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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

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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;'

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* 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*