



2023/0226(COD)

14.11.2023

AMENDMENTS

293 - 583

Draft opinion

Veronika Vrecionová

Plants obtained by certain new genomic techniques and their food and feed,
and amending Regulation (EU) 2017/625

Proposal for a regulation

(COM(2023)0411 – C9-0238/2023 – 2023/0226(COD))

AM_Com_LegOpinion

Amendment 293

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 6

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

There are no good reasons for weakening the existing GMO legislation, let alone abolishing it for the majority of new GM plants. The advancing knowledge of molecular genetics shows that the genome functions as a delicately balanced, integrated network. That genes function as networks, implies that any modification can have major consequences with respect to patterns of gene expression and an organism's biochemistry. Thus, the latest science suggests that the law governing genetic modification including NGT should be re-appraised and strengthened rather than weakened.

Amendment 294

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 6

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why

we propose to delete the specific rules dedicated to category 1 NGTs.

Amendment 295

Maria Noichl

Proposal for a regulation

Article 6

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 296

Veronika Vrecionová

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Amendment

Verification procedure of category 1 NGT
plant status ***prior to the deliberate release
for any other purpose than placing on the
market***

Verification procedure of category 1 NGT
plant status

Or. en

Justification

(merged Articles 6 and 7)

Amendment 297

Tom Vandenkendelaere

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Amendment

Verification procedure of category 1 NGT
plant status ***prior to the deliberate release
for any other purpose than placing on the***

Verification procedure of category 1 NGT
plant status

market

Or. en

Justification

No benefit in the installation of two different verification procedures. If the Member State can perform the verification for deliberate releases such as field trials, it can also do so for plants and plant products that are intended for placing on the market.

Amendment 298

Veronika Vrecionová

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status *prior to the deliberate release for any other purpose than placing on the market*

Amendment

Verification procedure of category 1 NGT plant status

Or. en

Amendment 299

Bert-Jan Ruissen

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market

Amendment

Verification procedure of category 1 NGT plant status *for requests submitted* prior to the deliberate release for any other purpose than placing on the market

Or. en

Amendment 300

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation
Article 6 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market

Amendment

Verification procedure of category 1 NGT plant status ***for requests submitted*** prior to the deliberate release for any other purpose than placing on the market

Or. en

Amendment 301
Annie Schreijer-Pierik

Proposal for a regulation
Article 6 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market

Amendment

Verification procedure of category 1 NGT plant status ***for requests submitted*** prior to the deliberate release for any other purpose than placing on the market

Or. en

Amendment 302
Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere

Proposal for a regulation
Article 6 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market

Amendment

Verification procedure of category 1 NGT plant status ***for request submitted*** prior to the deliberate release for any other purpose than placing on the market

Or. en

Justification

Clarification to the proposal text.

Amendment 303

Martin Hlaváček

Proposal for a regulation

Article 6 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status ***prior to the deliberate release for any other purpose than placing on the market***

Amendment

Verification procedure of category 1 NGT plant status ***(merged Articles 6 and 7)***

Or. en

Amendment 304

Tom Vandenkendelaere

Proposal for a regulation

Article 6 – paragraph 1

Text proposed by the Commission

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release ***of a*** NGT plant ***for any other purpose than placing*** on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ('verification request') to ***the*** competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State ***within whose territory the release is to take place in accordance with paragraphs 2 and 3 and the implementing act adopted in accordance with Article 27, point (b).***

Amendment

1. To obtain the declaration of category 1 NGT plant status referred to in Article 4(1), point (a), before undertaking a deliberate release ***or placing an*** NGT plant ***or plant product*** on the market, the person intending to undertake the deliberate release shall submit a request to verify whether the criteria set out in Annex I are met ('verification request') to ***a*** competent authority designated in accordance with Article 4(4) of Directive 2001/18/EC of the Member State.

Or. en

Amendment 305

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Jan Huitema, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 3 – point c

Text proposed by the Commission

(c) a description of the trait(s) and characteristics which have been introduced or modified;

Amendment

(c) a description of the trait(s) and characteristics which have been introduced or modified ***including information on the technique(s) used to obtain the trait(s);***

Or. en

Justification

To align with previous amendments on information in the database - see recital 23

Amendment 306

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 4

Text proposed by the Commission

4. The competent authority shall acknowledge receipt of the verification request to the requester ***without undue delay***, stating the date of receipt. It shall make available the request to the other Member States and to the Commission ***without undue delay***.

Amendment

4. The competent authority shall acknowledge receipt of the verification request to the requester ***within 10 working days***, stating the date of receipt. It shall make available the request to the other Member States and to the Commission ***within 10 working days***.

Or. en

Justification

The timeline should be more predictable with firm number of days to make it easier for

particularly SMEs to know the length of the process

Amendment 307

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 5

Text proposed by the Commission

5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission ***without undue delay*** of the inadmissibility of the verification request and shall provide the reasons of its decision.

Amendment

5. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the competent authority within 30 working days within the date of receipt of a verification request. The competent authority shall inform the requester, the other Member States and the Commission ***within 10 working days*** of the inadmissibility of the verification request and shall provide the reasons of its decision.

Or. en

Amendment 308

Veronika Vrecionová

Proposal for a regulation

Article 6 – paragraph 6

Text proposed by the Commission

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority ***shall make available*** the verification report to

Amendment

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority ***asks the European Food Safety Authority ('the***

the other Member States and to the Commission without undue delay.

Authority’) for scientific opinion on the verification report **and shall make it available** to the other Member States and to the Commission without undue delay.

