European Parliament
2024-2029

Committee on Environment, Climate and Food Safety
Committee on Public Health

2025/0405(COD)

06/11/2026

DRAFT COMPROMISE AMENDMENTS 1-20

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

Proposal for a directive
COM(2025)1031 – C10-0358/2025 – 2025/0405(COD))

Committee on Environment, Climate and Food Safety

Committee on Public Health

Draft report
(PE789.094v01-00)

Rapporteurs: Marta Temido, Adam Jarubas

COMPROMISE 1

Compromise Amendment 1- Article 2 (Definitions) and Article 3
Compromise supported by Co-Rapporteurs
Replacing amendments: 23, 193- 203

Proposal for a directive
Article 1 – paragraph 1
Directive 2001/18/EC
Article 2 – point 11

Text proposed by the Commission	*Amendment*
(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***;***'	(11) 'Status of Qualified Presumption of Safety' means the safety status assigned by the Authority to ***taxonomic units of*** micro-organisms on ***a case-by-case pre-*** assessment ***of their taxonomic identity, the related body of knowledge and potential*** safety concerns, ***conducted separately and without prejudice to the risk assessment of any individual notification.***

COMPROMISE 2
Compromise amendment 2 - Article 24a
Compromise supported by Co-Rapporteurs
Replacing amendments: 24, 204- 208

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 a – paragraph 2

Text proposed by the Commission	*Amendment*
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.	***deleted***

COMPROMISE 3

Compromise amendment 3 - Article 24b
Compromise supported by Co-Rapporteurs
Replacing amendments: 25, 43-44, 209 – 214, 352-353

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 b – paragraph 1

Text proposed by the Commission	*Amendment*
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.	***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 ***to the extent justified by the characteristics of the GMMs and without prejudice to the principles for 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***.

COMPROMISE 4

Compromise amendment 4 - Article 24c
Compromise supported by Co-Rapporteurs
replacing amendments: 26, 215 -225

Proposal for a directive
Article 1 – paragraph 1 – point 3

Directive 2001/18/EC
Article 24 c

Text proposed by the Commission	*Amendment*
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.***	***Consent for the placing on the market of GMMs shall, upon the first renewal in accordance with Article 17,*** be valid for an unlimited period***, unless the decision referred to in Articles 17(6) or 17(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 the results of monitoring, if so specified in the consent.***

COMPROMISE 5

Compromise amendment 5 - Article 24d
Compromise supported by Co-Rapporteurs
replacing amendments: 27-28, 226 – 243

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 d - Title

Text proposed by the Commission	*Amendment*
Detection methods	***Analytical*** methods ***for detection, identification and quantification***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 d – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***In cases where it is not feasible to provide a method for detection,***	1. ***Where*** the notifier duly ***justifies that it is not feasible to provide an***

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).	***analytical method for identification and quantification of the GMM concerned, the arrangements for complying*** with analytical method performance requirements shall be adapted as ***set out*** in the implementing act adopted in accordance with Article 24g(1), point (a). ***The adaption of those*** modalities ***shall not dispense the requirement to provide a method capable of detection.***
Proposal for a directive **Article 1 – paragraph 1 – point 3** Directive 2001/18/EC Article 24 d **–** paragraph 2	
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	2. The competent authority shall assess whether the information ***concerning the non-feasibility of*** the analytical method provided by the notifier justifies the application of adapted ***arrangements*** to comply with ***analytical*** method requirements in accordance with paragraph 1 ***The competent authority may request that the EURL, assisted by the ENGL, adopt guidance for applicants and competent authorities on minimum performance requirements for analytical methods.***
Proposal for a directive **Article 1 – paragraph 1 – point 3** Directive 2001/18/EC Article 24 d **–** paragraph 2 a (new)	
	2a. Where adapted modalities are applied in accordance with paragraph 1, the notifier shall: ***(a) deposit the DNA sequence of the GMM and of its parental organism, together with reference material, in a repository accessible to competent authorities, the Commission, EFSA and designated enforcement laboratories;***

	(b) submit an analytical method fulfilling the applicable minimum performance requirements as soon as such a method becomes technically feasible. The competent authority shall re-examine, on the occasion of each renewal of the consent, whether such a method has become feasible.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 d **–** paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Commission shall take necessary efforts to ensure obstacles to the identification and quantification of GMMs are removed, taking into account the findings and recommendations of the European Network of GMO Laboratories (ENGL).

COMPROMISE 6

Compromise Amendment 6 - Article 24e
Compromise supported by Co-Rapporteurs
replacing amendments: 29 – 36, 244-308, 354

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – Title

Text proposed by the Commission	*Amendment*
Low-risk GMMs	***Expedited procedure***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 1

Text proposed by the Commission	*Amendment*
A GMM shall ***be considered a 'low-risk GMM'*** where it fulfils all of the following criteria:	A GMM shall ***be eligible for the expedited procedure under this Article*** where it fulfils all of the following criteria:

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) it is taxonomically and molecularly well characterised;	(a) it is taxonomically and molecularly well characterised **o*n the lowest taxonomic level possible.***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) it belongs to a taxonomic unit having the Status of Qualified Presumption of Safety	(b) it belongs to a taxonomic unit having the Status of Qualified Presumption of Safety ***provided that the attribution of that status to the taxonomic unit concerned is not subject to a qualification restricting it to use for production purposes or to products not containing viable cells, and that the assessment has addressed the***

	effects of environmental release;

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***it*** does not ***contain genes*** of concern ***which are not naturally present in the parental organism,*** in particular acquired antimicrobial resistance genes.	(c) ***the genetic modification*** does not ***introduce or result in any genes*** of concern, in particular acquired antimicrobial resistance genes, ***or traits that give rise to potential harm to the environment, animal or human health***;

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) For the specific case of GMMs under this Article that are viruses or viroids, it shall be ensured that the competent authority has assessed that the virus or viroid is safe for

	environmental release taking into account replication capacity, genetic stability, potential for recombination, transmission pathways and the characteristics of the receiving environment.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e - paragraph 2

Text proposed by the Commission	*Amendment*
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.	2. The risk assessment of GMMs ***eligible for expedited procedure*** and the specific information requirements in notifications concerning their placing on the market shall be adapted to their characteristics, ***in particular the fact that they comply with the eligibility criteria as specified in paragraph 1 and while taking into account the principles for the environmental risk assessment laid down in Annex II.***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 2 – second subparagraph

Text proposed by the Commission	*Amendment*
The procedural requirements laid down in Title I shall be adapted as provided for in	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.	paragraph 3, point (d), to provide for the demonstration ***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.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(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);	(a) supplement this Directive by further specifying the ***eligibility*** criteria ***for an expedited procedure*** as referred to in paragraph 1, first subparagraph, points (a), (b) and (c);

