



2022/0216(COD)

14.3.2023

AMENDMENTS

328 - 624

Draft report
Nathalie Colin-Oesterlé
(PE738.661v01-00)

Standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

Proposal for a regulation
(COM(2022)0338 – C9-0226/2022 – 2022/0216(COD))

Amendment 328
Mathilde Androuët

Proposal for a regulation
Article 2 – paragraph 3 – subparagraph 1

Text proposed by the Commission

For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.

Amendment

For SoHOs that are used to manufacture products in accordance with Union legislation on medical devices, regulated by Regulation (EU) 2017/745, on medicinal products, regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC, including on advanced therapy medicinal products, regulated by Regulation (EC) No 1394/2007, or on food, regulated by Regulation (EC) No 1925/2006, or as the starting and raw material thereof, the provisions of this Regulation applicable to the activities of SoHO donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, and collection of SoHOs from donors or patients, ***as well as continuity of SoHO supply***, shall apply. Insofar as the activities of SoHO release, distribution, import and export relate to SoHOs prior to their distribution to an operator regulated by the other Union legislation referred to in this subparagraph, the provisions of this Regulation shall also apply.

Or. fr

Amendment 329
Stelios Kypouropoulos, Tomislav Sokol

Proposal for a regulation
Article 2 – paragraph 3 – subparagraph 2

Text proposed by the Commission

By way of derogation from the first subparagraph, in cases where SoHOs,

Amendment

By way of derogation from the first subparagraph, in cases where SoHOs,

SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection of SoHOs from patients shall apply.

SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection **and testing** of SoHOs from patients shall apply.

Or. en

Amendment 330
Susana Solís Pérez

Proposal for a regulation
Article 2 – paragraph 3 – subparagraph 2

Text proposed by the Commission

By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection of SoHOs from patients shall apply.

Amendment

By way of derogation from the first subparagraph, in cases where SoHOs, SoHO preparations, or products manufactured from SoHO, as referred to in that subparagraph, are exclusively for autologous use, only those provisions of this Regulation that concern the collection **and testing** of SoHOs from patients shall apply.

Or. en

Justification

Following the EMA's Good Manufacturing Practices, the provisions should apply for testing as well.

Amendment 331
Joanna Kopcińska

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission

4. Where non-viable SoHOs or their derivatives, as defined in Article 2, point (17), of Regulation (EU) 2017/745,

Amendment

4. Where non-viable SoHOs or their derivatives, as defined in Article 2, point (17), of Regulation (EU) 2017/745,

incorporate, as an integral part, a medical device, and where the action of the non-viable SoHOs or their derivatives is principal and not ancillary to that of the device, the non-viable SoHOs or their derivatives shall be governed by this Regulation. If the action of the non-viable SoHOs or their derivatives is ancillary to that of the device and not principal, the provisions of this Regulation, insofar as they concern donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients, shall apply.

incorporate, as an integral part, a medical device, and where the action of the non-viable SoHOs or their derivatives is principal and not ancillary to that of the device, the non-viable SoHOs or their derivatives shall be governed by this Regulation. If the action of the non-viable SoHOs or their derivatives is ancillary to that of the device and not principal, the provisions of this Regulation, insofar as they concern donor recruitment, donor history review and eligibility assessment, testing of donors for eligibility or matching purposes, collection of SoHOs from donors or patients, shall apply. ***In the case of SoHOs whose donation is not regulated by national law, the relevant procedures under health policy programme agreements shall apply.***

Or. pl

Amendment 332
Tilly Metz

Proposal for a regulation
Article 2 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. This Regulations further establishes provisions on:

(a) national emergency plans and the EU Strategy for critical SoHO supply sufficiency;

(b) SoHo Coordination Board;

(c) EU SoHO Platform.

Or. en

Amendment 333

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘blood’ means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;

Amendment

(1) ‘blood’ means the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body. ***It consists of a liquid part, plasma, and a solid consisting of red blood cells, leucocytes and platelets;***

Or. en

Amendment 334

Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation

Article 3 – paragraph 1 – point 1

Text proposed by the Commission

(1) ‘blood’ means ***the liquid that circulates in arteries and veins carrying oxygen to and carbon dioxide from the tissues of the body;***

Amendment

(1) “blood’ means ***whole blood collected from a donor and processed either for transfusion or for further manufacturing;***

Or. en

Amendment 335

Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation

Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(3) ‘cell’ means ***a mass of cytoplasm with or without a nucleus, that is bound externally by a cell membrane. Usually microscopic in size, cells are the smallest structural and functional unit of an organism;***

Amendment

(3) ***A typical cell is the smallest unit of an organism that has been generated directly through mitosis. A cell comprises a nucleus (eukaryotic cells) or nucleoid material (prokaryotic cells) and cytoplasm enclosed by a cell membrane.***

Or. en

Amendment 336
Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation
Article 3 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;

Amendment

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU, ***medicinal products regulated by Regulation (EC) No 726/2004 and Directive 2001/83/EC and investigational medicinal products regulated by Regulation (EC) No 536/2014;***

Or. en

Amendment 337
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body ***in whatever manner***, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;

Amendment

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body ***for health and medical purposes, respecting its human dignity and being able to form a new individual***, whether it contains cells or not and whether those cells are living or not; for the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;

Or. es

Amendment 338

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 5

Text proposed by the Commission

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU;

Amendment

(5) ‘substance of human origin’ (SoHO) means any substance collected from the human body in whatever manner, whether it contains cells or not and whether those cells are living or not. For the purposes of this Regulation, SoHO does not include organs in the sense of Article 3, point (h), of Directive 2010/53/EU, **but does include substances which can be extracted from them**;

Or. en

Amendment 339

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 6

Text proposed by the Commission

(6) ‘human application’ means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred (as in transfer to the uterus **or fallopian tube** of a woman), inseminated or otherwise added to the human body in order to create a biological, mechanical or physiological interaction with that body;

Amendment

(6) ‘human application’ means inserted, implanted, injected, infused, transfused, transplanted, ingested, transferred (as in transfer to the uterus of a woman), inseminated or otherwise added to the human body in order to create a biological, mechanical or physiological interaction with that body;

Or. en

Amendment 340

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 7

Text proposed by the Commission

(7) ‘SoHO activity’ means an action, or series of actions, that has a direct impact on the safety, quality *or* efficacy of SoHOs, as listed in Article 2(1);

Amendment

(7) ‘SoHO activity’ means an action, or series of actions, that has a direct impact on the safety, quality, efficacy *or functionality* of SoHOs, as listed in Article 2(1);

Or. en

Amendment 341
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘SoHO donor’ means any person who *has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;*

Amendment

(8) ‘SoHO donor’ means any person who, *freely and voluntarily, alive or deceased, has with informed prior consent and in the presence of a medical practitioner authorised the donation of SoHO for altruistic medical purposes to a SoHO organisation that respects human dignity. If the donor is a minor, the consent of the parents shall be required.*

Or. es

Amendment 342
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘SoHO donor’ means any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;

Amendment

(8) ‘SoHO donor’ means any person who has presented themselves *freely and voluntarily* to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not; *donors will*

have a guarantee that their donations are anonymous to recipients, and they will be unpaid;

Or. fr

Justification

Donation must remain an act performed freely and without payment so as not to lead to financial abuses that could adversely affect the health of recipients.

Amendment 343

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘SoHO donor’ means any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;

Amendment

(8) ‘SoHO donor’ means any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, ***or a deceased person who has authorised, or on his/her behalf a family member or authorised person, the donation of parts of his/her body after death,*** whether that donation is successful or not;

Or. en

Amendment 344

Tilly Metz

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘SoHO donor’ means ***any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;***

Amendment

(8) ‘SoHO donor’ means ***a living SoHO donor or a deceased SoHO donor;***

Amendment 345

Andreas Glück, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez, Jan Huitema

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘SoHO donor’ means any **person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs**, whether that donation is successful or not;

Amendment

(8) ‘SoHO donor’ means any **living SoHO donor or deceased SoHO donor**, whether that donation is successful or not;

Or. en

Justification

The definitions did not provide a distinction between living and deceased donors.

Amendment 346

Tudor Ciuhodaru

Proposal for a regulation

Article 3 – paragraph 1 – point 8

Text proposed by the Commission

(8) ‘SoHO donor’ means any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;

Amendment

(8) ‘SoHO donor’ means any person who has presented themselves **voluntarily** to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;

Or. ro

Amendment 347

Tilly Metz

Proposal for a regulation

Article 3 – paragraph 1 – point 8 a (new)

(8 a) 'living SoHO donor' means a living person who has presented themselves to a SoHO entity, or been presented by a person granting consent on their behalf, in accordance with national legislation, with a view to making a donation of SoHOs, whether that donation is successful or not, for the purpose of application to a person other than themselves, and other than situations of within couple use as defined in point (63);

Or. en

Amendment 348
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8a) 'donation' means a philanthropic act by a person of freely and voluntarily agreeing to provide a third party with a SoHO from that person's own body. Donations are deemed to be unpaid-for. Donations of reproductive cells are not covered by this Regulation in the case of post-mortem usage, which should be prohibited in all Member States.

Or. fr

Justification

Donation must remain an act performed freely and without payment so as not to lead to financial abuses that could adversely affect the health of recipients. In order to prevent abuses, furthermore, this Regulation cannot cover post-mortem usages of reproductive cells.

Amendment 349
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8 a) ‘SoHO donation’ means a process by which a person – or on his/her behalf a relative or authorised person – voluntarily and altruistically gives parts of their own body to other people in need, or authorises their use after their death. It includes the necessary medical formalities, examinations and treatments and monitoring of the SoHO donor, whether that donation is successful or not;

Or. en

Amendment 350

Andreas Glück, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez, Jan Huitema

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8 a) ‘Living SoHO donor’ means any living person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs either for autologous use or for allogeneic use.

Or. en

Justification

The definitions did not provide a distinction between living and deceased donors.

Amendment 351

Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8 b) ‘deceased SoHO donor’ means a person who has been referred to a SoHO entity and for whom consent or authorisation, or absence of expressed refusal to donation is in place, in accordance with national legislation;

Or. en

Amendment 352

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation

Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8 b) ‘living donor’ means any person who has presented themselves to a SoHO entity with a view to making a donation of SoHOs, whether that donation is successful or not;

Or. en

Amendment 353

Andreas Glück, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez, Jan Huitema

Proposal for a regulation

Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8 b) ‘Deceased SoHO donor’ means any deceased person who donates SoHO after death.

Or. en

Justification

The definitions did not provide a distinction between living and deceased donors.

Amendment 354

Tilly Metz

Proposal for a regulation

Article 3 – paragraph 1 – point 9

Text proposed by the Commission

(9) ‘SoHO recipient’ means the person to whom SoHOs are applied;

Amendment

(9) ‘SoHO recipient’ means the person to whom SoHOs are applied ***or such an application is envisaged***;

Or. en

Amendment 355

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation

Article 3 – paragraph 1 – point 10

Text proposed by the Commission

(10) ‘medically assisted reproduction’ means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception;

Amendment

(10) ‘medically assisted reproduction’ means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception ***and uses SoHOs for the preservation of fertility through collection and storage of SoHO substances for subsequent human application***;

Or. en

Amendment 356

Joanna Kopcińska

Proposal for a regulation

Article 3 – paragraph 1 – point 10

Text proposed by the Commission

(10) ‘medically assisted reproduction’ means the facilitation of conception by

Amendment

10) ‘medically assisted reproduction’ means the facilitation of conception by

intra-uterine insemination of sperm, in vitro fertilisation **or any other laboratory or medical intervention that promotes conception**;

intra-uterine insemination of sperm **or** in vitro fertilisation;

Or. pl

Justification

The original wording of the definition could extend to medical practitioners' offices using hormone therapy not necessarily for the purpose of medically assisted reproduction. It is therefore advisable to formulate the provision in such a way that it only applies to medically assisted reproduction procedures, without preparatory examinations and treatment.

Amendment 357
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 10

Text proposed by the Commission

(10) ‘medically assisted reproduction’ means the facilitation of conception by intra-uterine insemination of sperm, in vitro fertilisation **or any other laboratory or medical intervention that promotes conception**;

Amendment

(10) ‘medically assisted reproduction’ means the facilitation of conception by intra-uterine insemination of sperm **or** in vitro fertilisation **where conception meets the ethical rules laid down by the competent authorities of each Member State**;

Or. fr

Justification

Laboratory or medical intervention that promotes conception must be specifically defined in order to prevent any eugenic abuses or any serious risk that might harm women’s health.

Amendment 358
Stelios Kypouropoulos

Proposal for a regulation
Article 3 – paragraph 1 – point 10

Text proposed by the Commission

(10) ‘medically assisted reproduction’ means the facilitation of conception **by**

Amendment

(10) ‘medically assisted reproduction’ means the facilitation of conception

intra-uterine insemination of sperm, in vitro fertilisation or any other laboratory or medical intervention that promotes conception;

including all methods or techniques based on the manipulation of human reproductive cells;

Or. en

Amendment 359
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 1 – point 11

Text proposed by the Commission

Amendment

(11) ‘offspring from *medically assisted reproduction*’ means *fetuses* and children that are born following medically assisted reproduction;

(11) ‘offspring from *fertility treatments*’ means *embryos, foetuses* and children resulting from conception through *fertility treatments*;

Or. es

Amendment 360
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point 11

Text proposed by the Commission

Amendment

(11) ‘offspring from medically assisted reproduction’ means *fetuses and* children that are born following medically assisted reproduction;

(11) ‘offspring from medically assisted reproduction’ means children that are born following medically assisted reproduction;

Or. en

Amendment 361
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 1 – point 11

Text proposed by the Commission

Amendment

(11) ‘offspring from medically assisted reproduction’ means ***fetuses and*** children that are born following medically assisted reproduction;

(11) ‘offspring from medically assisted reproduction’ means children that are born following medically assisted reproduction;

Or. en

Amendment 362

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(11 a) ‘unborn offspring from medically assisted reproduction’ means embryos and foetuses conceived by medically assisted reproduction;

Or. en

Amendment 363

Andreas Glück, Véronique Trillet-Lenoir, Peter Liese

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point a

Text proposed by the Commission

Amendment

(a) has been subjected to one or more SoHO activities, ***including processing***, in accordance with defined quality and safety parameters;

(a) has been subjected to one or more SoHO activities in accordance with defined quality and safety parameters;

Or. en

Justification

According to Article 2, processing is already a SoHO activity so there is no need to mention it separately.

Amendment 364

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point b

Text proposed by the Commission

Amendment

(b) meets a pre-defined specification;
and

(b) meets a pre-defined specification;

Or. en

Amendment 365

Ondřej Knotek

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point b

Text proposed by the Commission

Amendment

(b) meets a pre-defined specification;
and

(b) meets a pre-defined specification;

Or. en

Amendment 366

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point c

Text proposed by the Commission

Amendment

(c) is intended for application to a recipient for a specific clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, or as the starting and raw material thereof;

(c) is intended for application to a recipient for a specific **and homologous** clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, or as the starting and raw material thereof; **and**

Or. en

Amendment 367

Ondřej Knotek

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point c

Text proposed by the Commission

(c) is intended for application to a recipient for a specific clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, or as the starting and raw material thereof;

Amendment

(c) is intended for application to a recipient for a specific clinical indication or is intended for distribution for manufacture of a product regulated by other Union legislation, or as the starting and raw material thereof; **and**

Or. en

Amendment 368

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point c a (new)

Text proposed by the Commission

Amendment

(c a) has not been substantially modified, such as to be considered as a medicinal product or advanced therapy, and is not intended to be applied in a non-homologous manner to the recipient.

