



*Committee on the Internal Market and Consumer Protection
Committee on Civil Liberties, Justice and Home Affairs*

2021/0106(COD)

13.6.2022

AMENDMENTS 1581 - 2005

Draft report

Brando Benifei, Dragoș Tudorache
(PE731.563v01-00)

Harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and
amending certain Union Legislative Acts

Proposal for a regulation
(COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

Amendment 1581

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 2 – introductory part

Text proposed by the Commission

2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic updating. It shall comprise the following steps:

Amendment

2. The risk management system shall consist of a continuous iterative process run throughout the entire lifecycle of a high-risk AI system, requiring regular systematic ***review and*** updating. It shall comprise the following steps:

Or. en

Amendment 1582

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks ***associated with each*** high-risk AI system;

Amendment

(a) identification and analysis of the known and ***the reasonably*** foreseeable risks ***that the*** high-risk AI system, ***and AI systems with indeterminate uses can pose to:***

(i) the health or safety of natural persons;

(ii) the legal rights or legal status of natural persons;

(iii) the fundamental rights of natural persons;

(iv) the equal access to services and opportunities of natural persons;

(v) the Union values enshrined in Article 2 TEU;

(vi) society at large and the environment.

Or. en

Amendment 1583

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks ***associated with each*** high-risk AI system;

Amendment

(a) identification and analysis of the known and ***the reasonably*** foreseeable risks ***that the*** high-risk AI system, ***and AI systems with indeterminate uses, can pose to:***

(i) the health or safety of natural persons;

(ii) the legal rights or legal status of natural persons;

(iii) the fundamental rights;

(iv) the equal access to services and opportunities of natural persons;

(v) the Union values enshrined in Article 2 TEU.

Or. en

Amendment 1584

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

(a) identification and analysis of the known and ***reasonably*** foreseeable risks associated with each high-risk AI system ***with respect to health, safety, fundamental rights, and the values of the Union as enshrined in Article 2 TEU;***

Or. en

Amendment 1585

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks ***associated with each*** high-risk AI system;

Amendment

(a) identification and analysis of the known and ***reasonable*** foreseeable risks ***of harms most likely to occur to the health, safety or fundamental rights in view of the intended purpose of the*** high-risk AI system;

Or. en

Amendment 1586

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system, ***including by means of a fundamental rights impact assessment as provided for in Article 9a;***

Or. en

Amendment 1587

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș,
Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 2 – point a

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks ***associated with each*** high-risk AI system;

Amendment

(a) identification and analysis of the known and foreseeable risks ***most likely to occur to health, safety and fundamental***

rights in view of the intended purpose of the high-risk AI system;

Or. en

Amendment 1588
Marion Walsmann

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

Text proposed by the Commission

(a) identification and analysis of the known and foreseeable risks associated with each high-risk AI system;

Amendment

(a) identification and analysis of the known and foreseeable risks ***to the health and safety or fundamental rights of a person*** associated with each high-risk AI system;

Or. en

Amendment 1589
Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Article 9 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(aa) identification of the risks, damage and harm actually caused by the high-risk AI system in the past, whether these are the result of use of the high-risk AI system for its intended purpose or of another use;

Or. fr

Amendment 1590
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 9 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) evaluation of how the principles of Article 4a are adhered to;

Or. en

Amendment 1591

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse; **deleted**

Or. en

Amendment 1592

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse; **deleted**

Or. en

Amendment 1593

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

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

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose ***or reasonably foreseeable use*** and under conditions of reasonably foreseeable misuse;

Or. en

Amendment 1594

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

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

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose ***or reasonably foreseeable use*** and under conditions of reasonably foreseeable misuse;

Or. en

Amendment 1595
Marion Walsmann

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

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose ***and under conditions of***

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose;

reasonably foreseeable misuse;

Or. en

Amendment 1596

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 2 – point b

Text proposed by the Commission

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse;

Amendment

(b) estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and under conditions of reasonably foreseeable ***use or*** misuse;

Or. en

Amendment 1597

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

(c) evaluation of ***other possibly arising*** risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Amendment

(c) evaluation of ***new risks consistent with those described in paragraph (2a) of this Article and identified*** based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Or. en

Amendment 1598

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 2 – point c

Text proposed by the Commission

Amendment

(c) evaluation of ***other possibly*** arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

(c) evaluation of ***new*** arising ***significant*** risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 61;

Or. en

Amendment 1599

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) sandbox experimentation on the functioning of the AI systems;

Or. fr

Amendment 1600

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 2 – point d

Text proposed by the Commission

Amendment

(d) adoption of ***suitable*** risk management measures in accordance with the provisions of the following paragraphs.

(d) adoption of ***appropriate and targeted*** risk management measures ***designed to address identified known and foreseeable risks to health and safety or fundamental rights***, in accordance with the provisions of the following paragraphs.

Or. en

Amendment 1601

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș,

Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 2 – point d

Text proposed by the Commission

(d) adoption of *suitable* risk management measures in accordance with the provisions of the following paragraphs.

Amendment

(d) adoption of ***appropriate and targeted*** risk management measures ***to address identified significant risks*** in accordance with the provisions of the following paragraphs.

Or. en

Amendment 1602

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The risks referred to in paragraph 2 shall concern only those which may be reasonably mitigated or eliminated through the development or design of the high-risk AI system, or the provision of adequate technical information.

Or. en

Amendment 1603

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements

set out in this Chapter 2. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards *or common specifications*.

set out in this Chapter 2, *with a view to treating risks effectively while ensuring an appropriate and proportionate implementation of the requirements*. They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards.

Or. en

Amendment 1604

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation Article 9 – paragraph 3

Text proposed by the Commission

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the generally acknowledged state of the art, including as reflected in *relevant harmonised standards or common specifications*.

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the generally acknowledged state of the art, including as reflected in *the common technical specifications adopted by the Commission or in relevant harmonised standards*.

Or. fr

Amendment 1605

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 9 – paragraph 3

Text proposed by the Commission

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the

combined application of the requirements set out in this Chapter 2. ***They shall take into account the generally acknowledged state of the art, including as reflected in relevant harmonised standards or common specifications.***

combined application of the requirements set out in this Chapter 2, ***with a view to minimising risks more effectively while achieving an appropriate balance in implementing the measures to fulfil those requirements.***

Or. en

Amendment 1606

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation **Article 9 – paragraph 3**

Text proposed by the Commission

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the ***generally acknowledged*** state of the art, including as reflected in relevant harmonised standards or common specifications.

Amendment

3. The risk management measures referred to in paragraph 2, point (d) shall give due consideration to the effects and possible interactions resulting from the combined application of the requirements set out in this Chapter 2. They shall take into account the state of the art, including as reflected in relevant harmonised standards or common specifications.

Or. en

Amendment 1607

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan, Vincenzo Sofo

Proposal for a regulation **Article 9 – paragraph 4 – introductory part**

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that ***any residual risk associated with each hazard as well as*** the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that the overall residual risk of the high-risk AI systems is ***reasonably*** judged ***to be*** acceptable, ***having regard to the benefits that the high-risk AI system is reasonably expected to deliver and,***

provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, ***subject to terms, conditions as made available by the provider, and contractual and license restrictions***. Those residual risks shall be communicated to the user.

Amendment 1608

Proposal for a regulation

Text proposed by the Commission

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard, as well as the overall residual risk of the high-risk AI systems, *is:*

Or. fr

Amendment 1609

Proposal for a regulation

Text proposed by the Commission

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual *significant* risk

with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

associated with each hazard as well as the overall residual risk of the high-risk AI systems is *reasonably* judged *to be* acceptable, *having regard to the benefits that the high-risk AI system is reasonably expected to deliver and* provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual *significant* risks shall be communicated to the user.

Or. en

Amendment 1610

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the *user*.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks *and the reasoned judgements made* shall be communicated to the *deployer and made available to AI subjects*.

Or. en

Amendment 1611

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any ***residual risk associated with each hazard as well as the overall*** residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. ***Those*** residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any ***significant*** residual risk of the high-risk AI systems is ***reasonably*** judged ***to be*** acceptable, ***having regards to the benefits that the high-risk AI system is reasonably expected to deliver and*** provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. ***Significant*** residual risks shall be communicated to the user.

Or. en

Amendment 1612

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or ***reasonably foreseeable use or*** under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 1613

Marion Walsmann

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose **or under conditions of reasonably foreseeable misuse**. Those residual risks shall be communicated to the user.

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose. Those residual risks shall be communicated to the user.

Or. en

Amendment 1614

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena JovevaIrena Joveva, Malik Azmani, Andrus Ansip, Dita Charanzová, Alin Mituța

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any **relevant** residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 1615

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 9 – paragraph 4 – introductory part

Text proposed by the Commission

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse. Those residual risks shall be communicated to the user.

Amendment

4. The risk management measures referred to in paragraph 2, point (d) shall be such that any residual risk associated with each hazard as well as the overall residual risk of the high-risk AI systems is judged acceptable, provided that the high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable **use or** misuse. Those residual risks shall be communicated to the user.

Or. en

Amendment 1616

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – introductory part

Text proposed by the Commission

In identifying the most appropriate risk management measures, the following shall be **ensured**:

Amendment

In identifying the most appropriate risk management measures, the following shall be **taken into account**:

Or. en

Amendment 1617

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – introductory part

Text proposed by the Commission

In identifying **the most** appropriate risk management measures, the following shall be **ensured**:

Amendment

In identifying appropriate risk management measures, the following **outcomes** shall be **pursued**:

Or. en

Amendment 1618

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) ***elimination or*** reduction of risks as far as possible through adequate design and development;

Amendment

(a) reduction of ***identified and evaluated*** risks as far as ***proportionate and technologically possible in light of the generally acknowledged state of the art and industry standards***, through adequate design and development ***of the high risk AI system in question***;

Or. en

Amendment 1619

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) elimination or reduction of risks as far as possible through adequate design and development;

Amendment

(a) elimination or reduction of risks as far as possible through adequate design and development ***involving relevant domain and other experts and internal and external stakeholders, including but not limited to representative bodies and the social partners***;

Or. en

Amendment 1620

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) elimination or reduction of risks as

Amendment

(a) elimination or reduction of risks as

far as *possible* through *adequate* design and development;

far as *commercially reasonable and technologically feasible in light of the generally acknowledged state of the art*, through *appropriate* design and development *measures*;

Or. en

Amendment 1621

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) elimination or reduction of risks as far as *possible* through adequate design and development;

Amendment

(a) elimination or reduction of *identified and evaluated* risks as far as *economically and technologically feasible* through adequate design and development *of the high-risk AI system*;

Or. en

Amendment 1622

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point a

Text proposed by the Commission

(a) *elimination or* reduction of risks as far as *possible* through adequate design and development;

Amendment

(a) reduction of *identified and evaluated* risks as far as *commercially reasonable and technologically feasible* through adequate design and development;

Or. en

Amendment 1623

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) *where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;* *deleted*

Or. en

Amendment 1624

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) where appropriate, implementation of adequate mitigation and control measures in relation to risks that cannot be eliminated;

(b) where appropriate, implementation of adequate mitigation and control measures in relation to **significant** risks that cannot be eliminated;

Or. en

Amendment 1625

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point b

Text proposed by the Commission

Amendment

(b) where appropriate, implementation of adequate mitigation and control measures **in relation to** risks that cannot be eliminated;

(b) where appropriate, implementation of adequate mitigation and control measures **addressing** risks that cannot be eliminated;

Or. en

Amendment 1626
Vincenzo Sofo, Kosma Zlotowski

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training *to users*.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, ***and relevant information on necessary competence training and authority for natural persons exercising such oversight.***

Or. en

Amendment 1627
Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, ***in particular as regards the risks referred to in paragraph 2, point (b) of this Article,*** and, where appropriate, training to users.

Amendment

(c) provision of adequate information pursuant to Article 13 and, where appropriate, training to users.

Or. en

Amendment 1628
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, ***in particular as***

Amendment

(c) provision of ***the required*** adequate information pursuant to Article 13 of this

regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.

Article, and, where appropriate, training to users.

Or. en

Amendment 1629

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to users.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point **(a) and** (b) of this Article, and, where appropriate, training to users.

Or. en

Amendment 1630

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c

Text proposed by the Commission

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to **users**.

Amendment

(c) provision of adequate information pursuant to Article 13, in particular as regards the risks referred to in paragraph 2, point (b) of this Article, and, where appropriate, training to **deployers**.

(This amendment applies throughout the text. Adopting it will necessitate corresponding changes throughout.)

Or. en

Amendment 1631

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the governance structures to mitigate risks.

Or. en

Amendment 1632

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä, Sylwia Spurek
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the **user and the environment** in which the system is intended to be used.

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the **deployer, to the socio-technical context** in which the system is intended to be used, **and to reasonably foreseeable use or misuse.**

Or. en

Amendment 1633

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

In eliminating or reducing risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended *or reasonably foreseeable* to be used.

Or. en

Amendment 1634

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

In *eliminating or reducing* risks related to the use of the high-risk AI system, due consideration *shall be given to* the technical knowledge, experience, education, training *to be expected by* the user *and* the environment in which the system is intended to be used.

Amendment

In *seeking to reduce* risks related to the use of the high-risk AI system, *providers shall take into* due consideration the technical knowledge, experience, education, training the user *may need, including in relation to* the environment in which the system is intended to be used.

Or. en

Amendment 1635

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 4 – subparagraph 2

Text proposed by the Commission

In *eliminating or reducing* risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

Amendment

In *seeking to eliminate or reduce* risks related to the use of the high-risk AI system, due consideration shall be given to the technical knowledge, experience, education, training to be expected by the user and the environment in which the system is intended to be used.

Or. en

Amendment 1636

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 4 – point a (new)

Text proposed by the Commission

Amendment

**(a) technically and structurally
minimised by the high-risk AI system;**

Or. fr

Amendment 1637

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 4 – point b (new)

Text proposed by the Commission

Amendment

**(b) deemed acceptable, provided that
the high-risk AI system is used for its
intended purpose or under conditions of
reasonably foreseeable misuse.**

Or. fr

Amendment 1638

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

**4a. Those residual risks shall be
communicated to the user.**

Or. fr

Amendment 1639

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be **tested** for the purposes of identifying the most appropriate risk management measures. **Testing** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be **evaluated** for the purposes of identifying the most appropriate **and targeted** risk management measures **and weighing any such measures against the potential benefits and intended goals of the system**. **Evaluations** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are **in compliance** with the **relevant** requirements set out in this Chapter.

Or. en

Amendment 1640

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be tested for the purposes of identifying **the most** appropriate risk management measures. Testing shall ensure that high-risk AI systems perform **consistently for** their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be tested for the purposes of identifying appropriate risk management measures **for the specific scenario in which the system will be operating and to ensure that a system is performing appropriately for a given use case**. Testing shall ensure that high-risk AI systems perform **in a manner that is consistent with** their intended purpose and they are in compliance with the requirements set out in this Chapter.

Or. en

Amendment 1641

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be **tested** for the purposes of identifying the most appropriate risk management measures. **Testing** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be **evaluated** for the purposes of identifying the most appropriate **and targeted** risk management measures **and weighing any such measures against the potential benefits and intended goals of the system**. **Evaluations** shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the **relevant** requirements set out in this Chapter.

Or. en

Amendment 1642

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently **for their intended purpose** and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently, **safely during reasonably foreseeable conditions of use or misuse**, and they are in compliance with the requirements set out in this Chapter.

Or. en

Amendment 1643

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation
Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be **tested** for the purposes of identifying the most appropriate risk management measures. **Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.**

Amendment

5. High-risk AI systems shall be **evaluated** for the purposes of identifying the most appropriate **and targeted** risk management measures **and weighing any such measures against the potential benefits and** intended **goals of the system.**

Or. en

Amendment 1644

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 9 – paragraph 5

Text proposed by the Commission

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter.