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) supplement this Directive by establishing, where necessary, additional ***low-risk*** criteria of ***GMMs*** as referred to in paragraph 1;	(b) supplement this Directive by establishing, where necessary, additional ***and, where applicable, cumulative eligibility*** criteria ***for an expedited procedure*** as referred to in paragraph 1 ***ensuring a high level of protection for human health, animal health and the environment;***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(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;	(c) amend ***Annex III*** of this Directive 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 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;***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 e – paragraph 3 – point d

Text proposed by the Commission	*Amendment*
(d) amend this Directive by setting out procedural requirements for the risk assessment ***of low-risk GMMs*** adapted to their characteristics.	(d) amend this Directive by setting out procedural requirements for the risk assessment of ***GMMs eligible for expedited procedure*** adapted to their characteristics, ***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 be science-based, 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.

COMPROMISE 7

Compromise amendment 7 - Article 24f
Compromise supported by Co-Rapporteurs
replacing amendments: 37-38, 309-330

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 f – Title

Text proposed by the Commission	*Amendment*

Monitoring and reporting of ***low-risk*** GMMs	Monitoring and reporting of GMMs ***eligible for expedited procedure after renewal of consent***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 f – paragraph 1

Text proposed by the Commission	*Amendment*
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.	If***, upon the renewal in accordance with Article 17***, 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 no ***longer*** needed, the notifier may propose not to ***re***submit a monitoring plan.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 f – paragraph 2

Text proposed by the Commission	*Amendment*
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.***	***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: ***a) specify the monitoring requirements, as provided in Article 19(3), point (f) or*** ***(b) state that monitoring is not required in which case the competent authority***

shall justify the decision and make this information publicly available.

COMPROMISE 8

Compromise amendment 8 - Articles 24fa (new), 24g, 24ga (new)
Compromise supported by Co-Rapporteurs
replacing amendments: 40-42; 331-338

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 f a (new)

Text proposed by the Commission	*Amendment*
	Article 24 fa
	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, assisted by the European Network of GMO Laboratories, shall publish detailed guidance to assist the notifier in the application of Article 24d.
	3. By … [12 months after the date of entry into force of this Directive], the Authority shall publish guidance on the environmental risk assessment and the post-market environmental monitoring of GMMs, as well as detailed guidance on the specific cases when it may be appropriate that post market monitoring be waived, in cooperation with the European Environment Agency. That guidance shall refer to each type of GMMs to which this Title refers, and their intended uses, and shall not be

	limited to microorganisms used in the food chain only.
	4. Article 24e shall apply from the date of publication of the guidance referred to in paragraph 3 or by …. [12 months after the date of entry into force of this Directive], whichever date comes first.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 g – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) adapted ***modalities*** to comply with analytical method requirements referred to in Article 24d(1);	a) adapted ***arrangements*** comply with analytical method requirements referred to in Article 24d(1);

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 g – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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.	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 ***eligible for an expedited procedure.***

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 g – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*

(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.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 g – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) the information referred to in Article 24f (2) concerning the post-market environmental monitoring plan.

Proposal for a directive
Article 1 – paragraph 1 – point 3
Directive 2001/18/EC
Article 24 g a (new)

Text proposed by the Commission	*Amendment*
	Article 24 ga
	Research
	The Commission shall through existing research programmes support the development, validation and further improvement of methods and approaches for the environmental risk assessment of GMMs. The Commission shall ensure that the results of research programmes are made publicly available and are taken into account in the guidance updates and requirements for the environmental risk assessment.

COMPROMISE 9

Compromise Amendment 9 -Evaluation on GMMs- Article 31a

Compromise supported by Co-Rapporteurs
replacing amendments: 45, 343, 464, 465

Proposal for a directive
Article 1 – paragraph 1 – point 4a (new)
Directive 2001/18/EC
Article 31 a (new)

Text proposed by the Commission	*Amendment*
	4a) In PART D, after Article 31, the following Article 31a is inserted:
	' Article 31a
	Reporting and evaluation
	1. By [five years after the date of application of this Directive], and every five years thereafter, the Commission shall submit to the European Parliament and to the Council a report on the implementation and functioning of Title II concerning GMMs.
	2. The report shall, in particular, assess: a) the effectiveness, proportionality and efficiency of the authorisation procedures for GMMs, including GMMs eligible for expedited procedure;
	b) the impacts on the environment, health, the agriculture system, including the organic and GMOs-free sectors of the measures of Title II;
	c) the impact of this Title on market access for biotechnology products in the Union;
	(d) the progress made on QPS assessments by the Authority;
	(e) the application of Article 24f in particular the impact and appropriateness of post market monitoring for GMMs eligible for expedited procedure including on innovation, the environment, human, and animal health.
	3. Where appropriate, the report shall be accompanied by a legislative proposal.

COMPROMISE 10

CA 10 - Organs Article 2
Compromise supported by Co-Rapporteurs
and replacing Amendment(s): 357, 358, 359, 360, 361, 362, 363, 448, 463

Proposal for a directive

Article 2 – paragraph 1 – point 1
Directive 2010/53/EU
Article 2 – paragraph 1

Text proposed by the Commission	*Amendment*
1. This Directive applies to the donation, testing, characterisation, procurement, processing, transport ***and transplantation*** of organs intended for transplantation.	1. This Directive applies to the donation, testing, characterisation, procurement, processing, ***including processing for autologous use,*** transport for transplantation ***and transplantation of organs intended for transplantation. It applies regardless of whether such an organ has undergone a processing operation, provided that the organ retains its physiological function after the process***.

Or. en

COMPROMISE 11

CA 11 - Organs Article 3
Compromise supported by Co-Rapporteurs
and replacing Amendment(s):
46,47,48,49,50,364,365,366,367,368,369,370,371,372,373,374,375,376,377,378,379,380,381,382,383,384,385,386,387,388

Article 2 – paragraph 1 – point 2 – point -a (new)
Directive 2010/53/EU
Article 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(a) the following points are inserted:
	(ba) 'clinical outcome monitoring plan' means a plan for the systemic collection and analysis of clinical outcome data to assess the effects of an organ processing method on the quality and safety of the processed organ, the clinical benefit and

	effectiveness of the organ transplantation or autologous use and to revise the benefit-risk assessment referred to in Article 6a (2).

