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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	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 - General approach

I. INTRODUCTION

1. On 16 December 2025, the Commission submitted to the Council and the European Parliament a 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[1]. This proposal was part of a wider health package and accompanies the European Biotech Act Regulation. The proposal was submitted without an impact assessment (IA) but a Commission staff working document[2] was published by the Commission on 26 May 2026 summarising the evidence supporting the legislative proposal.

[1] 17103/25
[2] 9833/26 + ADD1

2. The proposed Directive introduces targeted amendments to two sectoral Directives to achieve a more efficient regulatory process for Genetically Modified Micro-organisms (GMMs), including an expedited procedure for certain GMMs, and to update provisions to ensure safety and quality on organ transplantation while taking account of latest scientific and clinical developments. These reflect innovation in relation to organ processing enabling longer time windows between organ collection and transplantation.

3. The draft Directive is based on Articles 114 and 168(4) of the Treaty on the Functioning of the European Union (TFEU) (ordinary legislative procedure).

4. The opinion of the European Economic and Social Committee on the proposal was adopted on 18 March 2026[3], while the Committee of the Regions decided not to deliver an opinion on the proposal.

5. The Italian Chamber of Deputies submitted a positive assessment while raising concerns regarding the empowerments to the Commission. The Romanian Senate submitted an opinion, generally supporting the objectives of the proposal but raising proportionality concerns regarding the proposed amendments to Directive 2010/53/EU. The Swedish Parliament submitted a reasoned opinion raising subsidiarity concerns on the proposed amendments to Directive 2010/53/EU and questioned their added value. An opinion was received from the European Data Protection Supervisor on 27 May 2026[4].

6. The Working Party on Pharmaceuticals and Medical Devices (WPPMD) discussed the proposal at its meetings on 10 February, 5-6 March, 15-16 April, 8 May and 22 May and has largely agreed on the text in the annex to this note.

7. In the European Parliament, the Committee on Public Health (SANT) and the Committee on Environment, Climate and Food Safety (ENVI) have the lead responsibility. MEP Adam Jarubas (EPP, PL) and MEP Marta Temido (S&D, PT) were appointed rapporteurs.

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3 7842/26
4 9783/26

II. STATE OF PLAY

8. The Cyprus Presidency organised two meetings of the Working Party dedicated to presenting the proposal and to addressing specific comments and questions from delegations. The Presidency then presented three versions of compromise text at the Working Party, responding to requests from delegations with a focus, inter alia, on improving the clarity of the provisions, limiting and framing empowerments, and aligning provisions with relevant Union legislation. During the last meeting, several minor drafting suggestions were implemented to address remaining concerns. These were informally shared with delegations. Subsequently, the Presidency implemented some editorial adaptations to improve consistency and linguistic clarity, taking account of comments received from delegations and reflected the reception of the Staff Working Document and of the opinion of the European Data Protection Supervisor in the text.

9. Key issues addressed throughout the examination and adaptations implemented were the following (references listed reflect numbering in the proposed revision):

   In Article 1 (Amendments to Directive 2001/18/EC):

   - clarifying and specifying the proposed new definition on the Status of Qualified Presumption of Safety (addition to Article 2 of Directive 2001/18/EC);
   - providing more detail on the adaptation of information requirements and the empowerments foreseen (Article 24b);
   - maintaining a time-limited first consent, followed by a potentially unlimited renewed consent, however adding the possibility to restrict the validity of the renewed consent on justified grounds (Article 24c);
   - adapting the provisions on analytical methods; adding a possibility for the competent authorities to request support from the national reference laboratories (Article 24d);
   - adapting the terminology from “low-risk GMMs” to “GMMs eligible for an expedited procedure” to provide a more factual description; adapting the description of this category of GMMs for clarity; revision of the empowerments to better frame and clarify the provisions which can be revised via delegated acts (Article 24e);

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- specifying the role and competence by the competent authorities regarding the requirements for monitoring (Article 24f) and adding a related implementing act on information requirements in case a notifier proposes not to submit a monitoring plan (Article 24f and Article 24g paragraph 1(ba));
- adding a provision on guidance to assist notifiers (Article 24h);
- overall: alignment with terminology used in the Regulation on new genomic techniques, recently agreed by the co-legislators and adopted by the Council[5], and providing more detail with the aim of clarifying provisions to support the implementation of the provisions.

