopening Regulation (EU) 20216/2031.

- Broaden the current exemptions for five fruits as described in Implementing Regulation (EU) 2019/2072 to also include seeds, plants and fresh plant materials that are imported from third countries with the sole purpose of being handled or grown in contained facilities for research purposes or for destructive (often molecular) analysis
- Exempt the need for plant passports for seeds, plants and plant material that are only handled in containment facilities, through an update of the Implementing Regulation (EU) 2019/2072
- Adapt the Delegated Regulation (EU) 2019/829 to include a lighter regime for institutions receiving seeds and plant samples for destructive analysis.

Potential benefits:
By addressing the current obstacles in the EU Plant Health framework, the efficiency and resource-use of R&D for both crop protection and crop improvement innovations could be significantly reduced. This would enable European research and innovation institutes to accelerate their development processes, providing farmers with timely access to an enhanced toolbox of varieties & crop protection products for the needs they are confronted with (e.g. nutrient use, climate change, diseases etc.). With leaner regulatory frameworks and less administrative burden, the return on investment for research & development activities would improve, encouraging more companies & institutes to retain their R&D in Europe.

Animal Health

Relevant legislation:
Regulation (EU) 2016/429 on transmissible animal diseases (Animal Health Law, AHL)
Regulation (EU) 2021/632 of 13 April 2021 laying down rules for the application of Regulation (EU) 2017/625 (Official Controls Regulation, OCR)

Challenge(s):
The Animal Health Law (2016/429) has replaced all previous EU instruments/requirements for animal pathogen biosafety with a statement of intent that also enables Commission delegated acts to regulate biosafety, biosecurity, and bio-containment for listed animal pathogens, and movement of disease agents, vaccines and other biological products (Art. 16). In addition, this article refers to "any relevant international standards" as guidance for concrete measures. Specifically:

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- The regulation´s remit is limited to a current list of in total 58 diseases affecting animals (Regulation (EU) 2018/1629). Yet, many more biological agents cause infection and harm in animals (whether it is livestock, pet animals or wildlife), and require biosafety measures to prevent the spread from scientific facilities (not-withstanding that a few are also subject to the Workers' Protection Directive (2000/54), the GMM Contained Use Directive (2009/41), or in some cases national legislation).
- The resulting gap is posing significant regulatory uncertainty for the animal health sector. A concrete example is FMDV, where the *Minimum Biorisk Management Standards for laboratories working with foot-and-mouth disease virus (MBRMS) formed* an Annex to the FMDV Directive (2003/85/EC), which was subsequently repealed, leaving MBRMS without any legal power unless they are made a condition of the operating authorisation in a country, and possibly leading to an increased risk of virus escape (11).
- All EU Member States have agreed to the WOAH Biosafety and Biosecurity Standard (12), whereas this has not yet been implemented into law at the EU level or in EU Member States.

Cultures of animal pathogens are subject to official control upon importation in accordance with Implementing Regulation (EU) 2021/632, and an import permit must be applied for this purpose, even when the materials are approved for commercialisation. As a concrete example - an import permit and official control is required when importing *Bacillus thuringiensis (*a pathogen for insects) for research purposes, whereas anyone can freely buy *Bacillus thuringiensis* solutions as a biocontrol agent.

Considerations for simplification:

- A unified regulatory framework for work with biological agents that covers wild-type and genetically modified human, animal, and plant pathogens would be a game changer in the EU biosafety landscape and could facilitate a more integrated One Health approach.
- A common classification system for animal pathogens into biosafety hazard groups would reduce the burden for duty holders and regulators and would enable a more level playing field in EU Member States. The main difference between countries in relative risk is the epidemiological situation, i.e. where specific pathogens are enzootic or absent, and therefore would require less or more biocontainment. This could be included with ease in a classification system.
- Allow exemptions for commercially available products like *B. thuringiensis* bio-control solutions.

Potential benefits:

The proposed consideration could inform a more consistent approach to prevent the spread of animal pathogens, resulting in reduced suffering in affected animals as well as enhanced compliance with duty holders.

Common register of biological agents & pests

Relevant legislation:

Biological agents, as defined in the ISO standard for biorisk management (5) and pests are regulated through a number of regulations and treaties for very different purposes: human health, (bio)security, veterinary public health, plant health, transportation, import/export, protection of endangered species etc. Lists developed at EU level are often transposed into national lists with modifications.

