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2025/0405 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

This proposal accompanies the Regulation (EU) …/… [European Biotech Act], which establishes a legislative framework to strengthen the competitiveness of the health biotechnology sector. That Regulation creates and reinforces favourable conditions for health biotechnology, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety, and biosecurity. For the purposes of that Regulation, health biotechnology means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public-health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union. The overall context, rationale and objectives of that horizontal initiative are set out in detail in its accompanying Explanatory Memorandum. In order for the new framework to operate effectively within the existing acquis, targeted updates are required in two pieces of sectoral legislation.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms[1]

Genetically modified micro-organisms (GMMs) play a decisive role in biotechnology, both as a tool for manufacturing but also as products themselves. Micro-organisms reproduce and grow rapidly and can be easily engineered. Their applications are broad and diverse and go well beyond the health sector. Products explored for agri-food use include novel biofertilisers and biopesticides, biological food preservatives, and biosensors registering the contamination of food products. In the industrial sector GMMs can be used to remove harmful chemicals and gases, including CO_2, from effluents and emissions or to recover valuable metals like gold or lithium from electronics and battery waste. Similar GMMs can also be used in environmental applications to restore soil health and water quality. Also, applications to modulate the gut microbiome of cattle to reduce methane emissions are explored. A number of these products are already commercialised or in later stages of development in third countries, notably the USA and China. Together, these products could have a substantial impact on the EU economy and competitiveness, and contribute to, for example, the reduction of greenhouse gas emissions, the use of more sustainable tools in agriculture, the reduction of food waste, the removal of residues of pesticide and medicines use from the environment or the combat of antimicrobial resistance.

The development time and costs for a GMM are much lower compared to other genetically modified (GM) organisms such as GM plants. Hence, the regulatory framework needs to ensure that GMMs and their derived products reach the Union market before becoming obsolete.

[1] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj).

To unlock the innovation potential of GMMs and to render the EU market more attractive for their development, production and marketing, it is necessary to make the applicable rules on GMMs fit for purpose. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs) was primarily designed to regulate GM plants, making it less suitable for GMMs, which differ significantly from plants in terms of biological properties and capabilities as well as potential applications.

Directive 2010/53/EU on quality and safety of human organs intended for transplantation[2]

The area of solid organ transplantation, which forms part of the broader domain of Substances of Human Origin (SoHO), is subject to continuous innovation, in particular through technologies aimed at expanding the ex-vivo time window between procurement from the donor and transplantation into the recipient. The extension of this time window creates opportunities for applying different types of processing operations to maintain or improve the functional status of organs prior to transplantation. To achieve legal certainty, this Act introduces provisions clarifying how these processing activities can be organised under the oversight of the transplant authorities. Where such processing involves medicinal products, medical devices or SoHO preparations, transplant authorities shall collaborate closely with the corresponding competent authorities with the relevant expertise in those areas, ensuring coherent oversight and coordinated regulatory implementation.

- **Consistency with existing policy provisions in the policy area**

The targeted amendments to Directive 2001/18/EC are consistent with the overall objectives of that Directive, namely, to ensure a high level of protection of human health and the environment in the deliberate release and placing on the market of GMOs and to ensure the effective functioning of the internal market. The adjustments proposed here have the aim of creating a tailored, more efficient and streamlined regulatory framework for GMMs. They relate to the risk assessment, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs, as well as to the introduction of the concept of low-risk GMMs, including scientific criteria confirming this status, and set a framework for a streamlined authorisation procedure for eligible low-risk GMMs. These measures to be introduced reflect recent scientific assessments and are in line with scientific and technical progress after the adoption of the Directive.

The amendments to Directive 2010/53/EU are likewise consistent with its objective of ensuring high standards of quality and safety of human organs intended for transplantation. Clarifying the regulatory treatment of organ processing activities and strengthening oversight mechanisms aligns the Directive with current clinical practice and supports coordinated implementation across Member States.

Together, these targeted amendments preserve the protection objectives of the existing legislation while contributing to the objectives of the Biotechnology Act.

[2] Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj).

- **Consistency with other Union policies**

The proposal supports the wider objectives of the European Biotechnology Act, which forms part of the Union's strategic efforts to strengthen competitiveness, innovation capacity and the safe development of biotechnology across sectors. The proposal contributes to a more consistent, inclusive and predictable regulatory environment for biotechnology applications in the Union.

The amendments to Directive 2001/18/EC are coherent with Union policies promoting science-based risk assessment and proportionate regulatory requirements, including the work of the European Food Safety Authority (EFSA) in the area of GMMs. They also complement Union initiatives aimed at supporting research, innovation and the safe use of biotechnology in industrial, environmental and health-related applications.