Amendment

5. High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose **or reasonably foreseeable use** and they are in compliance with the requirements set out in this Chapter.

Or. en

Amendment 1645

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 6

Text proposed by the Commission

Amendment

6. *Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.* *deleted*

Or. en

Amendment 1646

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H          , Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 6

Text proposed by the Commission

Amendment

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system *and do not need to go beyond what is necessary to achieve that purpose.*

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system.

Or. fr

Amendment 1647

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 9 – paragraph 6

Text proposed by the Commission

Amendment

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose.

6. Testing procedures shall be suitable to achieve the intended purpose *or reasonably foreseeable use* of the AI system and do not need to go beyond what is necessary to achieve that purpose.

Or. en

Amendment 1648

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 6

Text proposed by the Commission

6. Testing procedures shall be suitable to achieve the intended purpose of the AI system ***and do not need to go beyond what is necessary to achieve that purpose.***

Amendment

6. ***Evaluation or*** testing procedures shall be suitable to achieve the intended purpose of the AI system.

Or. en

Amendment 1649

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 6 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

They shall test:

Or. fr

Amendment 1650

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 6 – point a (new)

Text proposed by the Commission

Amendment

(a) the ability of the high-risk AI system to generate an accurate and robust result;

Or. fr

Amendment 1651

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 6 – point b (new)

Text proposed by the Commission

Amendment

(b) the trustworthiness of the high-risk AI system and its ability to actually generate a result such as that expected in accordance with its intended purpose;

Or. fr

Amendment 1652

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 9 – paragraph 6 – point c (new)

Text proposed by the Commission

Amendment

(c) the structural and technical capacity of the high-risk AI system to ensure it cannot be used for purposes other than its intended purpose.

Or. fr

Amendment 1653

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

Amendment

7. The testing of the high-risk AI systems shall be performed, **as appropriate, at any point in time throughout the development process, and, in any event,** prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

7. The testing of the high-risk AI systems shall be performed prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment 1654**Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H          , Jean-Paul Garraud****Proposal for a regulation
Article 9 – paragraph 7***Text proposed by the Commission*

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***preliminarily defined*** metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against metrics and probabilistic thresholds that are ***preliminarily defined according to common standards or technical specifications and*** appropriate to the intended purpose of the high-risk AI system.

Or. fr

Amendment 1655**Pernando Barrena Arza, Cornelia Ernst****Proposal for a regulation
Article 9 – paragraph 7***Text proposed by the Commission*

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose ***or reasonably foreseeable use*** of the high-risk AI system.

Or. en

Amendment 1656

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended ***purpose*** of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended ***use or reasonably foreseeable misuse*** of the high-risk AI system.

Or. en

Amendment 1657

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***preliminarily*** defined metrics ***and*** probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against ***prior*** defined metrics, ***such as*** probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system.

Or. en

Amendment 1658

Kosma Zlotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 7

Text proposed by the Commission

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and ***probabilistic thresholds*** that are appropriate to the intended purpose of the high-risk AI system.

Amendment

7. The testing of the high-risk AI systems shall be performed, as appropriate, at any point in time throughout the development process, and, in any event, prior to the placing on the market or the putting into service. Testing shall be made against preliminarily defined metrics and ***rubrics*** that are appropriate to the intended purpose of the high-risk AI system.

Or. en

Amendment 1659

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Karen Melchior, Svenja Hahn, Morten Løkkegaard, Alin Mituţa, Michal Šimečka

Proposal for a regulation

Article 9 – paragraph 8

Text proposed by the Commission

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to be accessed by or have an impact on children ***or natural persons suffering from disabilities that render them legally unable to give their consent.***

Or. en

Amendment 1660

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 8

Text proposed by the Commission

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to ***be accessed by or have an impact on children.***

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration shall be given to whether the high-risk AI system is likely to:

Or. en

Justification

moved into subpoints

Amendment 1661
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 9 – paragraph 8

Text proposed by the Commission

8. When implementing the risk management system described in paragraphs 1 to 7, specific consideration ***shall be given*** to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Amendment

8. When implementing the risk management system described in paragraphs 1 to 7, ***shall give*** specific consideration to whether the high-risk AI system is likely to be accessed by or have an impact on children.

Or. en

Amendment 1662
Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä, Sylwia Spurek
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 9 – paragraph 8 – point a (new)

Text proposed by the Commission

Amendment

(a) adversely affect specific groups of people, in particular on the basis of

gender, sexual orientation, age, ethnicity, disability, religion, socio-economic standing, religion or origin, including asylum seekers including migrants, refugees and asylum seekers;

Or. en

Amendment 1663

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 8 – point b (new)

Text proposed by the Commission

Amendment

(b) have an adverse impact on the environment, or;

Or. en

Amendment 1664

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 8 – point c (new)

Text proposed by the Commission

Amendment

(c) be implemented on children;

Or. en

Amendment 1665

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 8 – point d (new)

Text proposed by the Commission

Amendment

(d) have an adverse effect on mental health, individual's behaviour;

Or. en

Amendment 1666

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 8 – point e (new)

Text proposed by the Commission

Amendment

(e) amplify the spread of disinformation and amplify polarisation;

Or. en

Amendment 1667

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 – paragraph 8 – point f (new)

Text proposed by the Commission

Amendment

(f) amplify the spread of disinformation and amplify polarisation;

Or. en

Amendment 1668

Kosma Zlotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 9 – paragraph 9

Text proposed by the Commission

Amendment

9. For *credit institutions regulated by Directive 2013/36/EU*, the aspects described in paragraphs 1 to 8 *shall be part*

9. For *AI systems already covered by Union law that requires a specific risk assessment*, the aspects described in

of the risk management procedures established by those institutions pursuant to Article 74 of that Directive.

paragraphs 1 to 8 *may be incorporated into that risk assessment, without the need to conduct a separate, additional risk assessment in order to comply with this Article.*

Or. en

Amendment 1669

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 9 – paragraph 9

Text proposed by the Commission

9. For *credit institutions regulated by Directive 2013/36/EU*, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by *those institutions pursuant to Article 74 of that Directive.*

Amendment

9. For *providers and AI systems already covered by Union law that require them to establish a specific risk management*, the aspects described in paragraphs 1 to 8 shall be part of the risk management procedures established by *that Union law or deemed to be covered as part of it.*

Or. en

Amendment 1670

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 9 – paragraph 9

Text proposed by the Commission

9. For *credit institutions regulated by Directive 2013/36/EU*, the aspects described in paragraphs 1 to 8 shall be *part of the risk management* procedures established by *those institutions pursuant to Article 74 of that Directive.*

Amendment

9. For *AI systems already covered by Union law that require them to carry out specific risk assessments*, the aspects described in paragraphs 1 to 8 shall be *combined with the risk assessment* procedures established by *that Union law or deemed to be covered as part of it.*

Or. en

Amendment 1671

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä, Sylwia Spurek

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9 a (new)

Text proposed by the Commission

Amendment

Article 9 a

***Fundamental rights impact assessments
for high-risk AI systems***

1. Providers, and deployers at each proposed deployment, must designate the categories of individuals and groups likely to be impacted by the system, assess the system's impact on fundamental rights, its accessibility for persons with disabilities, and its impact on the environment and broader public interest. Deployers of high-risk AI systems as defined in Article 6(2) shall, prior to putting the system into use, publish a fundamental rights impact assessment of the systems' impact in the context of use throughout the entire lifecycle. This assessment shall include at least:

- a) the intended purpose for which the system will be used;***
- b) the intended geographic and temporal scope of the system;***
- c) the potential risks of the use to the rights and freedoms of natural persons, including any indirect impacts or consequences of the systems;***
- d) the categories of natural persons and groups likely or foreseen to be affected;***
- e) the proportionality and necessity of the system's use;***
- f) verification of the legality of the use of the system in accordance with Union and national law;***
- g) any specific risk of harm likely to***

impact marginalised, vulnerable persons or groups at risk of discrimination, and risk of increasing existing societal inequalities;

h) the foreseeable impact of the use of the system on the environment over its entire life cycle, including but not limited to energy consumption;

i) any other negative impact on the public interest and clear plans relating to how the harms identified will be mitigated, and how effective this mitigation is expected to be; and

j) the governance system the deployer will put in place, including human oversight, complaint-handling and redress.

2. If adequate steps to mitigate the risks outlined in the course of the assessment in paragraph 1 cannot be identified, the system shall not be put into use. Market surveillance authorities, pursuant to Articles 65 and 67, may take this information into account when investigating systems which present a risk at national level.

3. The obligation outlined under paragraph 1 applies for each new deployment of the high-risk AI system.

4. Deployers shall consult with relevant stakeholders, in particular groups of natural persons exposed to heightened risks from the AI system, civil society and social partners when preparing the impact assessment. The impact assessment shall be repeated on a regular basis throughout the entire lifecycle.

5. Publication of the results of the impact assessment shall be part of the registration of use pursuant to Article 51(2).

6. Where the deployer is already required to carry out a data protection impact assessment under Article 35 of Regulation(EU) 2016/679 or Article 27 of Directive (EU) 2016/680, the impact assessment outlined in paragraph 1 shall

be conducted in conjunction to the data protection impact assessment and be published as an addendum.

7. Deployers of high-risk AI systems shall use the information provided under Article 13 to comply with their obligation under paragraph 1.

Or. en

Amendment 1672

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Techniques such as unsupervised learning and reinforcement learning that do not use validation and testing data sets shall be developed on the basis of training data sets the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1673

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be, *as far as this*

basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

can be reasonably expected and is feasible from a technical and economical point of view, developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1674

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed ***on the basis of*** training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be, ***as far this can be reasonably expected and is feasible from a technical point of view***, developed ***with the best efforts to ensure*** training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1675

Karlo Ressler

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be, ***with reasonable expectations and in accordance with the state-of-art***, developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5;

Amendment 1676

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5, **when applicable**.

Or. en

Amendment 1677

Kosma Zlotowski, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Amendment

1. High-risk AI systems which make use of techniques involving the training of models with data shall be developed on the basis of training, validation and testing data sets that meet the quality **and fairness** criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1678

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 10 – paragraph 1 a (new)

1 a. Validation datasets shall be separate datasets from both the testing and the training datasets, in order for the evaluation to be unbiased. If only one dataset is available, it shall be divided in three parts: a training set, a validation set, and a testing set. Each set shall comply with paragraph 3 of this Article.

Or. en

Amendment 1679

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 10 – paragraph 1 a (new)

1 a. Techniques such as unsupervised learning and reinforcement learning, that do not use validation and testing data sets, shall be developed on the basis of training data sets that meet the quality criteria referred to in paragraphs 2 to 5.

Or. en

Amendment 1680

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 10 – paragraph 1 b (new)

1 b. Techniques such as unsupervised learning and reinforcement learning, that do not use validation and testing datasets, shall be developed on the basis of training datasets that meet the quality criteria

referred to in paragraphs 2 to 4.

Or. en

Amendment 1681

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets *as well as data that is collected, fed into, or used by the AI system, after deployment of the system and throughout its lifecycle* shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Or. en

Amendment 1682

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices *for the entire lifecycle of data processing. Where relevant to appropriate risk management measures*, those practices shall concern in particular,

Or. en

Amendment 1683

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to **appropriate** data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to data governance and management practices ***appropriate for the context of the use as well as the intended purpose of the AI system***. Those practices shall concern in particular,

Or. en

Amendment 1684

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. ***throughout the entire lifecycle of the AI system***. Those practices shall concern in particular,

Or. en

Amendment 1685

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern ***in particular***,

Amendment

2. Training, ***machine-learning*** validation and testing data sets shall be subject to appropriate data governance and management practices ***during the expected lifetime***. Those practices shall concern,

where relevant:

Or. en

Amendment 1686

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei, Maria Grapini

Proposal for a regulation

Article 10 – paragraph 2 – introductory part

Text proposed by the Commission

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices. Those practices shall concern in particular,

Amendment

2. Training, validation and testing data sets shall be subject to appropriate data governance and management practices ***for the entire lifecycle of data processing.*** Those practices shall concern in particular,

Or. en

Amendment 1687

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

(a) the relevant design choices;

Amendment

(a) the relevant design choices, ***including the extent to which the functioning of the algorithms can be audited and reproduced;***

Or. fr

Amendment 1688

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the **relevant** design choices;

(a) the design choices **for training and machine learning validation**;

Or. en

Amendment 1689

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 10 – paragraph 2 – point a

Text proposed by the Commission

Amendment

(a) the **relevant** design choices;

(a) the design choices;

Or. en

Amendment 1690

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) data collection;

(b) data collection **processes**;

Or. en

Amendment 1691

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point b

Text proposed by the Commission

Amendment

(b) data collection;

(b) data collection **processes**;

Or. en

Amendment 1692

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) **relevant** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment

(c) data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Or. en

Amendment 1693

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) **relevant** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment

(c) data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Or. en

Amendment 1694

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 10 – paragraph 2 – point c

Text proposed by the Commission

(c) **relevant** data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment

(c) data preparation processing operations, such as annotation, labelling, cleaning, enrichment and aggregation;

Amendment 1695

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 10 – paragraph 2 – point d

Text proposed by the Commission

(d) the formulation of relevant assumptions, notably with respect to the information that the data are supposed to measure and represent;

Amendment

(d) the formulation of relevant, ***justified and reasonable*** assumptions, notably with respect to the information that the data are supposed to measure and represent;

Or. en

Amendment 1696

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point e

Text proposed by the Commission

(e) ***a prior assessment of the availability, quantity and suitability of the data sets that are needed;***

Amendment

deleted

Or. en

Amendment 1697

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – point e

Text proposed by the Commission

(e) ***a prior*** assessment of the availability, quantity and suitability of the data sets that are needed;

Amendment

(e) ***an*** assessment of the availability, quantity and suitability of the data sets that are needed;

Amendment 1698

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Radosław Sikorski, Janusz Lewandowski

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible biases ***defined as a statistical error or a top-down introduction of assumptions harmful to an individual, that are likely to affect health and safety of persons or lead to discrimination prohibited by Union law;***

Or. en

Amendment 1699

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

(f) examination in view of possible biases;

Amendment

(f) examination in view of possible ***unfair*** biases ***that are likely to affect the health and safety of persons or lead to discrimination prohibited under Union law;***

Or. en

Amendment 1700

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) examination in view of possible biases;

(f) examination in view of possible biases, ***that are likely to affect health and safety of persons or lead to discrimination prohibited by Union law***;

Or. en

Amendment 1701

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) examination ***in view*** of possible biases;

(f) examination of possible biases, ***especially where data outputs are used as an input for future operations(‘feedback loops’)***;

Or. en

Amendment 1702

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) examination in view of possible biases;

(f) examination in view of possible biases ***that are likely to affect the output of the AI system***;

Or. en

Amendment 1703

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 10 – paragraph 2 – point f

Text proposed by the Commission

Amendment

(f) examination in view of **possible** biases;

(f) examination in view of biases;

Or. en

Amendment 1704

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Vincenzo Sofo, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) the identification of any **possible** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

(g) the identification of any **other** data gaps or shortcomings **that materially increase the risks of harm to the health, natural environment and safety or the fundamental rights of persons**, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1705

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

Amendment

(g) the identification of **any possible** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

(g) the identification of **significant and consequential** data gaps or shortcomings, and how those gaps and shortcomings can be addressed;

Or. en

Amendment 1706

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of **relevant** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1707

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any possible** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of **significant** data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1708

Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 10 – paragraph 2 – point g

Text proposed by the Commission

(g) the identification of **any** possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Amendment

(g) the identification of possible data gaps or shortcomings, and how those gaps and shortcomings can be addressed.

