Amendment 282 Christophe Clergeau on behalf of the S&D Group Martin Häusling on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex I – point 4

Text proposed by the Commission

Amendment

(4) targeted inversion of a sequence of deleted any number of nucleotides;

Or. en

Amendment 283
Christophe Clergeau
on behalf of the S&D Group
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex I – point 5

Text proposed by the Commission

Amendment

(5) any other targeted modification of deleted any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders' gene pool.

Amendment 284
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex II – Part 1 – paragraph 3 – point c a (new)

Text proposed by the Commission Amendment

(c a) risk-management strategies

Or. en

Amendment 285
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex II – Part 1 – paragraph 3 – point c b (new)

Text proposed by the Commission

Amendment

(c b) overall risk evaluation

Or. en

Amendment 286
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation

Annex II – Part 1 – paragraph 4 – point a – point i a (new)

Text proposed by the Commission

Amendment

(i a) information relating to the genetic modification and their intended effects

Or. en

Amendment 287
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex II – Part 1 – paragraph 4 – point b – paragraph 1

Text proposed by the Commission

Amendment

Information shall be provided on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.

Information shall be provided to cover all relevant exposure routes to humans, livestock, and the environment. Exposure on the likelihood of each identified potential adverse effect. This shall be evaluated taking into consideration, as relevant, the characteristics of the receiving environment(s), the intended function, the dietary role, the expected level of use of the food and feed in the EU and the scope of the application for authorisation.

Or. en

Amendment 288
Martin Häusling
on behalf of the Verts/ALE Group

A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex II – Part 1 – paragraph 5

Text proposed by the Commission

Amendment

Any information on hazard identification and characterisation specified under Parts 2 and 3 shall only be required if the specific characteristics and the intended use of the category 2 NGT plant or category 2 NGT food or feed give rise to a plausible risk hypothesis that can be addressed utilising the specified information.

deleted

Amendment 289
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex II – Part 3 – point 1 a (new)

Text proposed by the Commission

Amendment

(1 a) Analysis of potential for persistence and invasiveness resulting from transport, loss, and spillage

Amendment 290
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Annex II – Part 3 – point 2

Text proposed by the Commission

Amendment

(2) Toxicology (2) *Ecotoxicology and* toxicology

Amendment 291
Martin Häusling
on behalf of the Verts/ALE Group

Report A9-0014/2024

Jessica Polfjärd

Plants obtained by certain new genomic techniques and their food and feed (COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

Proposal for a regulation Article 33 a (new) Directive 98/44/EC Article 4, Article 8, Article 9

Text proposed by the Commission

Amendment

Article33a

Amendments to Directive 98/44/EC

Directive 98/44/EC of the European Parliament and of the Council^{1a} is amended as follows:

- (1) Article 4 is amended as follows:
- (a) in paragraph 1, the following points are added:
- '(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [OJ please insert the number of this amending Regulation];
- (d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC and listed in Annex IB thereto.';
- (b) the following paragraph is added:
- '4. Paragraphs 2 and 3 shall be without prejudice to the exclusions from patentability covered in paragraph 1.';
- (2) in Article 8, the following paragraphs are added:
- '3. By way of derogation from paragraphs 1 and 2, a plant product, its parts or

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- genetic components shall not be patentable if they are obtained by a patentable technical process which is not distinguishable from plant products or from genetic parts or components of plant products which can be obtained by an essentially biological process.
- 4. By way of derogation from paragraph 1, the protection conferred by a patent on a biological material possessing specific characteristics shall not extend to plant material in which that biological material is incorporated and which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.
- 5. By way of derogation from paragraph 2, the protection conferred by a patent on a process that enables the production of a biological material possessing specific characteristics as a result of the invention shall not extend to plant material in which that biological material is incorporated and which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.';
- (3) in article 9, the following paragraphs are added:
- '2. By way of derogation from paragraph 1, a plant product containing or consisting of genetic information obtained by a patentable technical process shall not be patentable if it is not distinguishable from plant products containing or consisting of the same genetic information obtained by an essentially biological process.
- 3. By way of derogation from paragraph 1, the protection conferred by a patent on a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially

biological process.

4. The protection conferred by a patent on a technical process that enables the production of a product containing or consisting of genetic information shall not extend to plant material in which the product is incorporated and in which the genetic information is contained and performs its function but which is not distinguishable from plant material obtained or which can be obtained by an essentially biological process.'.

^{1a} Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ L 213, 30.7.1998, p. 13).