The amendments to Directive 2010/53/EU are consistent with broader Union policies on public health, quality and safety of medical treatments, and the effective functioning of cross-border healthcare systems. By clarifying the regulatory treatment of organ processing technologies, the proposal supports coordinated implementation across Member States and complements Union actions in adjacent areas, such as medicinal products, medical devices and substances of human origin.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

– Article 114 of the Treaty on the Functioning of the European Union ('TFEU') which provides the basis to take measures for the approximation of laws which have as their object the establishment and functioning of the internal market. In accordance with Article 114(3) TFEU, the proposal seeks to achieve the objective of a high level of health and safety protection;

– Article 168(4) TFEU, concerning the achievement of a high level of human health protection through the adoption, in order to meet common safety concerns, of measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; in the veterinary and phytosanitary fields which have as their direct objective the protection of public health; and measures setting high standards of quality and safety for medicinal products and devices for medical use.

- **Subsidiarity (for non-exclusive competence)**

In accordance with the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States.

The requirements for the placing on the market of GMMs as or in products are already harmonised at Union level under the existing legal framework applicable to GMOs. For the reasons explained above, the regulatory framework needs to be adapted to the specificities of GMMs. To this end, action needs to be taken by the Union by amending Directive 2001/18/EC.

To achieve the goals outlined above, an amendment to Directive 2010/53/EU is necessary, which can only be done at Union level.

- **Proportionality**

The proposal does not go beyond what is necessary to ensure the main objectives of Regulation (EU) …/… [European Biotech Act] and the existing sectoral legislation are met, namely safeguarding high standards for the protection of human health, animal health, patients and consumers, and the environment, while strengthening the competitiveness of the biotechnology sector.

Moreover, as regards the amendment of Directive 2001/18/EC, the proposal ensures proportionality by providing for the adaptation of risk assessment and other requirements to reflect the specificity of GMMs and creating tailored provisions for low-risk GMMs. These adaptations are intended to ensure that the applicable requirements do not go beyond what is necessary to ensure the legislation's objectives, and in particular a high level of safety for human health and the environment.

- **Choice of the instrument**

Since the proposal amends existing directives, a Directive is the appropriate instrument. This ensures that the necessary adjustments are made directly to Directives 2001/18/EC and 2010/53/EU while preserving their legal structure and transposition mechanisms.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks**

The Commission published in 2021 a study on new genomic techniques ('NGTs') applied to plants, animals and micro-organisms[3], which concluded that data was still too limited to take any policy actions in this area. The study identified limitations to the capacity of the GMO legislation to keep pace with scientific developments that cause implementation challenges and legal uncertainties. It concluded there were indications that the applicable legislation needed to be adapted to scientific and technological progress. As follow-up to the study, the Commission adopted a legal proposal on plants obtained by certain NGTs[4]. However, for other NGTs and for applications in other organisms, including micro-organisms, the study concluded that the necessary scientific knowledge was still limited or lacking, especially on safety aspects.

To address these knowledge gaps, the Commission requested EFSA and the European Union Reference Laboratory for genetically modified food and feed and the European Network of GMO laboratories (ENGL) to deliver reports on micro-organisms.

On 19 June 2024, EFSA adopted an opinion on the application of new developments in biotechnology to micro-organisms, in which it concluded that possible hazards relate to the changes introduced, regardless of the method used, and that the risk assessment should be based on the characteristics of the product containing or consisting of micro-organisms. It also

[3] Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16, SWD(2021) 92 final.

[4] COM(2023) 410 final.

concluded that for certain GMMs fewer requirements for risk assessment would be needed compared to those applicable to GMOs in general[5] and provided some criteria to identify those GMMs[6].

The EURL-ENGL delivered its report on the detection of micro-organisms obtained with NGTs[7] in 2025, pointing to certain challenges due to technical difficulties and to the fact that in some instances similar modifications to those obtained with NGTs may also occur naturally.

This opinion and report provide relevant scientific evidence for this proposal. EFSA's wider work on micro-organisms has also been taken into account[8].

For organ transplantation, implementation experience with Directive 2010/53/EU has shown the emergence of increasingly sophisticated organ preservation and processing technologies, which are not fully covered by the existing provisions but have clear implications for quality, safety and oversight.

In addition, the Commission has drawn on contacts with competent authorities, transplantation centres, industry and research organisations, which have stressed both the innovation potential of organ processing and the need for legal clarity and proportionate, science-based requirements.

- **Stakeholder consultations**

Concerning Directive 2001/18/EU, an external study commissioned by the European Commission is being carried out ('**Analysis of the Regulatory Framework for Biotechnology and Biomanufacturing in the EU**')[9]. The study provides an extensive mapping of the main EU and national legislations that apply to biotechnology and biomanufacturing products and processes – whether they are horizontal or sector-specific – and identifies, through surveys, interviews and workshops, the challenges, their causes and consequences for stakeholders. The study also assesses the impacts of policy options related to the EU regulatory framework. Evidence on the impacts of options on **genetically modified micro-organisms** has been collected through **25 interviews** (by November 2025).