In Article 2 (Amendments to Directive 2010/53/EU):

- further revising the scope of the Directive to clarify the relevance of the adaptations to the autologous use scenario, and clarifying the relationship between Directive 2010/53/EU and other relevant legal frameworks (revision of Article 2 of Directive 2010/53/EU);
- adding several new definitions, including on "autologous use", adapt the existing definition on "organ", adapt the proposed new definition on "processing" and remove the proposed adaptation of the definition on "transplantation", in order to improve the clarity of the provisions and alignment with other Union legislation (revision of Article 3 and of Part B of the Annex to Directive 2010/53/EU);
- adapting provisions in several instances to reflect the addition of a new definition on "processing" and to clarify which provisions are applicable to the "autologous use" of organs;
- describing in more detail the benefit-risk assessment to be carried out before introducing a new organ processing method, the related clinical outcome monitoring, and the delineation from other relevant legal frameworks in that context (Article 6a, para 1, 1a, 2, 2a, 2b);

[5] 17037/1/25 REV1

- highlighting the competence and role of national authorities and services in the authorisation of organ processing methods (Article 6a, para 2c), for providing treatment and ensuring continuity of care in specific clinical situations (Article 6a, para 2d), providing exemptions to established national processing methods (Article 6a, para 3a) – capturing also elements of the Commission proposal presented in paragraphs 9 and 10;
- adding further detail on derogations on benefit-risk assessments, clinical outcome monitoring plans and prior authorisation of organ processing methods in light of other relevant legal frameworks while ensuring collaboration with competent authorities responsible for the implementation of this Directive (Article 6a, para 3b);
- adapting terminology describing Member State obligations on processing technologies entailing the use of medicinal product, medical device or SoHO preparation to account for differences in national set-ups (Article 6a, para 4, 6, 7) and on collaboration between authorities (Article 6a, para 8);
- revising provisions on publication and communication on authorised organ processing methods (Article 6a, para 11);
- revising provisions on guidelines and related implementing acts on benefit-risk assessments, on identification of high-risk organ processing methods and on clinical outcome monitoring to provide a clearer framing for these acts and the collaboration between Commission and Member States (Article 6a, para 12 – combining elements of the Commission proposal presented in para 5 and 12);
- adding Article 16a on the use of personal data for reasons of public interest in the area of organ transplantation;
- overall: alignment with terminology used in other relevant Union legislation, provision of additional detail and reorganization of text elements to clarify provisions with a view to supporting implementation.

10. Finally, the transposition deadline was changed from 24 to 36 months in Article 3.

11. The text in several recitals was updated and some recitals added to provide explanations corresponding to the articles.

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12. The Presidency considers that the compromise text presented in the Annex[6] effectively responds to the concerns and outstanding matters expressed by the delegations. Therefore, the Presidency puts forward a compromise text that is considered well-balanced and that represents the shared position of the Council.

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III. Conclusions

13. The Permanent Representatives Committee is therefore invited to:

(a) examine the compromise text as set out in the annex to this note; and

(b) submit it to the Council (EPSCO) with a view to reaching a general approach at its meeting on 16 June 2026.

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[6] Changes compared to the Commission proposal are indicated in ~~strikethrough~~ for deletions and **bold** for insertions.

ANNEX

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2025/0405 (COD)

Draft

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

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[7],

~~Having regard to the opinion of~~**After consulting** the Committee of the Regions[8],

Acting in accordance with the ordinary legislative procedure,

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[7] OJ C , , p. .

[8] ~~OJ C , , p. .~~

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 **and feed** 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 **(TFEU)**.

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(2) Given that the objectives of Directive 2001/18/EC of the European Parliament and of the Council[9] and Directive 2010/53/EU of the European Parliament and of the Council[10] 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 **to ensure consistency** with the objectives and provisions laid down in Regulation (EU) …/… [European Biotech Act]. ~~Those adaptations are intended~~**This Directive aims** to improve **the functioning of the internal market with regard to genetically modified micro-organisms (GMMs) while maintaining a high level of safety for human health, animal health and the environment and to set high standards of quality and safety of organ processing methods. This should be done with a view to improving** consistency, legal clarity and the ~~smooth functioning~~**suitability** 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. **With regard to Article 114 of the TFEU, this Directive introduces specific provisions applicable to the placing on the market of GMMs. With regard to Article 168(4) of the TFEU, this Directive establishes a common approach regarding the authorisation by the competent authorities of organ processing methods.**

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9 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)

10 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)).

(3) ~~Genetically modified micro-organisms (GMMs)~~**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~~**biofertilisers, biostimulants**, biocontrol **agents**, **and for** 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[11]. 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.

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[11] 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., **Jimenez Saiz, R., Ruiz Garcia, L., Aguilera Entrena, J., Gennaro, A., Schoonjans, R., Kagkli, D. M.,** 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~~**2024.8895**

(5) ~~Considering that~~ Directive 2001/18/EC was **designed** primarily ~~designed to regulate~~**taking into account** genetically modified plants obtained by certain established genomic techniques, in particular techniques that introduce into an organism genetic material from non-crossable species (transgenesis)**. In view of this** 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**. This is intended** to enable innovative products to reach the market before they become obsolete and without disproportionate authorisation costs, while maintaining a high level of safety **for human health, animal health and the environment**.

(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, animal** 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[12], those provisions should cover GMMs in general without focus on specific techniques.

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12 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[13] 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 **relevant** 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 **environmental** 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 **2001/18/EC**.

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[13] 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).