Or. en

Amendment 1709

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) the presumable context of the use as well as the intended purpose of the AI System.

Or. en

Amendment 1710

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 10 – paragraph 2 – point g a (new)

Text proposed by the Commission

Amendment

(g a) verification of the legality of the sources of the data.

Or. en

Amendment 1711

René Repasi, Marc Angel, Andreas Schieder, Maria-Manuel Leitão-Marques

Proposal for a regulation

Article 10 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. the evaluation of the impacts of a high-risk AI system, designed to ensure it is functioning as intended, that there are no errors or risks left unaddressed and that the system continues to meet the state-of-the-art standards required by this Regulation (ex post requirement).

Or. en

Amendment 1712

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate *statistical* properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. *These* characteristics *of the data sets may* be met at the level of individual *data sets or a* combination *thereof*.

Amendment

3. Training *data sets*, validation and testing data sets, *including the labels, as well as data that is collected, fed into, or used by the AI system, after deployment of the system and throughout its lifecycle* shall be relevant, representative, free of errors and complete. They shall have the appropriate properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. *The required* characteristics *should* be met at the level of *each* individual *dataset, whether in combination or not*.

Training validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used.

Or. en

Amendment 1713

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, *free of errors* and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may

Amendment

3. Training, validation and testing data sets shall be relevant, representative and *as* complete *and close to zero error as possible, having regard to the intended purpose of the AI system*. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the

be met at the level of individual data sets or a combination thereof.

high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof. ***In case of observational data, a common approach on data requirements shall be defined together with regulators.***

Or. en

Amendment 1714

Nathalie Colin-Oesterlé

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, ***free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used.*** These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant, representative, ***reliable, limited in terms of bias, and complete.*** These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. fr

Amendment 1715

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk

Amendment

3. ***High-risk AI systems shall be designed and developed with the best efforts to ensure that*** training, validation and testing data sets shall be relevant, representative, ***and to the best extent possible,*** free of errors and complete ***in***

AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

accordance with industry standards. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1716

Krzysztof Hetman, Andrzej Halicki, Adam Jarubas, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing **data** sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing **datasets** sets shall be relevant, representative, ***up-to-date, and to the extent that it could be reasonably expected, taking into account the state of the art***, free of errors and ***as could be reasonably expected***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1717

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

Amendment

3. Training, validation and testing data sets ***shall be*** relevant, representative, ***free of errors and complete***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the ***data sets*** may be met at the level of individual data sets or a combination thereof.

3. ***High risk AI systems should be designed and developed with the best efforts to ensure that, where appropriate, training, validation and testing data sets are sufficiently relevant, representative and appropriately vetted for errors.*** They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the ***datasets*** may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1718

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Brando Benifei, Maria Grapini

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing ***data sets*** shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the ***data sets may*** be met at the level of individual data ***sets or a combination thereof***.

Amendment

3. Training ***datasets, and where applicable***, validation and testing ***datasets, including the labels***, shall be relevant, representative, ***up-to-date, and to the best extent possible***, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the ***datasets shall*** be met at the level of ***each*** individual data ***set***.

Or. en

Amendment 1719

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing **data sets** shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **data sets may** be met at the level of individual **data sets or a combination thereof**.

Amendment

3. Training, validation and testing **datasets** shall be relevant, representative, **up-to-date, and to the best extent possible, taking into account the state of the art,** free of errors and **be as complete as possible**. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the **datasets shall** be met at the level of **each** individual **dataset**.

Or. en

Amendment 1720

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant, **sufficiently diverse to mitigate bias, and, to the best extent possible**, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1721

Geoffroy Didier

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant, representative, **and to the best extent possible** free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk **uses of** AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Justification

Article 10(3) provides an obligation to use error-free datasets, which is disproportionate et impossible in practice. Indeed, even if it is necessary to strengthen data learning, it is impossible to guarantee a total absence of errors in the datasets used in the development processes of the systems (in machine-learning particularly).

The concept of zero error in data is contrary even to the notion of AI which conceptually integrates this ability to reproduce human analysis. With interventions of DG Connect, it seems that the authorities do not expect perfect datasets but as reliable as possible

Amendment 1722

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons **on which** the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant, representative, free of errors and **statistically** complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons **in relation to whom** the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a

combination thereof.

Or. en

Amendment 1723
Marion Walsmann

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, ***free of errors and complete***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant ***and*** representative. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1724
Jörgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets shall be relevant, representative, ***free of errors and complete***. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Amendment

3. Training, validation and testing data sets shall be relevant ***and*** representative. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used. These characteristics of the data sets may be met at the level of individual data sets or a combination thereof.

Or. en

Justification

It is impossible to create data sets that are completely free of errors, and no data set can ever be considered "complete" in the right sense of the word.

Amendment 1725

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 3

Text proposed by the Commission

3. Training, validation and testing data sets *shall be* relevant, representative, *free of errors and complete. They shall have the appropriate statistical properties, including, where applicable, as regards the persons or groups of persons on which the high-risk AI system is intended to be used.* These characteristics *of the data sets* may be met at the level of individual data sets or a combination thereof.

Amendment

3. ***High Risk AI systems should be designed and developed with the best efforts to ensure that, where appropriate, training datasets, machine-learning validation and testing data sets are sufficiently accurate, relevant and representative in view of the intended purpose of the AI system.*** These characteristics may be met at the level of individual data sets or a combination thereof.

Or. en

Amendment 1726

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In assessing the quality of a data set, account shall be taken to the extent to which the data set is constructed with a view to fulfilling in particular the following aspects:

a) provides a similar output for relevant demographic Groups impacted by the system;

b) minimizes disparities in outcomes for relevant demographic groups impacted by the system, in case where the system

allocates resources or opportunities to natural persons;

c) minimizes the potential for stereotyping, demeaning, or erasing relevant demographic groups impacted by the system where the system describes, depicts, or otherwise represents people, cultures, or society.

Or. en

Amendment 1727

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

deleted

Or. en

Amendment 1728

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended

Amendment

4. Training, validation and testing data sets *as well as data that is collected, fed into, or used by the AI system, after deployment of the system and throughout its lifecycle* shall take into account, to the extent required by the intended purpose *or reasonably foreseeable use* , the characteristics or elements that are

to be used.

particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1729

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation Article 10 – paragraph 4

Text proposed by the Commission

4. ***Training, validation and testing*** data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

4. Data sets shall take into account, to the extent required by the intended purpose, the ***foreseeable uses and reasonably foreseeable misuses of AI systems with indeterminate uses, the*** characteristics or elements that are particular to the specific geographical, ,behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1730

Sophia in 't Veld, Michal Šimečka

Proposal for a regulation Article 10 – paragraph 4

Text proposed by the Commission

4. Training, validation and testing data sets shall take into account, ***to the extent required by the intended purpose,*** the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is ***intended to be*** used.

Amendment

4. Training, validation and testing data sets shall take into account the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is used.

Amendment 1731**Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan****Proposal for a regulation****Article 10 – paragraph 4***Text proposed by the Commission*

4. Training, validation and testing data sets shall ***take into account***, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

4. Training, validation and testing data sets shall ***be sufficiently diverse to accurately capture***, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1732**Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel****Proposal for a regulation****Article 10 – paragraph 4***Text proposed by the Commission*

4. ***Training, validation and testing*** data sets shall take into account, to the extent required by the intended purpose, the characteristics or elements that are particular to the specific geographical, behavioural or functional setting within which the high-risk AI system is intended to be used.

Amendment

4. Data sets shall take into account, to the extent required by the intended purpose, the ***reasonably foreseeable uses and misuses of AI systems, the*** characteristics or elements that are particular to the specific geographical, ***cultural***, behavioural or functional setting within which the high-risk AI system is intended to be used.

Or. en

Amendment 1733

Proposal for a regulation
Article 10 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The processing of personal data to train, validate and test data sets of an AI system in order to meet the requirements of this Regulation shall be lawful for the purpose of the legitimate interest of the provider as referred to in Article 6(1f) GDPR or in accordance with Article 6(4) GDPR subject to appropriate safeguards in line with Article 89 GDPR for ensuring to the extent necessary and proportionate one or more of the following objectives:

- a) national and common security;***
- b) functioning of the internal market;***
- c) prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;***
- d) exercise of public authorities' official mission, such as tax and customs authorities, financial investigation units, independent administrative authorities, or financial market authorities responsible for the regulation and supervision of securities markets should not be regarded as recipients if they process personal data to train, validate and test an AI system which are necessary to carry out a particular inquiry in the general interest, in accordance with Union or Member State law;***
- e) network and information security to the extent necessary and proportionate for this purpose;***
- f) protection of an interest which is essential for the life of the data subject or that of another natural person, in particular where it is necessary for reasons of public interest in the areas of public health.***

Amendment 1734

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H            , Jean-Paul Garraud

**Proposal for a regulation
Article 10 – paragraph 5**

Text proposed by the Commission

Amendment

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued. **deleted**

Or. fr

Amendment 1735

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alamets  
on behalf of the Verts/ALE Group

**Proposal for a regulation
Article 10 – paragraph 5**

Text proposed by the Commission

Amendment

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process **deleted**

special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

Or. en

Amendment 1736

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. *To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.* ***deleted***

Or. en

Amendment 1737

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. *To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.*

deleted

Or. en

Amendment 1738

Axel Voss, Deirdre Clune

Proposal for a regulation

Article 10 – paragraph 5

Text proposed by the Commission

Amendment

5. To the extent that it is **strictly** necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems **may** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and

5. To the extent that it is necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems **will have a legal basis and necessary exception to** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate

freedoms of natural persons, including ***technical limitations on the re-use and use of*** state-of-the-art security and privacy-preserving measures, such as pseudonymisation, ***or*** encryption where anonymisation may significantly affect the purpose pursued.

safeguards for the fundamental rights and freedoms of natural persons, including:

(i) state-of-the-art security and privacy-preserving measures, such as ***data-minimization***, pseudonymisation, encryption, ***and*** where anonymisation may significantly affect the purpose pursued;

(ii) ***measures ensuring availability and resilience of processing systems and services, and the ability to restore the availability and access to special category personal data in a timely manner in the event of a physical or technical incident;***

(iii) ***processes for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures in order to ensure the security of the processing;***

(iv) ***measures for user identification, authorisation, protection of data during transmission, protection of data during storage, ensuring physical security of locations at which personal data are processed, internal IT and IT security governance and management, certification/assurance of processes and products;***

(v) ***measures for ensuring data minimisation, data quality, limited data retention, and data portability and ensuring erasure.***

Or. en

Amendment 1739

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Article 10 – paragraph 5

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued. ***This should also guarantee explainability of AI driven recommendations or decisions.***

Or. en

Amendment 1740

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 10 – paragraph 5

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as

5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as

pseudonymisation, or encryption ***or biometric template protection technologies*** where anonymisation may significantly affect the purpose pursued.

Or, en

Amendment 1741

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, H  l  ne Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 10 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. The dissemination of data by an AI system to other AI systems, whether or not they are of the same origin and whether or not they are installed on the same medium, shall be checked by the provider and may be retracted if necessary.

Or, fr

Amendment 1742

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 10 – paragraph 6

Text proposed by the Commission

Amendment

6. ***Appropriate data governance and management practices shall apply*** for the development of high-risk AI systems ***other than those which make use of*** techniques involving the training of models ***in order to ensure that those high-risk AI systems comply with paragraph 2.***

6. For the development of high-risk AI systems ***not using*** techniques involving the training of models, ***paragraphs 2 to 5 shall apply only to the testing data sets.***

Or, en

Amendment 1743

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. Providers and user may comply with the obligations set out in this Article through the use of third-parties that offer certified compliance services including verification of data governance, data set integrity, and data training, validation and testing practices.

Or. en

Amendment 1744

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. The training, testing and validation processes of data sets should have a duration based on the training periodicity of the systems, the timing of notification of incidents and the normal supervisory activity of the national competent authority

Or. en

Amendment 1745

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 10 – paragraph 6 b (new)

Text proposed by the Commission

Amendment

6 b. Where the provider cannot comply

with the obligations laid down in this Article because it does not have access to the data and/or the data is held exclusively by the user, the user may, on the basis of a contract, be made responsible for any infringement of this Article.

Or. en

Amendment 1746

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10 a

Environmental Impact of high-risk AI systems

1. High-risk AI systems shall be designed and developed making use of state-of-the-art methods to reduce energy use, resource use and waste, as well as to increase energy efficiency, and the overall efficiency of the system. They shall be designed and developed and set up with capabilities enabling the measurement and logging of the consumption of energy and resources, and other environmental impact the deployment and use of the systems may have over their entire lifecycle.

2. Member States shall ensure that relevant national authorities issue guidelines and provide support to providers and deployers in their efforts to reduce the environmental impact and resource use of high-risk AI systems.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 73 to detail the measurement and logging procedures, taking into account state-of-the-art methods, in particular to

enable the comparability of the environmental impact of systems, and taking into account the economies of scale.

Or. en

Amendment 1747

Milan Brglez, Hilde Vautmans, Catharina Rinzema

Proposal for a regulation

Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10 a

Risk management system for AI systems likely to interact with children

AI systems likely to interact with or impact on children shall implement a riskmanagement system addressing content, contact, conduct and contract risks to children;

Or. en

Amendment 1748

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

1. The technical documentation of a high-risk AI system shall be drawn up, ***where possible, relevant, and without compromising intellectual property rights or trade secrets***, before that system is placed on the market or put into service and shall be kept up-to date.

Or. en

Amendment 1749

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 11 – paragraph 1 – introductory part

Text proposed by the Commission

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

Amendment

1. The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date ***throughout its entire lifecycle, and where appropriate, beyond.***

Or. en

Amendment 1750

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up, ***where possible, relevant, and without compromising intellectual property rights or trade secrets,*** in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV ***or in the case of SME's and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority.***

Or. en

Amendment 1751

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall **be** drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall **vary according to each use of the AI system** and drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV **or in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent national authority.**

Or. en

Amendment 1752

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be **appropriate to the context of application or use of the AI system** and drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV **or any equivalent documentation meeting the same objectives, subject to approval of the**

competent authority.

Or. en

Amendment 1753

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Catharina Rinzema, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or, in the case of SMEs and start-ups, any equivalent documentation meeting the same objectives, subject to approval of the competent authority.*

Or. en

Amendment 1754

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituța

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the

AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV *or equivalent documentation meeting the same objectives, subject to the approval of the competent authority.*

Or. en

Amendment 1755

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide ***the national supervisory authority, the*** national competent authorities and notified bodies with all the necessary information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Or. en

Amendment 1756

Marion Walsmann

Proposal for a regulation

Article 11 – paragraph 1 – subparagraph 1

Text proposed by the Commission

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with ***all*** the necessary

Amendment

The technical documentation shall be drawn up in such a way to demonstrate that the high-risk AI system complies with the requirements set out in this Chapter and provide national competent authorities and notified bodies with the necessary

information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

information to assess the compliance of the AI system with those requirements. It shall contain, at a minimum, the elements set out in Annex IV.

Or. en

Amendment 1757

Nathalie Colin-Oesterlé

Proposal for a regulation

Article 11 – paragraph 1 – point 1 (new)

Text proposed by the Commission

Amendment

(1) Technical documentation is not mandatory, but it is recommended for the testing of a high-risk AI system before it is placed on the market or made available.

Or. fr

Amendment 1758

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 11 – paragraph 2

Text proposed by the Commission

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service **only** one single **and appropriate** technical documentation shall be drawn up **for each product**, containing all the information set out in Annex IV as well as the information required under those legal acts.

Or. en

Amendment 1759

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona

Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa

**Proposal for a regulation
Article 11 – paragraph 2**

Text proposed by the Commission

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in *Annex IV* as well as the information required under those legal acts.