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5 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 4: https://doi.org/10.2903/j.efsa.192024.8895

6 EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., … Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. https://doi.org/10.2903/j.efsa.2025.9705

7 Sowa, S., Broothaerts, W., Burns, M., De Loose, M., Debode, F. et al., Detection of microorganisms, obtained by new genomic techniques, in food and feed products, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/1846532, JRC143597

8 EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., … Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. https://doi.org/10.2903/j.efsa.2025.9705.

9 Impact assessment supporting study – Analysis of the regulatory framework for biotechnology and biomanufacturing in the EU; request for service No 1005/PP/GRO/IMA/24/2129/14500

Furthermore, stakeholders' views on GMMs expressed in the calls for evidence related to the Biotech Act[10] and the Food and Feed Safety Simplification Omnibus[11] stressing the recent innovations regarding GMMs and underlining the necessity to adapt the GMO framework to these developments have been taken into account.

Finally, targeted consultation activities are also being conducted in the context of the **supporting study for the evaluation of the European Food Safety Agency**[12].

- **Impact assessment**

Considering the political urgent need to address the policy challenges identified in the European Biotech Act (Regulation (EU) …/…), an impact assessment could not have been delivered in the timeframe available before the proposal's adoption. Instead, an analytical Staff Working Document (SWD) will be prepared. The analytical SWD will explain the proposal and will present the underlying evidence and impact analysis, including a cost–benefit assessment.

The provisions of the proposal concern simplification measures which typically do not offer viable alternatives and do not modify the objectives of the amended legislation. Nevertheless, the underlying policy rationale, options considered and supporting evidence were developed through stakeholder consultations and analyses conducted during the preparation of the European Biotech Act.

- **Regulatory fitness and simplification**

The proposal is part of the European Biotechnology Act having the main policy objectives of, *inter alia*, modernising and simplifying the regulatory framework, removing duplications and unnecessary administrative steps. The proposal is therefore aiming at improving the regulatory landscape of the biotechnology sector and reducing unnecessary burdens and costs for businesses and authorities, without undermining the protection of human health and the environment.

- **Fundamental rights**

The proposal respects the rights and principles enshrined in the Charter of Fundamental Rights of the European Union and does not undermine the level of protection of human health, animal welfare or the environment guaranteed under the existing legislative framework.

4. BUDGETARY IMPLICATIONS

The proposal has no direct implications for the Union budget.

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10 European Commission Have Your Say website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14627-Biotech-Act_en.

11 European Commission Have Your Say website: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14824-Food-and-feed-safety-simplification-omnibus_en

12 Performance Evaluation of European Food Safety Authority - Food Safety: https://food.ec.europa.eu/horizontal-topics/general-food-law/performance-evaluation-european-food-safety-authority_en

5. OTHER ELEMENTS

- **Detailed explanation of the specific provisions of the proposal**

Amendments to Directive 2001/18/EC (genetically modified micro-organisms)

This Directive introduces specific provisions in Part C of Directive 2001/18/EC on the placing on the market of GMMs as or in products other than food and feed with the aim of creating a tailored, more efficient and streamlined regulatory framework for GMMs while maintaining a high safety level for human health and the environment.

The provisions proposed relate to the risk assessment, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs. In relation to a tailored risk assessment, provision is made for the information requirements in Annex III of Directive 2001/18/EC to be amended by delegated act in order to adapt them to the specificities of GMMs, respecting the general principles for the environmental risk assessment of Annex II of Directive 2001/18/EC. The validity of consent granted by the competent authorities would last for an unlimited period of time for GMMs. The modalities to comply with detection method requirements in cases where it is not feasible to provide a method that detects, identifies and quantifies are also adapted in the proposal.

Further, the proposal would also introduce the concept of low-risk GMMs, including scientific criteria confirming this status, and set a framework for a streamlined authorisation procedure for eligible low-risk GMMs. It is proposed that, by way of delegated acts, the Commission supplements the low-risk criteria and amends the Directive to adapt the risk assessment information requirements in Annex III and certain procedural elements. The requirement for post-market environmental monitoring of low-risk GMMs is equally adapted in the proposal, providing the possibility to a notifier, based on certain conditions, to propose to omit post-market environmental monitoring.

Amendments to Directive 2010/53/EU (organ processing)

Scope

The scope of Directive 2010/53/EU is amended to expressly include processing alongside donation, testing, characterisation, procurement, transport and transplantation, and to clarify that where organs are used for research purposes, the Directive applies only where they are intended for transplantation into the human body.