Or. en

Amendment 369

Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation

Article 3 – paragraph 1 – point 12 – point c a (new)

Text proposed by the Commission

Amendment

(c a) does not involve a substantial manipulation or is intended for a non-homologous application.

Amendment 370

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 12 a (new)

Text proposed by the Commission

Amendment

(12 a) ‘competent authority’ means the body or bodies responsible for SoHO’s activities at national level, designated by each Member State;

Or. en

Amendment 371

Nicolás González Casares, Sara Cerdas

Proposal for a regulation

Article 3 – paragraph 1 – point 12 b (new)

Text proposed by the Commission

Amendment

(12 b) ‘national authority’ means the reference competent authority, at national level, appointed by each Member State and responsible for coordinating exchanges with the Commission and with the national SoHO authorities of other Member States;

Or. en

Amendment 372

Tudor Ciuhodaru

Proposal for a regulation

Article 3 – paragraph 1 – point 13

Text proposed by the Commission

Amendment

(13) ‘donor recruitment’ means any

(13) ‘donor recruitment’ means any

activity aimed at encouraging persons to become SoHO donors;

information and communication activity aimed at encouraging persons to become SoHO donors;

Or. ro

Amendment 373
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘donor recruitment’ means any activity aimed at encouraging persons to become SoHO donors;

Amendment

(13) ‘donor recruitment’ means any activity aimed at ***informing the public and*** encouraging persons to become SoHO donors;

Or. fr

Amendment 374
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 13

Text proposed by the Commission

(13) ‘donor recruitment’ means any activity aimed at encouraging persons to become SoHO donors;

Amendment

(13) ‘donor recruitment’ means any activity aimed at ***informing and*** encouraging persons to become SoHO donors;

Or. en

Amendment 375
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) 'collection' means a process by which SoHOs are removed, procured, excreted, secreted or obtained by any other manner, including any preparatory steps, such as hormone treatment, needed to facilitate the process;

Amendment

(14) 'collection' means a process by which SoHOs are removed, procured, excreted, secreted or obtained by any other manner, including any preparatory steps, such as hormone treatment, needed to facilitate the process; ***SoHOs cannot be procured from a donor who has not expressly requested that and whose state of health does not permit an informed choice to be made. Collection of SoHOs shall be strictly prohibited in connection with medically assisted suicide by a donor, since the substances injected may impair the quality of the donation.***

Or. fr

Justification

In order to prevent any ethical and financial abuses, collection from an individual who has expressed a wish to commit medically assisted suicide cannot be considered.

Amendment 376
Joanna Kopcińska

Proposal for a regulation
Article 3 – paragraph 1 – point 14

Text proposed by the Commission

(14) 'collection' means a process by which SoHOs are removed, procured, excreted, secreted or obtained by any other manner, ***including any preparatory steps, such as hormone treatment, needed to facilitate the process;***

Amendment

14) 'collection' means a process by which SoHOs are removed, procured, excreted, secreted or obtained by any other manner;

Or. pl

Justification

Justification, as set out previously.

Amendment 377
Andreas Glück, Peter Liese

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;

Amendment

(15) ‘processing’ means any operation involved in the ***non-autologous*** handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging; ***in autologous use it means only handling beyond minimal operations including immediate application of SoHO within a closed system;***

Or. en

Justification

In order to simplify exemptions from the Regulation in the case of autologous use, it would be useful to distinguish between autologous and non-autologous handling. When autologously used, processes such as reprocessing of blood or cutting of skin and cornea in order to establish applicability should be defined differently. Moreover, the term minimally processed should include all manipulations which are conducted within a closed system using a medical device.

Amendment 378

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;

Amendment

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging. ***It does not include activities involving a substantial modification of SoHOs that would make it a medicinal product or an advanced therapy;***

Or. en

Amendment 379

Ondřej Knotek, Susana Solís Pérez

Proposal for a regulation

Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;

Amendment

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging ***with the exception of activities requiring substantial manipulation;***

Or. en

Amendment 380

Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation

Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘processing’ means any operation involved in the ***handling*** of SoHOs, ***including washing, shaping, separation, fertilisation, decontamination, sterilisation, preservation and packaging;***

Amendment

(15) ‘processing’ means any operation involved in the ***different steps of preparation processes*** of SoHOs;

Or. en

Amendment 381

Joanna Kopcińska

Proposal for a regulation

Article 3 – paragraph 1 – point 15

Text proposed by the Commission

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation,

Amendment

(15) ‘processing’ means any operation involved in the handling of SoHOs, including washing, shaping, separation,

fertilisation, decontamination, sterilisation, preservation and packaging;

decontamination, sterilisation, preservation and packaging;

Or. pl

Justification

The act of fertilisation should not be grouped together with other, purely technical treatment processes.

Amendment 382
Tudor Ciuhodaru

Proposal for a regulation
Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(16) ‘quality control’ means several tests or checks to confirm that a SoHO activity or SoHO preparation meets pre-defined quality criteria;

Amendment

(16) ‘quality control’ means several tests or checks, ***based on common criteria***, to confirm that a SoHO activity or SoHO preparation meets pre-defined quality criteria;

Or. ro

Amendment 383
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 16

Text proposed by the Commission

(16) ‘quality control’ means ***several*** tests or checks to confirm that a SoHO activity or SoHO preparation meets pre-defined quality criteria;

Amendment

(16) ‘quality control’ means ***defined*** tests or checks to confirm that a SoHO activity or SoHO preparation meets pre-defined quality criteria;

Or. en

Amendment 384
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 17

Text proposed by the Commission

(17) 'storage' means the maintenance of SoHOs under appropriate controlled conditions until distribution;

Amendment

17) 'storage' means the maintenance of SoHOs under appropriate controlled conditions until distribution; ***particular attention should be paid to the storage and conservation of 'supernumerary' embryos, and ethical rules should be formally adopted in order to limit the number thereof to what is strictly necessary and to prevent eugenic abuses;***

Or. fr

Justification

The status of human embryos must be safeguarded as they are humanity's genetic heritage. They must not be impaired or genetically modified. Storing a large number of 'supernumerary' embryos increases the risk of eugenic abuses.

Amendment 385
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 17

Text proposed by the Commission

(17) 'storage' means the maintenance of SoHOs under appropriate controlled conditions until distribution;

Amendment

(17) 'storage' means the maintenance of SoHOs under appropriate controlled conditions until distribution ***or dispensing;***

Or. fr

Amendment 386
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 17

Text proposed by the Commission

Amendment

(17) ‘storage’ means the maintenance of SoHOs under appropriate controlled conditions until distribution;

(17) ‘storage’ means the maintenance of SoHOs under appropriate controlled conditions until distribution *or issuing*;

Or. en

Amendment 387

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(18) ‘release’ means a process through which it is verified that a SoHO or a SoHO preparation meets defined safety and quality criteria and the conditions of any applicable authorisation before distribution;

Amendment

(18) ‘release’ means a process through which it is verified that a SoHO or a SoHO preparation meets defined safety and quality criteria and the conditions of any applicable authorisation before distribution, *issuing, export or human application*;

Or. en

Amendment 388

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 18

Text proposed by the Commission

(18) ‘release’ means a process through which it is verified that a SoHO or a SoHO preparation meets defined safety and quality criteria and the conditions of any applicable authorisation before distribution;

Amendment

(18) ‘release’ means a process through which it is verified that a SoHO or a SoHO preparation meets defined safety and quality criteria and the conditions of any applicable authorisation before distribution *or until dispensing*;

Or. fr

Amendment 389

Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 18 a (new)

Text proposed by the Commission

Amendment

(18a) 'disposal' means completely destroying SoHOs for whatever reason. Strict monitoring rules must be complied with so as to ensure that the ultimate purpose of the disposal process is achieved.

Or. fr

Justification

The possibility of SoHOs intended for destruction being recovered for profit poses a high risk to human health.

Amendment 390
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 18 a (new)

Text proposed by the Commission

Amendment

(18a) 'dispensing' means the provision of SoHOs or SoHO preparations, possibly following a medical prescription, for application to a specific recipient;

Or. fr

Amendment 391
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 20

Text proposed by the Commission

Amendment

(20) 'import' means activities carried out to bring SoHOs or SoHO preparations into the Union from a third country, including the organisation of such activities

(20) 'import' means activities carried out to bring SoHOs or SoHO preparations into the Union from a third country, including the organisation of such activities

and physical verification of coherence with associated documentation, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling before release;

and physical verification of coherence with associated documentation, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling before release; ***each Member State will remain free to accept or reject SoHOs imported from a third country;***

Or. fr

Justification

This Regulation must protect Member States against global trafficking in human substances, which undermines human dignity and poses a serious risk to both donors and recipients.

Amendment 392 **Tudor Ciuhodaru**

Proposal for a regulation **Article 3 – paragraph 1 – point 20**

Text proposed by the Commission

(20) ‘import’ means activities carried out to bring SoHOs or SoHO preparations into the Union from a third country, including the organisation of such activities and physical verification of coherence with associated documentation, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling before release;

Amendment

(20) ‘import’ means activities carried out to bring SoHOs or SoHO preparations into the Union from a third country, including the organisation of such activities and physical verification of coherence with associated documentation ***and of the quality of the preparations, in accordance with EU standards***, the appropriateness of transport conditions, the integrity of packaging and the adequacy of labelling before release;

Or. ro

Amendment 393 **Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

Proposal for a regulation **Article 3 – paragraph 1 – point 21**

Text proposed by the Commission

Amendment

(21) ‘export’ means distribution of SoHOs or SoHO preparations to third countries;

(21) ‘export’ means distribution of SoHOs or SoHO preparations to third countries *outside the Union*;

Or. en

Amendment 394

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 21 a (new)

Text proposed by the Commission

Amendment

(21 a) ‘non-homologous use’ means a cell or tissue that, when applied to a recipient, ceases to have the same essential function, in the same anatomical or histological space as it had in its original environment in the donor;

Or. en

Amendment 395

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 21 b (new)

Text proposed by the Commission

Amendment

(21 b) ‘homologous use’ means a cell or tissue that when applied in a recipient maintains the same essential function, in the same anatomical or histological space as it had in its original environment in the donor;

Or. en

Amendment 396

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César

Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 22

Text proposed by the Commission

(22) ‘clinical outcome monitoring’ means evaluation of the health of a SoHO recipient for the purpose of monitoring the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy;

Amendment

(22) ‘clinical outcome monitoring’ means evaluation of the health of a SoHO recipient for the purpose of monitoring the results of a SoHO preparation application, maintaining care and demonstrating safety and efficacy **or functionality**;

Or. en

Amendment 397

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘autologous use’ means collection of SoHO from one individual for subsequent application to the same individual, **with or without further SoHO activities between collection and application**;

Amendment

(23) ‘autologous use’ means collection of SoHO from one individual for subsequent application to the same individual;

Or. en

Amendment 398

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 3 – paragraph 1 – point 23

Text proposed by the Commission

(23) ‘autologous use’ means collection of SoHO from one individual for **subsequent** application to the same individual, with or without further SoHO

Amendment

(23) ‘autologous use’ means collection of SoHO from one individual for application to the same individual, with or without further SoHO activities between

activities between collection and application;

collection and application;

Or. en

Amendment 399
Tudor Ciuhodaru

Proposal for a regulation
Article 3 – paragraph 1 – point 24

Text proposed by the Commission

(24) ‘SoHO entity’ means an organisation legally established in the Union that carries out one or more of the SoHO activities set out in Article 2(1);

Amendment

(24) ‘SoHO entity’ means an organisation legally established in the Union ***and accredited*** that carries out one or more of the SoHO activities set out in Article 2(1);

Or. ro

Amendment 400
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 27

Text proposed by the Commission

(27) ‘adverse occurrence’ means any incident that caused harm to a living SoHO donor, harm to a SoHO recipient or to offspring from medically assisted reproduction or that implied a risk of such harm;

Amendment

(27) ‘adverse occurrence’ means any incident ***associated with the donation or human application of SoHO*** that caused harm to a living SoHO donor, harm to a SoHO recipient or to offspring from medically assisted reproduction or that implied a risk of such harm;

Or. en

Amendment 401
Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 28 – point a

Text proposed by the Commission

(a) death;

Amendment

(a) death, *i.e. the irreversible cessation of an individual's vital functions by natural causes or as a result of medically assisted suicide*;

Or. fr

Amendment 402

Stelios Kypouropoulos, Tomislav Sokol, Peter Liese

Proposal for a regulation

Article 3 – paragraph 1 – point 28 – point b

Text proposed by the Commission

(b) life-threatening, *disabling* or incapacitating condition, including transmission of a pathogen that might cause such condition;

Amendment

(b) life-threatening, *irreversible* or incapacitating condition, including transmission of a pathogen that might cause such condition;

Or. en

Amendment 403

Joanna Kopcińska

Proposal for a regulation

Article 3 – paragraph 1 – point 28 – point h a (new)

Text proposed by the Commission

Amendment

h a) the transfer of embryos other than those intended.

Or. pl

Amendment 404

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 28 – point i

Text proposed by the Commission

Amendment

(i) prolonged sub-optimal health of a SoHO donor following single or multiple donations;

(i) prolonged sub-optimal health of a SoHO donor ***after stating a willingness to donate, or following single or multiple donations, or after detection of contagious or chronic diseases or infections that are or may be communicable.***

Or. fr

Justification

Precise and rigorous checks on the health of donors fosters recipients' confidence. An official schedule of donation deferrals must be shared between Member States.

Amendment 405

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 28 – point i a (new)

Text proposed by the Commission

Amendment

(i a) any other adverse occurrence specified by the EDQM guidelines.

Or. en

Amendment 406

Kateřina Konečná

Proposal for a regulation

Article 3 – paragraph 1 – point 28 – point i a (new)

Text proposed by the Commission

Amendment

(i a) any other adverse occurrences specified by EDQM guidelines;

Or. en

Justification

It is important to keep the regulation agile and updated to the latest scientific evidence.

Amendment 407

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 29

Text proposed by the Commission

(29) ‘SoHO rapid alert’ means a communication regarding *a SAO, a communicable disease outbreak* or other information that might be of relevance to the safety and quality of SoHOs in more than one Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate the implementation of mitigating measures;

Amendment

(29) ‘SoHO rapid alert’ means a communication regarding *an adverse occurrence* or other information that might be of relevance to the safety and quality of SoHOs in more than one Member State and is to be transmitted rapidly between competent authorities and the Commission to facilitate the implementation of *preventive or* mitigating measures;

Or. en

Amendment 408

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission *to* exchange information concerning SoHO activities;

Amendment

(31) ‘EU SoHO Platform’ means the digital platform established *and managed* by the Commission *for the* exchange *of* information concerning SoHO activities *at Union level, between competent authorities, the Commission, SoHO entities and other relevant entities, and to facilitate coordination and cross-border cooperation, between Member States, on SoHO*;

Or. en

Amendment 409

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission to exchange information concerning SoHO activities;

Amendment

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission, **and interoperable with the other existing Union platforms**, to exchange information concerning SoHO activities, **in particular between competent authorities, European Union agencies and the Commission**;

Or. fr

Amendment 410

Andreas Glück, Ondřej Knotek, Véronique Trillet-Lenoir, Peter Liese, Susana Solís Pérez, Michal Wiezik

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission to exchange information concerning SoHO activities;

Amendment

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission to exchange information concerning SoHO activities **which should be interoperable with existing and upcoming frameworks**;

Or. en

Justification

Mainly referring to the European Health Data Space.