(9) ~~Considering that the product cycles of GMMs are very short and new generation GMMs are developed in short timeframes~~**For reasons of proportionality**, ~~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~~**, upon its first renewal,** be valid for an unlimited period**, unless decided otherwise at the time of that renewal on the basis of the environmental risk assessment and the available information on the product concerned** ~~of time~~. Any measures necessary to protect human **health, animal** 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 **2001/18/EC**, 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[14]. Therefore, in cases where it is not feasible to provide an analytical method that ~~detects,~~ identifies and quantifies **the GMM as or in products concerned**, if duly justified by the notifier, the ~~modalities to comply~~**arrangements for complying** with analytical method performance requirements should be adapted by means of implementing acts.

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14 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[15] and provided some criteria to identify those GMMs[16]. 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~~**an expedited procedure for certain GMMs (hereafter 'GMMs eligible for an expedited procedure') that is** proportionate to the risks ~~the GMMs raise~~**these GMMs pose and takes into account the available information on them. For these GMMs fewer data requirements would be sufficient to conduct the environmental risk assessment while maintaining a high level of safety for human health, animal health and the environment**. Such adaptation should lead to a reduction of time to market for ~~low-risk~~ GMMs **eligible for an expedited procedure**, enabling innovation without lowering the safety standards.

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15 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., **Jimenez Saiz, R., Ruiz Garcia, L., Aguilera Entrena, J., Gennaro, A., Schoonjans, R., Kagkli, D. M.,** 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

16 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., ~~…~~ **Brétagne, S., Christensen, H., Cocconcelli, P.S., Herman, L., Prieto-Maradona, M., Mayo, B., Peláez, C., Saarela, M., Sánchez Serrano, J., Vernis, L., Yurkov, A., Aguilera, J., Anguita, M., Bozzi Cionci, N., Brozzi, R., Correia, S., García-Cazorla, Y., Istace F., Pettenati, E., Revez, E., Schoonjans, R., Valeri, P.,** 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

(12) Specifically, it is necessary to lay down the criteria defining ~~low-risk GMMs on the basis of~~**GMMs eligible for an expedited procedure. Such GMMs should be taxonomically and molecularly well characterized, considering their taxonomic identity, genome sequence and basic biological properties, should respect** general safety standards as expressed in the Authority's concept of Qualified Presumption of Safety (hereinafter referred to as "QPS")[17] and ~~an absence of~~ **should not entail** 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[18], including acquired antimicrobial resistance genes, virulence factors and genes known to contribute to the production of toxins or harmful metabolites.~~**introduced by or resulting from the genetic modification.**

(12a) The QPS approach has been implemented by the Authority since 2007 with the aim of facilitating the safety assessment of application dossiers for market authorisation through a simplified evaluation of microbial strains belonging to certain taxonomic units. It entails a pre-assessment of a micro-organism's taxonomic identity, the related body of knowledge and potential safety concerns for human health, animal health and the environment. The QPS assessment is conducted separately and independently of the risk assessment of applications for market authorisation of products. It is meant to support not to replace the overall risk assessment. In this regard, the use of QPS facilitates a harmonized and generic approach for a part of the assessment of the safety of micro-organisms within the Union. Furthermore, the list of QPS recommended microbiological agents is updated periodically, including to assess the suitability of new taxonomic units.

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[17] https://doi.org/10.5281/zenodo.1146566

[18] ~~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.~~

(12b) **The concept of QPS should be used to streamline the environmental risk assessment of certain GMMs that belong to a taxonomic unit for which specific safety concerns have been previously excluded based on scientific knowledge and history of use as part of its QPS assessment. In this case, such safety concerns do not require reassessment and the relevant safety data do not need to be provided again by notifiers. Any aspect not addressed by the QPS assessment, in particular as regards potential risks associated to the genetic modification or to specific uses of the GMM, should still be evaluated in the context of the GMM-specific environmental risk assessment. Thus, the QPS assessment should not replace the environmental risk assessment of specific aspects of GMMs that remains under the responsibility of the Member States competent authorities.**

(12c) **Genes of concern should be understood in a broad sense as any gene that can cause harm to human health, animal health or the environment if expressed by a GMM. The Authority, in the glossary of their guidance on the characterisation of micro-organisms[19], currently considers genes of concern as genes known to contribute to the production of toxins, harmful metabolites, therapeutic antimicrobials, as well as acquired genes conferring resistance to therapeutic antimicrobials and, for products containing living micro-organisms, virulence factors. In addition, any genes resulting from de novo design or other advanced applications of synthetic biology that provide functions that are new to nature should be considered genes of concern.**