Article 2 – paragraph 1 – point 2 – point -a (new)
Directive 2010/53/EU
Article 3 – point b b (new)

Text proposed by the Commission	*Amendment*
	(b) 'clinical outcome data' means data processed at clinical level following the application of a processed organ to a recipient, including, where relevant, organ function, graft survival, recipient survival and serious adverse events and reactions;

Article 2 – paragraph 1 – point 1 c (new)
Directive 2010/53/EU
Article 3 – point b c (new)

Text proposed by the Commission	*Amendment*
	(cc) 'significant change' means any modification to an organ processing method that is expected to affect clinical outcomes, organ viability, or properties like immunological compatibility;

Article 2 – paragraph 1 – point 2 – point a
Directive 2010/53/EU
Article 3 q

Text proposed by the Commission	*Amendment*
(q) "transplantation" means a process intended to restore certain functions of the human body by transferring an organ to a recipient;	(q) "transplantation" means a process intended to restore certain functions of the human body by transferring an organ ***from a donor*** to a recipient ***who, in the case of autologous use, are coincident***;

Article 2 – paragraph 1 – point 2 – point b
Directive 2010/53/EU
Article 3 point ka

Text proposed by the Commission	*Amendment*
(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***:	(ka) "***organ*** processing" means the handling of ***an organ***, including preservation ***of the organ itself***, application of ***medicinal products, medical devices or SoHO preparations*** and surgery, ***with a view*** to maintain***,*** improve ***or modify the functioning or the biological properties of the organ*** prior to transplantation and excluding:

Article 2 – paragraph 1 – point 2 – point b
Directive 2010/53/EU
Article 3 ka (–i) (new)

Text proposed by the Commission	*Amendment*
	(-i) the preparatory handling of the organ during the surgical transplantation intervention autologous use where it does not affect the functional status of the organ

Article 2 – paragraph 1 – point 2 – point b
Directive 2010/53/EU
Article 3 k a (ii)

Text proposed by the Commission	*Amendment*
(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.***	(ii) the use of a ***medicinal product*** with a pharmacological, immunological or metabolic action***, which is not specifically developed for the processing of the organ and whose therapeutic indication is autonomous and independent of that processing, that aims*** to treat or prevent a disease in the patient to whom the organ will be transplanted

Article 2 – paragraph 1 – point 2 – point b a (new)
Directive 2010/53/EU
Article 3 point s a (new)

Text proposed by the Commission	*Amendment*
	(ba) the following points are inserted:
	(sa) 'medicinal product' means a medicinal product as defined in Article 1 of Directive 2001/83/EC
	(sb) 'medical device' means a medical device as defined in Regulation (EU) 2017/745
	(sc) 'substance of human origin' or 'SoHO' Means a substance of human origin as defined in Regulation (EU) 2024/1938

COMPROMISE 12

CA 12 - Organs Article 4
Compromise supported by Co-Rapporteurs
and replacing Amendment(s): 389,390,51,52,53

Proposal for a directive

Article 2 – paragraph 1 – point 2 a (new)
Directive 2010/53/EU
Article 4 paragraph 1

Present text	*Amendment*
	(2a) Article 4 is amended as follows
Member States shall ensure that a framework for quality and safety is established to cover all stages of the chain from donation to transplantation or disposal, in compliance with the rules laid down in this Directive	"Member States shall ensure that a framework for quality and safety is established to cover all stages of the ***transplantation*** chain from donation ***to organ processing and*** transplantation or disposal, in compliance with the rules laid down in this Directive**.**"

(https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02010L0053-20100806&qid=1779799612116)

Article 2 – paragraph 1 – point 2 b (new)
Directive 2010/53/EU
Article 4 paragraph 2 (d)

Present text	*Amendment*

	(2 b) Article 4 paragraph 2, point (d) is amended as follows:
(d) the procurement preservation, packaging and labelling of organs in accordance with Articles 5, 6 and 8;	"(d) the procurement***, organ processing,*** preservation, packaging and labelling of organs in accordance with Articles 5, 6***, 6a*** and 8; "

(https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02010L0053-20100806&qid=1779799612116)

Article 2 – paragraph 1 – point 2 c (new)
Directive 2010/53/EU
Article 4 paragraph 3

Present text	*Amendment*
	(2c) Article 4 paragraph 3 is amended as follows
In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.	"In addition, the framework for quality and safety shall ensure that the healthcare personnel involved at all stages of the chain from donation ***to organ processing and*** transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel."

(https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02010L0053-20100806&qid=1779799612116)

Or. en

COMPROMISE 13

CA 13 - Organs Article 6a
Compromise supported by Co-Rapporteurs
and replacing Amendment(s) 391, 401, 402, 403, 404, 405, 395, 54, 392, 393, 394, 396, 397, 398, 399, 400, 406, 56, 407, 409, 410, 411, 412, 413, 414, 415, 57, 416, 417, 418, 58, 420, 421, 422, 423, 424, 59, 425, 426, 427, 428, 429, 430, 431, 432, 433, 434, 435, 436, 437, 438, 439, 440, 442, 419, 55, 408,443

Proposal for a directive

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU

Article 6a –1

Text proposed by the Commission	*Amendment*
	-1a An organ that undergoes processing, including through the use of medicinal products, medical devices or SoHO preparations, is subject to the rules on quality and safety for organs set out in this Directive and to the applicable Union and national concerning organ procurement, allocation and transplantation. The processing of donated human organs shall respect the principles of voluntary and unpaid donation, ensure patient safety, and contribute to equitable access to transplantation.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 1

Text proposed by the Commission	*Amendment*
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.	1. Transplantation centres shall not apply a processed organ to a recipient without prior authorisation by the competent authority ***referred to in Article 17***, 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.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 1a new

Text proposed by the Commission	*Amendment*
	1a. An organ processing authorisation shall be granted to a transplantation centre on the basis of an application which includes a clinical outcome monitoring plan and specifies the processing technology authorised. An organ processing authorisation granted to a transplantation centre shall not

constitute per se an authorisation for any other transplantation centre to carry out the same processing.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 1b new

Text proposed by the Commission	*Amendment*
	1b. Where an application for an organ processing authorisation is related to processing already authorised for a transplantation centre in another Member State, the competent authority shall take into account the available scientific evidence, benefit-risk assessment and relevant clinical outcome data relating to that processing. Where the scientific evidence and clinical data available remain insufficient, or where the benefit-risk assessment identifies a significant risk, the transplantation centre shall submit a proposal for a clinical-outcome monitoring plan in accordance with paragraph 3.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 2a new