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1. The Workers' protection Directive 2000/54/EC provides in Annex III a community classification for human pathogenic biological agents
2. Regulation (EU) 2016/429 on Animal Health lists the 5 most important diseases in Article 5 and further 40 animal pathogens in Annex II. However, it does not provide any hazard classification relating to activities with these biological agents. Regulation (EU) 2018/1629 broadens this list to a total of 58 diseases.
3. The Annex II of Implementing Regulation (EU) 2019/2072 to Regulation (EU) 2016/2031 on Plant Health lists the Union Quarantine Pests for plants.
4. Regulation (EC) No 428/2009 on dual-use items includes a list derived from the Australia Group list containing human, animal, and plant pathogens.
5. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) is implemented in the European Union through EU Regulations (EC) 338/97 and (EC) 865/2006.

Challenge(s):
Duty holders and regulators are overwhelmed by these lists that lack congruence leading to undue burden on duty holders, and unnecessary risks to public health, veterinary health and plant health. The lists are not coordinated and sometimes take years to be updated, if ever updated, leading to regulatory uncertainty that discourages investment in the European life sciences sectors.
Furthermore, there is no list of commercially approved genetically modified microorganisms for contained laboratory or industrial applications.

Considerations for simplification:
EBSA suggests the development of a central source for classification of biological agents & pests including viruses, bacteria, fungi, pests and parasites affecting humans, animals, and plants. This register should centrally collate and inform agent-specific requirements for biosafety, biosecurity, transport, import/export, disease notification, food safety etc. Such a central register would ease the burden on individual duty holders and significantly reduce the risk for non-compliances.

Developing coherence in the biological risk management framework for Europe

Relevant legislation:
The directive for workers' protection from biological agents (Directive 2000/54/EC), the directive for contained use of genetically modified microorganisms (Directive 2009/41/EC), the EU animal health law (Regulation (EU) 2016/429), and the plant health regime (Regulation (EU) 2016/2031) all regulate the use of biological agents or biological materials in contained facilities.

Challenge(s):
Many duty holders/activities fall under the purview of multiple regulations/regulators relative to biological risk management, in some Member States as many as four to six separate competent authorities. This creates a number of challenges:

- High regulatory burden required for the compliance with multiple regulatory regimes administered by separate regulators.

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- Poor coordination between regulations and regulators leaves gaps (where the regulators have either inadequate competency and/or authority) or may result in conflicting biorisk management requirements.
- The overlapping remit by separate regulators is a burden not only for duty holders but also for taxpayers. In addition, limited resources available to the regulators do not permit the required specialisation, contributing to poor oversight and higher cost for regulatory governance (13).
- Lack of agility to respond to new and emerging health threats.
- Overregulation and regulatory uncertainty discourage international investment.

Considerations for simplification:
One overarching regulatory framework for biorisk management under one competent authority oversight would be a gamechanger: The intent for containment, the (bio)risk management measures, and the administrative requirements for the contained use of human, animal, and plant pathogens, whether wild-type or genetically modified, are very similar and would benefit from a coherent risk-based regulatory approach:

- One regulatory framework would reduce the burden for duty holders.
- One regulatory framework under one well-resourced regulator with the required technical expertise (with the ability to draw in subject matter experts for the different subdisciplines) and authority would increase cost efficiencies in regulatory bodies.
- A European Biorisk Management task force to support national regulators with technical audits would be a resource that could strengthen local regulators. Biorisk Management in high containment facilities is a complex topic and regulators in the Member States are often not equipped to inspect these complex systems (11).

Looking at the global landscape, the World Health Organization (WHO) (14), the International Labour Organization (ILO) (8), the World Organisation for Animal Health (WOAH) (12) and the International Plant Protection Convention (IPPC) (15) all consider biological risk management as a priority. In the perspective of One Health, it would only be logical to combine the efforts to safeguard human, animal and plant health as well as environmental protection in a single regulatory framework.

Final reflections

EBSA fully supports the initiative of the European Commission leading to regulatory simplification and legal coherence in the life sciences domain. To name a few, the EU Life Science Strategy (16), the upcoming Biotech Act, and the 10th Framework Programme for Research and Innovation (FP10) will surely help in creating a more streamlined and supportive environment for institutions or companies performing diagnostics, research and development, or industrial applications in the life sciences domain.

We recommend conducting a risk-based review of the EU's regulatory framework for life sciences to reduce complexity. In this review, attention should be given to mapping and analysing overlaps and inconsistencies in EU legislation, as well as ensuring future-proofness of the regulations to cover for upcoming technological innovations. In this way, regulatory simplification, clarity and coherence will enable active research and innovation to remain in the EU.

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