Amendment 411

Tudor Ciuhodaru

Proposal for a regulation

Article 3 – paragraph 1 – point 31

Text proposed by the Commission

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission to exchange information concerning SoHO activities;

Amendment

(31) ‘EU SoHO Platform’ means the digital platform established by the Commission to exchange information concerning SoHO activities **and which is accessible in all the official EU languages**;

Or. ro

Amendment 412

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 33

Text proposed by the Commission

(33) ‘the compendium’ means a list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by competent authorities and by the SCB, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform;

Amendment

(33) ‘the compendium **of SoHO**’ means a list kept up-to-date by the SoHO Coordination Board of decisions, taken at Member State level, and opinions, issued by competent authorities and by the SCB **and the Classification Advisory Council**, on the regulatory status of specific substances, products or activities and published on the EU SoHO platform;

Or. en

Amendment 413

Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation

Article 3 – paragraph 1 – point 34 a (new)

Text proposed by the Commission

Amendment

(34 a) "Quality risk management system" : means a systematic process for the assessment, control, communication and review of the quality risks of a SoHo or SoHO preparation throughout its life cycle;

Amendment 414

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 38

Text proposed by the Commission

(38) ‘Union training’ means activities for the personnel of competent authorities and, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;

Amendment

(38) ‘Union training’ means **training** activities for the personnel of competent authorities and, where appropriate, for personnel of delegated bodies performing SoHO supervisory activities;

Or. en

Amendment 415

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 40

Text proposed by the Commission

(40) ‘SoHO establishment’ means a SoHO entity that carries out **both** processing and storage of SoHOs;

Amendment

(40) ‘SoHO establishment’ means a SoHO entity that carries out **processing and storage or** processing and **release or** storage **and release** of SoHOs;

Or. fr

Amendment 416

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 41

Text proposed by the Commission

(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in

Amendment

(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in

serious harm or risk of harm to *patients*;

serious harm or risk of harm to *recipients*;

Or. en

Amendment 417
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 41

Text proposed by the Commission

(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in serious harm or risk of harm to *patients*;

Amendment

(41) ‘critical SoHO’ means a SoHO for which an insufficient supply will result in serious harm or risk of harm to *recipients*;

Or. fr

Amendment 418
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 42

Text proposed by the Commission

(42) ‘critical SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for *patients*;

Amendment

(42) ‘critical SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for *recipients*;

Or. en

Amendment 419
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 42

Text proposed by the Commission

(42) ‘critical SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for *patients*;

Amendment

(42) ‘critical SoHO entity’ means a SoHO entity that carries out activities contributing to the supply of critical SoHOs and the scale of those activities is such that a failure to carry them out cannot be compensated by activities of other entities or alternative substances or products for *recipients*;

Or. fr

Amendment 420

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 42 a (new)

Text proposed by the Commission

Amendment

(42 a) ‘Classification Advisory Council’ means a body composed of representatives of the SoHO Coordination Board, the European Medicines Agency and the Medical Device Coordination Group with the responsibility of assisting the Member States and the Commission in determining the regulatory status of a substance, product or activity covered by this Regulation;

Or. en

Amendment 421

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 42 b (new)

Text proposed by the Commission

Amendment

(42 b) ‘SoHO Coordination Board (SCB)’ means a body set up by this

Amendment 422
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 45

Text proposed by the Commission

(45) ‘technical guidelines’ means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards;

Amendment

(45) ‘technical guidelines’ means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards *in line with the criteria laid down by the Member States’ competent authorities*;

Amendment 423
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 3 – paragraph 1 – point 45

Text proposed by the Commission

(45) ‘technical guidelines’ means a description of a series of methodological procedures and parameters that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards;

Amendment

(45) ‘technical guidelines’ means a description of a series of methodological procedures and parameters, *updated in accordance with the latest scientific evidence*, that, if followed, achieve a level of quality and safety of a SoHO activity or a SoHO preparation that is considered to be acceptable as a means to comply with regulatory standards;

Amendment 424

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 47 – introductory part

Text proposed by the Commission

(47) ‘traceability’ means the ability to locate and identify SoHOs during any step from collection through processing and storage **to** distribution or disposal, including the ability to:

Amendment

(47) ‘traceability’ means the ability to locate and identify SoHOs during any step from collection through processing and storage, distribution **or issuing, to human application** or disposal, including the ability to:

Or. en

Amendment 425

Tilly Metz

Proposal for a regulation

Article 3 – paragraph 1 – point 47 – introductory part

Text proposed by the Commission

(47) ‘traceability’ means the ability to locate and identify SoHOs during any step from collection through processing and storage to **distribution** or disposal, including the ability to:

Amendment

(47) ‘traceability’ means the ability to locate and identify SoHOs during any step from collection through processing and storage to **human application** or disposal, including the ability to:

Or. en

Amendment 426

Tilly Metz

Proposal for a regulation

Article 3 – paragraph 1 – point 51

Text proposed by the Commission

(51) ‘imputability’ means the likelihood that a serious adverse occurrence, in a SoHO donor, is related to the donation

Amendment

(51) ‘imputability’ means the likelihood that a serious adverse occurrence, in a SoHO donor, is related to the donation

process or, in a recipient, to the application of the SoHOs;

process or, in a recipient *or an offspring born from medically assisted reproduction*, to the application of the SoHOs;

Or. en

Amendment 427

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 51

Text proposed by the Commission

(51) ‘imputability’ means the likelihood that *a serious* adverse occurrence, in a SoHO donor, is related to the *donation* process or, in a recipient, to the application of the SoHOs;

Amendment

(51) ‘imputability’ means the likelihood that *an* adverse occurrence, in a SoHO donor, is related to the *collection* process or, in a recipient, to the application of the SoHOs;

Or. en

Amendment 428

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 3 – paragraph 1 – point 51

Text proposed by the Commission

(51) ‘imputability’ means the likelihood that *a serious* adverse occurrence, in a SoHO donor, is related to the donation process or, in a recipient, to the application of the SoHOs;

Amendment

(51) ‘imputability’ means the likelihood that *an* adverse occurrence, in a SoHO donor, is related to the donation process or, in a recipient, to the application of the SoHOs;

Or. en

Amendment 429

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 3 – paragraph 1 – point 59

Text proposed by the Commission

(59) ‘EDQM SoHO monograph’ means a specification of the critical quality parameters of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;

Amendment

(59) ‘EDQM SoHO monograph’ means a specification of the critical quality parameters ***related to the therapeutic indication*** of a particular SoHO preparation defined by the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe;

Or. en

Amendment 430
Joanna Kopcińska

Proposal for a regulation
Article 3 – paragraph 1 – point 60

Text proposed by the Commission

(60) ‘Annual SoHO Activity Report’ means the annual report published by the Commission aggregating the data reports from SoHO entities ***carrying out the following activities: donor recruitment, collection, distribution, import, export and human application of SoHOs;***

Amendment

(60) ‘Annual SoHO Activity Report’ means the annual report published by the Commission aggregating the data reports from SoHO entities ***on reactions and adverse events:***

Or. pl

Amendment 431
Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation
Article 3 – paragraph 1 – point 60

Text proposed by the Commission

(60) ‘Annual SoHO Activity Report’ means the annual report published by the Commission aggregating the data reports from SoHO entities carrying out the following activities: donor recruitment, collection, distribution, import, export and human application of SoHOs;

Amendment

(60) ‘Annual SoHO Activity Report’ means the annual report published by the Commission aggregating the data reports from SoHO entities carrying out the following activities: donor recruitment, collection, ***storage***, distribution, import, export and human application of SoHOs;

Amendment 432
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 1 – point 61

Text proposed by the Commission

(61) ‘reproductive cells’ means all cells *intended to be used for the purpose of medically assisted reproduction*;

Amendment

(61) ‘reproductive cells’ means all *sexually reproductive haploid cells, a female and a male gamete that unite to form a new individual, whose genetic load is unique and unrepeatable*;

Or. es

Amendment 433
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 1 – point 61

Text proposed by the Commission

(61) ‘*reproductive cells*’ means all cells intended to be used for the purpose of medically assisted reproduction;

Amendment

(61) ‘*SoHO for reproduction*’ means all cells intended to be used for the purpose of medically assisted reproduction *and embryos resulting from fertilisation*;

Or. en

Amendment 434
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 1 – point 62

Text proposed by the Commission

(62) ‘third party donation’ means a donation of *reproductive cells* by a person

Amendment

(62) ‘third party donation’ means a donation of *SoHO for reproduction* by a

to a **person** or a couple with whom the donor does not have an intimate physical relationship;

person to a **recipient** or a couple with whom the donor does not have an intimate physical relationship;

Or. en

Amendment 435
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point 62 a (new)

Text proposed by the Commission

Amendment

(62 a) ‘ID release’ means disclosure of personal identifying information about reproductive cells donor to donor-conceived offspring;

Or. en

Amendment 436
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 1 – point 63

Text proposed by the Commission

Amendment

(63) ‘within couple use’ means use of reproductive cells for medically assisted reproduction **from** two persons with an intimate physical relationship, where one person supplies their own oocytes and the other person supplies their own sperm;

(63) ‘within couple use’ means use of reproductive cells for medically assisted reproduction **between** two persons with an intimate physical relationship, where one person supplies their own oocytes and the other person supplies their own sperm. **Such gametes shall under no circumstances be applied to third parties;**

Or. en

Amendment 437
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point 63

Text proposed by the Commission

(63) ‘within couple use’ means use of reproductive cells for medically assisted reproduction from two persons with an intimate physical relationship, where one person supplies their own oocytes and the other person supplies their own sperm;

Amendment

(63) ‘within couple use’ means use of reproductive cells for medically assisted reproduction from two persons with an intimate physical relationship (**‘partners’**), where one person supplies their own oocytes and the other person supplies their own sperm;

Or. en

Amendment 438
Margarita de la Pisa Carrión

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

(64) ‘compensation’ means making good of any losses associated with donation;

Amendment

(64) ‘compensation’ means making good of any losses **and expenses** associated with donation; ***such compensation should help facilitate matters and remove obstacles for donors. It must be ensured that throughout the entire SoHO treatment, from donation to implantation in the recipient, the principle of compensation rather than that of profit-making is followed.***

Or. es

Amendment 439
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

(64) ‘compensation’ means making good of **any** losses associated with

Amendment

(64) ‘compensation’ means making good of **quantifiable** losses associated with

donation;

donation; *such compensation shall respect the principle of financial neutrality and not be intended as an incentive to donate;*

Or. en

Amendment 440
Mathilde Androuët

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

(64) ‘compensation’ means making good of any losses associated with donation;

Amendment

(64) ‘compensation’ means making good of any *quantifiable* losses associated with donation; *such compensation should never be intended or provided with a view to encouraging donations;*

Or. fr

Amendment 441
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

(64) ‘compensation’ means making good of any losses associated with donation;

Amendment

(64) ‘compensation’ means making good of any *quantifiable* losses associated with donation, *without any net gain or loss;*

Or. en

Amendment 442
Andreas Glück, Ondřej Knotek, Peter Liese, Susana Solís Pérez, Jan Huitema, Michal Wiezik

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

Amendment

(64) ‘compensation’ means making good of any **losses** associated with donation;

(64) ‘compensation’ means making good of any **expenses and inconveniences** associated with donation;

Or. en

Justification

This formulation allows for more flexibility with regards to compensation as losses could only be interpreted in financial terms. This is also a formulation that was previously used in the tissues and cells directive (Article 12). It does not oblige any Member State to make use of it, but allows compensations to be maintained as before.

Amendment 443

Stelios Kypouropoulos, Tomislav Sokol, Peter Liese

Proposal for a regulation

Article 3 – paragraph 1 – point 64

Text proposed by the Commission

Amendment

(64) ‘compensation’ means making good of any **losses** associated with donation;

(64) ‘compensation’ means making good of any **expenses and inconveniences** associated with donation;

Or. en

Amendment 444

Cristian-Silviu Buşoi

Proposal for a regulation

Article 3 – paragraph 1 – point 64

Text proposed by the Commission

Amendment

(64) ‘compensation’ means making good of any **losses** associated with donation;

(64) ‘compensation’ means making good of any **expenses and inconveniences** associated with donation;

Or. en

Amendment 445

Kateřina Konečná

**Proposal for a regulation
Article 3 – paragraph 1 – point 64**

Text proposed by the Commission

(64) ‘compensation’ means making good *of any losses* associated with donation;

Amendment

(64) ‘compensation’ means making good *any expenses and inconveniences* associated with donation;

Or. en

Justification

The proposed amendment recognizes that losses associated with the donation can be financial and non-financial. The inconvenience related to the donation can also differ significantly between different SoHO donations.

The proposed amendment is compatible with the Council of Europe’s DH BIO Guide interpreting the Oviedo Convention principle of prohibition of financial gain , and reflects wording contained in the EU Tissues and Cells Directive 2004/23/EC (article 12.1).

**Amendment 446
Alexandr Vondra, Joanna Kopcińska**

**Proposal for a regulation
Article 3 – paragraph 1 – point 64**

Text proposed by the Commission

(64) ‘compensation’ means making good *of any losses* associated with donation;

Amendment

(64) ‘compensation’ means making good *any expenses and inconveniences* associated with donation;

Or. en

**Amendment 447
Aldo Patriciello, Salvatore De Meo**

**Proposal for a regulation
Article 3 – paragraph 1 – point 64**

Text proposed by the Commission

(64) ‘compensation’ means making good *of any losses* associated with

Amendment

(64) ‘compensation’ means making good *any expenses and inconveniences*

donation;

associated with donation;

Or. en

Amendment 448
Giuseppe Ferrandino

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

Amendment

(64) ‘compensation’ means making good *of any losses* associated with donation;

(64) ‘compensation’ means making good *any expenses and inconveniences* associated with donation;

Or. en

Justification

The proposed amendment recognizes that losses associated with the donation can be financial and non-financial. The inconvenience related to the donation can also differ significantly between different SoHO donations.

The proposed amendment is compatible with the Council of Europe’s DH BIO Guide interpreting the Oviedo Convention principle of prohibition of financial gain , and reflects wording contained in the EU Tissues and Cells Directive 2004/23/EC (article 12.1).

Amendment 449
Stanislav Polčák

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

Amendment

(64) ‘compensation’ means making good *of any losses* associated with donation;

(64) ‘compensation’ means making good *any expenses and inconveniences* associated with donation;

Or. en

Amendment 450
Peter Liese

Proposal for a regulation
Article 3 – paragraph 1 – point 64

Text proposed by the Commission

(64) ‘compensation’ means making good *of any losses associated with* donation;

Amendment

(64) ‘compensation’ means making good *the expenses and inconveniences related to the* donation;

Or. en

Amendment 451
Tilly Metz

Proposal for a regulation
Article 3 – paragraph 1 – point 64 a (new)

Text proposed by the Commission

Amendment

(64 a) 'financial neutrality' means that no financial gain or loss will be incurred by compensated donors as a result of the donation;

Or. en

Amendment 452
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 1 – point 64 a (new)

Text proposed by the Commission

Amendment

(64 a) 'reimbursement' means the reimbursement of costs incurred by the donor associated with the donation process;

Or. en

Amendment 453

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 64 a (new)

Text proposed by the Commission

Amendment

(64a) ‘financial neutrality of a donation’ means that there will be no financial gains or losses for a donor as a result of a donation;

Or. fr

Justification

This definition has been added for consistency with the EDQM's Guide for the implementation of the principle of prohibition of financial gain with respect to the human body and its parts from living or deceased donors, which is cited numerous times in the Commission proposal and is useful to clarify the principle of voluntary and unpaid donation.