Text proposed by the Commission	*Amendment*
	2a. The benefit-risk assessment shall take into account the available scientific evidence and clinical data, the organ concerned, the processing applied including the use of a medicinal product, medical device or SoHO preparation, any risk arising from interaction with the processing applied to the organ,, the intended clinical indication, the expected benefits for the recipient and the risks associated with the processing, including any impact on the quality and safety of the organ. The competent authority may request additional scientific evidence or clinical data where necessary.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 3

Text proposed by the Commission	*Amendment*
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.	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. ***The clinical outcome monitoring plan shall specify the clinical outcomes to be monitored, the duration of the monitoring and the arrangements for reporting clinical outcome data to the competent authority.***

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 3 a

Text proposed by the Commission	*Amendment*
	3a. Where transplantation centres justify an urgent medical need and where the benefit-risk assessment, conducted with sufficient scientific evidence and clinical data, did not identify any significant risk, the competent authority shall process the application in accordance with a simplified and accelerated procedure. Where a change to the processing steps applied is urgently required to address a serious risk to the quality or safety of the organ or to the recipient, and prior written agreement cannot be obtained in time, the transplantation centre may make that change to the extent necessary to address that risk and shall inform the competent authority thereof without undue delay.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 3 b new

Text proposed by the Commission	*Amendment*
	3b. Where clinical outcome data reveal that risks significantly outweigh benefits, the competent authority shall restrict, suspend or withdraw the organ processing authorisation, as appropriate.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 4

Text proposed by the Commission	*Amendment*
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**.	4. Where the processing of an organ entails the use of a medicinal product, the competent authority shall verify that ***such use is allowed*** 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**.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 5

Text proposed by the Commission	*Amendment*
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.	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. ***Those guidelines shall provide for a risk-proportionate approach, taking into account relevant assessments already carried out under applicable Union law.***

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 5a

Text proposed by the Commission	*Amendment*
	5a. The guidelines referred to in paragraph 5 shall include specific requirements for the labelling of organs post-processing and shall require at a minimum the contact details, address, and, where different from that of the transplantation centre which performs the transplant, the emergency telephone number of the processing entity transplantation centre.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 6

Text proposed by the Commission	*Amendment*
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***.	6. Where the processing of an organ entails the use of a medical device, the competent authority shall verify that ***such use is allowed*** in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council***

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 7

Text proposed by the Commission	*Amendment*
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****.	7. Where the processing of an organ entails the use of a SoHO preparation, the competent authority shall verify that ***such use is allowed*** in accordance with Regulation (EU) 2024/1938 of the European Parliament and of the Council****

Article 2 – paragraph 1 – point 3

Directive 2010/53/EU
Article 6a paragraph 8

Text proposed by the Commission	*Amendment*
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.	8. Where applicable, ***the*** competent authorities ***referred to in*** 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 ***cooperate*** in order to exchange clinical outcome data under such Union legislative frameworks including the clinical outcome monitoring plan under this Directive. ***Such clinical outcome data shall be processed in full compliance with Regulation (EU)2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and Regulation (EU) 2025/327 on the European Health Data Space.***

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 8 paragraph 9a

Text proposed by the Commission	*Amendment*
	9a. The cross-border transport of a processed organ shall not be delayed or prohibited, provided that the processing activity complies with an authorisation or an approved clinical-outcome monitoring plan issued by the competent authority of the Member State of procurement. The cross-border transport of organs should also include the clear display of the unique reference identifier of the organ processing authorisation or approved clinical-outcome monitoring plan, as well as any specific preservation or environmental conditions required during transit.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU

Article 6a paragraph 9 b

Text proposed by the Commission	*Amendment*
	9b. Where a processed organ is to be transplanted to a recipient, the recipient shall, after assessment of the urgency of the clinical situation, receive appropriate and comprehensible information on the processing applied and on any additional risks or scientific uncertainty relevant to the recipient and, where the transplantation takes place in the context of an approved clinical-outcome monitoring plan, on the purpose of the monitoring and any follow-up applicable to the recipient, in accordance with national law.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 10

Text proposed by the Commission	*Amendment*
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.	10. Competent authorities may ***restrict the scope of,*** suspend ***or withdraw*** the authorisation where there is reasonable ground to suspect that the performed processing activities are not in compliance with the authorisation. ***Such decision shall state the reason where possible and shall be communicated without undue delay to the transplant center.***

Article 2 – paragraph 1 – point 3
Directive 2010/53/EC
Article 6a

Text proposed by the Commission	*Amendment*
	10a. Organs that have undergone processing shall remain fully incorporated, without possibility of alternative pathways of access, into the official system of waiting lists and organ allocation, in accordance with the criteria

	established by the national competent authorities.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EC
Article 6a

Text proposed by the Commission	*Amendment*
	10b. The selection of donors of organs intended to be processed shall be carried out in accordance with scientific and ethical criteria approved by the competent authorities for organs.
	The donation coordinators and the procurement organisations, designated pursuant to this Directive, will take the responsibility of the management of the donation process.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 11

Text proposed by the Commission	*Amendment*
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.	11. The Commission shall ***establish and maintain a Union register*** of operations that have been authorised as organ processing or have received approval for a clinical outcome monitoring plan, including ***the types of organs concerned***, where relevant, the use of medicinal products, medical devices or SoHO preparations.

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 6a paragraph 12

Text proposed by the Commission	*Amendment*
12. The Commission shall adopt implementing acts ***laying down detailed*** rules for ***the application and authorisation***	12. The Commission shall adopt implementing acts ***concerning the*** rules for ***applications for*** organ processing ***authorisations, clinical-outcome monitoring plans, reporting of clinical***

of organ processing in accordance with the procedure referred to in Article 30(2).	***outcome data and exchange of information between competent authorities*** in accordance with the procedure referred to in Article 30(2).

Or. en

COMPROMISE 14

CA 14 - Organs Article 11
Compromise supported by Co-Rapporteurs
and replacing Amendment(s) 436,444, 445, 446, 447

Proposal for a directive

Article 2 – paragraph 1 – point 3
Directive 2010/53/EU
Article 11 - paragraph 1

Present text	*Amendment*
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, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.	"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,*** preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities."

(https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02010L0053-20100806&qid=1779799612116)

Article 2 – paragraph 1 – point 3 a (new)
Article 11 – paragraph 5a

Text proposed by the Commission	*Amendment*
	(3a) The traceability and serious adverse reaction and event notification systems established under this Article and Article 10 shall also apply to organs that

have undergone a process within the meaning of Article 6a, including the specific monitoring of any adverse effect related to the process itself or to the medicinal product or other technology employed.