Definitions

The definition of “transplantation” is adjusted to reflect a process intended to restore certain functions of the human body by transferring an organ to a recipient.

A new definition of “processing” is added, covering operations involving the handling of organs, including but not limited to preservation, application of chemotherapy and surgery, performed to maintain or improve organ function prior to transplantation. The definition excludes:

- preparatory handling during the surgical transplantation intervention;
- the repurposing of organs into tissues or cells;

- the use of substances with a pharmacological, immunological or metabolic action where the primary aim is to treat or prevent a disease in the recipient and not to process the organ.

Organ processing regime (new Article 6a)
A new Article 6a:

- requires transplantation centres to obtain prior authorisation from the competent authority before applying a processed organ to a recipient, with an exception for clinical outcome monitoring plans forming part of a processed organ authorisation;
- obliges transplantation centres to perform a benefit–risk assessment of the processing, including the intended clinical indication;
- provides that where evidence is limited or risks are significant, the benefit–risk assessment and a clinical outcome monitoring plan must be submitted for approval by the competent authority;
- requires competent authorities, where processing involves a medicinal product, medical device or SoHO preparation, to verify that this product or preparation used is authorised or certified under the relevant Union framework (Directive 2001/83/EC of the European Parliament and of the Council[13], Regulation (EC) No 726/2004 of the European Parliament and of the Council[14], Regulation (EU) 2017/745 of the European Parliament and of the Council[15] and Regulation (EU) 2024/1938 of the European Parliament and of the Council[16], and to cooperate with the authorities designated under those frameworks, including on clinical outcome data;
- requires the Commission to publish a list of authorised organ processing operations, including where relevant associated products;
- empowers the Commission to adopt implementing acts specifying detailed rules for organ processing authorisation, in accordance with the comitology procedure referred to in Article 30(2) of Directive 2010/53/EU.

Annex Part B

Information required to characterise an organ and a donor is laid down in Annex to Directive 2010/53/EU including a Part A (minimum data) and Part B (complementary data). Part B is amended to add “Processing” as a step applied to the organ with the aim of improving its

[13] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/2025-01-01

[14] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj .

[15] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj .

[16] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC, OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj.

functional status and potentially affecting its quality and safety, with examples such as preservation, application of chemotherapy and surgery.

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amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and Article 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Regulation (EU) …/… [European Biotech Act] establishes a framework to strengthen the competitiveness of the health biotechnology sector in the Union, from research and development to the timely placing on the Union market and production of biotechnology innovations and products, while safeguarding high standards of protection of human health, patient safety and animal health, the environment, ethics, quality of products, food and feed safety and biosecurity. For the purposes of that Regulation, health biotechnology means the application of biotechnology for the promotion, protection, or restoration of human health and biotechnological applications relevant to animal health, plant health, veterinary public health, and food safety, insofar as these areas contribute directly or indirectly to the protection of human health and align with the Union's public-health objectives, as set out under Article 168 of the Treaty on the Functioning of the European Union.

(2) Given that the objectives of Directive 2001/18/EC of the European Parliament and of the Council[3] and Directive 2010/53/EU of the European Parliament and of the Council[4] are closely linked to those of Regulation (EU) …/… [European Biotech Act], and considering that, since the adoption of those Directives, significant progress in biotechnology has taken place, it is appropriate to adapt them in order to align with new technological realities and with the objectives and provisions laid down in

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1 OJ C , , p. .

2 OJ C , , p. .

3 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1, ELI: http://data.europa.eu/eli/dir/2001/18/oj)

4 Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14, ELI: http://data.europa.eu/eli/dir/2010/53/oj)).

Regulation (EU) …/… [European Biotech Act]. Those adaptations are intended to improve consistency, legal clarity and the smooth functioning of the Union legislative framework for biotechnology, and eventually to ensure the availability of safe and high-quality therapies and other products for Union citizens.

(3) Genetically modified micro-organisms (GMMs), such as bacteria, algae, fungi and viruses, as or in products for uses other than food and feed are subject to the requirements of Directive 2001/18/EC. Since the adoption of that Directive, significant progress in biotechnology has taken place, and GMMs can now be used for example as or in fertilisers, biocontrol, bioremediation, wastewater treatment, biomining and bioleaching, offering benefits in the wider agri-food, industrial and environmental sectors.

(4) Following a Commission mandate, on 19 June 2024, the European Food Safety Authority ('the Authority') adopted an opinion on the application of new developments in biotechnology to micro-organisms[5]. It concluded that possible hazards relate to the changes introduced, regardless of the method used, and that the risk assessment should be based on the characteristics of the product containing or consisting of micro-organisms. It also concluded that for certain GMMs, fewer requirements for risk assessment would be needed compared to those applicable to GMOs in general. Finally, the Authority considered that, for certain GMMs, the need for post-market environmental monitoring (PMEM) may be waived based on the environmental risk assessment.