Amendment 454

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation

Article 3 – paragraph 1 – point 64 b (new)

Text proposed by the Commission

Amendment

(64 b) ‘financial neutrality’ means a situation in which the donor does not experience net economic gains or losses associated with a donation;

Or. en

Amendment 455

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 3 – paragraph 1 – point 65

Text proposed by the Commission

Amendment

(65) ‘allogeneic use’ means collection of SoHO from one individual for

(65) ‘allogeneic donor’ means any person who make a donation to a SoHO

subsequent application to another individual;

entity for subsequent application to another individual;

Or. en

Amendment 456

Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70 a) ‘risk-based approach’ shall mean one that uses techniques to determine the areas of risk where ‘risk’ is identified as the probability of an event occurring that will have an impact on the achievement of objectives, taking into account the severity of its outcome and/or the likelihood of non-detection by other methods.

Or. en

Amendment 457

Stanislav Polčák

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70 a) ‘risk-based approach’ shall mean one that uses techniques to determine the areas of risk where ‘risk’ is identified as the probability of an event occurring that will have an impact on the achievement of objectives, taking into account the severity of its outcome and/or the likelihood of non-detection by other methods.

Or. en

Amendment 458

Giuseppe Ferrandino

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70 a) ‘risk-based approach’ shall mean one that uses techniques to determine the areas of risk where ‘risk’ is identified as the probability of an event occurring that will have an impact on the achievement of objectives, taking into account the severity of its outcome and/or the likelihood of non-detection by other methods.

Or. en

Justification

It is importance to define “risk-based approach” in the EU SoHO Regulation as regards a number of aspects regulated by such Regulation.

The proposed definition reflects the same definition in the European Medicines Agency (“EMA”) Guideline on good pharmacovigilance practices (GVP) Module IV – Pharmacovigilance audits of 12 December 2012.

Amendment 459

Aldo Patriciello, Salvatore De Meo

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70 a) ‘risk-based approach’ shall mean one that uses techniques to determine the areas of risk where ‘risk’ is identified as the probability of an event occurring that will have an impact on the achievement of objectives, taking into account the severity of its outcome and/or the likelihood of non-detection by other methods.

Or. en

Amendment 460

Cristian-Silviu Buşoi

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70 a) ‘risk-based approach’ shall mean one that uses techniques to determine the areas of risk where ‘risk’ is identified as the probability of an event occurring that will have an impact on the achievement of objectives, taking into account the severity of its outcome and/or the likelihood of non-detection by other methods.

Or. en

Amendment 461

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70 a) ‘informed consent’ means consent by the donor to make a free and non-coercive donation or consent by the recipient to accept a treatment with a SoHO, after receiving clear, comprehensive and comprehensible information;

Or. en

Amendment 462

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

(70a) ‘donor base resilience’ means the

*capacity of the donation collection system
to rely on a large number of donors;*

Or. fr

Amendment 463

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 3 – paragraph 1 – point 70 b (new)

Text proposed by the Commission

Amendment

*(70b) 'patient blood management' means
an innovative organisational approach for
optimising the care of patients with
haemorrhagic disorders, for example
anaemia, which is based on the following
three pillars:*

- (a) optimising the patient's blood mass;*
- (b) minimising blood loss;*
- (c) improving the patient's tolerance to
anaemia;*

Or. fr

Amendment 464

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 70 a (new)

Text proposed by the Commission

Amendment

*(70a) 'patient blood management' means
an innovative organisational approach for
the best possible management of patients
undergoing surgery at risk of bleeding,
based on the following three pillars:*

- (a) optimising the patient's blood mass;*
- (b) minimising blood loss;*
- (c) improving the patient's tolerance to
anaemia;*

Justification

Definition based on the World Health Organisation resolution referred to in recital 24a.

Amendment 465

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 70 b (new)

Text proposed by the Commission

Amendment

(70 b) ‘European autonomy’ means the situation where the Union has the capacity to self-supply SoHO, being self-sufficient from third countries to cover most of the demand, with the exception of those SoHOs which require global management due to their intrinsic characteristics.

Or. en

Amendment 466

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 70 b (new)

Text proposed by the Commission

Amendment

(70b) ‘donor base resilience’ means the capacity of the donation collection system to rely on a large number of donors to address the emergence of a health crisis;

Or. fr

Amendment 467

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 70 c (new)

Text proposed by the Commission

Amendment

(70c) ‘free and informed consent’ means that the donor’s agreement has been obtained freely without coercion and after access to clear, comprehensive information in line with his or her capacity to understand;

Or. fr

Amendment 468

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 3 – paragraph 1 – point 70 c (new)

Text proposed by the Commission

Amendment

(70 c) ‘SoHO clinical study’ means an experimental evaluation of a SoHO or a SoHO preparation in humans, with the objective of drawing conclusions regarding its efficacy and safety.

Or. en

Amendment 469

Mathilde Androuët

Proposal for a regulation

Article 3 – paragraph 1 – point 70 d (new)

Text proposed by the Commission

Amendment

(70d) ‘national self-sufficiency’ means Member States’ lack of dependence on another State as regards the collection and manufacture of SoHOs, the transport of those substances and any other SoHO activity.

Or. fr

Justification

Transporting SoHOs increases the risk that they will become contaminated, since their packaging will not be strong enough if shipments take too long. National self-sufficiency should therefore be encouraged as far as possible.

Amendment 470

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are compatible with Union law, **and are proportionate to the risk to human health.**

Amendment

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are compatible with Union law. ***In particular, Member States may introduce requirements for donations, including the prohibition or restriction of imports of SoHO, to ensure a high level of health protection and to achieve the objective defined in Article 54, provided that the conditions of the Treaties are met. Such measures shall not hinder coordination between Member States or European autonomy.***

Or. en

Amendment 471

Jan Huitema, Catharina Rinzema, Véronique Trillet-Lenoir, Michal Wiezik, Martin Hojsík

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on

Amendment

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on

condition that those national measures are compatible with Union law, and are proportionate to the risk to human health.

condition that those national measures are ***based on scientific evidence, are compatible with Union law, do not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation***, and are proportionate to the risk to human health.

Or. en

Justification

National eligibility criteria in various member states are disabling MSM to donate SoHO material, in particular blood. This is based on - and continues the narrative of - stigmatization of the MSM community. By requiring Member States to have sexual-behavior based screening criteria, this Regulation ensures a non-discriminatory, science-based and risk-based approach.

Amendment 472 **Margarita de la Pisa Carrión**

Proposal for a regulation **Article 4 – paragraph 1**

Text proposed by the Commission

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation ***on condition that those national measures are compatible with Union law, and*** are proportionate to the risk to human health.

Amendment

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation ***in order to comply with national provisions in this field on condition that those national measures*** are proportionate to the risk to human health.

Or. es

Amendment 473 **Joanna Kopcińska**

Proposal for a regulation **Article 4 – paragraph 1**

Text proposed by the Commission

Amendment

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are compatible with ***Union law, and are proportionate to the risk to human health.***

1. Member States may maintain or introduce within their territories measures that are more stringent than the ones provided for in this Regulation on condition that those national measures are compatible with ***the law.***

Or. pl

Amendment 474
Mathilde Androuët

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. Member States may introduce additional measures to help set up a national and European supply chain and to achieve the objective of national self-sufficiency. Such measures may also aim to reinforce the principle of voluntary and unpaid donation.

Or. fr

Justification

Asserting European Union and Member State self-sufficiency means limiting imports of SoHOs from outside Europe; they have not been recovered in keeping with the principle of voluntary and unpaid donation.

Amendment 475
Joanna Kopcińska

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission

Amendment

2. Member States ***shall*** make available to the public details of measures put in place in accordance with paragraph 1 ***without undue delay***, including on the

2. Member States ***may*** make available to the public details of measures put in place in accordance with paragraph 1, including on the internet.

internet. *The SoHO National Authority shall submit the details of any more stringent measure to the EU SoHO Platform referred to in Chapter XI.*

Or. pl

Amendment 476
Mathilde Androuët

Proposal for a regulation
Article 5 – paragraph 3 – point a

Text proposed by the Commission

(a) have the autonomy to act and make decisions independently and impartially while respecting the internal administrative organisational requirements determined by *the Constitutions of the Member States*;

Amendment

(a) have the autonomy to act and make decisions independently and impartially while respecting the internal administrative organisational requirements determined by *each Member State's own legislation*;

Or. fr

Amendment 477
Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation
Article 5 – paragraph 3 – point b – point ii

Text proposed by the Commission

(ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients or the general public;

Amendment

(ii) to order the immediate suspension or cessation of a SoHO activity that poses immediate risk to SoHO donors, SoHO recipients or the general public *or do not comply with the conditions of its authorisation or the requirements of this Regulation*;

Or. en

Amendment 478
Tudor Ciuhodaru

Proposal for a regulation
Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment

(c) have sufficient **human and material** resources, **as well as** operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. ro

Amendment 479
Cristian-Silviu Buşoi

Proposal for a regulation
Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment

(c) have sufficient resources, operational capacity, and **subject matter** expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. en

Amendment 480
Alexandr Vondra

Proposal for a regulation
Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment

(c) have sufficient resources, operational capacity, and **subject matter** expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. en

Amendment 481

Giuseppe Ferrandino

Proposal for a regulation

Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment

(c) have sufficient resources, operational capacity, and **subject matter** expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. en

Justification

To strengthen the implementation of oversight in the field of SoHO in the EU Member States, it is necessary to ensure that competent authorities have experts or consult experts on the specifics of each SoHO covered by the legislation. For instance, keeping in mind that plasma for manufacturing of plasma-derived therapeutics is different from labile blood components used for transfusion purposes in terms of processes, it is critical to ensure that there are provisions applicable to plasma for manufacturing, involving experts with relevant expertise.

Amendment 482

Aldo Patriciello, Salvatore De Meo

Proposal for a regulation

Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment

(c) have sufficient resources, operational capacity, and **subject matter** expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. en

Amendment 483

Susana Solís Pérez

Proposal for a regulation

Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources,

Amendment

(c) have sufficient resources,

operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

operational capacity, and **subject matter** expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. en

Amendment 484

Stanislav Polčák

Proposal for a regulation

Article 5 – paragraph 3 – point c

Text proposed by the Commission

(c) have sufficient resources, operational capacity, and expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Amendment

(c) have sufficient resources, operational capacity, and **subject matter** expertise to achieve the aims of, and fulfil their obligations under, this Regulation;

Or. en

Amendment 485

Tilly Metz

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

4. Each Member State shall designate a single SoHO National Authority, in conformity with Member States' constitutional requirements, responsible for coordinating exchanges with the Commission and with other Member States' SoHO National Authorities.

Amendment

4. Each Member State shall designate a single SoHO National Authority, in conformity with Member States' constitutional requirements, responsible for coordinating exchanges with the Commission and with other Member States' SoHO National Authorities. ***The Commission shall make publicly available the list of SoHO National Authorities on the EU SoHO Platform.***

Or. en

Amendment 486

Sirpa Pietikäinen

Proposal for a regulation
Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. Member States shall designate their SoHO National Authorities to create a national plasma strategy, in order to increase their collection capacity and the security of the collection and patients, as well as ensuring the sufficient training and know-how of staff working on SoHO;

Or. en

Amendment 487
Mathilde Androuët

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

Amendment

2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.

2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. ***Personnel shall not have engaged in any activity, beyond an appropriate point in time prior to working for the competent authorities concerned, which may detract from their independence.***

Or. fr

Amendment 488
Tilly Metz

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.

Amendment

2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. ***All relevant personnel shall make an annual declaration of their interests, which shall be published on the authorities' web-portal.***

Or. en

Amendment 489
Tudor Ciuhodaru

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission

2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation that may, directly or indirectly, affect the impartiality of their professional conduct.

Amendment

2. Competent authorities shall ensure that their personnel have no direct or indirect economic, financial or personal interest that might be considered prejudicial to their independence and, in particular, that they are not in a situation ***of incompatibility*** that may, directly or indirectly, affect the impartiality of their professional conduct.

Or. ro

Amendment 490
Mathilde Androuët

Proposal for a regulation
Article 8 – paragraph 1

Text proposed by the Commission

1. Without prejudice to Article 75,

Amendment

1. Without prejudice to Article 75,

competent authorities shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health.

competent authorities shall carry out their supervisory activities in a transparent manner, ***including in connection with the application of contracts for the supply of medicinal products all or some of whose active substances are derived from SoHOs***, and they shall make accessible and clear to the public decisions taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health.

Or. fr

Amendment 491

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

1. Without prejudice to Article 75, competent authorities shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health.

Amendment

1. Without prejudice to Article 75, competent authorities shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health. ***They shall also be transparent about the criteria used for the assessment and authorisation of SoHO preparations and SoHO entities.***

Or. en

Amendment 492

Joanna Kopcińska

Proposal for a regulation Article 8 – paragraph 1

Text proposed by the Commission

Amendment

1. Without prejudice to Article 75, competent authorities shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions ***taken in cases where a SoHO entity has failed to comply with an obligation under this Regulation and where such failure causes or may cause a serious risk to human health.***

1. Without prejudice to Article 75, competent authorities shall carry out their supervisory activities in a transparent manner and they shall make accessible and clear to the public decisions ***to revoke, suspend or reinstate authorisation for SoHO activities.***

Or. pl

Amendment 493

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

**Proposal for a regulation
Article 9 – paragraph 1**

Text proposed by the Commission

Amendment

1. Competent authorities shall be responsible for the SoHO supervisory activities referred to in Chapter III in order to verify the effective compliance of SoHO entities in their territory with the requirements set out in this Regulation.

1. Competent authorities shall be responsible for the SoHO supervisory activities referred to in Chapter III in order to verify the effective compliance of SoHO entities ***and SoHO preparations authorised*** in their territory with the requirements set out in this Regulation.

Or. en

Amendment 494

Alexandr Vondra

**Proposal for a regulation
Article 9 – paragraph 2 – point a**

Text proposed by the Commission

Amendment

(a) a sufficient number of suitably qualified personnel to carry out the supervisory functions provided for in this Regulation;

(a) a sufficient number of suitably qualified personnel ***and subject matter experts on specific types of SoHOs*** to carry out the supervisory functions provided for in this Regulation;

Amendment 495

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

(b) procedures to ensure the independence, impartiality, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;

Amendment

(b) procedures to ensure the independence, impartiality, **transparency**, effectiveness, quality, suitability for purpose and consistency of their SoHO supervisory activities;

Or. en

Amendment 496

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) appropriate and properly maintained facilities and equipment to ensure that personnel can perform their SoHO supervisory activities efficiently and effectively;

Amendment

(c) appropriate and properly maintained facilities and equipment to ensure that personnel can perform their SoHO supervisory activities efficiently, **safely** and effectively;

Or. en

Amendment 497

Mathilde Androuët

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) appropriate and properly

Amendment

(c) appropriate and properly

maintained facilities and equipment to ensure that personnel can perform their SoHO supervisory activities efficiently and effectively;

maintained facilities and equipment to ensure that personnel can perform their SoHO supervisory activities *safely*, efficiently and effectively;

Or. fr

Amendment 498

Stelios Kypouropoulos, Tomislav Sokol, Peter Liese

Proposal for a regulation

Article 14 – paragraph 1

Text proposed by the Commission

1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with authorities established in other relevant Union legislation referred to in Article 2(3), *as relevant*. In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33).

Amendment

1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with authorities established in other relevant Union legislation referred to in Article 2(3), *such as the European Medicine Agency (EMA)*. In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33). *The EMA and the SoHO Coordination Board (SCB) shall have close collaboration and establish a permanent panel for reviewing such questions, while consulting other authorities, such as the Medical Devices Coordination Group.*

Or. en

Justification

To avoid different approaches being taken by the SCB and the EMA on the classification of borderline products it is important to ensure collaboration between the two entities.

Amendment 499

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 1

Text proposed by the Commission

Amendment

1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with ***authorities established in other relevant Union legislation referred to*** in Article 2(3), ***as relevant***. In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33).