Article 2 – paragraph 1 – point 3 b (new)
Article 11 – paragraph 5b

Text proposed by the Commission	*Amendment*
	(3b) The Commission shall establish a Union Alert Mechanism for Organ Processing for the rapid exchange between competent authorities and the Commission of information on serious adverse events and reactions and other serious safety concerns associated with organ processing that may be relevant to more than one Member State. Where a competent authority identifies such a serious safety concern, it shall notify the Commission and the competent authorities of Member States in which the processing concerned has been authorised, without undue delay. Competent authorities that receive such information shall assess whether action is necessary in relation to organ processing authorisations under their responsibility.

Or. en

COMPROMISE 15

CA 15 - Organs Article 16
Compromise supported by Co-Rapporteurs
and replacing Amendment(s) 60, 61, 449, 450

Proposal for a directive

Article 2 – paragraph 1 – point 3 a (new)
Directive 2010/53/EU
Article 16

Present text	*Amendment*

	(3 a) Article 16 is amended as follows
Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with Union provisions on the protection of personal data, such as ***Directive 95/46/EC***, and in particular Article ***8(3), Articles 16 and 17 and Article 28(2)*** thereof. Pursuant to ***Directive 95/46/EC***, Member States shall take all necessary measures to ensure that:	"Member States shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities ***and all organ processing***, in conformity with Union provisions on the protection of personal data, such as ***Regulation (EU) 2016/679***, and in particular Article ***9(3), 29, 32, and 36(4)*** thereof. Pursuant to ***Regulation (EU)2016/679***, Member States shall take all necessary measures to ensure that:"

(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0053-20100806)

Article 2 – paragraph 1 – point 3 b (new)
Directive 2010/53/EU
Article 16 (a)

Present text	*Amendment*
	(3 b) Article 16 (a) is amended as follows
(a) the data processed are kept confidential and secure in accordance with Articles ***16 and 17 of Directive 95/46/EC***. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be penalised in accordance with Article 23 of this Directive;	"(a) the data processed ***including the clinical outcome data containing personal data*** are kept confidential and secure in accordance with Articles ***29 and 32 of Regulation (EU)2016/679***. Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be penalised in accordance with Article 23 of this Directive;"

(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0053-20100806)

Article 2 – paragraph 1 – point 3 c (new)
Directive 2010/53/EU
Article 16 (b)

Present text	*Amendment*
	(3 c) Article 16 (b) is amended as follows

(b) donors and recipients whose data are processed within the scope of this Directive are not identifiable, except as permitted by Article 8(2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by Article 8(2) and (3) of Directive 95/46/EC, including medical purposes, and by national provisions implementing that Directive shall be penalised in accordance with Article 23 of this Directive;	"(b) donors and recipients whose data are processed within the scope of this Directive are not identifiable***, whereas data made accessible shall be anonymised or, where anonymisation would defeat the purpose pursued, pseudonymised***, except as permitted by Article 8(2) and (3) of Directive 95/46/EC, and national provisions implementing that Directive. Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by Article 8(2) and (3) of Directive 95/46/EC, including medical purposes, and by national provisions implementing that Directive shall be penalised in accordance with Article 23 of this Directive;"

(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02010L0053-20100806)

Article 2 – paragraph 1 – point 3 c (new)
Article 16 a (new)

Text proposed by the Commission	*Amendment*
	(3c) 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:
	(i) to ensure patient safety and high standards of quality and safety of human organs and healthcare; or
	(ii) for cross-border data sharing within the Union to support the analysis of transplant outcomes across larger patient cohorts.'
	Participants in the clinical investigation shall be informed thereof, including of the possibility of such secondary use, as part of the informed consent process.

Or. en

COMPROMISE 16

CA 16 - Organs Article 22 a (new)
Compromise supported by Co-Rapporteur
and replacing Amendment(s) 62, 441, 456

Proposal for a directive

Article 2 – paragraph 1 – point 4
Directive 2010/53/EU
Article 22 a (new)

Text proposed by the Commission	*Amendment*
	1. By [five years after the date of application of this Directive], and every three years thereafter, the Commission shall submit to the European Parliament and the Council a report on the application of Article 2 of this Directive concerning organ processing. The report shall assess, in particular:
	(a) the number and types of organ processing authorisations granted, restricted in scope, suspended or withdrawn;
	(b) the quality and safety of processed organs and relevant clinical outcomes;
	(c) the impact of organ processing on organ useand transplantation outcomes;
	(d) the differences between Member States onaccess to organ processing;
	(e) the impact of the cost and availability of technologies used for organ processing on access to transplantation and organ processing;
	(f) the consistency of the assessment and authorisation of organ processing between Member States;
	(g) the functioning of cooperation and exchange of safety and clinical outcome information between competent authorities; and (h) the good functioning of existing practices of electronic health data exchange between Member States in

	the European Health Data Space (EHDS), specifically assessing the extent of reciprocal access, any duplications of reporting obligations, and the need to create guidelines on common technical and semantic specifications within the scope of this Directive.

Article 2 – paragraph 1 – point 4
Directive 2010/53/EU
Article 22

Text proposed by the Commission	*Amendment*
	2. By [two years after the date of entry into force of this Directive] the Commission shall assess the implementation and effectiveness of cross-border cooperation in organ transplantation, with a view to maximising access to life-saving transplantation throughout the Union.
	In particular, the Commission shall assess the feasibility of establishing:
	(a) a European framework for voluntary cooperation between Member States in cross-border organ allocation, building on existing European organ exchange organisations and bilateral agreements, with a view to enabling participating Member States to mutually recognise high urgency patients at imminent risk of death who require urgent life-saving organ transplantation, irrespective of the Member State in which the patient is registered or the organ becomes available;
	(b a Union-wide paired kidneys exchange mechanism aiming to identify and match donor-recipient pairs, particularly for highly sensitised patients across the territories of all Member States.
	On the basis of the assessments referred to in the first subparagraph, point (a) and (b), the Commission shall propose the necessary measures to address identified barriers and strengthen cross-border cooperation, with the objective of saving

	lives and improving equitable access to transplantation throughout the Union.

Or. en

COMPROMISE 17

CA 17 - Organs Article Annex B
Compromise supported by Co-Rapporteurs
and replacing Amendment(s) 457, 458, 459, 460, 461, 462

Proposal for a directive

Article 2 – paragraph 1 – point 4
Directive 2010/53/EU
Annex B

Text proposed by the Commission	*Amendment*
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.	Processing steps applied to the organ with the aim ***to maintain, , restore or improve the functioning of an organ or modify its functions or properties*** and with a potential impact on its quality and safety, including in particular, , preservation, application of ***medicinal products, medical devices, SoHO preparations,*** chemotherapy and surgery.