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service one single technical documentation shall be drawn up containing all the information set out in *paragraph 1* as well as the information required under those legal acts.

Or. en

**Amendment 1760
Andrea Caroppo, Salvatore De Meo**

**Proposal for a regulation
Article 11 – paragraph 2**

Text proposed by the Commission

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service *one single* technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.

Amendment

2. Where a high-risk AI system related to a product, to which the legal acts listed in Annex II, section A apply, is placed on the market or put into service *appropriate* technical documentation shall be drawn up containing all the information set out in Annex IV as well as the information required under those legal acts.

Or. en

**Amendment 1761
Axel Voss, Deirdre Clune, Eva Maydell**

**Proposal for a regulation
Article 11 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2 a. To ensure that a single technical documentation is possible, terms and definitions related to this required documentation and any required documentation in the appropriate Union sectoral legislation shall be aligned as much as possible;

Or. en

Amendment 1762

Jürgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 11 – paragraph 3

Text proposed by the Commission

Amendment

3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to amend Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the system with the requirements set out in this Chapter.

deleted

Or. en

Amendment 1763

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 11 – paragraph 3

Text proposed by the Commission

Amendment

3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to *amend* Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the

3. The Commission is empowered to adopt delegated acts in accordance with Article 73 to *add to* Annex IV where necessary to ensure that, in the light of technical progress, the technical documentation provides all the necessary information to assess the compliance of the

system with the requirements set out in this Chapter.

system with the requirements set out in this Chapter.

Or. fr

Amendment 1764

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 11 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

Or. en

Justification

moved up from Article 18.

Amendment 1765

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems *is* operating. Those logging capabilities shall conform to recognised standards or common specifications.

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems *are* operating. Those logging capabilities shall conform to recognised standards or common specifications. ***Where possible,***

these capabilities shall be local ones and the logs shall be stored on the medium employed by the user of the AI system.

Or. fr

Amendment 1766
Morten Løkkegaard

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Amendment

1. ***Where reasonably practicable*** high-risk AI systems, ***which are capable of changing behaviour during operation,*** shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Or. en

Justification

This article requires automatic recording of events (logs) while high-risk AI systems is operating. In the case where the AI is incapable of changing behaviour during the lifetime of the product, there is nothing supporting this requirement, so it is suggested that it only applies in case the AI in question is actually capable of changing behaviour. Furthermore, for machine manufacturers this requirement will be problematic and a big burden to implement, as approximately half of all the machines on the market are not online, making it unclear how to perform logging. One of the most basic recommendations regarding cyber security is not to connect your machines to the internet. This requirement will therefore risk making machines in Europe more exposed to cyber-attacks. Additionally, there might be examples where the logging of data is in conflict with legislation regarding data protection, such as GDPR or local Member State regulation, which makes the requirements for logging problematic.

Amendment 1767
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall ***be designed and developed with capabilities enabling*** the automatic recording of events ('logs') ***while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.***

1. High-risk AI systems shall ***technically allow*** the automatic recording of events ('logs') ***over the durations of the lifetime of the system.***

Or. en

Amendment 1768

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

1. High-risk AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating. Those logging capabilities shall conform to ***the state of the art and*** recognised standards or common specifications.

Or. en

Amendment 1769

Kosma Zlotowski, Patryk Jaki

Proposal for a regulation
Article 12 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed with ***capabilities enabling the automatic recording of events ('logs') while the high-risk AI systems is operating.*** Those logging

1. High-risk AI systems shall be designed and developed with ***appropriate technical and organizational measures to enable effective monitoring and human oversight*** by those ***using the system as well***

capabilities shall conform to recognised standards or common specifications.

as effective supervision by regulators.

Or. en

Amendment 1770

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

1. **High-risk** AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the **high-risk** AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Amendment

1. **All** AI systems shall be designed and developed with capabilities enabling the automatic recording of events ('logs') while the AI systems is operating. Those logging capabilities shall conform to recognised standards or common specifications.

Or. en

Amendment 1771

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. **The logging capabilities shall** ensure a level of traceability of the AI system's functioning **throughout its lifecycle that** is appropriate to the intended purpose of the system.

Amendment

2. **In order to** ensure a level of traceability of the AI system's functioning **which** is appropriate to the intended purpose of the system, **the logging capabilities shall enable the recording of events relevant for the identification of situations that may:**

(i) result in the AI system presenting a risk within the meaning of Article 65 (1); or

(ii) lead to a substantial modification that facilitates the post market monitoring referred to in Article 61.

Amendment 1772

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning ***throughout its lifecycle*** that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning that is appropriate to the intended purpose of the system. ***The storage period should be determined on the business needs and informational value, without exceeding a maximum of 10 fiscal years***

Or. en

Amendment 1773

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose ***or reasonably foreseeable use*** of the system.

Or. en

Amendment 1774

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning throughout its lifecycle that is appropriate to the intended purpose **or reasonably foreseeable use** of the system.

Or. en

Amendment 1775

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 12 – paragraph 2

Text proposed by the Commission

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning **throughout** its lifecycle that is appropriate to the intended purpose of the system.

Amendment

2. The logging capabilities shall ensure a level of traceability of the AI system's functioning **while the AI system is used within** its lifecycle that is appropriate to the intended purpose of the system.

Or. en

Amendment 1776

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 3

Text proposed by the Commission

3. ***In particular, logging capabilities shall enable the monitoring of the operation of the high-risk AI system with respect to the occurrence of situations that may result in the AI system presenting a risk within the meaning of Article 65(1) or lead to a substantial modification, and facilitate the post-***

Amendment

deleted

market monitoring referred to in Article 61.

Or. en

Amendment 1777

Kosma Złotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 12 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. For records constituting trade secrets as defined in Article 2 of Directive (EU) 2016/943, provider may elect to confidentially provide such trade secrets only to relevant public authorities to the extent necessary for such authorities to perform their obligations hereunder.

Or. en

Amendment 1778

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

Amendment

4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:

deleted

(a) recording of the period of each use of the system (start date and time and end date and time of each use);

(b) the reference database against which input data has been checked by the system;

(c) the input data for which the search has led to a match;

(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).

Or. en

Amendment 1779

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

Amendment

4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum: *deleted*

(a) recording of the period of each use of the system (start date and time and end date and time of each use);

(b) the reference database against which input data has been checked by the system;

(c) the input data for which the search has led to a match;

(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).

Or. en

Amendment 1780

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

Amendment

4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a *deleted*

minimum:

(a) recording of the period of each use of the system (start date and time and end date and time of each use);

(b) the reference database against which input data has been checked by the system;

(c) the input data for which the search has led to a match;

(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).

Or. en

Amendment 1781

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 – introductory part

Text proposed by the Commission

Amendment

4. For high-risk AI systems referred to in ***paragraph 1, point (a) of Annex III***, the logging capabilities shall provide, at a minimum:

4. For high-risk AI systems referred to in Annex III, the logging capabilities shall provide, at a minimum:

Or. en

Amendment 1782

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 12 – paragraph 4 – point a

Text proposed by the Commission

Amendment

(a) recording of the period of each use of the system (***start date and time and end date and time of each use***);

(a) recording of the period of each use of the system;

Amendment 1783

Brando Benifei, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Marc Angel

Proposal for a regulation

Article 12 – paragraph 4 – point c

Text proposed by the Commission

Amendment

(c) the input data for which the search has led to a match; **deleted**

Or. en

Justification

this and the previous amendment are consistent with the expansion of the prohibitions to remote biometric identification.

Amendment 1784

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. For high-risk self-learning AI systems the logging of self-learning shall be maintained. The logging shall provide, at a minimum:

- (a) the input data used for self-learning;**
- (b) the used algorithms of the input data interpretation;**
- (c) the results of self-learning.**

Or. en

Amendment 1785

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 12 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. Where a decision and/or proposal of decision is the outcome of an AI system, the logging shall cover information comprehensively sufficient for further human manual review of the decision/proposal with no need to refer to the AI system itself. The logging shall provide, at a minimum:

- (a) the input data;**
- (b) the reference database, if such present;**
- (c) the algorithms that could have been used;**
- (d) the algorithms that actually have been used;**
- (e) output data (decision and/or proposal);**
- (f) comprehensive mechanism of how the input data resulted into the output data.**

Or. en

Amendment 1786

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 12 – paragraph 4 c (new)

Text proposed by the Commission

Amendment

4 c. For all high-risk AI systems, including those mentioned in paragraphs 4–6 above, the logging shall provide, at a minimum:

- (a) log-in information (user, date, time, authentication type);**
- (b) the input data;**
- (c) the output data.**

Or. en

Amendment 1787

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 12 – paragraph 4 d (new)

Text proposed by the Commission

Amendment

4 d. The Commission is empowered to adopt delegated acts in accordance with Article 73 to define more minimum logging requirements for AI systems or their certain types.

Or. en

Amendment 1788

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – title

Text proposed by the Commission

Amendment

Transparency and provision of information
to **users**

Transparency and provision of information
to **deployers and AI subjects**

Or. en

Amendment 1789

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 1

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to **interpret** the system's **output and use it appropriately**. An appropriate type and degree of transparency shall be ensured, with a view

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to **reasonably understand** the system's **functioning**. An appropriate type and degree of transparency shall be ensured, **depending**

to achieving compliance with the relevant obligations of the user and of the provider set out in **Chapter 3** of this Title.

on the intended purpose of the system, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in **Article 16 and Article 29** of this Title. ***The explanation shall be provided at least in the language of the country where the AI system is deployed.***

Transparency shall thereby mean that, to the extent that can be reasonably expected and is feasible in technical terms at the time when the AI system is placed on the market, the AI system is interpretable to the provider, in that the provider can understand the rationale of decisions taken by the high risk AI system, while enabling the user to understand and use the AI system appropriately, by generally knowing how the AI system works and what data it processes.

Or. en

Amendment 1790

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Catharina Rinzema, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title.

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable users to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the user and of the provider set out in Chapter 3 of this Title. ***Transparency shall thereby mean that, to the extent that can be reasonably expected and is feasible in technical terms, the AI systems output is interpretable by the user and the user is able to understand the***

general functionality of the AI system and its use of data.

Or. en

Amendment 1791

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 13 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable **users** to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the **user** and of the provider set out in Chapter 3 of this Title.

Amendment

1. High-risk AI systems shall be designed and developed in such a way to ensure that their operation is sufficiently transparent to enable **deployers** to interpret the system's output and use it appropriately. An appropriate type and degree of transparency shall be ensured, with a view to achieving compliance with the relevant obligations of the **deployer** and of the provider set out in Chapter 3 of this Title. *Where individuals are passively subject to AI systems (AI subjects), information to ensure an appropriate type and degree of transparency shall be made publicly available, with full respect to the privacy, personality, and related rights of subjects.*

Or. en

Amendment 1792

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, **complete**, correct and

Amendment

2. High-risk AI systems shall be accompanied by **comprehensible** instructions for use in an appropriate digital format or **made** otherwise **available**

clear information that *is* relevant,
accessible and comprehensible to users.

that include concise, correct and clear
information that *helps supporting
informed decision-making by users and is
reasonably* relevant, accessible and
comprehensible to users.

Or. en

Amendment 1793

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 13 – paragraph 2

Text proposed by the Commission

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to users.

Amendment

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that *helps supporting informed decision-making by users and is* relevant, accessible and comprehensible to users.

Or. en

Amendment 1794

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – paragraph 2

Text proposed by the Commission

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, complete, correct and clear information that is relevant, accessible and comprehensible to *users*.

Amendment

2. High-risk AI systems shall be accompanied by instructions for use in an appropriate digital format or otherwise that include concise, *statistically* complete, correct and clear information that is relevant, accessible and comprehensible to *deployers*.

Or. en

Amendment 1795

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – introductory part

Text proposed by the Commission

3. The information referred to in paragraph 2 shall specify:

Amendment

3. ***To the extent necessary to achieve the outcomes referred to in paragraph 1,*** the information referred to in paragraph 2 shall specify:

Or. en

Amendment 1796

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point a

Text proposed by the Commission

(a) the identity and the contact details of the provider ***and***, where applicable, of ***its*** authorised representative;

Amendment

(a) the identity and the contact details of the provider, where applicable, of ***their*** authorised representative;

Or. en

Amendment 1797

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – introductory part

Text proposed by the Commission

(b) the ***characteristics***, capabilities and limitations of performance of the high-risk AI system, including:

Amendment

(b) the capabilities and limitations of performance of the high-risk AI system ***that are relevant to the material risks associated with the intended purpose,*** including ***where appropriate***:

Or. en

Amendment 1798

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Amendment

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity, ***including an overview of the capabilities and performance metrics of the AI system, and of representative use cases based on the intended purpose;***

Or. en

Amendment 1799

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of ***accuracy***, robustness and cybersecurity;

Amendment

(ii) ***the performance metrics and its appropriateness, including*** the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of ***performance***, robustness and cybersecurity;

Or. en

Justification

This amendment is necessary as Article 13 is referred to in Article 9 and in Article 29, i.e. it is relevant for risk management and for the obligations placed on users. "The most appropriate risk management measures" in Article 9 (4) cannot be identified if Article 13 is not amended. In addition, we are introducing amendments to the obligations of providers in Article 16 and these should be reflected in Article 13 as well, in order to ensure consistency of the provisions.

Amendment 1800

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 13 – paragraph 3 – point b – point ii

Text proposed by the Commission

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Amendment

(ii) the level of accuracy, robustness and cybersecurity referred to in Article 15 against which the high-risk AI system has been tested and validated ***before being placed on the market*** and which can be expected, and any known and foreseeable circumstances that may have an impact on that expected level of accuracy, robustness and cybersecurity;

Or. fr

Amendment 1801

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 13 – paragraph 3 – point b – point iii

Text proposed by the Commission

(iii) ***any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;***

Amendment

deleted

Justification

This aspect is misplaced under this Article and should rather be part of the risk assessment.

Amendment 1802

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation**Article 13 – paragraph 3 – point b – point iii***Text proposed by the Commission*

(iii) ***any*** known or foreseeable ***circumstance***, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights;

Amendment

(iii) ***the*** known or foreseeable ***circumstances***, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health and safety or fundamental rights, ***including, where appropriate, illustrative examples of such limitations and of scenarios for which the system should not be used;***

Or. en

Amendment 1803

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation**Article 13 – paragraph 3 – point b – point iii***Text proposed by the Commission*

(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, which may lead to risks to the health ***and*** safety ***or*** fundamental rights;

Amendment

(iii) any known or foreseeable circumstance, related to the use of the high-risk AI system in accordance with its intended purpose or under conditions of reasonably foreseeable ***use or*** misuse, which may lead to risks to the health, safety, fundamental rights, ***the environment, or democracy;***

Or. en

Amendment 1804

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point b – point v

Text proposed by the Commission

(v) *when appropriate, specifications for the* input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.

Amendment

(v) *relevant information about user actions that may influence system performance, including type or quality of* input data, or any other relevant information in terms of the training, validation and testing data sets used, taking into account the intended purpose of the AI system.

Or. en

Amendment 1805

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation

Article 13 – paragraph 3 – point b – point v

Text proposed by the Commission

(v) when appropriate, specifications for the input data, or any other relevant information in terms of the *training, validation and testing* data sets used, taking into account the intended purpose of the AI system.

Amendment

(v) when appropriate, specifications for the input data, or any other relevant information in terms of the data sets used, *including their limitation and assumptions*, taking into account the intended purpose, *the foreseeable and reasonably foreseeable misuses* of the AI system.

Or. en

Justification

This amendment is necessary as Article 13 is referred to in Article 9 and in Article 29, i.e. it is relevant for risk management and for the obligations placed on users. "The most appropriate risk management measures" in Article 9 (4) cannot be identified if Article 13 is not amended. In addition, we are introducing amendments to the obligations of providers in Article 16 and these should be reflected in Article 13 as well, in order to ensure consistency of the

provisions.