1. In all cases where questions arise as to the regulatory status of a substance, product or activity, competent authorities shall consult with ***the Classification Advisory Council, defined*** in article 67(a) In such cases, competent authorities shall also consult the compendium referred to Article 3 point (33).

Or. en

Amendment 500

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

In the course of the consultation referred to in paragraph 1, the competent authorities may also submit a request to the SCB for its opinion on the regulatory status of the substance, product or activity under this Regulation and shall do so in all cases where the competent authorities, after the consultations referred to in paragraph 1, are not in a position to take a decision in that respect.

deleted

Or. en

Amendment 501

Margarita de la Pisa Carrión

Proposal for a regulation

Article 14 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

In the course of the consultation referred to in paragraph 1, the competent authorities

In the course of the consultation referred to in paragraph 1, the competent authorities

may also submit a request to the SCB for its opinion on the regulatory status of the substance, product or activity under this Regulation ***and shall do so in all cases where the competent authorities, after the consultations referred to in paragraph 1, are not in a position to take a decision in that respect.***

shall submit a request to the SCB for its opinion on the regulatory status of the substance, product or activity under this Regulation.

Or. es

Amendment 502

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The competent authorities may also indicate that they consider there is a need that the SCB consults, in accordance with Article 68(1), point (b), with the equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).

Amendment

deleted

Or. en

Amendment 503

Tilly Metz

Proposal for a regulation

Article 14 – paragraph 2 – subparagraph 2

Text proposed by the Commission

The competent authorities may also indicate that they consider there is a need that the SCB consults, in accordance with Article 68(1), point (b), with the equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).

Amendment

The SCB ***shall consult***, in accordance with Article 68(1), point (b), with the equivalent advisory bodies established in other relevant Union legislation referred to in Article 2(3).

Amendment 504

Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation

Article 14 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. In deviation from paragraphs 1 and 2, the following procedure shall apply when a substance or product may possibly be considered a medicinal product:

(a) The question shall automatically be referred to the EMA and the SCB and the full dossier shall be made available.

(b) The EMA and the SCB shall establish a permanent panel for reviewing such questions. The panel shall, where relevant, also consult other authorities mentioned in paragraph 1, such as the Medical Devices Coordination Group.

(c) The panel shall seek to reach an opinion by consensus. An opinion adopted by consensus shall be implemented by the competent authorities. If no consensus can be reached, the question shall be referred to the Commission for a decision in accordance with paragraph 4.

The members of the panel shall be appointed by the EMA and the SCB based on their specific expertise, including for the EMA in particular expertise in the area of advanced therapy medicinal products. The EMA shall ensure the secretariat of the panel and collaborate with the SCB in maintaining the compendium.

Or. en

Justification

The classification of borderline products needs to be based on scientific criteria while ensuring predictability and avoiding duplicity or potential contradictions between bodies. A

joint panel composed of experts of the two authorities makes sense to guarantee a streamlined approach. Please bear in mind that tapping into the EMA's existing expertise in advanced therapy medicinal products (ATMPs) is of particular relevance given the Commission's intention to eliminate a number of standing committees including the Committee for Advanced Therapies (CAT).

Amendment 505

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 3

Text proposed by the Commission

3. The competent authorities shall inform the **SCB** of the subsequent decision taken in their Member State, following the consultations referred to in paragraph 1 of this Article, regarding the regulatory status of the substance, product or activity concerned under this Regulation and on any consensus reached as a result of those consultations for publication in the compendium by the SCB.

Amendment

3. The competent authorities shall inform the **Classification Advisory Council** of the subsequent decision taken in their Member State, following the consultations referred to in paragraph 1 of this Article, regarding the regulatory status of the substance, product or activity concerned under this Regulation and on any consensus reached as a result of those consultations for publication in the compendium by the SCB. ***To the extent possible, Member States shall accept the opinion of the Classification Advisory Council. Otherwise, they shall inform the Classification Advisory Council as soon as possible of the decision taken and its justification.***

Or. en

Amendment 506

Tilly Metz

Proposal for a regulation

Article 14 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Where the SCB opinion was requested pursuant to paragraph 2, national competent authorities shall

follow its conclusion. If national authorities decide not to follow SCB's opinion, they shall inform the SCB and provide justification in a timely manner.

Or. en

Amendment 507

Tilly Metz

Proposal for a regulation

Article 14 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The Commission may, upon a duly substantiated request of a Member State following the consultation referred to in **paragraph 1**, or on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions between the SCB and the advisory bodies established in other relevant Union legislation, in accordance with Article 68(1), point (b).

Amendment

The Commission may, upon a duly substantiated request of a Member State following the consultation referred to in **paragraphs 1 and 2**, or on its own initiative **after a consultation with the SCB and relevant advisory bodies established under Union legislation referred to in Article 2(3)**, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions between the SCB and the advisory bodies established in other relevant Union legislation, in accordance with Article 68(1), point (b).

Or. en

Amendment 508

Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation

Article 14 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The Commission may, upon a duly substantiated request of a Member State

Amendment

The Commission may, upon a duly substantiated request of a Member State

following the consultation referred to in paragraph 1, or on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions between the SCB and the advisory bodies established in other relevant Union legislation, in accordance with Article 68(1), point (b).

following the consultation referred to in paragraph 1, or on its own initiative, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions between the SCB and the advisory bodies established in other relevant Union legislation, in accordance with Article 68(1), point (b), **or in accordance with paragraph 2a (c).**

Or. en

Justification

Coherence with the introduction of the joint EMA-SCB panel for a unified and science-based approach in borderline classification cases.

Amendment 509

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The Commission may, upon a duly substantiated request of a Member State following the consultation referred to in paragraph 1, **or on its own initiative**, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions **between the SCB and the advisory bodies established in other relevant Union legislation, in accordance with Article 68(1), point (b).**

Amendment

The Commission may, upon a duly substantiated request of a Member State **or the Classification Advisory Council**, following the consultation referred to in paragraph 1, by means of implementing acts, determine the regulatory status of a substance, product or activity under this Regulation, in case questions arise in that respect, notably when these questions cannot be resolved at the Member State level, or in discussions **in the Classification Advisory Council. This decision shall be based on the most up-to-date scientific evidence.**

Or. en

Amendment 510

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

Amendment

5. *For SoHOs that are intended to be subsequently used to manufacture products under other Union legislation, or as the starting and raw material thereof, as referred to in Article 2(3), or SoHOs that are intended to be combined with medical devices, as referred to in Article 2(4), the competent authority shall cooperate with the authorities responsible for the supervisory activities under the relevant Union legislation, with a view to ensuring coherent oversight. During the process, the competent authorities may seek the assistance of the SCB.* **deleted**

Or. en

Amendment 511

Susana Solís Pérez, Ondřej Knotek, Véronique Trillet-Lenoir

Proposal for a regulation Article 14 – paragraph 6

Text proposed by the Commission

Amendment

6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated on the basis of a request for advice from a SoHO entity, as referred to in Article 40.

6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated on the basis of a request for advice from a SoHO entity, as referred to in Article 40, **or in the case of paragraph 2a, the EMA.**

Or. en

Justification

Coherence with the introduction of the joint EMA-SCB panel for a unified and science-based approach in borderline classification cases.

Amendment 512

Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation

Article 14 – paragraph 6

Text proposed by the Commission

6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated ***on the basis of a request for advice*** from a SoHO entity, as referred to in Article 40.

Amendment

6. The consultation and cooperation referred to in paragraphs 1, 2 and 5 may also be initiated from a SoHO entity, as referred to in Article 40.

Or. en

Amendment 513

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 6

Text proposed by the Commission

6. The consultation ***and cooperation*** referred to in ***paragraphs 1, 2 and 5*** may also be initiated on the basis of a request for advice from a SoHO entity, as referred to in Article 40.

Amendment

6. The consultation referred to in ***paragraph 1*** may also be initiated on the basis of a request for advice from a SoHO entity, as referred to in Article 40.

Or. en

Amendment 514

Susana Solís Pérez, Véronique Trillet-Lenoir, Ondřej Knotek

Proposal for a regulation

Article 14 – paragraph 7 – subparagraph 1

Text proposed by the Commission

The Commission may, by means of implementing acts, lay down rules concerning procedures for consultation referred to in paragraph 1 and cooperation

Amendment

The Commission may, by means of implementing acts, lay down rules concerning procedures for consultation referred to in paragraph 1 and cooperation

referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).

referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3). ***The Commission may also lay down rules concerning the procedure referred to in paragraph 2a and the operation of the permanent panel in coherence with the specific provisions foreseen in Regulation (EC) 726/2004, Directive 2001/83/EC and Regulation (EU) 2017/745.***

Or. en

Justification

Coherence with the introduction of the joint EMA-SCB panel for a unified and science-based approach while taking into account specific horizontal EU legislation already in place:

- Regulation (EC) 726/2004: authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*
- Directive 2001/83/EC: medicinal products for human use*
- Regulation (EU) 2017/745: medical devices*

Amendment 515

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 14 – paragraph 7 – subparagraph 1

Text proposed by the Commission

The Commission may, by means of implementing acts, lay down rules concerning procedures for consultation referred to in paragraph 1 ***and cooperation referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).***

Amendment

The Commission may, by means of implementing acts, lay down rules concerning procedures for consultation referred to in paragraph 1.

Or. en

Amendment 516
Tilly Metz

Proposal for a regulation
Article 14 – paragraph 7 – subparagraph 1

Text proposed by the Commission

The Commission may, by means of **implementing** acts, lay down rules concerning procedures for consultation referred to in paragraph 1 and cooperation referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).

Amendment

The Commission may, by means of **delegated** acts, lay down rules concerning procedures for consultation referred to in paragraph 1 and cooperation referred to in paragraph 5 by the competent authorities when they consult the authorities established in other relevant Union legislation referred to in Article 2(3).

Or. en

Amendment 517
Tilly Metz

Proposal for a regulation
Article 14 – paragraph 7 – subparagraph 2

Text proposed by the Commission

Those **implementing** acts shall be adopted in accordance with the **examination** procedure **referred to** in Article 79(2).

Amendment

Those **delegated** acts shall be adopted in accordance with the procedure **laid down** in Article 77.

Or. en

Amendment 518
Tilly Metz

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission

(a) have, or have access to, a sufficient number of personnel so that SoHO supervisory activities can be performed

Amendment

(a) have, or have access to, a sufficient number of personnel so that SoHO supervisory activities can be performed

efficiently and effectively;

efficiently and effectively; ***the declarations shall be made publicly available on the authorities' web-portal;***

Or. en

Amendment 519
Joanna Kopcińska

Proposal for a regulation
Article 16 – paragraph 2 – point a

Text proposed by the Commission

(a) declare in writing any direct or indirect interests referred to in Article 7(2) ***and update that declaration yearly and whenever the declared information changes or any new interest arises;***

Amendment

(a) ***before any inspection procedure is initiated,*** declare in writing any direct or indirect interests referred to in Article 7(2) ***relating to inspection activities of the entity concerned;***

Or. pl

Amendment 520
Tudor Ciuhodaru

Proposal for a regulation
Article 16 – paragraph 2 – point d

Text proposed by the Commission

(d) participate in training in the subject matter and on the obligations of competent authorities resulting from this Regulation, as referred to in paragraph 3.

Amendment

(d) participate ***regularly*** in training ***at national or European level*** in the subject matter and on the obligations of competent authorities resulting from this Regulation, as referred to in paragraph 3 ***so as to be up to date with any changes or updates to the provisions of the Regulation.***

Or. ro

Amendment 521
Tudor Ciuhodaru

Proposal for a regulation

Article 16 – paragraph 3

Text proposed by the Commission

3. Competent authorities, in cooperation with delegated bodies as necessary, shall develop and implement training programmes for the purpose of ensuring that personnel performing SoHO supervisory activities receive the training referred to in paragraph 2, points (b), (c) and (d). Competent authorities shall maintain records of the training undertaken by their personnel. Competent authorities shall provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such Union training is available and appropriate.

Amendment

3. Competent authorities, in cooperation with delegated bodies as necessary, shall develop and implement training programmes **at national level** for the purpose of ensuring that personnel performing SoHO supervisory activities receive the training referred to in paragraph 2, points (b), (c) and (d). Competent authorities shall maintain records of the training undertaken by their personnel. Competent authorities shall provide opportunities for their personnel to participate in the Union training referred to in Article 69 where such Union training is available and appropriate.

Or. ro

Amendment 522
Joanna Kopcińska

Proposal for a regulation
Article 17

Text proposed by the Commission

Article 17

Obligations as regards Commission controls

Competent authorities and delegated bodies shall cooperate with the Commission for the performance of Commission controls referred to in Article 70. In particular, they shall:

(a) take appropriate follow-up measures to remedy the shortcomings identified through the controls provided for in Article 70;

(b) give the necessary technical assistance and provide the available documentation, upon justified request, and other technical support that Commission experts request

Amendment

deleted

to enable them to perform controls efficiently and effectively; and

(c) give the necessary assistance to ensure that the Commission experts have access to all premises or part of premises, and to information, including IT systems, relevant for the execution of their duties.

Or. pl

Amendment 523
Joanna Kopcińska

Proposal for a regulation
Article 18 – paragraph 3 – point e

Text proposed by the Commission

Amendment

(e) the name and curriculum vitae of the responsible person for release of SoHOs as referred to in Article 38, if the SoHO entity releases SoHOs or SoHO preparations. *deleted*

Or. pl

Amendment 524

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 20 – paragraph 3

Text proposed by the Commission

Amendment

3. SoHO preparation authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO preparation, that Member State may decline to recognise the validity

3. SoHO preparation authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific SoHO preparation, that Member State may decline to recognise the validity

of the SoHO preparation authorisation of another Member State pending verification that the more stringent measure has been met.

of the SoHO preparation authorisation of another Member State pending verification that the more stringent measure has been met. ***This information shall be notified, without undue delay, in the EU SoHO Platform.***

Or. en

Amendment 525

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 21 – paragraph 1

Text proposed by the Commission

1. Competent authorities shall have procedures in place to allow that applications for the authorisation of SoHO preparations are submitted in accordance with Article 41. They shall provide guidelines and templates for the submission of applications for SoHO preparation authorisation. When developing these guidelines and templates, competent authorities shall ***consult*** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). Competent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations.

Amendment

1. Competent authorities shall have procedures in place to allow that applications for the authorisation of SoHO preparations are submitted in accordance with Article 41. They shall provide guidelines and templates for the submission of applications for SoHO preparation authorisation. When developing these guidelines and templates, competent authorities shall ***follow*** the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). Competent authorities may establish simplified procedures for applications concerning modifications to previously authorised SoHO preparations.

Or. en

Amendment 526

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation Article 21 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) grant a conditional authorisation for the use of the SoHO preparation in all cases where clinical outcome data is required for authorisation, pursuant to Article 22(4), points (d) and (e);

(c) grant a conditional authorisation for the use of the SoHO preparation in all cases where clinical outcome data is required for authorisation, pursuant to Article 22(4), points (d) and (e); ***In this case, an appropriate information for practitioners and patients on the conditional nature of the authorization is put in place by the SoHO entity ;***

Or. en

Amendment 527

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation Article 21 – paragraph 4

Text proposed by the Commission

4. Competent authorities shall conclude the SoHO preparation authorisation steps, referred to in paragraph 2 of this Article, within 3 months from receipt of the application, excluding the time needed for clinical outcome monitoring or studies. They may suspend this time limit for the duration of the consultation processes referred to in Article 14(1) and (2).