(5) Considering that Directive 2001/18/EC was primarily designed to regulate genetically modified plants obtained by certain established genomic techniques, in particular techniques that introduce into an organism genetic material from non-crossable species (transgenesis) and taking into account the Authority's conclusions on GMMs, as well as the biological properties, capabilities and potential applications of GMMs, which differ significantly from those of plants, Directive 2001/18/EC should be adapted to the specificities of GMMs to enable innovative products to reach the market before they become obsolete and without disproportionate authorisation costs, while maintaining a high level of safety.

(6) For that reason, Directive 2001/18/EC should be amended to introduce specific provisions applicable to the placing on the market of GMMs with the aim of creating a tailored, more efficient and streamlined legislative framework, while maintaining a high level of safety for human health and the environment. Considering that possible hazards relate to the changes introduced into the genome of a micro-organism regardless of the method used, and that micro-organisms are often modified through a combination of different techniques, including both established and new genomic techniques[6], those provisions should cover GMMs in general without focus on specific techniques.

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5 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 4: https://doi.org/10.2903/j.efsa.192024.8895

6 Parisi, C., Rodríguez-Cerezo, E., Current and future market applications of new genomic techniques, EUR 30589 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-30206-3, doi:10.2760/02472, JRC123830.

(7) For the purpose of Directive 2001/18/EC, the definitions of 'micro-organism' and 'GMM' should be based on those of Directive 2009/41/EC of the European Parliament and of the Council[7] with the exclusion of animal and plant cells in culture. In order to ensure that the overall applicable framework on GMOs remains consistent, animal and plant cells should be subject to the same rules, regardless of whether they are in culture, not in culture or embedded in the complete organisms. The specific provisions should therefore cover only micro-organisms in the biological sense, including the taxonomic groups Archaea and Bacteria, the unicellular species and life stages of Protozoa, Chromista and Fungi, as well as filamentous fungi and viruses, while excluding animal and plant cells in culture.

(8) To reflect the specific properties of GMMs, the information requirements as set down in Annex III to Directive 2001/18/EC to be used in the risk assessment should be adapted based on the available information and evidence in relation to GMMs, while respecting the principles for the environmental risk assessment of GMOs laid down in Annex II to that Directive. In order to carry out those adaptations, the power to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the information requirements laid down in Annex III to the Directive.

(9) Considering that the product cycles of GMMs are very short and new generation GMMs are developed in short timeframes, with new products building on the experience gained with previous ones, including as regards the risk assessment, the limitation of the period of validity of the consent laid down in Directive 2001/18/EC implies a burden for operators and national competent authorities while bringing limited value to the safety of such products given the short life-time of those products. Directive 2001/18/EC already lays down measures to ensure that any new relevant information is provided by the notifier, as well as safeguard measures in case new risks are identified. Therefore, Directive 2001/18/EC should provide that consents granted for the placing on the market of GMMs should be valid for an unlimited period of time. Any measures necessary to protect human health and the environment should continue to be adopted anytime where such consents granted do no longer meet the safety conditions set out in that Directive, taking into account new information that has become available as well as scientific and technical progress.

(10) On 2 October 2025, the European Network of GMO Laboratories (ENGL) Working Group on New Mutagenesis Techniques published a report on the analytical possibilities and challenges related to the detection of micro-organisms modified using new genomic techniques, concluding that analytical testing is not feasible for certain GMMs obtained through those techniques, especially in the context of routine laboratory control[8]. Therefore, in cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method performance requirements should be adapted by means of implementing acts.

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7 Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms, OJ L 125, 21.5.2009, p. 75, ELI: http://data.europa.eu/eli/dir/2009/41/oj).

8 Sowa, S., Broothaerts, W., Burns, M., De Loose, M., Debode, F. et al., Detection of microorganisms, obtained by new genomic techniques, in food and feed products, Publications Office of the European Union, Luxembourg, 2025, https://data.europa.eu/doi/10.2760/1846532, JRC143597.

(11) Furthermore, for certain GMMs, the Authority concluded that fewer data requirements for risk assessment would be needed[9] and provided some criteria to identify those GMMs[10]. Thus, Directive 2001/18/EC should establish specific requirements for GMMs with an inherently low risk profile to ensure that the risk assessment and procedures are proportionate to the risks the GMMs raise. Such adaptation should lead to a reduction of time to market for low-risk GMMs, enabling innovation without lowering the safety standards.

(12) Specifically, it is necessary to lay down the criteria defining low-risk GMMs on the basis of general safety standards as expressed in the Authority's concept of Qualified Presumption of Safety (hereinafter referred to as "QPS")[11] and an absence of genes of concern not naturally present in the parental organism as described in the glossary of the Authority's guidance on the characterisation of micro-organisms[12], including acquired antimicrobial resistance genes, virulence factors and genes known to contribute to the production of toxins or harmful metabolites.