Amendment 1806

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – paragraph 3 – point d

Text proposed by the Commission

(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the **users**;

Amendment

(d) the human oversight measures referred to in Article 14, including the technical measures put in place to facilitate the interpretation of the outputs of AI systems by the **deployers**;

Or. en

Amendment 1807

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) a description of the mechanisms included within the AI system that allow users to properly collect, store and interpret the logs in accordance with Art 12(1), where relevant.

Or. en

Amendment 1808

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) a description of the mechanisms included within the AI system that allow users to properly collect, store and interpret the logs in accordance with Article 12(1).

Or. en

Amendment 1809

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(e a) the level of extraction and consumption of natural resources.

Or. en

Amendment 1810

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 13 a (new)

Text proposed by the Commission

Amendment

Article 13 a

Transparency for affectees of AI systems

1) High-risk AI systems shall be designed, developed and used in such a way that an affectee can obtain an explanation from the developer and user for any decision taken or supported by a high-risk AI system that significantly affects the affectee;

2) Providers and users of high-risk AI systems shall provide access to the person of persons designated with the exercise of 'human oversight' as described in Art. 14 to discuss and to clarify the facts, circumstances and reasons having led to

the decision by the AI system;

3) Providers and users of high-risk AI systems shall provide the affectee with a written statement of the reasons for any decision taken or supported by a high-risk AI system;

4) Where the affectee is not satisfied with the explanation or the written statement of reasons obtained or consider that the decision referred to in paragraph (1) jeopardizes their health, safety or fundamental rights, the provider or user, as the case may be, shall review that decision, upon reasonable request by the affectee. The provider or user, as the case maybe, shall respond to such request by providing the affectee with a substantiated reply without undue delay and in any event within one week of receipt of the request.

Or. en

Amendment 1811

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation Article 14 – paragraph 1

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they ***can be effectively overseen*** by natural persons during the ***period in which*** the AI system ***is in use***.

Amendment

1. ***Where proportionate to the risks associated with the high-risk system and where technical safeguards are not sufficient***, high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they ***allow informed oversight*** by natural persons during the ***expected lifetime of the device***. ***Oversight capabilities should be tailored to the AI system's intended purpose and the context of use and take into account cases where human oversight may compromise the correct and safe functioning of the AI system.***

Amendment 1812

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

**Proposal for a regulation
Article 14 – paragraph 1**

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Amendment

1. ***Where proportionate to the risks associated with the high-risk system and where technical safeguards are not sufficient,*** high-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Amendment 1813

Krzysztof Hetman, Adam Jarubas, Andrzej Halicki, Jerzy Buzek, Janusz Lewandowski, Radosław Sikorski

**Proposal for a regulation
Article 14 – paragraph 1**

Text proposed by the Commission

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.

Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use, ***where required by the risk analysis as foreseen in the product legislations listed in Annex II.***

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Text proposed by the Commission

Amendment

1. High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use, *and to allow for thorough investigation after an incident.*

Or. en

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Text proposed by the Commission

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, ***in particular when such*** risks persist notwithstanding the application of other requirements set out in this Chapter.

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, ***provided that those risks, if they persist notwithstanding the application of other requirements set out in this Chapter, do not result in a requirement for the high-risk AI system to be recalled or withdrawn.***

Or. fr

Pernando Barrena Arza, Cornelia Ernst, Kateřina Konečná

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when **a high-risk AI system is** used in accordance with **its intended purpose** or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when **AI systems that pose risks to health and safety or fundamental rights or AI systems subjected to the transparency obligations ex Article 52 are** used in accordance with **their foreseeable uses** or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Amendment 1817

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission

2. Human oversight shall aim at preventing or minimising the risks to health, safety **or** fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety, fundamental rights, **democracy, or the environment** that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable **use or** misuse, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Amendment 1818

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

**Proposal for a regulation
Article 14 – paragraph 2**

Text proposed by the Commission

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose ***or under conditions of reasonably foreseeable misuse***, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Amendment

2. Human oversight shall aim at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose, in particular when such risks persist notwithstanding the application of other requirements set out in this Chapter.

Or. en

Justification

Misuse should not be part of the compliance system. Preventing it should be/is part of robustness and security requirements.

Amendment 1819

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 14 – paragraph 3 – introductory part**

Text proposed by the Commission

3. Human oversight shall be ensured through either one or all of the following measures:

Amendment

3. ***The degree of*** human oversight ***shall be adapted to the specific risks, the level of automation, and context of the AI system and*** shall be ensured through either one or all of the following ***types of*** measures:

Or. en

Amendment 1820

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

3. Human oversight shall be ensured through either one or all of the following measures:

Amendment

3. ***The degree of*** human oversight ***shall be adapted to the specific risks, the level of automation, and context of the AI system and*** shall be ensured through either one or all of the following measures:

Or. en

Amendment 1821

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 14 – paragraph 3 – introductory part

Text proposed by the Commission

3. Human oversight shall be ensured through either one or ***all*** of the following ***measures***:

Amendment

3. Human oversight shall be ensured through either one or ***both*** of the following:

Or. en

Amendment 1822

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 14 – paragraph 3 – point a

Text proposed by the Commission

(a) identified ***and built***, when technically feasible, into the high-risk AI system ***by the provider*** before it is placed on the market or put into service;

Amendment

(a) ***measures*** identified ***by the provider building human oversight***, when technically feasible, into the high-risk AI system before it is placed on the market or put into service;

Or. en

Amendment 1823

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point a

Text proposed by the Commission

(a) identified and built, when technically feasible, into the high-risk AI system by the provider before it is placed on the market or put into service;

Amendment

(a) identified and built, when technically feasible **and appropriate**, into the high-risk AI system by the provider before it is placed on the market or put into service;

Or. en

Amendment 1824

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 14 – paragraph 3 – point b

Text proposed by the Commission

(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the **user**.

Amendment

(b) **other measures** identified by the provider before placing the high-risk AI system on the market or putting it into service and that are appropriate to be implemented by the **deployer, such as user guides**.

Or. en

Amendment 1825

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b

Text proposed by the Commission

(b) identified by the provider before placing the high-risk AI system on the market or putting it into service and that

Amendment

(b) identified by the provider **operationalized** before placing the high-risk AI system on the market or putting it

are appropriate to be implemented by the user.

into service and that are appropriate to be implemented by the user;

Or. en

Amendment 1826

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b a (new)

Text proposed by the Commission

Amendment

(b a) required of the user, if appropriate, for their implementation;

Or. en

Amendment 1827

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 3 – point b b (new)

Text proposed by the Commission

Amendment

(b b) included during the development, testing, or monitoring processes.

Or. en

Amendment 1828

Barbara Thaler, Lukas Mandl, Axel Voss, Deirdre Clune

Proposal for a regulation

Article 14 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The commission, in accordance with the relevant stakeholders, shall provide comprehensive guidelines, in order to clarify the required form of human supervision for high-risk AI

systems.

Or. en

Amendment 1829

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – introductory part

Text proposed by the Commission

4. *The measures referred to in paragraph 3 shall enable the individuals* to whom human oversight is assigned *to do* the following, as appropriate to the circumstances:

Amendment

4. *For the purpose of implementing paragraphs 1 to 3, the high-risk AI system shall be provided to the user in such a way that natural persons* to whom human oversight is assigned *can* do the following, as appropriate *and proportionate* to the circumstances *and instructions for use and in accordance with industry standards*:

Or. en

Amendment 1830

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – introductory part

Text proposed by the Commission

4. *The measures referred to in paragraph 3 shall enable* the individuals to whom human oversight is assigned *to do the following*, as appropriate to the circumstances:

Amendment

4. *For the purpose of implementing paragraphs 1 to 3, the high-risk AI system shall be provided to the user in such a way that* the individuals to whom human oversight is assigned *are enabled* as appropriate *and proportionate*, to the circumstances *and in accordance with industry standards*:

Or. en

Amendment 1831

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point a

Text proposed by the Commission

(a) **fully** understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Amendment

(a) **to be aware and sufficiently** understand the **relevant** capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Or. en

Amendment 1832

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point a

Text proposed by the Commission

(a) **fully** understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Amendment

(a) **to be aware of and sufficiently** understand the capacities and limitations of the high-risk AI system and be able to duly monitor its operation, so that signs of anomalies, dysfunctions and unexpected performance can be detected and addressed as soon as possible;

Or. en

Amendment 1833

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

Amendment

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), ***in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons***;

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias');

Or. en

Amendment 1834

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), ***in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons***;

Amendment

(b) remain aware of the possible tendency of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias');

Or. en

Amendment 1835

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 14 – paragraph 4 – point b

Text proposed by the Commission

(b) ***remain aware of the possible tendency*** of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural

Amendment

(b) ***mitigate the risk*** of automatically relying or over-relying on the output produced by a high-risk AI system ('automation bias'), in particular for high-risk AI systems used to provide information or recommendations for decisions to be taken by natural persons;

persons;

Or. en

Amendment 1836

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point c

Text proposed by the Commission

(c) ***be able*** to correctly interpret the high-risk AI system's output, taking into account ***in particular the characteristics of the system and*** the interpretation tools and methods available;

Amendment

(c) to correctly interpret the high-risk AI system's output, taking into account ***for example*** the interpretation tools and methods available;

Or. en

Amendment 1837

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point c

Text proposed by the Commission

(c) be able to correctly interpret the high-risk AI system's output, taking into account ***in particular the characteristics of the system and*** the interpretation tools and methods available;

Amendment

(c) be able to correctly interpret the high-risk AI system's output, taking into account, ***for example***, the interpretation tools and methods available;

Or. en

Amendment 1838

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point d

Text proposed by the Commission

Amendment

(d) be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

(d) **to** be able to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Or. en

Amendment 1839

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 14 – paragraph 4 – point d

Text proposed by the Commission

Amendment

(d) be **able** to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

(d) be **free** to decide, in any particular situation, not to use the high-risk AI system or otherwise disregard, override or reverse the output of the high-risk AI system;

Or. en

Amendment 1840

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 4 – point e

Text proposed by the Commission

Amendment

(e) be able to intervene on the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure.

(e) be able to intervene on the operation of the high-risk AI system or interrupt, **where reasonable and technically feasible**, the system through a “stop” button or a similar procedure, **except if the human interference increases the risk or would negatively impact the performance in consideration of generally acknowledge state-of-the-art.**

Or. en

Amendment 1841

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 14 – paragraph 4 – point e

Text proposed by the Commission

(e) be able to intervene on the operation of the high-risk AI system or interrupt the system *through a “stop” button or a similar procedure.*

Amendment

(e) **to** be able to intervene on the operation of the high-risk AI system, **halt** or interrupt the system **where reasonable and technically feasible and except if the human interference increases the risks or would negatively impact the performance in consideration of generally acknowledged state-of-the-art.**

Or. en

Amendment 1842

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 14 – paragraph 4 – point e

Text proposed by the Commission

(e) be able to intervene **on** the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure.

Amendment

(e) be able to intervene **in** the operation of the high-risk AI system or interrupt the system through a “stop” button or a similar procedure **that allows the system to come to a halt in a safe state.**

Or. en

Amendment 1843

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 5

Text proposed by the Commission

Amendment

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been *separately* verified and confirmed by at least two natural persons *on-site or remotely, except for temporary actions or decisions which cannot be delayed due to safety or security reasons for the purpose of law enforcement*.

Or. en

Amendment 1844

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons.

Amendment

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the user on the basis of the identification resulting from the system unless this has been verified and confirmed by at least two natural persons *separately*.

Or. en

Amendment 1845

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation Article 14 – paragraph 5

Text proposed by the Commission

5. For high-risk AI systems referred to in point 1(a) of Annex III, the measures

Amendment

5. For high-risk AI systems referred to in point 1(a) *and 1(b)* of Annex III, the

referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the **user** on the basis of the **identification resulting** from the system unless this has been verified and confirmed by at least two natural persons.

measures referred to in paragraph 3 shall be such as to ensure that, in addition, no action or decision is taken by the **deployer** on the basis of the **output** from the system unless this has been verified and confirmed by at least two natural persons.

Or. en

Amendment 1846

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. For the purpose of implementing paragraph 2, in the case where the result of an identification is inconclusive, the human oversight requirements from paragraphs 3 to 5 shall be performed directly internally by the closest entity to the user in the supply chain of the high-risk AI system.

Or. en

Amendment 1847

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 14 – paragraph 5 b (new)

Text proposed by the Commission

Amendment

5 b. With the exception of high-risk AI systems referred to in point 1(a) of Annex III, the measures referred to in paragraph 3 shall not be interpreted as requiring a human to review every action or decision taken by the AI system. Full automation of such systems shall be possible provided that technical measures are put in place to comply with provisions in paragraphs 1 to 4.

Amendment 1848**Axel Voss, Deirdre Clune, Eva Maydell****Proposal for a regulation****Article 15 – paragraph 1***Text proposed by the Commission*

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their *lifecycle*.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose ***and to the extent that can be reasonably expected and is in accordance with relevant industry standards***, an appropriate level of accuracy, ***reliability***, robustness and cybersecurity, and ***the basic pillars of information security and protection, such as confidentiality, integrity and availability as well as to*** perform consistently in those respects throughout their ***lifetime while taking their evolving nature into account***.

Amendment 1849**Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini****Proposal for a regulation****Article 15 – paragraph 1***Text proposed by the Commission*

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, ***the foreseeable uses and reasonably foreseeable misuses***, an appropriate level of ***performance (such as accuracy, reliability and true positive rate)***, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Justification

Consequential amendment related to our amendments of Annex IV. It is needed to ensure consistency of the provisions throughout the text.

Amendment 1850

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation**Article 15 – paragraph 1***Text proposed by the Commission*

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose ***and to the extent that can be reasonably expected and is in accordance with relevant industry standards***, an appropriate level of accuracy, robustness and cybersecurity, and perform consistently in those respects throughout their lifecycle.

Or. en

Amendment 1851

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation**Article 15 – paragraph 1***Text proposed by the Commission*

1. High-risk AI systems shall be designed and developed in such a way that they achieve, in the light of their intended purpose, an appropriate level of accuracy, robustness and cybersecurity, ***and perform consistently in those respects*** throughout their lifecycle.

Amendment

1. High-risk AI systems shall be designed and developed in such a way that they achieve ***security by design and by default***, in the light of their intended purpose, an appropriate level of accuracy, ***reliability***, robustness, ***resilience, safety*** and cybersecurity throughout their lifecycle.

Amendment 1852

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. To address the technical aspects of how to measure the appropriate levels of accuracy and robustness in paragraph 1, the European Artificial Intelligence Board shall bring together national metrology and benchmarking authorities and provide non-binding guidance on the matter as per Article 56(2a) of this Regulation.

Or. en

Amendment 1853

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 2

Text proposed by the Commission

Amendment

2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be ***assessed by an independent entity and*** declared in the accompanying instructions of use. ***The language used shall be clear, free of misunderstandings or misleading statements.***

Or. en

Amendment 1854

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar,

Maria Grapini

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. The levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

Amendment

2. ***The performance metrics and its appropriateness, including*** the levels of accuracy and the relevant accuracy metrics of high-risk AI systems shall be declared in the accompanying instructions of use.

Or. en

Justification

Consequential amendment related to our amendments of Annex IV. It is needed to ensure consistency of the provisions throughout the text.

Amendment 1855

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. The ***levels of accuracy*** and the ***relevant accuracy metrics of high-risk AI systems*** shall be declared in the accompanying instructions of use.

Amendment

2. The ***range of expected performance*** and the ***operational factors that affect that performance***, shall be declared, ***where possible***, in the accompanying instructions of use.