Or. en

COMPROMISE 18

Compromise amendment 18 - on Joint Recitals
replacing Amendment(s): 1-3, 20-21, 70, 73, 181-184

Proposal for a directive
Recital 1

Text proposed by the Commission	*Amendment*
(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	(1) Regulation (EU) …/… [European Biotech Act] establishes a framework to strengthen the ***sustainability, safety and*** competitiveness of the health biotechnology sector in the Union, from research and development to the timely

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.	placing on the Union market and production of biotechnology ***and medical*** innovations and products, while ***setting and*** 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.

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(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 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.	(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 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. ***However, given the highly divergent content of those two Directives, it would have been appropriate to present two separate legal***

proposals to adapt them.

[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)).

[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)).

Proposal for a directive
Recital 18

Text proposed by the Commission	*Amendment*
(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 Council18.	(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 GMM ***eligible for an expedited procedure*** concerning Directive 2001/18/EC, as well as the establishment of detailed rules for the authorisation of organ processing, concerning Directive 2010/53/EU ***and the coordination and exchange of information and interoperable data between competent authorities responsible for organ processing and those responsible for medicinal products, medical devices and SoHO***. Those implementing acts should be adopted in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[18] .

Or. en

COMPROMISE 19

Compromise amendment 19- on GMMs Recitals
replacing Amendment(s):7-15, 74-88, 91-140, 142, 146, 147, 345

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) The precautionary principle, enshrined in Article 191(2) of the TFEU is of paramount importance and requires that where scientific uncertainty exists regarding potential risks to health or the environment, preventive measures should be taken. This principle empowers Union institutions and Member States to act proactively to avoid or minimise threats to health and the environment. In applying the provisions of this Directive, the precautionary principle should be respected, ensuring that any environmental release of GMMs has, according to the latest scientific evidence, been deemed safe for the environment, human and animal health, including adverse impacts on microbial communities.

Proposal for a directive
Recital 3

Text proposed by the Commission	*Amendment*
(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,	(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.	wastewater treatment, biomining and bioleaching, offering benefits in the wider agri-food, industrial and environmental sectors***. However, while the Union has practical experience with the contained release of GMMs in accordance with Directive 2009/41/EC, additional experience and research is needed into the uncontained release under the provisions of this Directive.*** ***Therefore, in parallel with the application this Directive, the Union should support further research into the environmental applications of GMMs.***
	Or. en

Proposal for a directive
Recital 4

Text proposed by the Commission	*Amendment*
(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.	(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, ***on the basis of scientific evidence already available on the GMM in question***. Finally, the Authority considered that, for certain GMMs, ***on a case-by-case basis,*** the need for post-market environmental monitoring (PMEM) may be waived based on the environmental risk assessment. ***The Authority also found that the current guidance available for PMEM is not sufficient. It recommended***

	a future update to include potential adverse effects resulting from the deliberate environmental release.
[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	[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
	Or. en

Proposal for a directive
Recital 5

Text proposed by the Commission	*Amendment*
(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.	(5) Directive 2001/18/EC was ***designed*** primarily ***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, animal and environmental health***.
	Or. en

Proposal for a directive
Recital 6

Text proposed by the Commission	*Amendment*
(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.	(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 ***science-based***, 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[6] , those provisions should cover GMMs in general without focus on specific techniques.
[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.	[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.

Or. en

Proposal for a directive
Recital 7

Text proposed by the Commission	*Amendment*
(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	(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.	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 and fungi, ***viruses and viroids***, while excluding animal***, plant cells in culture. However, for the specific case of viruses and viroids, it should be ensured that the competent authority has assessed that the virus or viroid is safe for environmental release taking into account replication capacity, genetic stability, potential for recombination, transmission pathways and the characteristics of the receiving environment.***
[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).	[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).

Or. en

Proposal for a directive
Recital 8

Text proposed by the Commission	*Amendment*
(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	(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 ***and evidence related to the safety and risk assessment of the GMM***. In order to carry out those adaptations, the power to adopt delegated acts in accordance with Article 290 of the

Commission in respect of amending the information requirements laid down in Annex III to the Directive.	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.

Or. en

Proposal for a directive
Recital 9

Text proposed by the Commission	***Amendment***
(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.	(9) ***T***he 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. ***However, the renewal of consent remains the principal occasion on which an authorisation is re-examined in the light of evidence generated after it was granted. Therefore, given the need to limit burden to operators and national competent authorities while upholding the precautionary principle, Directive 2001/18/EC should provide that consents*** for the placing on the market of GMMs should be valid, ***after a first renewal,*** for an unlimited period of time, ***unless decided otherwise at the time of the renewal on the basis of the environmental risk assessment and the available specific information on the GMM. Considering that microorganisms placed on the market as or in products can replicate independently of the operator and cannot be recovered from the environment, the renewal and PMEM are considered appropriate. At the same time, it is important to ensure that the competent authorities are able to maintain effective oversight of such products***. Any measures necessary to protect human ***or 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, taking into account new information that has become available as well as scientific and technical progress. ***In this context, the appropriateness of an unlimited period of validity should be carefully assessed, including whether a defined validity period or an appropriate review mechanism may be necessary to ensure continued compliance with the safety requirements laid down in Directive 2001/18/EC.***

Or. en

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(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.	(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 ***identification and quantification methods are not feasible*** for certain GMMs obtained through those techniques, ***or may fail to meet the current minimum performance requirements for analytical methods of GMO testing.[8] In such cases, it should be considered how effective control of such products could be ensured in the production chain and on the market where no reliable detection method exists, and whether competent authorities would be able to exercise appropriate oversight of such GMMs***. Therefore, in cases where it is not ***yet*** feasible to ***provide an analytical method for identification or quantification of GMMs as or in products concerned, or meet these requirements minimum performance requirements***, if duly justified by the notifier, the ***arrangements*** to comply with analytical

	method performance requirements should be adapted by means of implementing acts, ***until an analytical method for identification or quantification can be provided or minimum performance requirements can be met***.
[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.	[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.
	Or. en

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(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.	(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 ***an expedited procedure for certain GMMs (hereafter 'GMMs eligible for an expedited procedure)' where, on a case-by-case basis, the available information demonstrates that the*** specific ***GMM and its intended use can be adequately assessed with fewer data*** requirements, ***due to existing data already available on the GMM, whilst maintaining a high level of protection of human health animal health and environment. Eligibility for the expedited procedure should not be based solely on the characteristics of the parental microorganism or the absence of genes of concern but should also take into account the effects of the genetic modification on the characteristics, behaviour or manifestation of traits that give rise to potential harm to the***

environment, animal or human health; . Such adaptation should lead to a reduction of time to market for GMMs ***eligible for expedited procedure***, enabling innovation without lowering the safety standards ***or protection to human, animal and environmental health***.