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[19] **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., Brétagne, S., Christensen, H., Cocconcelli, P.S., Herman, L., Prieto-Maradona, M., Mayo, B., Peláez, C., Saarela, M., Sánchez Serrano, J., Vernis, L., Yurkov, A., Aguilera, J., Anguita, M., Bozzi Cionci, N., Brozzi, R., Correia, S., García-Cazorla, Y., Istace F., Pettenati, E., Revez, E., Schoonjans, R., Valeri, P., 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) While the basic criteria to be fulfilled for a GMM to be ~~considered a low-risk GMM~~**eligible for an expedited procedure** should be established in Directive 2001/18/EC**, in order to reflect the rapid evolution of scientific and technological knowledge in this area**, 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~~**, in particular by specifying the criterion of gene of concern taking into account the Authority's guidance. The Commission should also be empowered to add** further **cumulative** criteria ~~if necessary~~**only to the extent justified by available evidence of advances in scientific knowledge and technological progress and experience gained from the release of comparable micro-organisms**. 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 **data requirements for the environmental** risk assessment ~~requirements and~~**of GMMs eligible for an expedited procedure to the extent justified by their characteristics, including by specifying which data is not required given their compliance with the eligibility criteria for an expedited procedure. Furthermore, the Commission should be empowered to adapt** the authorisation procedure to provide for the demonstration of ~~low-risk status~~**the eligibility criteria**, to streamline certain procedural elements and to expedite the timelines to reflect the adapted risk assessment requirements.

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(14) In line with the recommendations of the Authority[20], and in order to not impose disproportionate administrative burden, ~~low-risk~~ GMMs **eligible for an expedited procedure** 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, **animal health** or on the environment. **Therefore, it should be possible for the competent authority not to require post-market monitoring for environmental effects where duly justified, on the basis of the results of any previous release, the findings of the environmental risk assessment, the characteristics of the GMM, the characteristics and scale of its expected use and the characteristics of the receiving environment.**

(14a) Provision should be made for the Authority to adopt guidance to assist notifiers in the preparation and the presentation of the notification for the placing on the market of GMMs, including as regards the monitoring plan for environmental effects.

(14b) It is of particular importance that the Commission carries out appropriate consultations during its preparatory work and prior to adopting delegated acts, including at national expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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20 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., **Jimenez Saiz, R., Ruiz Garcia, L., Aguilera Entrena, J., Gennaro, A., Schoonjans, R., Kagkli, D. M.,** 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

(14c) **Composite vascular tissues, such as hands or faces, are differentiated parts of the human body, containing skin, muscles, bones, tendons and vessels that require surgical connection of blood vessels and, where indicated, of nerves, for transplantation. Once transplanted, they maintain their structure, vascularisation and capacity to develop physiological functions at a significantly autonomous level. They are also subject to the same time constraints as organs because of their vulnerability to ischaemia, the absence of storage options and the need for immunosuppressive therapy. Therefore, composite vascular tissues should be considered as organs for the purposes of this Directive.**

(15) Processing, including preservation, of human organs **outside the body** 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~~**methods** not only allows for more efficient organisational set-up, but also for improving **the functional status of** human organs during the extended ~~ex-vivo~~ time window **outside the body**, 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.

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(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 **outside the body, either for allogenic or for autologous use**, 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~~**The purpose of the processing** should be ~~laid down to clarify which~~**to maintain or improve the functioning or to modify the properties** 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~~**organ, without altering its original functions. Such modification** of the ~~European Parliament and~~**organ's properties may include, for example, the genetic modification** of the ~~Council[21], Regulation (EC) No 726/2004 of the European Parliament and of the Council[22], Regulation (EU) 2017/745 of the European Parliament and of the Council[23] and Regulation (EU) 2024/1938 of the European Parliament and of the Council[24]. Such provisions~~**organ to improve immunocompatibility or the administration of medicinal products to prevent the transmission of a disease from the donor to the recipient . Member States** should ~~aim to at ensuring coherence and efficient coordination among~~**establish requirements regarding the authorisation by the competent** authorities ~~operating under those frameworks. Directive 2010/53/EU~~**of organ processing methods that are new. Such requirements** should ~~therefore be amended accordingly~~**include an authorisation in cases where the benefit risk-assessment identifies a high risk to the quality of the organ and for the safety and effectiveness of the transplantation or autologous use, as well as clinical outcome**

~~21~~ ~~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).~~

~~22~~ ~~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).~~

~~23~~ ~~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).~~

~~24~~ ~~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).~~

monitoring plans where available scientific evidence and clinical data are insufficient to enable a comprehensive assessment.

(17a) With a view to ensure streamlined procedures and to avoid duplication, the requirements set out in this Directive on benefit risk-assessment, clinical outcome monitoring plans and authorisation of new organ processing methods should not apply where such methods are used within a clinical trial, a clinical investigation, a performance study or a SoHO clinical study that are authorised in accordance with the applicable Union health legislation for the same clinical indication and scope of authorised use. Similarly, such requirements should not apply where organ processing methods consist in the use of a medicinal product, a medical device, or SoHO preparation in accordance with the terms of the authorisation or of the results of the applicable conformity assessment procedure, as applicable. The competent authorities responsible for the implementation of the provisions of Directive 2010/53/EU and of the national law governing organ procurement, allocation and transplantation should also be informed prior to authorisation of clinical studies, so as to be able to ensure compliance with those provisions.