Or. en

Amendment 1856

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. The ***levels of accuracy*** and the ***relevant accuracy metrics of high-risk AI***

Amendment

2. The ***range of expected performance*** and the ***operational factors***

systems shall be declared in the accompanying instructions of use.

that affect that performance shall be declared in the accompanying instructions of use.

Or. en

Amendment 1857

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be **resilient** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be **designed and developed with safety and security by design mechanism by default so that they achieve, in the light of their intended purpose, an appropriate level of cyber resilience** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 1858

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be **resilient** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be **designed and developed with safety and security-by-design mechanism so that they achieve, in the light of their intended purpose, an appropriate level of cyber resilience** as regards **to** errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their

interaction with natural persons or other systems.

Or. en

Amendment 1859

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 3 – introductory part

Text proposed by the Commission

3. High-risk AI systems shall be **resilient** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Amendment

3. High-risk AI systems shall be **robust** as regards errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, in particular due to their interaction with natural persons or other systems.

Or. en

Amendment 1860

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission

The robustness of high-risk AI systems may be achieved through technical redundancy solutions, which may include backup or fail-safe plans.

Amendment

The robustness of high-risk AI systems may be achieved through **diverse** technical redundancy solutions, which may include **reasonably designed** backup or fail-safe plans **by the appropriate provider or user or as mutually agreed by the provider and the user**.

Or. en

Amendment 1861

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

High-risk AI systems that continue to learn after being ***placed on the market or*** put into service shall ***be developed in such a way to*** ensure that ***possibly*** biased outputs ***due to outputs used as an input for future operations ('feedback loops')*** are duly addressed with appropriate mitigation measures.

Amendment

High-risk AI systems that continue to learn after being put into service shall ensure that ***'feedback loops' caused by*** biased outputs ***are adequately*** addressed with appropriate mitigation measures.

Or. en

Amendment 1862

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ***due to outputs used as*** an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

Amendment

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ***influencing*** an input for future operations ('feedback loops') are duly addressed with appropriate mitigation measures.

Or. en

Amendment 1863

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ***due to outputs used as an*** input for future operations (‘feedback loops’) are duly addressed with appropriate mitigation measures.

High-risk AI systems that continue to learn after being placed on the market or put into service shall be developed in such a way to ensure that possibly biased outputs ***influencing*** input for future operations (‘feedback loops’) are duly addressed with appropriate mitigation measures.

Or. en

Amendment 1864

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 15 – paragraph 3 – subparagraph 2 a (new)

Text proposed by the Commission

Amendment

It shall be possible for the user, the provider, the national competent authority or authorities and the Commission, as appropriate, to audit and reproduce the functioning of the high-risk AI systems.

Or. fr

Amendment 1865

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. In accordance with Article 42 (2), the compliance with Article 15 for high-risk AI systems that have already been certified or for which a statement of conformity has been issued under a cybersecurity scheme pursuant to Regulation (EU) 2019/881 shall be assumed.

Or. en

Amendment 1866

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 4 – introductory part

Text proposed by the Commission

4. High-risk AI systems shall be ***resilient as regards*** attempts by unauthorised third parties to alter their use or performance ***by exploiting the system vulnerabilities***.

Amendment

4. High-risk AI systems shall be ***adequately protected against*** attempts by unauthorised third parties to alter their use or performance.

Or. en

Amendment 1867

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The technical solutions aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Amendment

The technical solutions aimed at ensuring ***and organisational measures designed to uphold*** the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Or. en

Amendment 1868

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The technical solutions ***aimed at ensuring*** the cybersecurity of high-risk AI systems shall be appropriate to the relevant

Amendment

The technical solutions ***and organisational measures designed to uphold*** the cybersecurity of high-risk AI systems shall

circumstances and the risks.

be appropriate to the relevant
circumstances and the risks.

Or. en

Amendment 1869

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 1

Text proposed by the Commission

The technical **solutions** aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Amendment

The technical **and organisational measures** aimed at ensuring the cybersecurity of high-risk AI systems shall be appropriate to the relevant circumstances and the risks.

Or. en

Amendment 1870

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission

The technical solutions **to address AI specific vulnerabilities shall** include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset (‘data poisoning’), inputs designed to cause the model to make a mistake (‘adversarial examples’), or model flaws.

Amendment

The technical solutions **may** include, where appropriate, measures to prevent and control for attacks trying to manipulate the training dataset (‘data poisoning’), inputs designed to cause the model to make a mistake (‘adversarial examples’), or model flaws, **or exploratory attacks that may aim to extract knowledge, algorithms, trade secrets or training information from the AI.**

Or. en

Amendment 1871

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 4 – subparagraph 2

Text proposed by the Commission

The technical **solutions** to address AI specific vulnerabilities shall include, where appropriate, measures to prevent and control **for** attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Amendment

The technical **and organisational measures** to address AI specific vulnerabilities shall include **at least**, where appropriate, measures to prevent and control attacks trying to manipulate the training dataset ('data poisoning'), inputs designed to cause the model to make a mistake ('adversarial examples'), or model flaws.

Or. en

Amendment 1872

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 15 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. High risk AI shall be accompanied by security solutions and patches for the lifetime of the product it is embedded in, or in case of the absence of dependence on a specific product, for a time that needs to be stated by the manufacturer and cannot be less than 10 years.

Or. en

Amendment 1873

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 15 a (new)

Article 15 a

Sustainable AI systems reporting

1. Providers of high-risk AI systems shall make publicly available information on the energy consumption of the AI system, in particular its carbon footprint with regard to the development of hardware, computational resources, as well as algorithm design and training, testing and validating processes of the high-risk AI systems. The provider shall include this information in the technical documentation referred to in Article 11.

2. The Commission shall develop, by means of an implementing act, a standardised document to facilitate the disclosure of information on the energy used in the training and execution of AI systems and their carbon intensity.

Or. en

Amendment 1874

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Title III – Chapter 3 – title

3 OBLIGATIONS OF PROVIDERS
AND **USERS** OF HIGH-RISK AI
SYSTEMS and other parties

3 OBLIGATIONS OF PROVIDERS
AND **DEPLOYERS** OF HIGH-RISK AI
SYSTEMS and other parties

Or. en

Amendment 1875

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 16 – title

Text proposed by the Commission

Amendment

Obligations of providers of high-risk AI systems

Obligations of providers **and deployers** of high-risk AI systems

Or. en

Amendment 1876

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

Providers of high-risk AI systems shall:

As long as providers of high-risk AI systems ***exercise full control over the systems, they*** shall:

Or. en

Amendment 1877

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 16 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

Providers of high-risk AI systems shall:

Providers ***and, where applicable, deployers*** of high-risk AI systems shall:

Or. en

Amendment 1878

Kosma Zlotowski, Eugen Jurzyca, Patryk Jaki, Adam Bielan

Proposal for a regulation

Article 16 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) ensure that their high-risk AI

(a) ensure that their high-risk AI

systems are compliant with the requirements set out in Chapter 2 of this Title;

systems are compliant with the requirements set out in Chapter 2 of this Title *before placing them on the market or putting them into service, and shall be responsible for compliance of these systems after that point only to the extent that they exercise actual control over relevant aspects of the system*;

Or. en

Amendment 1879

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point a

Text proposed by the Commission

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

Amendment

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title *before placing them on the market or putting them into service*;

Or. en

Amendment 1880

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 16 – paragraph 1 – point a

Text proposed by the Commission

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title;

Amendment

(a) ensure that their high-risk AI systems are compliant with the requirements set out in Chapter 2 of this Title *as long as the provider exercise control over the AI systems*;

Or. en

Amendment 1881

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) indicate their name, registered trade name or registered trade mark, the address at which they can be contacted on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as applicable;

Or. en

Amendment 1882

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, Petar Vitanov, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) indicate their name, registered trade name or registered trade mark, and their address on the high-risk AI system or, where that is not possible, on its packaging or its accompanying documentation, as appropriate;

Or. en

Amendment 1883

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) ensure that the performance of

their high-risk AI system is measured appropriately, including its level of accuracy, robustness and cybersecurity;

Or. en

Amendment 1884

Sophia in 't Veld, Michal Šimečka

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) ensure that, in the case of a general purpose AI system, the reasonably foreseeable uses of this system are assessed.

Or. en

Amendment 1885

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 16 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) include name and contact information;

Or. en

Amendment 1886

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Marina Kaljurand, Maria Grapini, Brando Benifei

Proposal for a regulation

Article 16 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) provide specifications for the input data, or any other relevant information in terms of the data sets used, including their limitation and assumptions, taking into account of the intended purpose and the foreseeable and reasonably foreseeable misuses of the AI system;

Or. en

Amendment 1887

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 16 – paragraph 1 – point c

Text proposed by the Commission

(c) draw-up the technical documentation of the high-risk AI system;

Amendment

(c) draw-up the technical documentation of the high-risk AI system *referred to in Article 18*;

Or. en

Amendment 1888

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point c

Text proposed by the Commission

(c) *draw-up the technical documentation of the high-risk AI system*;

Amendment

(c) *keep the* documentation *referred to in Article 18*;

Or. en

Amendment 1889

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

(d) when under their control, keep the logs automatically generated by their high-risk AI systems;

Amendment

(d) when under their control, keep the logs automatically generated by their high-risk AI systems ***for a period of at least two years, or as long as is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law;***

Or. en

Amendment 1890

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

(d) when under their control, keep the logs automatically generated by their high-risk AI systems;

Amendment

(d) when under their control, keep the logs automatically generated by their high-risk AI systems, ***in accordance with Article 20;***

Or. en

Amendment 1891

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 16 – paragraph 1 – point d

Text proposed by the Commission

(d) ***when under their control,*** keep the logs automatically generated by their high-risk AI systems;

Amendment

(d) keep the logs automatically generated by their high-risk AI systems ***as referred to in Article 20;***

Or. en

Amendment 1892

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure prior to its placing on the market or putting into service, **and ensure it is periodically reviewed;**

Or. fr

Amendment 1893

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure **as referred to in Article 43**, prior to its placing on the market or putting into service;

Or. en

Amendment 1894

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant **conformity** assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ensure that the high-risk AI system undergoes the relevant **independent third party** assessment procedure, prior to its placing on the market or putting into service;

Amendment 1895

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ensure that the high-risk AI system undergoes the relevant ***third party*** conformity assessment procedure, prior to its placing on the market or putting into service;

Or. en

Amendment 1896

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service;

Amendment

(e) ensure that the high-risk AI system undergoes the relevant conformity assessment procedure, prior to its placing on the market or putting into service ***or use***;

Or. en

Amendment 1897

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point e

Text proposed by the Commission

(e) ***ensure that the high-risk AI system undergoes*** the relevant conformity

Amendment

(e) ***carry out*** the relevant conformity assessment procedure, ***as provided for in***

assessment procedure, prior to its placing on the market or putting into service;

Article 19, prior to its placing on the market or putting into service;

Or. en

Amendment 1898

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) take the necessary corrective **actions**, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Amendment

(g) take the necessary corrective **action**, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title, ***before the high-risk AI system concerned is placed on the market, made available on the market or put into service, or before a high-risk AI system that has been withdrawn or recalled is placed on the market, made available on the market or put into service once again;***

Or. fr

Amendment 1899

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Amendment

(g) take the necessary corrective actions ***as referred to in Article 21***, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1900

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point g

Text proposed by the Commission

(g) take the necessary corrective actions, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Amendment

(g) take the necessary corrective actions ***as referred to in Art 21***, if the high-risk AI system is not in conformity with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1901

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point i

Text proposed by the Commission

(i) ***to*** affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;

Amendment

(i) affix the CE marking to their high-risk AI systems to indicate the conformity with this Regulation in accordance with Article 49;

Or. en

Amendment 1902

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 16 – paragraph 1 – point j

Text proposed by the Commission

(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Amendment

(j) upon ***reasoned*** request of a national competent authority, ***provide the relevant information and documentation to*** demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Amendment 1903

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 16 – paragraph 1 – point j

Text proposed by the Commission

(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Amendment

(j) upon request of **a national supervisory authority or** a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title.

Or. en

Amendment 1904

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 16 – paragraph 1 – point j

Text proposed by the Commission

(j) upon request of a national competent authority, demonstrate the conformity of the high-risk AI system **with the requirements set out in Chapter 2 of this Title.**

Amendment

(j) upon **reasoned** request of a national competent authority, **provide the relevant information and documentation to** demonstrate the conformity of the high-risk AI system.

Or. en

Amendment 1905

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point j a (new)

Text proposed by the Commission

Amendment

(j a) refrain from placing on the market or putting into service a High-Risk AI system that:

(i) is not in conformity with the requirements set out in Chapter 2 of this Title; or

(ii) poses a risk of harm to health, safety or fundamental rights despite its conformity with the requirements set out in Chapter 2 of this Title.

Or. en

Amendment 1906

Rob Rooker

on behalf of the ECR Group

Proposal for a regulation

Article 16 – paragraph 1 – point j a (new)

Text proposed by the Commission

Amendment

(j a) conduct and publish a fundamental rights impact assessment.

Or. en

Amendment 1907

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 16 – paragraph 1 – point j b (new)

Text proposed by the Commission

Amendment

(j b) ensure that the individual to whom human oversight is assigned shall either be fully independent from the provider or user or, be adequately protected against negative consequences for their position within the organisation, resulting from or related to their exercise of human oversight.

Or. en

Amendment 1908
Vincenzo Sofo, Kosma Zlotowski

Proposal for a regulation
Article 16 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The obligations contained in paragraph 1 shall be without prejudice to obligations applicable to providers of high-risk AI systems arising from Regulation (EU) 2016/679 of the European Parliament and of the Council and Regulation (EU) 2018/1725 of the European Parliament and of the Council

Or. en

Amendment 1909
Salima Yenbou, Samira Rafaela, Monica Semedo, Karen Melchior, Peter Pollák

Proposal for a regulation
Article 16 a (new)

Text proposed by the Commission

Amendment

Article 16 a

Obligations of users of high-risk AI systems

Users of high-risk AI systems shall conduct and publish a fundamental rights impact assessment, detailing specific information relating to the context of use of the high-risk AI system in question, including:

- (a) the affected persons,***
- (b) intended purpose,***
- (c) geographic and temporal scope,***
- (d) assessment of the legality and fundamental rights impacts of the system,***
- (e) compatibility with accessibility legislation,***

(f) potential direct and indirect impact on fundamental rights,

(g) any specific risk of harm likely to impact marginalised persons or those at risk of discrimination,

(h) the foreseeable impact of the use of the system on the environment,

(i) any other negative impact on the public interest,

(j) clear steps as to how the harms identified will be mitigated and how effective this mitigation is likely to be.

Or. en

Amendment 1910

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Amendment

1. ***Unless existing risk management systems are already in place to warrant the quality of the high-risk AI systems,*** providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1911

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall **put** a quality management system **in place that ensures** compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Amendment

1. ***In case there are no risk management systems already in place,*** providers ***and users*** of high-risk AI systems shall ***implement*** a quality management system ***to ensure*** compliance with this Regulation ***and corresponding obligations***. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1912

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Amendment

1. Providers ***and, where applicable, deployers*** of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1913

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems

Amendment

1. Providers of high-risk AI systems

shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

shall put a quality management system in place, ***certified by an independent third party*** that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall include at least the following aspects:

Or. en

Amendment 1914

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures ***and*** instructions, and shall include at least the following aspects:

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures ***or*** instructions, and shall include at least the following aspects:

Or. en

Amendment 1915

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – introductory part

Text proposed by the Commission

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. ***That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions, and shall***

Amendment

1. Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation ***and that shall be incorporated as part of an existing quality management system under sectoral legislation or as provided by the International***

include at least the following aspects:

Organisation for Standardization.