Amendment

4. Competent authorities shall conclude the SoHO preparation authorisation steps, referred to in paragraph 2 of this Article, within 3 months from receipt of the application, excluding the time needed for clinical outcome monitoring or studies. They may suspend this time limit for the duration of the consultation processes referred to in Article 14(1) and (2) ***or if further information are required from the SoHO entity who made the request.***

Or. en

Amendment 528

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation Article 21 – paragraph 6 – subparagraph 1 – point a

Text proposed by the Commission

(a) such preparation, or any of the activities performed for that preparation, do not comply with the conditions of its

Amendment

(a) such preparation, or any of the activities performed for that preparation, do not comply with the conditions of its

authorisation or the requirements of this Regulation; *and*

authorisation or the requirements of this Regulation; *or*

Or. en

Amendment 529

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 21 – paragraph 8

Text proposed by the Commission

8. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the competent authorities have confirmed that the SoHO preparation in question does not comply with subsequently updated criteria for authorisation or the SoHO entity has ***repeatedly*** failed to comply with the conditions of its authorisation.

Amendment

8. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO preparation if the competent authorities have confirmed that the SoHO preparation in question does not comply with subsequently updated criteria for authorisation or the SoHO entity has failed to comply with the conditions of its authorisation.

Or. en

Amendment 530

Mathilde Androuët

Proposal for a regulation

Article 21 a (new)

Text proposed by the Commission

Amendment

Article 21a

Exceptional derogation from the obligation to authorise SoHO preparations in situations where there is no therapeutic alternative

1. By way of derogation from Article 21 of this Regulation, and after consulting the relevant best practices approved and documented by the SCB in accordance with Article 68(1)(c), the competent authorities may authorise, on an

exceptional basis and at the request of a prescribing doctor within a SoHO entity, SoHO preparations in situations where the procedures referred to in Article 21 have not been followed, provided that:

(a) provision has been made for the use of such preparations for a given patient, in cases where that patient has no therapeutic alternative, when treatment cannot be postponed or when his or her condition is life-threatening;

(b) the preparation is deemed to be safe and effective on the basis of the available clinical data.

2. The competent authorities shall inform the national SoHO authority of the authorised derogation. The national SoHO authority shall inform the Commission and the other Member States of any decision to authorise the distribution or preparation for immediate application of SoHOs in accordance with paragraph 1.

Or. fr

Justification

The only possibility for derogation in the Commission proposal concerns continuity of supply. An additional derogation seems necessary where therapeutic alternatives cannot be offered to a given patient. Such cases could be, for example, cell therapies for burn victims or for patients who have suffered accidental irradiation.

Amendment 531

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 21 a (new)

Text proposed by the Commission

Amendment

Article 21 a

Conditional authorisation of SoHO preparations in exceptional situations

1. In exceptional cases, and subject to a

medical prescription, the competent authorities may consult the best practices approved and documented by the SCB in accordance with Article 68(1)(c) and authorise the conditional and temporary use of certain SoHOs preparations in cases where:

(a) the potential recipient of those SoHO preparations is at vital risk, has no available therapeutic alternatives and their treatment cannot be postponed;

(b) available clinical data indicate that the SoHO preparation will be safe and effective.

2. The competent authorities shall, without undue delay, enter information on conditional authorisations of SoHO preparations into the EU SoHO Platform referred to in Chapter XI.

3. After receiving conditional and temporary authorisation for a SoHO preparation, the SoHO entity shall, in parallel, initiate a regular authorisation procedure for that SoHO preparation in accordance with Article 21.

Or. en

Amendment 532
Tudor Ciuhodaru

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

1. The assessment of a SoHO preparation, shall include a review of all SoHO activities that are performed for that SoHO preparation and that might influence the safety, quality and efficacy of the SoHO preparation.

Amendment

1. The assessment of a SoHO preparation shall include a review of all SoHO activities that are performed for that SoHO preparation and that might influence the safety, quality and efficacy of the SoHO preparation, ***to make sure it maintains all the properties for being compatible with recipients.***

Or. ro

Amendment 533

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 22 – paragraph 5

Text proposed by the Commission

5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), competent authorities shall ***consider, in the cases where the applicant has proposed to record, and recorded, the results of the clinical outcome monitoring in an existing clinical registry, that this is an acceptable method, provided that those competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data.***

Amendment

5. When assessing the SoHO preparation pursuant to paragraph 4, points (e) and (g), competent authorities shall ***verify that the clinical studies and their results have been correctly recorded in the EU SoHO Platform.***

Or. en

Amendment 534

Tudor Ciuhodaru

Proposal for a regulation

Article 24 – paragraph 5

Text proposed by the Commission

5. Competent authorities shall ensure that the specific induction training is complemented by specialised training for assessment of processing methods and technologies used for specific types of SoHO preparations and by continuous training, as appropriate, throughout the career of the assessors. Competent authorities shall make all reasonable efforts to ensure that assessors that participate in joint assessments have completed the relevant Union training referred to in Article 69(1) and are included in the list referred to in Article 69(5).

Amendment

5. Competent authorities shall ensure that the specific induction training is complemented by ***regular*** specialised training for assessment of processing methods and technologies used for specific types of SoHO preparations and by continuous training, as appropriate, throughout the career of the assessors ***to keep step with technical developments in the field.*** Competent authorities shall make all reasonable efforts to ensure that assessors that participate in joint assessments have completed the relevant Union training referred to in Article 69(1)

and are included in the list referred to in Article 69(5).

Or. ro

Amendment 535
Mathilde Androuët

Proposal for a regulation
Article 25 – paragraph 2

Text proposed by the Commission

2. Competent authorities shall authorise as SoHO establishments the SoHO entities that both process and store SoHOs in accordance with Article 27.

Amendment

2. Competent authorities shall authorise as SoHO establishments the SoHO entities that both process and store ***or process and release or store and release*** SoHOs in accordance with Article 27.

Or. fr

Amendment 536
Margarita de la Pisa Carrión

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission

4. ***Paragraph 3 shall not apply to SoHO entities that import SoHO.***

Amendment

deleted

Or. es

Amendment 537
Joanna Kopcińska

Proposal for a regulation
Article 25 – paragraph 6 – subparagraph 1 a (new)

Text proposed by the Commission

Amendment

The implementing acts shall take into account the specific administrative and

Amendment 538
Margarita de la Pisa Carrión

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission

1. Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of importing SoHO entities.

Amendment

1. Competent authorities shall establish and maintain a system for receiving and processing requests for the authorisation of importing SoHO entities. ***SoHO entities shall ensure that SoHOs and their preparations are imported where European supply management and the domestic supply chain are not compromised.***

Amendment 539
Mathilde Androuët

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission

3. Importing SoHO entity authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the

Amendment

3. Importing SoHO entity authorisations shall be valid throughout the Union for the period defined in the terms of the authorisation, when such a time period has been defined, or until a competent authority has suspended or withdrawn the authorisation or the entity has ceased to conduct SoHO activities. Where a Member State has adopted a more stringent measure, in accordance with Article 4, which relates to a specific importing SoHO entity authorisation, that Member State may decline to recognise the

validity of the importing SoHO entity authorisation of another Member State ***pending verification that the*** more stringent measure has been met.

validity of the importing SoHO entity authorisation of another Member State. ***That refusal shall end once the Member State which has adopted a*** more stringent measure has ***verified that the correct application of that measure by the Member State which granted the authorisation*** has been met. ***It may be based on the principle of voluntary and unpaid donation, in accordance with Article 4(1)(a) of this Regulation.***

Or. fr

Amendment 540
Margarita de la Pisa Carrión

Proposal for a regulation
Article 26 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The Commission shall adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining an importing SoHO entity authorisation system.

Amendment

The Commission shall adopt implementing acts to specify uniform procedures and working methods for establishing and maintaining an importing SoHO entity authorisation system. ***Such entities shall comply with the technical and ethical specifications in force within the Union in order to maintain an optimal level of quality, safety and efficiency.***

Or. es

Amendment 541
Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission

1. ***Competent authorities*** shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as SoHO establishments

Amendment

1. ***The SoHO coordination Board*** shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as SoHO

are submitted in accordance with Article 49. ***When developing these guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).***

establishments are submitted in accordance with Article 49.

Or. en

Amendment 542
Joanna Kopcińska

Proposal for a regulation
Article 27 – paragraph 1

Text proposed by the Commission

1. Competent authorities shall provide guidelines ***and templates to allow that*** applications from SoHO entities for their authorisation as SoHO establishments ***are submitted*** in accordance with Article 49. When developing these guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Amendment

1. Competent authorities shall provide guidelines ***to facilitate the submission of*** applications from SoHO entities for their authorisation as SoHO establishments in accordance with Article 49. When developing these guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Or. pl

Amendment 543
Joanna Kopcińska

Proposal for a regulation
Article 27 – paragraph 2 – point a

Text proposed by the Commission

(a) acknowledge receipt of the application within 14 working days;

Amendment

deleted

Or. pl

Justification

This is a competence of national administrative law.

Amendment 544
Joanna Kopcińska

Proposal for a regulation
Article 27 – paragraph 2 – point b

Text proposed by the Commission

(b) assess the application;

Amendment

(b) assess the application ***on the basis of the provisions of national administrative law***;

Or. pl

Amendment 545
Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation
Article 27 – paragraph 2 – point e

Text proposed by the Commission

(e) carry out an on-site system inspection of the applicant SoHO establishment and, where applicable, of third parties contracted by the SoHO establishment to perform SoHO activities, pursuant to Article 29;

Amendment

(e) carry out an on-site system inspection of the applicant SoHO establishment ***in the year following the launch of the site*** and, where applicable, of third parties contracted by the SoHO establishment to perform SoHO activities, pursuant to Article 29;

Or. en

Amendment 546
Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation
Article 27 – paragraph 3 – subparagraph 1 – point a

Text proposed by the Commission

(a) does not comply with the conditions of its authorisation or the provisions of this Regulation; ***and***

Amendment

(a) does not comply with the conditions of its authorisation or the provisions of this Regulation; ***or***

Amendment 547

Tilly Metz

Proposal for a regulation

Article 27 – paragraph 3 – subparagraph 1 – point a

Text proposed by the Commission

Amendment

(a) does not comply with the conditions of its authorisation or the provisions of this Regulation; **and**

(a) does not comply with the conditions of its authorisation or the provisions of this Regulation;

Or. en

Amendment 548

Tilly Metz

Proposal for a regulation

Article 27 – paragraph 3 – subparagraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) does not follow up on corrective or preventive action following an inspection by national authorities pursuant to Article 29(14); and

Or. en

Amendment 549

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 27 – paragraph 5

Text proposed by the Commission

Amendment

5. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO establishment if the competent authorities have confirmed that the SoHO establishment no longer complies with

5. Competent authorities may, in accordance with national legislation, withdraw the authorisation of a SoHO establishment if the competent authorities have confirmed that the SoHO establishment no longer complies with

updated criteria for authorisation or the SoHO establishment has **repeatedly** failed to comply with the conditions of its authorisation.

updated criteria for authorisation or the SoHO establishment has failed to comply with the conditions of its authorisation.

Or. en

Amendment 550

Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation

Article 28 – paragraph 1

Text proposed by the Commission

1. **Competent authorities** shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as importing SoHO entities are submitted in accordance with Article 43. ***In developing these guidelines and templates, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).***

Amendment

1. ***The SoHO Coordination Board*** shall provide guidelines and templates to allow that applications from SoHO entities for their authorisation as importing SoHO entities are submitted in accordance with Article 43.

Or. en

Amendment 551

Joanna Kopcińska

Proposal for a regulation

Article 28 – paragraph 2 – point a

Text proposed by the Commission

(a) ***acknowledge receipt of the application within 14 working days;***

Amendment

deleted

Or. pl

Amendment 552

Joanna Kopcińska

Proposal for a regulation
Article 28 – paragraph 2 – point b

Text proposed by the Commission

(b) assess the application;

Amendment

(b) assess the application ***on the basis of the provisions of national administrative law***;

Or. pl

Amendment 553
Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation
Article 28 – paragraph 5 – point a

Text proposed by the Commission

(a) that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; ***and***

Amendment

(a) that the SoHO entity in question does not comply with the conditions of the authorisation or the provisions of this Regulation; ***or***

Or. en

Amendment 554
Tilly Metz

Proposal for a regulation
Article 28 – paragraph 5 – point b

Text proposed by the Commission

(b) that this non-compliance, or suspected non-compliance, implies a risk to the safety of recipients or offspring from medically assisted reproduction.

Amendment

(b) that this non-compliance, or suspected non-compliance, implies a risk to the safety of ***SoHO donors***, recipients or offspring from medically assisted reproduction.

Or. en

Amendment 555
Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation
Article 28 – paragraph 7

Text proposed by the Commission

7. Competent authorities may, in accordance with national legislation, withdraw the authorisation of an importing SoHO entity if the competent authorities have confirmed that the importing SoHO entity no longer complies with updated criteria for authorisation or the importing SoHO entity has **repeatedly** failed to comply with the conditions of its authorisation.

Amendment

7. Competent authorities may, in accordance with national legislation, withdraw the authorisation of an importing SoHO entity if the competent authorities have confirmed that the importing SoHO entity no longer complies with updated criteria for authorisation or the importing SoHO entity has failed to comply with the conditions of its authorisation.

Or. en

Amendment 556

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 28 – paragraph 9

Text proposed by the Commission

9. By derogation from paragraph 1, in case of emergency competent authorities may authorise imports of SoHOs for immediate application to a specific recipient when justified by the clinical circumstances on a case-by-case basis.

Amendment

9. By derogation from paragraph 1, in ***the exceptional situations described in Article 21(a) or in*** case of emergency, ***as described in Article 64,*** competent authorities may authorise imports of SoHOs for immediate application to a specific recipient when justified by the clinical circumstances on a case-by-case basis.

Or. en

Amendment 557

Alexandr Vondra, Joanna Kopcińska

Proposal for a regulation
Article 29 – paragraph 5 – introductory part

Text proposed by the Commission

5. By derogation from paragraph 4, competent authorities may conduct inspections, in full or in part, by means of a remote **document review**, provided that:

Amendment

5. By derogation from paragraph 4, competent authorities may conduct inspections, in full or in part, by means of a remote **inspection**, provided that:

Or. en

Amendment 558
Alexandr Vondra

Proposal for a regulation
Article 29 – paragraph 7 – subparagraph 1

Text proposed by the Commission

Inspectors shall verify that SoHO establishments meet the general standards concerning SoHO donor protection laid down in Article 53, **the standards concerning the voluntary and unpaid nature of SoHO donations laid down in Article 54**, the standards concerning information to be provided prior to consent or authorisation laid down in Article 55 and the general standards concerning recipient and offspring protection laid down in Article 58, as applicable.

Amendment

Inspectors shall verify that SoHO establishments meet the general standards concerning SoHO donor protection laid down in Article 53, the standards concerning information to be provided prior to consent or authorisation laid down in Article 55 and the general standards concerning recipient and offspring protection laid down in Article 58, as applicable.

Or. en

Amendment 559
Alexandr Vondra

Proposal for a regulation
Article 29 – paragraph 11

Text proposed by the Commission

11. The interval between **two on-site** inspections **shall not exceed 4 years**.

Amendment

11. The interval between inspections **should be decided based on the necessary frequency to mitigate any identified risks and it should be unified across the EU risk-based approach**.

Amendment 560

Stanislav Polčák

Proposal for a regulation

Article 29 – paragraph 11

Text proposed by the Commission

11. The interval between two on-site inspections shall not exceed 4 years.

Amendment

11. The interval between two on-site inspections shall ***be decided based on the necessary frequency to mitigate any identified risks and shall*** not exceed 4 years.