[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

[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

Or. en

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(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	(12) Specifically, it is necessary to lay down the criteria defining GMMs ***eligible for expedited procedure. Such GMMs should be taxonomically and molecularly well characterised, considering their taxonomic identity, genome sequence and basic biological properties, should respect*** general safety standards as expressed in the Authority's concept of Qualified

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.

Presumption of Safety (hereinafter referred to as "QPS")[11] and ***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[12] , 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***.

[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.

[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.

Or. en

Proposal for a directive
Recital 12 a (new)

Text proposed by the Commission	*Amendment*
	(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 harmonised 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.

Proposal for a directive
Recital 12 b (new)

Text proposed by the Commission	*Amendment*
	(12b) The concept of QPS can be used to facilitate 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.(AM125)

Proposal for a directive
Recital 12 c (new)

Text proposed by the Commission	*Amendment*
	(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.

Or. en

Proposal for a directive
Recital 12 d (new)

Text proposed by the Commission	*Amendment*
	(12d) It is important that the criteria for eligibility for an expedited procedure take into account evolving scientific evidence and accumulated knowledge and safety experience. In order to ensure that the criteria remain fit for purpose, and for the purposes of the implementation of Directive 2001/18/EC, the criteria and QPS assessment should be proactively reviewed and kept up to date by the Commission and Authority, respectively.

Or. en

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(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.	(13) While the basic criteria to be fulfilled for a GMM to be ***eligible for an expedited procedure*** 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 and scientifically justifiable***. ***The Commission should also be empowered to add further cumulative criteria, where applicable, 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 environmental*** risk assessments ***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 ***eligibility for an expedited procedure***, to streamline certain procedural elements and to expedite the timelines to reflect the adapted risk assessment requirements.
	Or. en

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(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.***	(14) In line with the recommendations of the Authority, and in order not to impose a disproportionate administrative burden, ***GMMs eligible for expedited procedure may not have the obligation to establish a post-market environmental monitoring plan upon the renewal of consent, if the competent authority considers in a justified decision that the GMM does not require post-market environmental monitoring. Therefore, it after the first renewal of consent, the competent authority may not to require post-market monitoring for environmental effects, 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 and effects on human or animal health. The justification by the competent authority to waive the monitoring should be made publicly available.***
[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	[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

Or. en

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Following the EFSA opinion, the Authority should adopt and update 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. To inform this guidance, the Commission should leverage existing Union research funds to support the development, validation and further improvement of methods and approaches for the environmental risk assessment of GMMs.

Proposal for a regulation
Recital 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) Given that this proposal for a Directive was not accompanied by an impact assessment, 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.

Proposal for a regulation
Recital 14 c (new)

Text proposed by the Commission	*Amendment*
	(14c) In order to ensure that the rules applicable to genetically modified microorganisms remain effective and based on the best available scientific evidence, the Commission should regularly evaluate the implementation and functioning of Title II. The Commission should submit a report to the European Parliament and to the Council five years after the date of application of this Directive and every five years thereafter. That report should assess, in particular, the effectiveness, proportionality and efficiency of the authorisation procedures for GMMs, including the expedited procedure; the impacts of the measures of Title II on the environment, on health and on the agricultural system, including the organic and GMO-free sectors; the impact of Title II on market access for biotechnology products in the Union; and the progress made by the Authority on assessments of qualified presumption of safety (QPS). Where appropriate, the report should be accompanied by a legislative proposal, so that the framework can be adjusted in the light of scientific and technological developments and of the experience gained.

COMPROMISE 20

CA 20 - Organs Recitals
Compromise supported by Rapporteur
and replacing Amendment(s): 4-6, 16-19, 22, 71-72, 143, 148-180, 185-192

Proposal for a directive

Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) As information about organs reveals information about the health status of the donor and thus qualifies as

	'data concerning health' under Article 4(15) General data protection Regulation (EU)2016/679, it is necessary to ensure robust data protection safeguards. Information about organs may also constitute genetic data under Article 4(13) GDPR, notably if it contains an analysis of the deoxyribonucleic acid (DNA) of the donor or otherwise provides information about the inherited or acquired genetic characteristics of a natural person which give unique information about their physiology or health. Both data concerning health and genetic data are considered special categories of data under Article 9(1) GDPR and thus subject to heightened protection. As organ processing requires the processing of personal data, including health data, it should be designed by respecting the principles of data protection; that would imply that processing of personal data should be limited to achieving the objectives and the fulfilment of obligations of this Directive. Article 17 of Directive 2010/53/EU guarantees that the fundamental right to protection of personal data is fully and effectively applied in all organ transplantation activities including organ processing, in conformity with Union provisions on the protection of personal data such as Regulation (EU)2016/679.

Recital 15

Text proposed by the Commission	*Amendment*
(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.	(15) ***Organ*** processing, including preservation, ***repair and other techniques aimed at maintaining or improving the viability of donated*** human organs ***while preserving their status as donated human organs,*** is increasingly frequent and allows the time window between procurement from the donor and transplantation into the recipient to be extended.

Recital 16

Text proposed by the Commission	*Amendment*
(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.	(16) ***Organ*** processing ***methods*** not only ***allow*** 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 ***or to enhance post-transplant outcomes***. 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. ***Oversight by the competent authority should also promote transparency by ensuring that healthcare professionals and patients have access to clear and relevant information on the intended use, benefits, risks and, where available, clinical outcomes of organ processing techniques.***

Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) Article 3(2)(c) of the Charter of Fundamental Rights of the European Union provides that, in the fields of medicine and biology, the human body and its parts shall not, as such, give rise to financial gain. This principle is intended to safeguard human dignity by preventing the commercialisation of the human body and its parts. Accordingly, human organs should not be regarded as commercial commodities, irrespective of the processing or modifications to which they are subjected or of the therapeutic, preventive or other purposes for which they may subsequently be used. Therefore, organs intended for transplantation should remain within the scope of this Directive irrespective of any processing applied to them.

Recital 16 b (new)

Text proposed by the Commission	*Amendment*
	(16b) Where processing involves new techniques or substantial modification of organs, appropriate ethical oversight should also be ensured. The development and use of such techniques should contribute to improved outcomes for all patients and should not lead to commercialisation of the human body and its parts or to inequalities in access to transplantation, while respecting the principles of voluntary and unpaid donation and the non-commercialisation of the human body and its parts.