PUBLIC

(17b) 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 methods used for organ processing outside the body 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[25], Regulation (EC) No 726/2004 of the European Parliament and of the Council[26], Regulation (EC) 1394/2007 of the European Parliament and of the Council, Regulation (EU) 2017/745 of the European Parliament and of the Council[27], Regulation (EU) 2017/746 of the European Parliament and of the Council, and Regulation (EU) 2024/1938 of the European Parliament and of the Council[28]. Directive 2010/53/EU should therefore be amended accordingly. The provisions on organ processing in this Directive should apply without prejudice to Union legislation on genetically modified organisms.

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25 **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).**

26 **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).**

27 **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).**

28 **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).**

(17c) **With regard to provisions on processing of organs set out in this directive, it is important to recall that the human body and it parts as such are not to give rise to financial gain.**

(17d) **In order to ensure a high level of human health protection in the field of organ donation, transplantation and autologous use, Member States should ensure that personal data, including data concerning health and genetic data, collected for donation, allocation, organ processing, transplantation and follow-up should be capable of further processing for reasons of public interest in the area of public health, in particular to ensure patient safety and high standards of quality and safety of health care or cross-border data sharing within the Union to support the analysis of transplant and autologous use outcomes across larger patient cohorts. Such processing should be deemed to be in the public interest in the area of public health. Regulation (EU) 2016/679 of the European Parliament and of the Council lays down the applicable rules for such processing, subject to appropriate safeguards for the rights and freedoms of data subjects.**

(17e) **With a view to facilitate the implementation of the provisions on organ processing in this Directive, the Commission may adopt guidelines regarding the methodology for the benefit-risk assessment, the identification of high-risk organ processing methods and the clinical outcome monitoring plan.**

PUBLIC

(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~~**arrangements for complying** with analytical method **performance** requirements and the supporting information to be submitted to demonstrate the fulfilment of the criteria for being considered a ~~low-risk~~ GMM **eligible for an expedited procedure** concerning Directive 2001/18/EC, as well as the establishment of ~~detailed rules~~**minimum requirements** for the ~~authorisation of~~**benefit risk-assessment, the identification of high risk** organ processing **methods and the clinical outcome monitoring plan, where necessary to facilitate cross-border exchange of organs**, 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[29].

(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.

(19a) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on 28 May 2026[30]

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29 -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).

30 9783/26

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 **European Food Safety** Authority **(hereafter "the Authority")** to selected groups of micro-organisms ~~on the basis of an assessment showing no~~**as a result of a case-by-case pre-assessment of their taxonomic identity, the related body of knowledge and potential** safety concerns~~;’~~ **for human health, animal health and the environment.**

* 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)~~**eu/eli/dir/2009/41/oj)**.;’

PUBLIC

(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~~**24h** 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.~~

PUBLIC

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 information requirements for notifications shall be adapted to the characteristics of GMMs .

To this end, 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~~**to the extent justified by the characteristics of the GMMs without prejudice to the principles of the environmental risk assessment laid down in Annex II. When preparing delegated acts under this paragraph, the Commission shall base itself on** scientific **evidence related to the safety and risk assessment of GMMs, including relevant scientific opinions from the Authority**~~and technical progress~~.

PUBLIC

Article 24c

Validity of the consent

1. ~~Without prejudice to Article 20(2) and (3) and Article 23, the~~ Consent granted ~~under Part C~~**for the placing on the market of GMMs** shall**, upon the first renewal in accordance with Article 17,** be valid for an unlimited period ~~of time and~~**, unless the decision referred to in** Article ~~17 shall not apply~~**17(6) or (8) or Article 18(2) provides that the renewal is for a limited period on justified grounds based on the findings of the environmental risk assessment carried out pursuant to this Directive and on experience with the use, including results of monitoring, if so specified in the consent**.

2. The second sentence of Article 17(6) and the second sentence of Article 17(8) shall not apply.

Article 24d

Analytical~~Detection~~ methods

1. ~~In cases~~ Where **the notifier duly justifies that** it is not feasible to provide ~~a~~**an analytical** 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~~**GMM concerned, the arrangements for complying** with analytical method performance requirements shall be adapted as ~~specified~~**set out** 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~~**arrangements for complying with analytical** method **performance** requirements in accordance with paragraph 1.

2a. Where appropriate, the competent authority of the Member State that prepares the assessment report referred to in Article 14 may request expert assistance from the relevant national reference laboratories referred to in Article 32 of Regulation (EC) 1829/2003 or in Article 100 of Regulation (EU) 2017/625 to assess whether the information provided by the notifier in accordance with paragraph 1 justifies the application of adapted arrangements for complying with analytical method performance requirements.