Or. en

Amendment 561

Stelios Kypouropoulos, Tomislav Sokol, Peter Liese

Proposal for a regulation

Article 29 – paragraph 11

Text proposed by the Commission

11. The interval between ***two on-site*** inspections shall not exceed 4 years.

Amendment

11. The interval between inspections ***should be decided based on the necessary frequency to mitigate any identified risks and*** shall not exceed 4 years.

Or. en

Amendment 562

Joanna Kopcińska

Proposal for a regulation

Article 29 – paragraph 16

Text proposed by the Commission

16. For the purpose of standardised inspections referred to in paragraph 1 of this Article, competent authorities shall consult the relevant best practices agreed

Amendment

16. For the purpose of standardised inspections referred to in paragraph 1 of this Article, competent authorities shall consult the relevant best practices agreed

and documented by the SCB as referred to in Article 68(1), point (c).

and documented by the SCB as referred to in Article 68(1), point (c), *provided that they do not contravene the national legal provisions in force in the Member State concerned.*

Or. pl

Amendment 563
Joanna Kopcińska

Proposal for a regulation
Article 31 – paragraph 4 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

The inspection shall be conducted in the official language of the country concerned, including the inspection report. Forms in all the official languages of the European Union shall be acceptable during the submission of an inspection application.

Or. pl

Amendment 564
Joanna Kopcińska

Proposal for a regulation
Article 31 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. 7. In exceptional cases, an inspection request may be refused or dismissed if it has not been justified.

Or. pl

Amendment 565
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 32 – paragraph 1 – subparagraph 2

Text proposed by the Commission

In exceptional cases, competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement set out in the first subparagraph.

Amendment

In exceptional cases, competent authorities may consider that a person's considerable and relevant experience may exempt this person from the requirement set out in the first subparagraph. ***They shall also perform their duties impartially, transparently and free from conflicts of interest.***

Or. en

Amendment 566
Tilly Metz

Proposal for a regulation
Article 32 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. All inspectors shall act in an impartial manner and be independent of any direct or indirect conflicts of interest. Inspectors shall declare such impartiality in writing; such declarations shall be made available on the authorities' web-portal.

Or. en

Amendment 567
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission

Amendment

2. Competent authorities shall provide inspectors with a specific induction training before inspectors take up their

2. Competent authorities shall provide inspectors with a specific induction training before inspectors take up their

duties. For the specific induction training, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

duties. For the specific induction training, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c). ***The designation criteria shall be clear and transparent.***

Or. en

Amendment 568
Joanna Kopcińska

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission

2. Competent authorities ***shall provide inspectors with a*** specific induction training ***before*** inspectors take up their duties. For the specific induction training, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Amendment

2. Competent authorities ***may organise*** specific induction training ***for*** inspectors ***before they*** take up their duties. For the specific induction training, competent authorities shall consult the relevant best practices agreed and documented by the SCB as referred to in Article 68(1), point (c).

Or. pl

Amendment 569
Tilly Metz

Proposal for a regulation
Article 32 – paragraph 3 – point a

Text proposed by the Commission

(a) the inspection techniques and procedures to be followed, including practical exercises;

Amendment

(a) the inspection techniques and procedures to be followed, including practical exercises ***and conflict of interest rules***;

Or. en

Amendment 570

Mathilde Androuët

**Proposal for a regulation
Article 32 – paragraph 5**

Text proposed by the Commission

5. Inspectors may be assisted by technical experts provided that the competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set out in Articles 7 and 76.

Amendment

5. Inspectors may be assisted by technical experts provided that the competent authorities ensure that those experts comply with the requirements of this Regulation, in particular with the obligations set out in Articles 7 and 76. ***Competent authorities shall ensure that inspectors have not worked as assessors as defined in Article 24 of this Regulation for at least one year.***

Or. fr

**Amendment 571
Margarita de la Pisa Carrión**

**Proposal for a regulation
Article 34 – paragraph 1**

Text proposed by the Commission

1. Competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHOs as referred to in Article 45.

Amendment

1. Competent authorities shall verify that SoHO entities have appropriate procedures in place to ensure traceability and coding of SoHOs as referred to in Article 45. ***The authorities shall ensure that enhanced traceability is put in place for donations where the medical, bioethical and legal implications are of particular relevance. In such cases, access to information and traceability shall be guaranteed for the recipient and the offspring conceived following fertility treatment.***

Or. es

**Amendment 572
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César**

Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 34 – paragraph 2

Text proposed by the Commission

2. Competent authorities shall establish procedures for the unique identification of SoHO establishments that are subject to the provisions on the Single European Code in Article 46. Competent authorities shall ensure that such identification complies with the technical standards defined for that coding system. For this purpose, competent authorities may use a SoHO establishment identification code generated by the EU SoHO Platform.

Amendment

2. Competent authorities shall establish procedures for the unique identification of SoHO establishments that are subject to the provisions on the Single European Code in Article 46. Competent authorities shall ensure that such identification complies with the technical standards defined for that coding system. For this purpose, competent authorities may ***preferably*** use a SoHO establishment identification code generated by the EU SoHO Platform.

Or. en

Amendment 573

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 34 a (new)

Text proposed by the Commission

Amendment

Article 34 a

Monitoring of SoHO availability and continuity of supply

1. As part of the national plans to ensure the continuity of SoHO supply referred to in Article 61(a), the competent authorities shall establish a digital platform through which they can exchange information on the availability of SoHO in the national territory in a fast and efficient manner. Through this system, competent authorities may request national SoHO entities to provide information on the availability of a certain SoHO product in specific situations of need. They shall also take into account alerts sent by national

SoHO entities concerning the availability of SoHO and potential shortages. The competent authorities shall ensure that this digital platform is available no later than two years after the entry into force of this Regulation.

2. The competent authorities shall be responsible for monitoring the availability of SoHO at national level. They shall provide guidance to SoHO entities to facilitate the exchange of information on the availability of SoHO referred to in Article 46(a).

3. The competent authorities shall store and analyse information on the availability of SoHO and its fluctuations over time, as well as trends in demand and potential shortages of SoHO and shall draw up reports containing that information which may be made available to other Member States through the EU SoHO Platform as defined in Article 73 (Article 35).

Or. en

Amendment 574
Joanna Kopcińska

Proposal for a regulation
Article 35 – paragraph 1

Text proposed by the Commission

1. Competent authorities shall be responsible for the management of vigilance associated with SoHO activities. They shall provide guidance ***and templates*** for the submission of SAO notifications and of SAO investigation reports as referred to in Article 47.

Amendment

1. Competent authorities shall be responsible for the management of vigilance associated with SoHO activities. They shall provide guidance for the submission of SAO notifications and of SAO investigation reports as referred to in Article 47.

Or. pl

Amendment 575

Joanna Kopcińska

**Proposal for a regulation
Article 35 – paragraph 10**

Text proposed by the Commission

10. Competent authorities shall submit to their SoHO National Authorities ***an annual*** summary of the SAO notifications and SAO investigation reports received. The SoHO National Authorities shall submit an annual summary of those SAO notifications and investigation reports to the EU SoHO Platform referred to in Chapter XI before 31 May of the subsequent year and shall make an aggregated version of that summary available to the public in their Member State, including on the internet. They shall include in the annual summary the numbers and types of those SAO reported to them that meet thresholds of seriousness and imputability that are agreed at Union level within the SCB.

Amendment

10. Competent authorities shall submit to their SoHO National Authorities ***a*** summary of the SAO notifications and SAO investigation reports received ***in accordance with the provisions of the national law of the Member State concerned***. The SoHO National Authorities shall submit an annual summary of those SAO notifications and investigation reports to the EU SoHO Platform referred to in Chapter XI before 31 May of the subsequent year and shall make an aggregated version of that summary available to the public in their Member State, including on the internet. They shall include in the annual summary the numbers and types of those SAO reported to them that meet thresholds of seriousness and imputability that are agreed at Union level within the SCB.

Or. pl

Amendment 576

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

**Proposal for a regulation
Article 36 a (new)**

Text proposed by the Commission

Amendment

Article 36 a

Authorisation and registry of clinical studies with SoHO

1. Competent authorities shall authorise clinical studies with SoHO after verifying that the study has been granted a positive recommendation by a Research Ethics Committee and that it has been registered

in the EU SoHO Platform, in accordance with paragraph 3.

2. Competent authorities shall inform, instruct and assist SoHO entities in their Member State about the authorization and registration processes of clinical studies with SoHO. Competent authorities shall provide SoHO entities with guidelines and assistance regarding technical and ethical aspects of clinical studies with SoHO.

3. Competent authorities shall verify that each SoHO clinical study registered in the EU SoHO Platform contains the following information:

a) the name or business name and address of the SoHO entity or entities carrying out the study, and the name and contact details of the researchers and a contact person;

b) positive recommendation by a Research Ethics Committee;

c) summary of study design;

d) date of commencement and completion of the various stages of the study;

e) not more than one year after the end of the study, a summary of the results and conclusions;

f) a summary of the study and the results obtained, intended for the general public.

4. In cases where more than one SoHO entity participates in a clinical study and these SoHO entities are located in different Member States, the clinical study shall only require an authorization by one competent authority of the Union.

5. Competent authorities shall be responsible for ensuring that the information on SoHO clinical studies in their Member State included in the EU SoHO Platform is consistent and shall introduce any changes in the EU SoHO Platform without undue delay.

6. SoHO entities responsible for clinical studies shall report, without undue delay, adverse occurrences detected during the

study in accordance with Article 47(1).

7. The Commission may adopt implementing acts to facilitate the registration of information into the EU SoHO Platform. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 79(2).

Or. en

Amendment 577

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 38 – paragraph 2

Text proposed by the Commission

2. The responsible person for release of SoHOs shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in the relevant field.

Amendment

2. The responsible person for release of SoHOs shall be in possession of a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned and shall have at least 2 years of experience in the relevant field. ***The SoHO entity shall ensure that the person responsible for the release of SoHO receives adequate and up-to-date training, appropriate to their job and responsibilities, including specific training on those SoHOs that require it.***

Or. en

Amendment 578

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation Article 40 – paragraph 1

Text proposed by the Commission

Amendment

1. SoHO entities shall not release or, in an autologous context, prepare and apply immediately to a recipient, SoHO preparations without prior SoHO preparation authorisation. In cases where a SoHO entity modifies an activity carried out for an authorised SoHO preparation, it shall obtain an authorisation for that modified SoHO preparation.

1. SoHO entities shall not release or, in an autologous context, prepare and apply immediately to a recipient, SoHO preparations without prior SoHO preparation authorisation. In cases where a SoHO entity modifies an activity carried out for an authorised SoHO preparation, it shall obtain an authorisation for that modified SoHO preparation. ***A substantial change is a change that has an impact on the quality, safety or efficacy of a SoHO preparation.***

Or. en

Amendment 579

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 40 – paragraph 3

Text proposed by the Commission

3. SoHO entities may request to their competent authorities a derogation from the requirement for a SoHO preparation authorisation in the exceptional circumstances referred to in **Article 64**.

Amendment

3. SoHO entities may request to their competent authorities a derogation from the requirement for a SoHO preparation authorisation in the exceptional circumstances referred to in **Articles 21(a) 64**.

Or. en

Amendment 580 Tudor Ciuhodaru

Proposal for a regulation Article 41 – paragraph 2 – point a – point ii

Text proposed by the Commission

(ii) any specific SoHO collection procedures;

Amendment

(ii) any specific SoHO collection procedures ***with a view to maintaining all the properties to be compatible with recipients;***

Amendment 581

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 41 – paragraph 2 – point c

Text proposed by the Commission

(c) in cases where the indicated risk is other than negligible, a proposal for clinical outcome monitoring to demonstrate **safety, quality and** efficacy of the SoHO preparation, in line with the results of the risk assessment;

Amendment

(c) in cases where the indicated risk is other than negligible, a proposal for clinical outcome monitoring to demonstrate efficacy of the SoHO preparation, in line with the results of the risk assessment;

Or. en

Amendment 582

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 41 – paragraph 4

Text proposed by the Commission

4. SoHO entities shall perform the clinical outcome monitoring once a conditional authorisation has been granted pursuant to Article 21(2), point (c), and submit the results to their competent authorities. In conducting the clinical investigation study as referred to in paragraph 3, points (b) and (c), for the SoHO preparation concerned, the applicant **may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data.**

Amendment

4. SoHO entities shall perform the clinical outcome monitoring once a conditional authorisation has been granted pursuant to Article 21(2), point (c), and submit the results to their competent authorities. In conducting the clinical investigation study as referred to in paragraph 3, points (b) and (c), for the SoHO preparation concerned, the applicant **shall register that study and the results obtained in the SoHO EU Platform in accordance with Article 36 (a).**

Or. en

Amendment 583

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 41 – paragraph 4

Text proposed by the Commission

4. SoHO entities shall perform the clinical outcome monitoring once a conditional authorisation has been granted pursuant to Article 21(2), point (c), and submit the results to their competent authorities. In conducting the clinical investigation study as referred to in paragraph 3, points (b) and (c), for the SoHO preparation concerned, the applicant may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data.

Amendment

4. SoHO entities shall perform the clinical outcome monitoring once a conditional authorisation has been granted pursuant to Article 21(2), point (c), and submit the results **and their analysis** to their competent authorities **at the frequency determined in the authorisation**. In conducting the clinical investigation study as referred to in paragraph 3, points (b) and (c), for the SoHO preparation concerned, the applicant may use an existing clinical registry to record its results provided that their competent authorities have verified that the registry has data quality management procedures in place that ensure accuracy and completeness of data.

Or. en

Amendment 584

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 41 – paragraph 5

Text proposed by the Commission

5. SoHO entities shall not make any change to the chain of activities performed for an authorised SoHO preparation, without the prior written approval of their competent authorities. SoHO entities shall also inform their competent authorities of changes in the SoHO preparation authorisation holder's details.

Amendment

5. SoHO entities shall not make any change to the chain of activities performed for an authorised SoHO preparation, without the prior written approval of their competent authorities. **A substantial change is a change that has an impact on the quality, safety or efficacy of a SoHO preparation.** SoHO entities shall also inform their competent authorities of changes in the SoHO preparation

Amendment 585

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

**Proposal for a regulation
Article 41 a (new)**

Text proposed by the Commission

Amendment

Article 41 a

Clinical studies with SoHO

- 1. SoHO entities may conduct clinical studies with SoHO, in the context of the monitoring plans defined in Article 41 or beyond it, with the aim of comparing or improving treatments.***
- 2. Clinical studies shall always have the safety and well-being of the participants in the study as a priority and they shall respect the provisions of Articles 53, 54, 55, 56, 58 and 59 of this Regulation, concerning the protection of donors and recipients. SoHO entities intending to start a clinical study shall seek to obtain more robust and reliable data, through collaboration with other SoHO entities, if necessary.***
- 3. SoHO entities must apply for a favorable opinion from the Research Ethics Committee before starting any clinical study. The Committee shall assess the ethical, legal and methodological aspects of the study, to determine the capacity of the study design to draw robust conclusions, as well as well-being and safety-related aspects of the participants, before issuing a favorable opinion for the study.***
- 4. The person responsible for the clinical study shall be adequately trained.***
- 5. Before starting the clinical study,***

SoHO entities shall register it on the EU SoHO Platform, where they shall also record the results after the end of the study, in accordance with Article 36 (a).

6. SoHO entities shall request approval of the clinical study to competent authorities before starting a clinical study with SoHO, in accordance with Article 36(a). SoHO entities may request assistance regarding administrative, technical and ethical aspects of the clinical study to the competent authorities, in accordance with Article 36(a).

Or. en

Amendment 586

Véronique Trillet-Lenoir, Max Orville

Proposal for a regulation

Article 43 – paragraph 1

Text proposed by the Commission

1. SoHO entities shall send applications for authorisation as importing SoHO entities to their competent authorities.

Amendment

1. SoHO entities shall send applications for authorisation as importing SoHO entities to their competent authorities *of their territory*.