Recital 16 c (new)

Text proposed by the Commission	*Amendment*
	(16c) The Commission should assess options for connecting and expanding existing cross-border cooperation in organ allocation, including organ exchange organisations, joint waiting lists and paired donation registries, building on the experience, expertise and operational structures developed by Eurotransplant, Scandiatransplant, the South Alliance for Transplant and EURO-KEP. Such cooperation should aim to ensure that all patients in the Union have equitable access to life-saving organ transplantation, irrespective of the Member State in which they reside or are registered, including patients at imminent risk of death, while respecting the voluntary participation of Member States.

Recital 17

Text proposed by the Commission	*Amendment*
(17) To ensure a consistent and comprehensive legislative framework by providing clarity for all actors involved,	(17) To ensure a consistent and comprehensive legislative framework by providing ***legal*** clarity ***and coherence***

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.***

[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

across EU legislation for all actors involved, Directive 2010/53/EU should cover processing of organs ***for both allogenic and autologous use*** beyond preservation of such organs. ***Processing should remain limited to interventions performed on donated human organs after procurement and before or during surgical transplantation for the purposes of preservation, repair, restoration or improvement of viability and*** should ***not alter the legal status*** of the ***organ as a donated human organ***.

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).

Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) 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 procedures 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, Regulation (EC) No 726/2004 of the European Parliament and of the Council , Regulation (EU) 2017/745 of the European Parliament and of the Council and Regulation (EU) 2024/1938 of the European Parliament and of the Council.

Recital 17 b (new)

Text proposed by the Commission	*Amendment*
	(17b) Where medicinal products are intended solely for use during organ processing and their effects are exerted through the processed organ, it is appropriate that their use be authorised by the competent authority responsible for organ processing in accordance with this

	Directive, rather than being subject to a marketing authorisation under Directive 2001/83/EC or Regulation (EC) No 726/2004. This should be without prejudice to the applicable requirements of Union pharmaceutical legislation relating to manufacturing authorisations, good manufacturing practice, quality, safety and regulatory oversight. 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.

Recital 17 c (new)

Text proposed by the Commission	*Amendment*
	(17c) Where the processing of an organ raises questions concerning the application of the Union legislation on medicinal products, medical devices or SoHO preparations, the competent authorities under the respective Union legislative frameworks should cooperate within their respective competences with a view to ensuring a consistent application of those frameworks and avoiding gaps in regulatory oversight.

Recital 17 d (new)

Text proposed by the Commission	*Amendment*
	(17d) Enhanced cooperation among the EU, Member States and their competent authorities should facilitate the safe cross-border exchange of legally donated human organs, including organs that have undergone authorised processing, and improve timely and equitable access to transplantation, particularly where the necessary processing techniques are not available in the Member State where the transplantation is to take place. Particular attention should be given to patients with specific difficulties in finding a

	compatible organ,, including highly sensitised patients with very high panel-reactive antibody (PRA) levels, who face significantly reduced prospects of finding a compatible kidney through conventional allocation systems. Expanding the pool of potential donor-recipient pairs across national borders could substantially improve their opportunities for transplantation. The Commission should therefore assess options for strengthening cross-border cooperation in organ transplantation, including a European framework for voluntary cross-border organ allocation and a Union-wide paired kidney exchange mechanism, based on a voluntary participation by Member States, building on existing cooperation arrangements. . It should propose the necessary measures to address barriers and improve timely and equitable access to life-saving transplantation for all patients throughout the Union, particularly those at imminent risk of death and highly sensitised patients.

Recital 17 e (new)

Text proposed by the Commission	*Amendment*
	(17e) Where the processing of an organ entails the use of a medicinal product, medical device or SoHO preparation, compliance of that medicinal product, medical device or SoHO preparation with the applicable Union legislation should not in itself be considered sufficient to establish the safety of the processing of the organ. The benefit-risk assessment should also take into account the interaction between the processing applied to the organ and the medicinal product, medical device or SoHO preparation concerned.

Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) Organ processing techniques should be authorised on the basis of the available scientific evidence and clinical data, taking into account the processing steps applied to the organ, the organ concerned, the intended clinical indication, the expected benefits for the recipient, the risks associated with the processing and any remaining scientific and clinical uncertainty.

Recital 18 b (new)

Text proposed by the Commission	*Amendment*
	(18b) To ensure a high level of human health protection in organ donation, transplantation and autologous use, personal data, including data concerning health and genetic data, collected for donation, allocation, organ processing, transplantation and follow-up should, where necessary and proportionate, be permitted to be further processed for reasons of public interest in the area of public health. Such processing may include cross-border data sharing within the Union to ensure patient safety and high standards of quality and safety of healthcare and to support the analysis of transplantation and autologous-use outcomes across larger patient cohorts. Such processing should be carried out in accordance with Regulation (EU) 2016/679 and be subject to appropriate and specific safeguards for the rights and freedoms of data subjects.

Recital 18 c (new)

Text proposed by the Commission	*Amendment*
	(18c) The Commission should, in cooperation with Member States, competent authorities and relevant scientific and professional bodies,

periodically review authorised organ processing techniques, including available evidence on their safety, quality and clinical outcomes, in order to ensure that the requirements applicable to organ processing remain adapted to scientific and technological developments.

Recital 18 d (new)

Text proposed by the Commission	*Amendment*
	(18d) The Commission and competent authorities should ensure appropriate consultation of patient organisations, scientific and clinical experts and relevant civil society stakeholders in the development of guidance, recommendations and evaluation frameworks concerning novel organ processing techniques.

Recital 18 e (new)

Text proposed by the Commission	*Amendment*
	(18e) Serious adverse events and reactions and other serious safety concerns associated with organ processing identified in one Member State may have implications for the quality and safety of processed organs applied in other Member States. Such information should therefore be rapidly exchanged between competent authorities through an EU Alert Mechanism for Organ Processing.

Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) Member States and the Commission should, within their respective competences, monitor the impact of the cost and availability of technologies used for organ processing,

including the impact of intellectual property rights, on access to transplantation.

Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) The use of technologies developed or supplied by economic operators for organ processing should be without prejudice to the principles governing organ donation laid down in this Directive. Economic interests relating to such technologies should not influence organ allocation or recipient selection.

Recital 19 c (new)

Text proposed by the Commission	*Amendment*
	(19c) Where a processed organ is to be applied to a recipient, the recipient should receive appropriate and comprehensible information concerning the processing applied and, where relevant, any additional risks or scientific uncertainty associated with that processing, in accordance with applicable national rules on consent.

Recital 19 d (new)

Text proposed by the Commission	*Amendment*
	(19d) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on 27 May 2026.

Or. en