(13) While the basic criteria to be fulfilled for a GMM to be considered a low-risk GMM should be established in Directive 2001/18/EC, the Commission should be empowered, in accordance with Article 290 of the Treaty on the Functioning of the European Union, to supplement Directive 2001/18/EC by further specifying these criteria and adding further criteria if necessary. Moreover, the Commission should be empowered, in accordance with Article 290 of the Treaty on the Functioning of the European Union, to amend Directive 2001/18/EC by adapting the risk assessment requirements and the authorisation procedure to provide for the demonstration of low-risk status, to streamline certain procedural elements and to expedite the timelines to reflect the adapted risk assessment requirements.

(14) In line with the recommendations of the Authority[13], and in order to not impose disproportionate administrative burden, low-risk GMMs should not be subject to the obligation to establish a post-market environmental monitoring plan if the GMM does not give rise to concerns that warrant monitoring, such as indirect, delayed or unanticipated effects on human health or on the environment.

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9 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 3.3.2.9.: https://doi.org/10.2903/j.efsa.2024.8895

10 EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., … Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705. https://doi.org/10.2903/j.efsa.2025.9705

11 https://doi.org/10.5281/zenodo.1146566

12 EFSA Scientific Committee, Bennekou, S. H., Allende, A., Bearth, A., Casacuberta, J., Castle, L., Coja, T., Crépet, A., Halldorsson, T. I., Hoogenboom, R., Jokelainen, P., Knutsen, H. K., Lambré, C., Nielsen, S. S., Turck, D., Civera, A. V., Villa, R. E., Zorn, H., Gómez, M. A., … Glandorf, B. (2025). Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain. EFSA Journal, 23(11), e9705; page 22: https://doi.org/10.2903/j.efsa.2025.9705.

13 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Mullins, E., Bresson, J.-L., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., Guerche, P., Hejatko, J., Moreno, F. J., Naegeli, H., Nogué, F., Rostoks, N., Sánchez Serrano, J. J., Savoini, G., Veromann, E., Veronesi, F., Cocconcelli, P. S., Glandorf, D., Herman, L., Dalmay, T. (2024). New developments in biotechnology applied to microorganisms. EFSA Journal, 22(7), e8895; point 3.3.2.9.: https://doi.org/10.2903/j.efsa.2024.8895

(15) Processing, including preservation, of human organs is increasingly frequent and allows the ex-vivo time window between procurement from the donor and transplantation into the recipient to be extended.

(16) The uptake of those preservation and processing technologies not only allows for more efficient organisational set-up, but also for improving human organs during the extended ex-vivo time window, increasing treatment options for patients on waiting lists. Such activities need to be subject to oversight by the competent authorities in order to ensure their quality, optimise the effectiveness of transplants and protect recipients' health.

(17) To ensure a consistent and comprehensive legislative framework by providing clarity for all actors involved, Directive 2010/53/EU should cover processing of organs, beyond preservation of such organs. In order to ensure coherence and efficient coordination among authorities operating under different Union legislative frameworks in the health area, provisions should be laid down to clarify which of the technologies used fall under Union legislative frameworks other than Directive 2010/53/EU, in particular the frameworks established in Directive 2001/83/EC of the European Parliament and of the Council[14], Regulation (EC) No 726/2004 of the European Parliament and of the Council[15], Regulation (EU) 2017/745 of the European Parliament and of the Council[16] and Regulation (EU) 2024/1938 of the European Parliament and of the Council[17]. Such provisions should aim to at ensuring coherence and efficient coordination among authorities operating under those frameworks. Directive 2010/53/EU should therefore be amended accordingly.

(18) To ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should cover, in particular, the adapted modalities to comply with analytical method requirements and the supporting information to be submitted to demonstrate the fulfilment of the criteria for being considered a low-risk GMM concerning Directive 2001/18/EC, as well as the establishment of detailed rules for the authorisation of organ processing, concerning Directive 2010/53/EU. Those implementing acts should be adopted in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[18].

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14 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

15 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

16 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

17 Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).