Or. en

Amendment 587

Véronique Trillet-Lenoir, Max Orville, Susana Solís Pérez

Proposal for a regulation

Article 43 – paragraph 4

Text proposed by the Commission

4. The importing SoHO entity authorisation holder shall be based in the Union, and be responsible for the physical reception and visual examination and verification of imported SoHOs prior to their release. The importing SoHO entity shall verify coherence between the SoHO

Amendment

4. The importing SoHO entity authorisation holder shall be based in the Union, and be responsible for the physical reception and visual examination and verification of imported SoHOs prior to their release. The importing SoHO entity shall verify coherence between the SoHO

received and the associated documentation and conduct an examination of the integrity of packaging and the compliance of labelling and transport conditions with the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59.

received and the associated documentation and conduct an examination of the integrity of packaging and the compliance of labelling and transport conditions with the relevant standards and technical guidelines as referred to in Articles 57, 58 and 59.

The importing SoHO entity shall make sure and certify that the imported SoHOs are of equivalent quality to what is required by European regulations.

Or. en

Amendment 588

Tilly Metz

Proposal for a regulation

Article 44 – paragraph 4

Text proposed by the Commission

4. SoHO entities shall submit to the EU SoHO Platform an annual summary of the data collected pursuant to this Article. In cases where national or international registries collect activity data meeting the criteria defined in the SoHO platform and such registries have been verified by competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, SoHO entities may delegate the submission of the activity data referred to in this Article to such registries. The Commission shall aggregate the annual summaries of the SoHO entities, prepare and publish an Annual SoHO Activity Report.

Amendment

4. SoHO entities shall submit to the EU SoHO Platform an annual summary of the data collected pursuant to this Article. In cases where national or international registries collect activity data meeting the criteria defined in the SoHO platform and such registries have been verified by competent authorities as having in place data quality management procedures that ensure accuracy and completeness of data, SoHO entities may delegate the submission of the activity data referred to in this Article to such registries. ***National competent authorities shall ensure all data from national registries are submitted to the EU SoHO Platform in accordance with Article 18(4).*** The Commission shall aggregate the annual summaries of the SoHO entities, prepare and publish an Annual SoHO Activity Report.

Or. en

Amendment 589

Tilly Metz

**Proposal for a regulation
Article 45 – paragraph 2 – point c**

Text proposed by the Commission

Amendment

(c) does not reveal the identity of the donor;

(c) does not **directly** reveal the identity of the donor;

Or. en

Justification

The code is pseudonymised and hence can be linked back to the donor.

**Amendment 590
Mathilde Androuët**

**Proposal for a regulation
Article 46 – paragraph 2 – point d**

Text proposed by the Commission

Amendment

(d) SoHOs imported into the Union ***in case of emergency*** authorised directly by competent authorities pursuant to Article 28(9);

(d) SoHOs imported into the Union authorised directly by competent authorities pursuant to Article 28(9);

Or. fr

**Amendment 591
Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel**

**Proposal for a regulation
Article 46 a (new)**

Text proposed by the Commission

Amendment

Article 46 a

Availability of SoHO

1. SoHO entities shall have a digital system to record and monitor their SoHO stocks.

2. SoHO institutions shall report to the competent authorities information on the availability of SoHO, when required or on their own initiative when there is a risk of shortage, through the channel authorised by the competent authorities for that purpose, as described in Article 34 (a).

Or. en

Amendment 592

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation Article 47 – paragraph 1

Text proposed by the Commission

1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse occurrences, including adverse occurrences detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41.

Amendment

1. SoHO entities shall maintain a system for detecting, investigating and recording information concerning adverse occurrences, including adverse occurrences detected during clinical outcome monitoring as part of a SoHO preparation authorisation application as referred to in Article 41 ***or as part of a clinical study with SoHO, as referred to in Article 41(a).***

Or. en

Amendment 593

Joanna Kopcińska

Proposal for a regulation Article 47 – paragraph 2

Text proposed by the Commission

2. Where applicable, SoHO entities shall make all reasonable efforts to encourage prospective parents of children born from third party donation to commit to communicate information concerning any genetic conditions that emerge, as those children grow up, to the SoHO entity

Amendment

2. Where applicable, SoHO entities shall make all reasonable efforts to encourage prospective parents of children born from third party donation to commit to communicate information concerning any genetic conditions that emerge, as those children grow up, to the SoHO entity

where they were treated. ***That entity shall communicate, without undue delay, the information to the SoHO entity that distributed or applied the reproductive cells with a view to preventing further distribution of SoHO from the implicated SoHO donor.***

where they were treated.

Or. pl

Amendment 594
Tilly Metz

Proposal for a regulation
Article 47 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Where SAO notification concerns public health matters, competent authorities shall communicate essential information to the general public and the SCB without delay.

Or. en

Amendment 595

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 48 – paragraph 1

Text proposed by the Commission

Amendment

1. SoHO establishments shall not carry out any activities without prior SoHO establishment authorisation. This shall apply whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.

1. SoHO establishments shall not carry out any ***SoHO*** activities without prior SoHO establishment authorisation. This shall apply whether all activities are carried out by the establishment itself or one or more are contracted to another SoHO entity.

Or. en

Amendment 596
Andreas Glück, Ondřej Knotek, Jan Huitema

Proposal for a regulation
Article 50 – paragraph 1

Text proposed by the Commission

1. SoHO establishments shall establish, maintain and update, as necessary, a quality management system achieving a high level of quality of SoHOs by **following**, in particular, the Good Practice Guidelines published by the EDQM and which are included in the technical guidelines referred to in Article 56(4), point (a), and Article 59(4), point (a).

Amendment

1. SoHO establishments shall establish, maintain and update, as necessary, a quality management system achieving a high level of quality of SoHOs by **taking into account**, in particular, the Good Practice Guidelines published by the EDQM and which are included in the technical guidelines referred to in Article 56(4), point (a), and Article 59(4), point (a).

Or. en

Justification

Some Member States have developed well established guidelines. If national standards are on an equivalent to EDQM Good Practice Guidelines, Members States shall continue to apply them. At the same time, they shall always consider the developments and updates of the EDQM Guidelines in order to guarantee a high level of safety.

Amendment 597
Joanna Kopcińska

Proposal for a regulation
Article 51 – title

Text proposed by the Commission

51 **Physician**

Amendment

51 **Physicians and embryologists**

Or. pl

Amendment 598
Joanna Kopcińska

Proposal for a regulation
Article 51 – paragraph 1 – introductory part

Text proposed by the Commission

1. Each SoHO establishment shall designate a physician who resides and carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:

Amendment

1. Each SoHO establishment shall designate a physician *or embryologist* who resides and carries out its tasks in the same Member State and who shall at least fulfil the following conditions and have the following qualifications:

Or. pl

Amendment 599
Joanna Kopcińska

Proposal for a regulation
Article 51 – paragraph 1 – point a

Text proposed by the Commission

(a) possession of formal qualification as a physician;

Amendment

(a) possession of formal qualification as a physician *or have a degree in biology, biotechnology or medical analytics*;

Or. pl

Amendment 600
Joanna Kopcińska

Proposal for a regulation
Article 51 – paragraph 2 – introductory part

Text proposed by the Commission

2. The *physician* referred to in paragraph 1 shall be responsible for at least the following tasks:

Amendment

2. The *person* referred to in paragraph 1 shall be responsible for at least the following tasks:

Or. pl

Amendment 601
Tilly Metz

Proposal for a regulation
Article 51 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) investigation of suspected adverse occurrences in SoHO donors **and** recipients;

(b) investigation of suspected adverse occurrences in SoHO donors, recipients **and, where relevant, offspring from medically assisted reproduction;**

Or. en

Amendment 602
Tilly Metz

Proposal for a regulation
Article 51 – paragraph 3

Text proposed by the Commission

Amendment

3. By derogation from paragraph 2, in the case of SoHO entities that are authorised as SoHO establishments in accordance with Article 25(3), the physician shall be responsible for those tasks that are relevant to the SoHO activities performed by the SoHO entities and that have a direct influence on the health of SoHO donors **and** recipients.

3. By derogation from paragraph 2, in the case of SoHO entities that are authorised as SoHO establishments in accordance with Article 25(3), the physician shall be responsible for those tasks that are relevant to the SoHO activities performed by the SoHO entities and that have a direct influence on the health of SoHO donors, recipients, **and, where relevant, offspring from medically assisted reproduction.**

Or. en

Amendment 603

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation
Article 52 – paragraph 2

Text proposed by the Commission

Amendment

2. SoHO entities shall protect the health of living donors before, during and after the donation.

2. SoHO entities shall protect the **physical and mental** health of living donors before, during and after the donation.

Amendment 604

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 52 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. SoHOs from living donors shall be obtained from individuals whose state of health is such that no adverse effects on their health are expected/likely as a result of donation.

Or. en

Amendment 605

Kateřina Konečná

Proposal for a regulation

Article 52 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation.

Or. en

Justification

This objective is central to donor protection but it is only referred to in recital (13). It should be added to this list of “Objectives regarding SoHO donor protection”.

Amendment 606

Tilly Metz

Proposal for a regulation

Article 52 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. *SoHOs should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation.*

Or. en

Justification

Echoing text stated in recital 13.

Amendment 607

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Cyrus Engerer, Robert Hajšel

Proposal for a regulation

Article 53 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) *ensure that donors are not discriminated on grounds not specified in the technical guidelines listed in Article 56, based on scientific evidence, and intended to avoid potential risks to the health of SoHO recipients or donors;*

Or. en

Amendment 608

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 53 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it;

(b) provide donors or their relatives or any persons granting authorisation on their behalf, in accordance with national legislation, with the information referred to in Article 55 and in a way that is adequate in view of their capacity to understand it, ***so that they can give free and informed***

consent;

Or. en

Amendment 609

Nicolás González Casares, Sara Cerdas, Tudor Ciuhodaru, Romana Jerković, César Luena, João Albuquerque, Biljana Borzan, Robert Hajšel

Proposal for a regulation

Article 53 – paragraph 1 – point f

Text proposed by the Commission

(f) verify the eligibility of the donor on the basis of a donor health evaluation that aims to minimise any risk that the donation might pose to the donor's health;

Amendment

(f) verify the eligibility of the donor on the basis of a donor health evaluation, ***including mental health-related aspects that could be altered by the donation process***, that aims to minimise any risk that the donation might pose to the donor's health;

Or. en

Amendment 610

Mathilde Androuët

Proposal for a regulation

Article 53 – paragraph 1 – point g

Text proposed by the Commission

(g) document the results of the donor health evaluation referred to in point (f);

Amendment

(g) document the results of the donor health evaluation referred to in point (f), ***including donor vaccination schedules***;

Or. fr

Amendment 611

Adam Jarubas, Ewa Kopacz, Bartosz Arłukowicz

Proposal for a regulation

Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 and demonstrate that ***their health is not compromised***;

Amendment

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 and demonstrate that ***they meet medical conditions if required in specific donation types on the basis of the latest available scientific evidence and medical expertise***;

Or. en

Amendment 612
Joanna Kopcińska

Proposal for a regulation
Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 and demonstrate that their health is not compromised;

Amendment

(j) verify, ***where justified***, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 and demonstrate that their health is not compromised;

Or. pl

Amendment 613
Giuseppe Ferrandino

Proposal for a regulation
Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 ***and demonstrate that their health is not compromised***;

Amendment

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56;

Or. en

Amendment 614
Cristian-Silviu Buşoi

Proposal for a regulation
Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 **and demonstrate that their health is not compromised**;

Amendment

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56;

Or. en

Amendment 615
Aldo Patriciello, Salvatore De Meo

Proposal for a regulation
Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 **and demonstrate that their health is not compromised**;

Amendment

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56;

Or. en

Amendment 616
Alexandr Vondra

Proposal for a regulation
Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical

Amendment

(j) verify, by means of a registry, that donors are not donating more frequently than indicated as safe in technical

guidelines as referred to in Article 56 **and demonstrate that their health is not compromised**;

guidelines as referred to in Article 56;

Or. en

Amendment 617

Andreas Glück, Peter Liese, Susana Solís Pérez, Michal Wiezik

Proposal for a regulation

Article 53 – paragraph 1 – point j

Text proposed by the Commission

(j) verify, by means of **a registry**, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56 **and demonstrate that their health is not compromised**;

Amendment

(j) **for donations referred to in paragraph 3**, verify, by means of **interconnected registries**, that donors are not donating more frequently than indicated as safe in technical guidelines as referred to in Article 56;

Or. en

Justification

The respective criteria are listed in paragraph 3 and it should be clear that interconnected registries should only be established in the cases mentioned and not for all SoHOs.

Amendment 618

Adam Jarubas, Ewa Kopacz, Bartosz Arłukowicz

Proposal for a regulation

Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for monitoring the donor's health after the donation in cases **where the SoHO donations imply a significant risk to a donor as referred to** in paragraph 3;

Amendment

(k) develop and implement a plan for monitoring the donor's health after the donation in cases **specified** in paragraph 3;

Or. en

Amendment 619
Alexandr Vondra

Proposal for a regulation
Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for monitoring the donor's health after the donation in cases *where the SoHO donations imply a significant risk to a donor as* referred to in paragraph 3;

Amendment

(k) develop and implement a plan for monitoring the donor's health after the donation in cases referred to in paragraph 3;

Or. en

Amendment 620
Kateřina Konečná

Proposal for a regulation
Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for monitoring the donor's health after the donation in cases *where the SoHO donations imply a significant risk to a donor as* referred to in paragraph 3;

Amendment

(k) develop and implement a plan for monitoring the donor's health after the donation in cases referred to in paragraph 3;

Or. en

Justification

The Regulation should refrain from defining the risk level of specific procedures, as this should be determined at a technical level on the basis of the latest available scientific evidence.

Amendment 621
Andreas Glück, Ondřej Knotek, Susana Solís Pérez, Michal Wiezik

Proposal for a regulation
Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for

Amendment

(k) develop and implement a plan for

monitoring the donor's health after the donation in cases *where the SoHO donations imply a significant risk to a donor as* referred to in paragraph 3;

monitoring the donor's health after the donation in cases referred to in paragraph 3;

Or. en

Justification

No need for a duplication. The respective criteria are listed in paragraph 3.

Amendment 622

Aldo Patriciello, Salvatore De Meo

Proposal for a regulation

Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for monitoring the donor's health after the donation in cases *where the SoHO donations imply a significant risk to a donor as* referred to in paragraph 3;

Amendment

(k) develop and implement a plan for monitoring the donor's health after the donation in *the* cases referred to in paragraph 3;

Or. en

Amendment 623

Giuseppe Ferrandino

Proposal for a regulation

Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for monitoring the donor's health after the donation in cases *where the SoHO donations imply a significant risk to a donor as* referred to in paragraph 3;

Amendment

(k) develop and implement a plan for monitoring the donor's health after the donation in *the* cases referred to in paragraph 3;

Or. en

Justification

As different types of donation imply different risks for donors, with varying levels of

significance, the monitoring of donor health should be proportionate to those levels of risk. An assessment should be conducted on the basis of science and medical expertise. The Regulation should refrain from defining the risk level of specific procedures, as this should be determined at a technical level on the basis of the latest available scientific evidence.

Amendment 624
Cristian-Silviu Buşoi

Proposal for a regulation
Article 53 – paragraph 1 – point k

Text proposed by the Commission

(k) develop and implement a plan for monitoring the donor's health after the donation in cases *where the SoHO donations imply a significant risk to a donor as* referred to in paragraph 3;

Amendment

(k) develop and implement a plan for monitoring the donor's health after the donation in *the* cases referred to in paragraph 3;

Or. en