Or. en

Amendment 1916

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation

Article 17 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system; *deleted*

Or. en

Amendment 1917

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for the management of modifications to the high-risk AI system; *deleted*

Or. en

Amendment 1918

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system; *deleted*

Or. en

Amendment 1919

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) techniques, procedures and systematic actions to be used for the development, quality control and quality assurance of the high-risk AI system; *deleted*

Or. en

Amendment 1920

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) examination, test and validation procedures to be carried out before, during and after the development of the high-risk AI system, and the frequency with which they have to be carried out; *deleted*

Or. en

Amendment 1921

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

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

Text proposed by the Commission

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title; **deleted**

Or. en

Amendment 1922
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title; **deleted**

Or. en

Amendment 1923
Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

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

Text proposed by the Commission

Amendment

(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, the means to be used to **(e) technical specifications, including standards, to be applied and, where the relevant harmonised standards are not applied in full, *or do not cover all of the***

ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

relevant requirements, the means to be used to ensure that the high-risk AI system complies with the requirements set out in Chapter 2 of this Title;

Or. en

Amendment 1924

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;

deleted

Or. en

Amendment 1925

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market **or** putting into service of high-risk AI systems;

(f) systems and procedures for data management, including **data acquisition**, data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market, putting into service, **and deployment** of high-risk AI systems;

Amendment 1926

Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before **and** for the purposes of the placing on the market or putting into service of high-risk AI systems;

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before for the purposes of the placing on the market or putting into service of high-risk AI systems, **and after deployment of the high-risk AI**;

Or. en

Amendment 1927

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 17 – paragraph 1 – point f

Text proposed by the Commission

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service of high-risk AI systems;

Amendment

(f) systems and procedures for data management, including data collection, data analysis, data labelling, data storage, data filtration, data mining, data aggregation, data retention and any other operation regarding the data that is performed before and for the purposes of the placing on the market or putting into service **or use** of high-risk AI systems;

Or. en

Amendment 1928
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(g) the risk management system referred to in Article 9; **deleted**

Or. en

Amendment 1929
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(h) the setting-up, implementation and maintenance of a post-market monitoring system, in accordance with Article 61; **deleted**

Or. en

Amendment 1930
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62; **deleted**

Or. en

Amendment 1931
Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López

Aguilar, Marina Kaljurand, Maria Grapini

Proposal for a regulation

Article 17 – paragraph 1 – point i

Text proposed by the Commission

(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;

Amendment

(i) procedures related to the reporting of serious incidents and of malfunctioning, ***including near misses***, in accordance with Article 62;

Or. en

Justification

One example of near miss for AI systems is the case of a self-driving car running a red light, but not hitting anyone on that occasion. This could have been a serious incident if the car had hit a pedestrian, for example. Fixing this issue before another such incident occurs is important. Hence, the importance of near miss reporting.

There are several references to 'near misses' in different legislations such as Directive (EU) 2016/798 on railway safety and ECM Regulation 445/2011.

Amendment 1932

Pernando Barrena Arza, Cornelia Ernst

Proposal for a regulation

Article 17 – paragraph 1 – point i

Text proposed by the Commission

(i) procedures related to the reporting of serious incidents and of malfunctioning in accordance with Article 62;

Amendment

(i) procedures related to the reporting of serious incidents and of malfunctioning, ***including near misses***, in accordance with Article 62;

Or. en

Amendment 1933

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 17 – paragraph 1 – point j

Text proposed by the Commission

Amendment

**(j) *the handling of communication
with national competent authorities,
competent authorities, including sectoral
ones, providing or supporting the access
to data, notified bodies, other operators,
customers or other interested parties;*** *deleted*

Or. en

Amendment 1934

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner,
Ondřej Kovařík, Jan-Christoph Oetjen**

Proposal for a regulation

Article 17 – paragraph 1 – point j

Text proposed by the Commission

Amendment

**(j) the handling of communication
with national competent authorities,
competent authorities, including sectoral
ones, *providing or supporting the access
to data, notified bodies, other operators,
customers or other interested parties;***

**(j) the handling of communication
with national competent authorities,
competent authorities, including sectoral
ones;**

Or. en

Amendment 1935

**Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner,
Ondřej Kovařík, Jan-Christoph Oetjen**

Proposal for a regulation

Article 17 – paragraph 1 – point k

Text proposed by the Commission

Amendment

**(k) *systems and procedures for record
keeping of all relevant documentation and
information;*** *deleted*

Or. en

Amendment 1936

Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(k) systems and procedures for record keeping of all relevant documentation and information; **deleted**

Or. en

Amendment 1937
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(l) resource management, including security of supply related measures; **deleted**

Or. en

Amendment 1938
Axel Voss, Deirdre Clune, Eva Maydell

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

Text proposed by the Commission

Amendment

(m) an accountability framework setting out the responsibilities of the management and other staff with regard to all aspects listed in this paragraph. **deleted**

Or. en

Amendment 1939
Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

deleted

Or. en

Amendment 1940
Marion Walsmann

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation ***and can be fulfilled by further elaborating existing quality management systems.***

Or. en

Amendment 1941
Alessandra Basso, Marco Campomenosi, Isabella Tovaglieri, Mara Bizzotto, Silvia Sardone, Annalisa Tardino

Proposal for a regulation
Article 17 – paragraph 2

Text proposed by the Commission

Amendment

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's organisation.

2. The implementation of aspects referred to in paragraph 1 shall be proportionate to the size of the provider's ***and user's*** organisation.

Or. en

Amendment 1942

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 17 – paragraph 3

Text proposed by the Commission

3. For providers that are credit institutions regulated by Directive 2013/36/EU, ***the obligation to put a quality management system in place shall be deemed to be fulfilled by complying with the rules on internal governance arrangements, processes and mechanisms pursuant to Article 74 of that Directive. In that context, any harmonised standards referred to in Article 40 of this Regulation shall be taken into account.***

Amendment

3. ***This Article applies without prejudice to the obligations*** for providers that are credit institutions regulated by Directive 2013/36/ EU.

Or. en

Amendment 1943

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 17 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. High-risk AI systems shall make use of high quality models, that use relevant, justified and reasonable parameters and features and optimise for justified goals;

Or. en

Amendment 1944

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation

Article 17 – paragraph 3 b (new)

Text proposed by the Commission

Amendment

3 b. High-risk AI systems shall only be used in a different domain or environment where they are generalisable to such domain or environment

Or. en

Amendment 1945

Brando Benifei, Christel Schaldemose, Andreas Schieder, Alex Agius Saliba, Bettina Vollath, Tsvetelina Penkova, René Repasi, Birgit Sippel, Maria Grapini, Adriana Maldonado López, Maria-Manuel Leitão-Marques, Marc Angel

**Proposal for a regulation
Article 18**

Text proposed by the Commission

Amendment

Article 18

deleted

Obligation to draw up technical documentation

1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV.

2. Providers that are credit institutions regulated by Directive 2013/36/EU shall maintain the technical documentation as part of the documentation concerning internal governance, arrangements, processes and mechanisms pursuant to Article 74 of that Directive.

Or. en

Justification

Given the addition of new paragraph 4 in Article 11, Article 18 is not needed anymore.

Amendment 1946

Axel Voss, Deirdre Clune, Eva Maydell

**Proposal for a regulation
Article 18 – paragraph 1**

Text proposed by the Commission

Amendment

1. **Providers of high-risk AI systems** shall **draw up** the technical **documentation** referred to in Article 11 **in accordance with** Annex IV.

1. **The provider** shall, **for a period of 3 years after the AI system has been placed on the market or put into service, keep at the disposal of the national competent authorities:**

(a) the technical **documentation** referred to in Article 11 **and** Annex IV;

(b) **the documentation concerning the quality management system referred to in Article 17;**

(c) **the documentation concerning the changes approved by notified bodies where applicable;**

(d) **the decisions and other documents issued by the notified bodies where applicable;**

(e) **the EU declaration of conformity referred to in Article 48.**

Or. en

Amendment 1947

Jörgen Warborn, Arba Kokalari, Tomas Tobé

**Proposal for a regulation
Article 18 – paragraph 1**

Text proposed by the Commission

Amendment

1. Providers of high-risk AI systems shall draw up the technical **documentation** referred to in Article 11 in accordance with Annex IV.

1. Providers of high-risk AI systems shall draw up the technical **documentation** referred to in Article 11 in accordance with Annex IV. **When applicable, the technical documentation shall be treated as containing trade secrets as regulated by Directive (EU) 2016/943.**

Or. en

Amendment 1948

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä

on behalf of the Verts/ALE Group

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV.

Amendment

1. Providers of high-risk AI systems shall draw up the technical documentation referred to in Article 11 in accordance with Annex IV ***and make it available at the request of a national competent authority.***

Or. en

Amendment 1949

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 19 – title

Text proposed by the Commission

Conformity assessment

Amendment

Independent Third party Conformity assessment

Or. en

Amendment 1950

Kateřina Konečná, Pernando Barrena Arza, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall ensure that their systems undergo ***the relevant*** conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an

Amendment

1. Providers of high-risk AI systems shall ensure that their systems undergo ***an independent third party*** conformity assessment procedure in accordance with Article 43 ***and Annex VII***, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity

EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.

assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49. ***The conformity assessment shall be publicly available.***

Or. en

Amendment 1951

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation Article 19 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, ***prior to their placing*** on the market or ***putting*** into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.

Amendment

1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, ***before they are placed on the market, made available*** on the market or ***put*** into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.

Or. fr

Justification

Brings the text into line with the definitions set out in Article 3.

Amendment 1952

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation Article 19 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.

Amendment

1. Providers of high-risk AI systems shall ensure that their systems undergo the relevant conformity assessment procedure in accordance with Article 43, prior to their placing on the market or putting into service ***or use***. Where the compliance of the AI systems with the requirements set out in Chapter 2 of this Title has been demonstrated following that conformity assessment, the providers shall draw up an EU declaration of conformity in accordance with Article 48 and affix the CE marking of conformity in accordance with Article 49.

Or. en

Amendment 1953

Jürgen Warborn, Arba Kokalari, Tomas Tobé

Proposal for a regulation

Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law. ***When applicable, the automatically generated logs shall be treated as containing trade secrets as regulated by Directive (EU) 2016/943.***

Or. en

Amendment 1954

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul

Garraud

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall **keep** the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Amendment

1. Providers of high-risk AI systems shall **guarantee the storage of** the logs automatically generated by their high-risk AI systems, **where possible on the media employed by users**, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of **the** high-risk AI system and applicable legal obligations under Union or national law.

Or. fr

Amendment 1955

Pernando Barrena Arza, Kateřina Konečná, Cornelia Ernst, Elena Kountoura

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose **or reasonably foreseeable use** of high-risk AI system and applicable legal obligations under Union or national law.

Or. en

Amendment 1956

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș,

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of **industry standards**, the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Or. en

Amendment 1957

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the **user** or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by virtue of a contractual arrangement with the **deployer** or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under Union or national law.

Or. en

Amendment 1958

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 20 – paragraph 1

Text proposed by the Commission

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by *virtue of a contractual arrangement with the user or otherwise by law. The logs shall be kept for a period that is appropriate in the light of the intended purpose of high-risk AI system and applicable legal obligations under* Union or national law.

Amendment

1. Providers of high-risk AI systems shall keep the logs automatically generated by their high-risk AI systems, to the extent such logs are under their control by *law as well as under their factual control and to the extent that it is technically feasible. They shall keep them* for a period *of at least six months, unless provided otherwise in* applicable Union or national law.

Or. en

Amendment 1959
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Amendment

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately, *where applicable, investigate the causes in collaboration with the user and,* take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Or. en

Amendment 1960
Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä

on behalf of the Verts/ALE Group

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that system into conformity, to withdraw it or to recall it, as appropriate. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Amendment

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately ***inform the competent authorities and*** take the necessary corrective actions to bring that system into conformity, to withdraw it, ***to disable it***, or to recall it, as appropriate. They shall inform the distributors ***and deployers*** of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Or. en

Amendment 1961

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective ***actions to bring that system into conformity, to withdraw it or to recall it, as appropriate***. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Amendment

Providers of high-risk AI systems which consider or have reason to consider that a high-risk AI system which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective ***action to withdraw or recall the system, as appropriate, so as to bring it into conformity***. They shall inform the distributors of the high-risk AI system in question and, where applicable, the authorised representative and importers accordingly.

Or. fr

Amendment 1962

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 21 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

In the cases referred to in paragraph 1, providers shall immediately inform the distributors of the high-risk AI system and, where applicable, the legal representative, importers and users accordingly. They shall also immediately inform the national supervisory authority and the national competent authorities of the Member States where they made the AI system available or put it into service, and where applicable, the notified body of the non-compliance and of any corrective actions taken.

Or. en

Amendment 1963

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

Amendment

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known **to** the provider of the system, **that** provider shall immediately inform the national competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known **by** the provider of the system, **the** provider shall immediately inform **the national supervisory authority and** the national competent authorities of the Member States in which it made the system available and, where applicable, **the user**, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken. **Where**

applicable, the provider shall also inform the users of the high-risk AI system.

Or. en

Amendment 1964

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the ***national competent*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

Amendment

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the ***market surveillance*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular ***the nature*** of the non-compliance and of any ***relevant*** corrective actions taken ***by the provider***.

Or. en

Amendment 1965

Svenja Hahn, Dragoş Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoş, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the ***national competent*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the

Amendment

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and that risk is known to the provider of the system, that provider shall immediately inform the ***market surveillance*** authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the

non-compliance and of any corrective actions taken.

non-compliance and of any corrective actions taken.

Or. en

Amendment 1966

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and ***that risk is known to*** the provider of the system, that provider shall immediately inform the ***national*** competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

Amendment

Where the high-risk AI system presents a risk within the meaning of Article 65(1) and the provider of the system ***becomes aware of that risk***, that provider shall immediately inform the competent authorities of the Member States in which it made the system available and, where applicable, the notified body that issued a certificate for the high-risk AI system, in particular of the non-compliance and of any corrective actions taken.

Or. en

Amendment 1967

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Alin Mituța

Proposal for a regulation

Article 23 – title

Text proposed by the Commission

Cooperation with competent authorities

Amendment

Cooperation with competent authorities,
the AI Office and the Commission

Or. en

Amendment 1968

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in ***an official Union language determined by the Member State concerned***. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Amendment

Providers of high-risk AI systems shall, upon ***a reasoned*** request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in ***a language that can be easily understood by that national competent authority***. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. ***Any information submitted in accordance with the provision of this article shall be considered by the national competent authority a trade secret of the company that is submitting such information and kept strictly confidential.***

Or. en

Amendment 1969

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Ondřej Kovařík, Jan-Christoph Oetjen

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this

Amendment

Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this

Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. ***Any information submitted in accordance with the provision of this article shall be considered by the national competent authority a trade secret of the company that is submitting such information and kept strictly confidential.***

Or. en

Amendment 1970

Dragoş Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ştefănuţă, Ramona Strugariu, Dragoş Pîslaru, Lucia Ďuriš Nicholsonová, Irena Joveva, Malik Azmani, Alin Mituţa

Proposal for a regulation Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a national competent authority, provide ***that authority*** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. ***Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.***

Amendment

Providers of high-risk AI systems ***and where applicable, users*** shall, upon request by a national competent authority ***or where applicable, by the AI Office or the Commission***, provide ***them*** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned.

Or. en

Amendment 1971

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a national competent authority, provide **that authority** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. ***Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.***

Amendment

Providers ***and, where applicable, users*** of high-risk AI systems shall, upon request by a national ***supervisory authority or a national*** competent authority ***or, where applicable, by the Board or the Commission***, provide ***them*** with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned.

Or. en

Amendment 1972

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a ***national*** competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language

Amendment

Providers of high-risk AI systems shall, upon request by a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member

determined by the Member State concerned. Upon a ***reasoned*** request from a ***national*** competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control ***by virtue of a contractual arrangement with the user or otherwise by law***.