18 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(19) Since the objectives of this Directive, including to ensure legal clarity across Member States cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2001/18/EC

Directive 2001/18/EC is amended as follows:

(1) in Article 2, the following points (9), (10) and (11) are added:

'(9) 'micro-organism' means a micro-organism as defined in Article 2, point (a), of Directive 2009/41/EC of the European Parliament and of the Council*, with the exception of animal and plant cells in culture;

(10) 'genetically modified micro-organism' or 'GMM' means a genetically modified micro-organism as defined in Article 2, point (b), of Directive 2009/41/EC, with the exception of genetically modified animal and plant cells in culture;

(11) 'Status of Qualified Presumption of Safety' means the safety status assigned by the Authority to selected groups of micro-organisms on the basis of an assessment showing no safety concerns;'

* Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (OJ L 125, 21.5.2009, p. 75, ELI: http://data.europa.eu/eli/dir/2009/41/oj).';

(2) In Part C, after the heading 'PLACING ON THE MARKET OF GMOs AS OR IN PRODUCTS' the following title is inserted:

'**TITLE I**

GENERAL PROVISIONS APPLICABLE TO GMOs AS OR IN PRODUCTS'

(3) after Article 24, the following title and Articles 24a to 24g are inserted:

'TITLE II

SPECIFIC PROVISIONS APPLICABLE TO GENETICALLY MODIFIED MICRO-ORGANISMS (GMMs) AS OR IN PRODUCTS

Article 24a

Subject matter and status of GMMs

1. This Title lays down specific rules for the placing on the market of genetically modified micro-organisms (GMMs) as or in products.

2. Articles 24e and 24f shall apply only to the placing on the market of GMMs with a low-risk profile as or in products.

3. Unless otherwise provided for in this Title, the rules of this Directive applicable to GMOs as or in products shall apply to GMMs as or in products.

Article 24b

Adaptation of information requirements

The Commission is empowered to adopt delegated acts in accordance with Article 29a to amend Annex III in order to provide for specific information requirements in notifications concerning the placing on the market of GMMs, so as to adapt them to scientific and technical progress.

Article 24c

Validity of the consent

Without prejudice to Article 20(2) and (3) and Article 23, the consent granted under Part C shall be valid for an unlimited period of time and Article 17 shall not apply.

Article 24d

Detection methods

1. In cases where it is not feasible to provide a method for detection, identification and quantification of the transformation event as detailed in point 7 of Section A of Annex IV, to which Article 13(2), point (a), refers, and where this is duly justified by the notifier, the modalities to comply with analytical method performance requirements shall be adapted as specified in the implementing act adopted in accordance with Article 24g(1), point (a).
2. The competent authority shall assess whether the information on the analytical method provided by the notifier justifies the application of adapted modalities to comply with detection method requirements in accordance with paragraph 1.

Article 24e

Low-risk GMMs

1. A GMM shall be considered a ‘low-risk GMM’ where it fulfils all of the following criteria:
   (a) it is taxonomically and molecularly well characterised;
   (b) it belongs to a taxonomic unit having the Status of Qualified Presumption of Safety;
   (c) it does not contain genes of concern which are not naturally present in the parental organism, in particular acquired antimicrobial resistance genes.

   The Commission may supplement those criteria by establishing further criteria, as provided for in paragraph 3, point (b), based on available scientific evidence concerning the safety of GMMs and on experience gained from the release of comparable micro-organisms.
2. The risk assessment of low-risk GMMs and the specific information requirements in notifications concerning their placing on the market shall be adapted to their characteristics.

The procedural requirements laid down in Title I shall be adapted as provided for in paragraph 3, point (d), to provide for the demonstration of low-risk status, to streamline certain procedural elements and to expedite the timelines. Such adaptations shall ensure a high level of protection of human health and the environment as well as the necessary consultations of competent authorities and the public.

3. The Commission is empowered to adopt delegated acts in accordance with Article 29a to:

(a) supplement this Directive by further specifying the low-risk criteria of GMMs as referred to in paragraph 1, first subparagraph, points (a), (b) and (c);

(b) supplement this Directive by establishing, where necessary, additional low-risk criteria of GMMs as referred to in paragraph 1;

(c) amend this Directive by providing for specific information requirements in Annex III in notifications concerning the placing on the market of low-risk GMMs;

(d) amend this Directive by setting out procedural requirements for the risk assessment of low-risk GMMs adapted to their characteristics.

Article 24f

Monitoring and reporting of low-risk GMMs

1. If, on the basis of the results of any release notified in accordance with Article 6, of the findings of the environmental risk assessment carried out in accordance with Article 13(2), point (b), of the characteristics of the GMM, of the characteristics and scale of its expected use, and of the characteristics of the receiving environment, the notifier considers that a monitoring plan referred to in Article 13(2), point (e), is not needed, the notifier may propose not to submit a monitoring plan.

2. The written consent referred to in Article 19 shall either specify the monitoring requirements, as provided in Article 19(3), point (f), or state that monitoring is not required.

Article 24g

Implementing acts

1. The Commission shall adopt implementing acts concerning:

(a) adapted modalities to comply with analytical method requirements referred to in Article 24d(1);

(b) the supporting information to be submitted in the notification referred to in Article 13(2) to demonstrate fulfilment of the criteria referred to in Article 24e(1) for being considered a low-risk GMM.

2. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 30(2).';

(4) Article 29a is replaced by the following:

'Article 29a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 16(2), Article 21(2) and (3), Article 24b, Article 24e(3), Article 26(2) and Article 27 shall be conferred on the Commission for a period of five years from *[the date of entry into force of this Directive]*. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegations of power referred to in Article 16(2), Article 21(2) and (3), Article 24b, Article 24e(3), Article 26(2) and Article 27 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making**.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Article 16(2), Article 21(2) and (3), Article 24b, Article 24e(3), Article 26(2) and Article 27 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.'

** OJ L 123, 12.5.2016, p. 1.'.

Article 2

Amendments to Directive 2010/53/EU

Directive 2010/53/EU is amended as follows:

(1) in Article 2, paragraph 1 is replaced by the following:

'1. This Directive applies to the donation, testing, characterisation, procurement, processing, transport and transplantation of organs intended for transplantation.'

(2) Article 3 is amended as follows:

(a) point (q) is replaced by the following:

‘(q) “transplantation” means a process intended to restore certain functions of the human body by transferring an organ to a recipient;’

(b) the following point (ka) is inserted:

‘(ka) “processing” means any operation involving the handling of organs, including but not limited to preservation, application of chemotherapy and surgery, performed to maintain or improve the functional status of an organ prior to transplantation, with the exception of the preparatory handling of the organ during the surgical transplantation intervention, and excluding the following:

(i) the repurposing of organs into tissues or cells;

(ii) the use of a substance with a pharmacological, immunological or metabolic action with the aim to treat or prevent a disease in the patient to whom the organ will be transplanted, where such use does not constitute processing of the organ.’

(3) the following Article 6a is inserted:

‘Article 6a

Organ processing

1. Transplantation centres shall not apply a processed organ to a recipient without prior authorisation by the competent authority, other than in the context of an approved clinical-outcome monitoring plan referred to in paragraph 3 of this Article, as part of an organ processing authorisation.

2. The transplantation centre shall conduct a benefit-risk assessment of the processing of the organ, considering with the intended clinical indication for which the organ processing authorisation is requested.

The transplantation centre shall submit the benefit-risk assessment to the competent authority for revision.

3. In cases where the scientific evidence and clinical data available to perform the benefit-risk assessment are not sufficient, or where the assessment identifies a significant risk, the transplantation centre shall submit a proposal for a clinical-outcome monitoring plan for approval by the competent authority.

4. Where the processing of an organ entails the use of a medicinal product, the competent authority shall verify that the medicinal product has been authorised by a competent authority of a Member State or by the European Commission in accordance with Directive 2001/83/EC of the European Parliament and of the Council* or Regulation (EC) No 726/2004 of the European Parliament and of the Council**.

5. Competent authorities shall, after consulting the authorities designated under Directive 2001/83/EC, publish guidelines setting out the necessary requirements for the benefit-risk assessment and the management of the organ after the administration of the medicinal product.

6. Where the processing of an organ entails the use of a medical device, the competent authority shall verify that the medical device has been certified by a

notified body in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council***.

7. Where the processing of an organ entails the use of a SoHO preparation, the competent authority shall verify that the SoHO preparation has been authorised by the competent authority in accordance with Regulation (EU) 2024/1938 of the European Parliament and of the Council****.

8. Where applicable, competent authorities under this Directive and the competent authorities under Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2017/745 and Regulation (EU) 2024/1938 shall collaborate in order to exchange clinical outcome data under such Union legislative frameworks including the clinical outcome monitoring plan under this Directive.

9. Transplant centres shall not make any significant change regarding the steps of the processing applied, without prior written agreement of the competent authority.

10. Competent authorities may suspend the authorisation where there is reasonable ground to suspect that the performed processing activities are not in compliance with the authorisation.

11. The Commission shall publish a list of operations that have been authorised as organ processing or have received approval for a clinical outcome monitoring plan, including, where relevant, the use of medicinal products, medical devices or SoHO preparations.

12. The Commission shall adopt implementing acts laying down detailed rules for the application and authorisation of organ processing in accordance with the procedure referred to in Article 30(2).

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* Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

** Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

*** Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

**** Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, 2024/1938, 17.07.2024, ELI: http://data.europa.eu/eli/reg/2024/1938/oj).';

(4) in Part B of the Annex, the following entry is added:

'Processing

Processing steps applied to the organ with the aim of improving its functional status and with a potential impact on its quality and safety, including in particular, but not limited to, preservation, application of chemotherapy and surgery.'

Article 3

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by *[24 months from the date of entry into force]* at the latest. They shall forthwith communicate to the Commission the text of those provisions.

2. When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

3. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

Entry into Force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg,

For the European Parliament	*For the Council*
The President	*The President*