Article 24e

~~Low-risk GMMs~~**Expedited procedure**

1. A GMM shall be ~~considered a 'low-risk GMM'~~**eligible for the expedited procedure under this Article** 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~~**the genetic modification** does not ~~contain genes~~**introduce or result in any gene** 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~~**the** placing on the market **of GMMs eligible for an expedited procedure** shall be adapted to their characteristics**, in particular the fact that they comply with the eligibility criteria as specified in paragraph 1**.

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~~**that the GMM meets the eligibility criteria for expedited procedure**, 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~~**eligibility** criteria ~~of GMMs~~**for an expedited procedure** as referred to in paragraph 1, ~~first subparagraph,~~ points (a), (b) and (c);

(b) supplement this Directive by establishing, where necessary, additional**, cumulative eligibility** ~~low-risk~~ criteria ~~of GMMs~~**for an expedited procedure** as referred to in paragraph 1 **to the extent justified by advances in scientific knowledge concerning the safety of GMMs, technological progress and experience gained from the release of comparable micro-organisms**;

PUBLIC

(c) amend ~~this Directive~~**Annex III** by providing for specific information requirements **for GMMs eligible for an expedited procedure to the extent justified by the characteristics of these GMMs and without prejudice to the principles for the environmental risk assessment laid down in Annex II. The Commission shall notably consider which information specified** in Annex III ~~in notifications concerning the placing on the market of low-risk GMMs~~**shall not be required as a result of compliance with the eligibility criteria and the data pre-assessed by the Authority in the context of the attribution of the Status of Qualified Presumption of Safety to the taxonomic unit**;

PUBLIC

(d) amend this Directive by setting out procedural requirements for the **environmental** risk assessment of ~~low-risk GMMs adapted to their~~**GMMs eligible for an expedited procedure, as provided for in paragraph 2, second subparagraph, to the extent justified by the** characteristics **of these GMMs and without prejudice to the principles for the environmental risk assessment laid down in Annex II. Such procedural requirements shall ensure a high level of protection of human health, animal health and the environment as well as the necessary consultations of competent authorities and the public.**

When preparing delegated acts under this paragraph, the Commission shall base itself on scientific evidence related to the safety and risk assessment of GMMs, including relevant scientific opinions from the Authority.

When preparing delegated acts as provided in point (a), the Commission shall list gene functions and characteristics that have the potential to cause harm to human health, animal health or the environment to specify the criterion of gene of concern in Article 24e(1), point (c).

When adopting delegated acts as provided in point (b), the Commission shall publish a report to justify the additional eligibility criteria for the expedited procedure, including an up-to-date scientific literature review concerning the safety of GMMs and their environmental risk assessment and characterisation. These delegated acts shall not extend the scope of GMMs eligible for the expedited procedure.

PUBLIC

Article 24f

Monitoring and reporting of ~~low-risk~~ GMMs **eligible for an expedited procedure**

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 competent authority shall assess the proposal referred to in paragraph 1 and take the final decision on whether monitoring is required.** 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.

PUBLIC

Article 24g

Implementing acts

1. The Commission shall adopt implementing acts concerning:

   (a) adapted ~~modalities to comply~~**arrangements for complying** with analytical method **performance** 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 **eligible for an expedited procedure**.

   (ba) The supporting information to be included in the notification referred to in Article 13(2) when it is proposed not to submit a monitoring plan, as referred to in Article 24f.

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

Article 24h

Guidance

1. The Authority shall publish detailed guidance to assist notifiers in the preparation and the presentation of the notification for the placing on the market of GMMs in accordance with this Title.

2. The European Union Reference Laboratories (EURL), assisted by the European Network of GMO laboratories (ENGL), shall publish detailed guidance to assist the notifier in the application of Article 24d. '

PUBLIC

(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**.

PUBLIC

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..'

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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, **as well as to the processing of organs intended for autologous use**.

1b. In the case of organs processed outside the body with the use of a substance with pharmacological, immunological or metabolic action within the meaning of Article 1(2), point (b) of Directive 2001/83/EC, with the aim to treat or prevent a disease in the patient to whom the organ will be transplanted, this Directive applies to the organ processing method prior to transplantation or autologous use, while the use of the substance is governed by the rules set out in Directive 2001/83/EC, Regulation (EC) 1394/2007***, Regulation (EC) No 726/2004 and Regulation (EU) No 536/2014, as applicable.**

1c. In the case of organs processed with the use of a substance of human origin (hereafter ‘SoHO’) preparation within the meaning of Regulation (EU) 2024/1938, with the aim to treat or prevent a disease in the patient to whom the organ will be transplanted, this Directive applies to the organ processing method prior to transplantation or for autologous use, while the use of the SoHO preparation is governed by the rules set out in Regulation (EU) 2024/1938.’

PUBLIC

1d. An organ that undergoes processing, including through the use of medicinal products, medical devices or SoHO preparations, remains an organ subject to the rules on quality and safety for organs set out in this Directive and to the applicable national provisions regarding organ procurement, allocation and transplantation.'