State concerned. Upon a request from a competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control.

Or. en

Amendment 1973

Andrea Caroppo, Salvatore De Meo

Proposal for a regulation

Article 23 – paragraph 1

Text proposed by the Commission

Providers of high-risk AI systems shall, upon request by a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Amendment

Providers of high-risk AI systems shall, upon ***reasoned*** request by a national competent authority, provide that authority with all the information and documentation ***they deem*** necessary to demonstrate the conformity of the high-risk AI system with the requirements set out in Chapter 2 of this Title, in an official Union language determined by the Member State concerned. Upon a reasoned request from a national competent authority, providers shall also give that authority access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Or. en

Amendment 1974

Dragoș Tudorache, Olivier Chastel, Vlad Gheorghe, Nicolae Ștefănuță, Ramona Strugariu, Dragoș Pîslaru, Lucia Ľuriš Nicholsonová, Malik Azmani, Alin Mîtuța, Michal Šimečka, Irena Joveva

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Upon a reasoned request by a national competent authority or, where applicable, by the Commission, providers and, where applicable, users shall also give the requesting national competent authority or the Commission, as applicable, access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law. The national competent authorities or, where applicable, the Commission, shall keep confidential all trade secrets contained in the information received, in accordance with Article 70(2).

Or. en

Amendment 1975

Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 23 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

Upon a reasoned request by a national supervisory authority or a national competent authority or, where applicable, by the Board or the Commission, providers and, where applicable, users shall also give them access to the logs automatically generated by the high-risk AI system, to the extent such logs are under their control by virtue of a contractual arrangement with the user or otherwise by law.

Or. en

Amendment 1976

Proposal for a regulation
Article 23 a (new)

Text proposed by the Commission

Amendment

Article 23 a

***Clarification of responsibilities along the
AI value chain***

1. Concerning high risk AI systems, any natural or legal person shall be considered a new provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

(a) they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;

(b) they make a substantial modification or modify the intended purpose of a high-risk AI system already placed on the market or put into service;

(c) they modify the intended purpose of a non high-risk AI system already placed on the market or put into service, in a way which makes the modified system a high-risk AI System;

(d) they adapt a general purpose AI system system, already placed on the market or put into service, to a specific intended purpose.

2 . Where the circumstances referred to in paragraphs 1(a), (b) and (c) occur, the former provider shall no longer be considered a provider for the purposes of this Regulation. The former provider shall upon request and without compromising its own intellectual property rights or trade secrets, provide the new provider with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this

Regulation.

3. The original provider of a general purpose AI system shall, without compromising its own intellectual property rights or trade secrets and to the extent appropriate and feasible:

(a) ensure that the general purpose AI system which may be used as high-risk AI system complies with the requirements established in Article 9, 10, 11, 13(2)/(3) and 15 of this Regulation;

(b) comply with the obligations set out in Art 16aa, 16e, 16f, 16g, 16i, 16j, 48 and 61 of this Regulation;

(c) assess the reasonable foreseeable misuses of the general purpose AI system that may arise during the expected lifetime and install mitigation measures against those cases based on the generally acknowledged state of the art;

(d) provide the new provider referred to in paragraph 1(d) with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

4. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations referred to in Article 16 under either of the following scenarios:

(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer; or

(ii) the high-risk AI system is put into service under the name or trademark of the product manufacturer after the product has been placed on the market.

5. Third parties involved in the sale and the supply of software including general purpose application programming interfaces (API), software tools and components, providers who develop and

train AI systems on behalf of a deploying company in accordance with their instruction, or providers of network services shall not be considered providers for the purposes of this Regulation.

Or. en

Amendment 1977

Svenja Hahn, Nicola Beer, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 23 a (new)

Text proposed by the Commission

Amendment

Article 23 a

Conditions for other persons to be subject to the obligations of a provider

1. Concerning high risk AI systems any natural or legal person shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16, in any of the following circumstances:

(a) they put their name or trademark on a high-risk AI system already placed on the market or put into service, without prejudice to contractual arrangements stipulating that the obligations are allocated otherwise;

(b) they make a substantial modification to or modify the intended purpose of a high-risk AI system already placed on the market or put into service;

(c) they modify the intended purpose of a non-high-risk AI system already placed on the market or put it to service, in a way which makes the modified system a high-risk AI system;

(d) they fulfil the conditions referred in Article 3a(2).

2. Where the circumstances referred to in paragraph 1 occur, the provider that initially placed the high-risk AI system on

the market or put it into service shall no longer be considered a provider for the purposes of this Regulation. The initial provider subject to the previous sentence, shall upon request and without compromising its own intellectual property rights or trade secrets, provide the new provider referred to in paragraph (1a), (1b) or (1c) with all essential, relevant and reasonably expected information that is necessary to comply with the obligations set out in this Regulation.

3. For high-risk AI systems that are safety components of products to which the legal acts listed in Annex II, section A apply, the manufacturer of those products shall be considered the provider of the high-risk AI system and shall be subject to the obligations referred to in Article 16 under either of the following scenarios:

(i) the high-risk AI system is placed on the market together with the product under the name or trademark of the product manufacturer; or

(ii) the high-risk AI system is put into service under the name or trademark of the product manufacturer after the product has been placed on the market.

4. Third parties involved in the sale and the supply of software including general purpose application programming interfaces (API), software tools and components, providers who develop and train AI systems on behalf of a deploying company in accordance with their instruction, or providers of network services shall not be considered providers for the purposes of this Regulation.

Or. en

Justification

Following a proposal by the Council, this article in combination with new Art. 3a on General Purpose AI, Art 16, 25, 26, 27, 29 aims at adequately addressing the roles of the various actors involved in developing and deploying AI systems. The new article clarifies which actor is responsible in which situation.

Amendment 1978

Svenja Hahn, Nicola Beer, Morten Løkkegaard, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 24

Text proposed by the Commission

Amendment

Article 24

deleted

Obligations of product manufacturers

Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.

Or. en

Amendment 1979

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 24

Text proposed by the Commission

Amendment

Article 24

deleted

Obligations of product manufacturers

Where a high-risk AI system related to products to which the legal acts listed in Annex II, section A, apply, is placed on the market or put into service together with the product manufactured in accordance with those legal acts and under the name of the product

manufacturer, the manufacturer of the product shall take the responsibility of the compliance of the AI system with this Regulation and, as far as the AI system is concerned, have the same obligations imposed by the present Regulation on the provider.

Or. en

Amendment 1980

Petar Vitanov, Birgit Sippel, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation

Article 25

Text proposed by the Commission

Amendment

Article 25

deleted

Authorised representatives

1. Prior to making their systems available on the Union market, where an importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:

(a) keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);

(b) provide a national competent authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this

Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;

(c) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.

Or. en

Justification

Article moved so that it does not cover only high-risk AI systems.

Amendment 1981

Svenja Hahn, Dragoș Tudorache, Nicola Beer, Morten Løkkegaard, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 25 – paragraph 1

Text proposed by the Commission

1. Prior to making their systems available on the Union market, ***where an importer cannot be identified***, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Amendment

1. Prior to making their systems available on the Union market providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Or. en

Amendment 1982

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 1

Text proposed by the Commission

1. Prior to making their systems available on the Union market, ***where an***

Amendment

1. Prior to making their systems available on the Union market, providers

importer cannot be identified, providers established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

established outside the Union shall, by written mandate, appoint an authorised representative which is established in the Union.

Or. en

Amendment 1983

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 25 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. As of the time they are appointed, authorised representatives must be able to correspond, exchange technical information and carry out the duties required of them under this Regulation with the national authorities and in the official languages of all the Member States.

Or. fr

Amendment 1984

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – introductory part

Text proposed by the Commission

Amendment

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. The mandate shall empower the authorised representative to carry out the following tasks:

2. The authorised representative shall perform the tasks specified in the mandate received from the provider. ***For the purpose of this Regulation***, the mandate shall empower the authorised representative to carry out ***only*** the following tasks:

Or. en

Amendment 1985

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 25 – paragraph 2 – point a

Text proposed by the Commission

(a) ***keep a copy of the EU declaration of conformity and the technical documentation at the disposal of the national competent authorities and national authorities*** referred to in Article 63(7);

Amendment

(a) ***carry out or commission the*** conformity ***assessment*** referred to in Article 43;

Or. fr

Amendment 1986

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point a

Text proposed by the Commission

(a) ***keep a copy of*** the EU declaration of conformity and the technical documentation ***at the disposal of the national competent authorities and national authorities referred to in Article 63(7);***

Amendment

(a) ***ensure that*** the EU declaration of conformity and the technical documentation ***have been drawn up and that an appropriate conformity assessment procedure has been carried out by the provider;***

Or. en

Amendment 1987

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 25 – paragraph 2 – point b

Text proposed by the Commission

(b) ***provide a national competent***

Amendment

(b) ***keep a copy of the EU declaration***

authority, upon a reasoned request, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;

of conformity and the technical documentation at the disposal of the national competent authorities and national authorities referred to in Article 63(7);

Or. fr

Amendment 1988

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation

Article 25 – paragraph 2 – point b

Text proposed by the Commission

(b) provide a national competent authority, *upon a reasoned request*, with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider *by virtue of a contractual arrangement with the user or otherwise by law*;

Amendment

(b) provide a national competent authority with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider;

Or. en

Amendment 1989

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point b a (new)

Text proposed by the Commission

Amendment

(b a) keep at the disposal of the national competent authorities and national authorities referred to in Article 63(7), for a period ending 3 years after the high-risk AI system has been placed on the market or put into service, a copy of the EU declaration of conformity, the technical documentation and, if applicable, the certificate issued by the notified body;

Or. en

Amendment 1990

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 25 – paragraph 2 – point c

Text proposed by the Commission

(c) *cooperate with competent* national *authorities*, upon a reasoned request, *on any action the latter takes in relation to* the high-risk AI system.

Amendment

(c) *provide a* national *competent authority*, upon a reasoned request, *with all the information and documentation necessary to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title, including access to the logs automatically generated by the* high-risk AI system *to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law;*

Or. fr

Amendment 1991

Svenja Hahn, Nicola Beer, Sandro Gozi, Vlad-Marius Botoș, Moritz Körner, Jan-Christoph Oetjen

Proposal for a regulation

Article 25 – paragraph 2 – point c

Text proposed by the Commission

(c) cooperate with competent national

Amendment

(c) cooperate with competent national

authorities, upon a reasoned request, on any action the latter takes *in relation to the* high-risk AI system.

authorities, upon a reasoned request, on any action the latter takes to *reduce and mitigate the risks posed by a* high-risk AI system *covered by the authorised representative's mandate*.

Or. en

Amendment 1992

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point c

Text proposed by the Commission

(c) cooperate with **competent** national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.

Amendment

(c) cooperate with national **supervisory** authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system;

Or. en

Amendment 1993

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 25 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(c a) comply with the registration obligations referred to in Article 51 or, if the registration is carried out by the provider itself, ensure that the information referred to in point 3 of Annex VIII is correct.

Or. en

Amendment 1994

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation
Article 25 – paragraph 2 – point c a (new)

Text proposed by the Commission

Amendment

(ca) cooperate with competent national authorities, upon a reasoned request, on any action the latter takes in relation to the high-risk AI system.

Or. fr

Amendment 1995
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 25 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission

Amendment

The authorised representative shall terminate the mandate if it considers or has reason to consider that the provider acts contrary to its obligations under this Regulation. In such a case, it shall also immediately inform the market surveillance authority of the Member State in which it is established, as well as, where applicable, the relevant notified body, about the termination of the mandate and the reasons thereof.

Or. en

Amendment 1996
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 26 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

1. Before placing a high-risk AI system on the market, importers of such system shall ensure that:

1. Before placing a high-risk AI system on the market, importers of such system shall ensure that ***such a system is in conformity with this Regulation by***

ensuring that:

Or. en

Amendment 1997

Jean-Lin Lacapelle, Virginie Joron, Markus Buchheit, Hélène Laporte, Jean-Paul Garraud

Proposal for a regulation

Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) the appropriate conformity assessment procedure has been carried out by the provider of that AI system

Amendment

(a) the appropriate conformity assessment procedure has been carried out by the provider of that AI system ***following its import and prior to its deployment;***

Or. fr

Amendment 1998

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point a

Text proposed by the Commission

(a) the ***appropriate*** conformity assessment procedure has been carried out by the provider of that AI system

Amendment

(a) the ***relevant*** conformity assessment procedure ***referred to in Article 43*** has been carried out by the provider of that AI system;

Or. en

Amendment 1999

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point c

Text proposed by the Commission

(c) the system bears the required

Amendment

(c) the system bears the required

conformity marking and is accompanied by the required documentation and instructions of use.

conformity marking and is accompanied by the required documentation and instructions of use;

Or. en

Amendment 2000

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) the authorised representative referred to in Article 25 has been established by the Provider.

Or. en

Amendment 2001

Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation

Article 26 – paragraph 2

Text proposed by the Commission

Amendment

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

2. Where an importer considers or has reason to consider that a high-risk AI system is not in conformity with this Regulation, ***or is falsified, or accompanied by falsified documentation*** it shall not place that system on the market until that AI system has been brought into conformity. Where the high-risk AI system presents a risk within the meaning of Article 65(1), the importer shall inform the provider of the AI system and the market surveillance authorities to that effect.

Or. en

Amendment 2002

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission

3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system ***or, where that is not possible***, on its packaging or its accompanying documentation, ***as*** applicable.

Amendment

3. Importers shall indicate their name, registered trade name or registered trade mark, and the address at which they can be contacted on the high-risk AI system ***and***, on its packaging or its accompanying documentation, ***where*** applicable.

Or. en

Amendment 2003
Axel Voss, Deirdre Clune, Eva Maydell

Proposal for a regulation
Article 26 – paragraph 4

Text proposed by the Commission

4. Importers shall ***ensure that, while a high-risk AI system is under their responsibility***, where applicable, ***storage or transport conditions do not jeopardise its compliance with the requirements set out in Chapter 2 of this Title***.

Amendment

4. Importers shall ***keep, for a period ending 3 years after the AI system has been placed on the market or put into service, a copy of the certificate issued by the notified body, where applicable, of the instructions for use and of the EU declaration of conformity***.

Or. en

Amendment 2004
Petar Vitanov, Bettina Vollath, Tsvetelina Penkova, Juan Fernando López Aguilar, Maria Grapini

Proposal for a regulation
Article 26 – paragraph 5

Text proposed by the Commission

5. Importers shall provide national

Amendment

5. Importers shall provide ***the***

competent authorities, upon a reasoned request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by *that national competent authority*, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action national competent authority *takes* in relation to that system.

national supervisory authority and the national competent authorities, upon a reasoned request, with all *the* necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by *them*, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider by virtue of a contractual arrangement with the user or otherwise by law. They shall also cooperate with those authorities on any action *the national supervisory authority and the* national competent authority *take* in relation to that system.

Or. en

Amendment 2005

Sergey Lagodinsky, Kim Van Sparrentak, Alexandra Geese, Alviina Alametsä
on behalf of the Verts/ALE Group

Proposal for a regulation **Article 26 – paragraph 5**

Text proposed by the Commission

5. Importers shall provide national competent authorities, upon *a reasoned* request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider *by virtue of a contractual arrangement with the user or otherwise by law*. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.

Amendment

5. Importers shall provide national competent authorities, upon request, with all necessary information and documentation to demonstrate the conformity of a high-risk AI system with the requirements set out in Chapter 2 of this Title in a language which can be easily understood by that national competent authority, including access to the logs automatically generated by the high-risk AI system to the extent such logs are under the control of the provider. They shall also cooperate with those authorities on any action national competent authority takes in relation to that system.