(2) Article 3 is amended as follows:

(-a) point (h) is replaced by the following:

'(h) 'organ' means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation; a composite vascularised tissue is also considered an organ.'

~~(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~~**points are** inserted:

'(aa) 'autologous use' means an organ removed from and applied in the same person.'

(ab) 'clinical outcome monitoring plan' means a programme aiming to gather evidence on the effects of an organ processing method on the quality of the organ and on the safety and effectiveness of the organ transplantation or autologous use, as demonstrated by recipient outcomes.

(ba) 'composite vascularised tissue' means a differentiated part of the human body containing multiple tissue types that require surgical connection of blood vessels and, where indicated, of nerves, for transplantation;

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(ga) 'high-risk organ processing method' means an organ processing method associated with an increased likelihood of graft failure or a serious adverse health outcome for the recipient.

(gb) 'medical device' means a medical device as defined in Article 2, point (1) of Regulation (EU) No 2017/745 of the European Parliament and the Council, including an in vitro diagnostic medical device as defined in Article 2, point (2) of Regulation (EU) No 2017/746**** of the European Parliament and the Council;**

(gc) 'medicinal product' means a medicinal product as defined in Article 1, paragraph 2 of Directive 2001/83/EC of the European Parliament and of the Council.

(ka) ~~"~~'processing~~"~~' means any operation involving the handling of organs **outside the body**, including but not limited to preservation, application of ~~chemotherapy~~**medicinal products, medical devices or SoHO preparations** and surgery, performed **with the aim** to maintain or improve the ~~functional status~~**functioning** of an organ **or modify its properties, such as immunocompatibility** prior to transplantation**, or autologous use**, with the exception of the preparatory handling of the organ ~~during~~**within** the surgical **field during the** transplantation intervention~~, and excluding the following:~~ **or during autologous use;'**

(oa) 'significant change' means any modification to an organ processing method that is reasonably expected to affect clinical outcomes, organ viability, or properties like immunological compatibility.

(ob) 'SoHO preparation' means a SoHO preparation as defined in Article 3, point (37) of Regulation (EU) No 2024/1938 of the European Parliament and the Council;

~~(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.'~~

(2a) In Article 4, paragraph 2, point (d) is replaced by the following:

''(d) the procurement, processing, packaging and labelling of organs in accordance with Articles 5, 6, 6a and 8;''

(3) the following Article 6a is inserted:

'Article 6a

Organ processing

1. **Member States shall ensure that prior to the introduction of a new organ processing method, a benefit risk assessment is conducted taking into account the intended clinical indication and all available evidence on the effects of the method on the quality of the organ and on the safety and effectiveness of the** transplantation ~~centres~~**or autologous use. The benefit risk assessment** shall ~~not apply a processed organ to a recipient without prior authorisation by~~**be documented and shall be communicated to** 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~~ **in accordance with national law**.

1a. Where the scientific evidence and clinical data available to perform the benefit risk assessment of the organ processing method are not sufficient, Member States shall ensure that the method is not used outside the context of a clinical outcome-monitoring plan approved by the competent authority.

2. **Where the scientific evidence and clinical data available are sufficient to perform the benefit risk assessment and the**~~The transplantation centre shall conduct a~~ benefit-risk assessment ~~of the processing of the organ, considering with the intended clinical indication for which~~**identifies a high risk, Member States shall ensure that** the organ processing **method is not used without prior** authorisation ~~is requested~~**by the competent authority, other than in the context of an approved clinical-outcome monitoring plan**.

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

2a. The evidence gathered in the approved clinical outcome monitoring shall be submitted to the competent authority to support, where applicable, the authorisation of the organ processing method in accordance with national law.

2b. Where the organ processing method entails the use of a medicinal product, a medical device or a SoHO preparation, the available evidence on its use shall be considered in the benefit-risk assessment and in the design of the clinical outcome monitoring plan, without performing an independent benefit-risk assessment on the use of the medicinal product, the medical device or the SoHO preparation concerned.

The authorisation of the organ processing method in accordance with this Directive is without prejudice to the rules set out in Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EC) No 1394/2007, Regulation (EU) 2024/1938, Regulation (EU) No 536/2014, Regulation (EU) 2017/745 and Regulation (EU) 2017/746, with respect to the medicinal products, medical devices or SoHO preparations used.

2c. When establishing national requirements for the authorisation of organ processing methods, Member State shall ensure high standards of quality and safety and take into account any guidelines published pursuant to paragraph 12 of this Article.

Member States shall specify the conditions for introducing significant changes regarding the steps of the authorised organ processing method, as well as on the suspension or withdrawal of the authorisation of the organ processing method.

Member States shall, upon request of the Commission or another Member State, provide information on the national requirements referred to in this paragraph and their implementation.

2d. Member States may maintain or introduce national provisions allowing the use of an organ processing method without authorisation and outside an approved

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clinical outcome monitoring plan on an exceptional basis, where necessary to treat a patient with no therapeutic alternative and an imminent need of transplantation or autologous use.

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.~~

3a. This Article shall not apply to organ processing methods that are well established in the Member State concerned before [24 months from the entry into force of this directive].

Member States shall publish a list of the organ processing methods that are well established on their territories and shall communicate it to the Commission.

3b. The provisions in this Article on benefit risk-assessment, clinical outcome monitoring plan and prior authorisation of organ processing methods shall not apply where such method consists in:

(a) the use of an investigational medicinal product in a clinical trial authorised in accordance with Regulation (EU) 536/2014, or of an investigational device in a clinical investigation authorised in accordance with Article 62 of Regulation (EU) 2017/745, or of a device for performance study in a performance study authorised in accordance with Article 58 of Regulation (EU) 2017/746, or of a SoHO preparation that is not yet authorized in a SoHO clinical study authorised in accordance with Regulation (EU) 2024/1938, for the same clinical indication and scope of authorised use according to the clinical trial, clinical investigation or clinical outcome monitoring protocol, as applicable;

(b) the use of a medicinal product in accordance with the terms of the marketing authorisation, or of a medical device in accordance with the results of the applicable conformity assessment procedure or of a SoHO preparation in accordance with the terms of the SoHO preparation authorisation specifically intended for that organ processing method.

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Member States shall ensure that, prior to the authorisation referred to in point (a) of this paragraph, the competent authorities responsible for the implementation of this Directive are informed, so that they can assess and ensure compliance with the rules laid down in this Directive and national provisions governing organ procurement, allocation and transplantation.

4. Where the processing of an organ entails the use of a medicinal product, ~~the competent authority~~**Member States** shall ~~verify~~**ensure** 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~~**Member States** shall ~~verify~~**ensure** that the medical device has been ~~certified by a notified body~~**placed on the market or put into service** in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council*** **and Regulation (EU) 2017/746 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~~**Member States** shall ~~verify~~**ensure** 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~~**organ processing involves the use of medicinal products, medical devices or SoHO preparations ,** the competent authorities ~~under~~**and the authorities responsible for implementing the requirements of** Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) 2017/745**, Regulation (EU) 2017/746** and Regulation (EU) 2024/1938 shall collaborate **so that the competent authorities responsible for the implementation of this Directive can ensure compliance with the rules laid down in this Directive and national provisions governing organ procurement, allocation and transplantation, and**~~in order~~ to exchange clinical outcome data ~~under such Union legislative frameworks including the clinical outcome monitoring plan under this Directive~~**, information on vigilance and inspections, or any other issue affecting quality of the organ or safety or effectiveness of the transplantation or autologous use, without prejudice to applicable rules on data protection and confidentiality**.

~~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. **Member States shall communicate to each other and to the Commission the organ processing methods that are authorised on their territory in accordance with this Article.** 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~~**host a platform to facilitate this exchange of information**.

12. The Commission ~~shall~~**may, in cooperation with competent authorities, establish guidelines regarding the methodology for the benefit-risk assessment, including the identification of high-risk organ processing methods, and the clinical outcome monitoring plan.**

The Commission may 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)~~.~~**, setting out, where necessary to ensure high standards of quality and safety of organs in cross-border transplantation, minimum requirements related to the methodology for the benefit risk-assessment, including on the identification of high-risk organ processing methods, and the clinical outcome monitoring plan.**

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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).;

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******* Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, pp. 121–137, ELI: http://data.europa.eu/eli/reg/2007/1394/oj)**

******** Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, pp. 176–332, ELI: http://data.europa.eu/eli/reg/2017/746/oj)'**

(3a) In Article 11, paragraph 1 is replaced by the following:

'(1) Member States shall ensure that there is a reporting system in place to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, processing and transport of organs, as well as any serious adverse reaction observed during or after transplantation or autologous use which may be connected to those activities.'

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(3b) In Article 16, paragraph 1, in the first sentence, "all organ donation and transplantation activities" is replaced by the following:

'all organ donation and transplantation activities as well as in the context of processing of organs.'

(3c) the following Article 16a is inserted:

'Article 16a

Use of personal data for reasons of public interest in the area of organ transplantation

Member States shall ensure that the processing of personal data, including data concerning health and genetic data, collected in the context of organ donation and transplantation activities, as well as the processing of organs, may be carried out for purposes beyond those for which the data were initially collected, where necessary:

1. **to ensure patient safety and high standards of quality and safety of human organs and healthcare; or**

2. **for cross-border data sharing within the Union to support the analysis of transplant outcomes across larger patient cohorts.**

Such processing of personal data shall be deemed to be in the public interest in the area of public health.'

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

‘Processing

Processing steps applied to the organ with the aim **to maintain or improve the functioning of an organ or modify its properties such as immunocompatibility prior to transplantation, or autologous use,**~~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~~**medicinal products, medical devices or SoHO preparations** and surgery.’

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Article 3

Transposition

1. Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive by [~~24~~**36** 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
The President

For the Council
The President

PUBLIC