Or. en

Amendment 309
Martin Hlaváček

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority **shall make available** the verification report to the other Member States and to the Commission without undue delay.

Amendment

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority **asks the European Food Safety Authority (‘the Authority’)** for scientific opinion on the verification report **and shall make it available** to the other Member States and to the Commission without undue delay.

Or. en

Amendment 310
Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall

Amendment

6. If the verification request is not deemed inadmissible in accordance with paragraph 5, the competent authority shall

verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission *without undue delay*.

verify whether the NGT plant fulfils the criteria set out in Annex I and prepare a verification report within 30 working days from the date of receipt of a verification request. The competent authority shall make available the verification report to the other Member States and to the Commission *within 10 working days*.

Or. en

Amendment 311

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Jan Huitema, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make *comments* to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make *reasoned objections* to the verification report, *as regards the fulfilment of the criteria set out in Annex I*, within 20 days from the date of receipt of that report. *Such reasoned objections shall solely refer to the criteria as set out in Annex I and shall include a scientific justification.*

Or. en

Justification

'comments' is very unspecific. It is necessary to make sure this is better defined so they are not used as political roadblocks but rather are of a scientific nature.

Amendment 312

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

Amendment

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

7. The other Member States and the Commission may make **reasoned scientific objections** to the verification report within 20 days from the date of receipt of that report. ***These objections must solely refer to the fulfilment of the criteria as set out in Annex I and must include a scientific justification.***

Or. en

Justification

The verification procedure should be science based. Any intervention should be scientifically justified and based on correct application of the equivalence criteria set in Annex I, to make the verification process effective and predictable (within a reasonable timeframe) based on clear criteria and the scientific expertise of competent authorities.

Amendment 313

Annie Schreijer-Pierik

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

Amendment

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

7. The other Member States and the Commission may make **reasoned objections** to the verification report within 20 days from the date of receipt of that report. ***These reasoned objections must solely refer to the fulfilment of the criteria as set out in Annex I and must include a scientific justification.***

Or. en

Justification

The criteria in Annex I need further clarification to allow a common understanding between national authorities and developers. The verification procedure should not allow for unjustified political consideration. Any intervention of the Commission or another Member State should be scientifically justified. Breeding companies invest up to 20% of their turnover in R&D and rely on legal certainty for their investments. The verification process should therefore be effective and predictable (within a reasonable timeframe) based on clear criteria

and scientific expertise.

Amendment 314

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make **reasoned objections** to the verification report within 20 days from the date of receipt of that report. ***These reasoned objections must solely refer to the fulfilment of the criteria as set out in Annex I and must include a scientific justification.***

Or. en

Justification

The verification procedure should be science based and not allow for unjustified political considerations. Any intervention of the Commission or another member state should be scientifically justified and based on correct application of the equivalence criteria (Annex I). The verification process should therefore be effective and predictable (within a reasonable timeframe) based on clear criteria and the scientific expertise of Member States competent authorities.

Amendment 315

Bert-Jan Ruissen

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make **reasoned objections** to the verification report within 20 days from the date of receipt of that report. ***These reasoned objections must solely refer to the fulfilment of the criteria as set out in Annex I and must include a***

Amendment 316

Daniel Buda, Dan-Ștefan Motreanu

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make **reasoned objections** to the verification report within 20 days from the date of receipt of that report. **Such reasoned objections shall solely refer to the criteria as set out in Annex I and shall include a scientific justification.**

Amendment 317

Martin Hlaváček

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make comments to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make **reasoned** comments **together with a scientific justification as regards the fulfilment of the criteria set out in Annex I**, to the verification report within 20 days from the date of receipt of that report.

Amendment 318

Ulrike Müller, Martin Hlaváček, Elsi Katainen

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make comments to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make ***scientifically justified*** comments to the verification report, ***with regard to the compliance with criteria set out in Annex I***, within 20 days from the date of receipt of that report.

Or. en

Amendment 319
Daniela Rondinelli

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make ***comments*** to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make ***reasoned scientific objections*** to the verification report ***with regard to whether the criteria set out in Annex I have been met*** within 20 days from the date of receipt of that report.

Or. it

Amendment 320
Herbert Dorfmann

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make ***comments*** to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make ***reasoned objections*** to the verification report ***with regard to whether the criteria set out in Annex I have been met*** within 20 days

from the date of receipt of that report.

Or. it

Amendment 321

Anne Sander

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The *other Member States* and the *Commission may make comments to* the verification report within 20 days from the date of receipt of that report.

Amendment

7. The *Commission, after consulting EFSA*, and the *other Member States may issue a reasoned scientific opinion on* the verification report within 20 days from the date of receipt of that report.

Or. fr

Amendment 322

Tom Vandenkendelaere

Proposal for a regulation

Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make *comments* to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make *reasoned objections* to the verification report within 20 days from the date of receipt of that report.

Or. en

Justification

A ‘comment’ is too light to trigger a procedure at the level of the European Commission. Only reasoned objections should qualify for this.

Amendment 323

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission

7. The other Member States and the Commission may make **comments** to the verification report within 20 days from the date of receipt of that report.

Amendment

7. The other Member States and the Commission may make **reasoned scientific opinion** to the verification report within 20 days from the date of receipt of that report.

Or. en

Amendment 324
Veronika Vrecionová

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission

7. The **other Member States and the Commission may make comments** to the verification report within **20** days from the date of receipt of that report.

Amendment

7. The **Authority shall issue its scientific opinion** to the verification report within **30** days from the date of receipt of that report.

Or. en

Amendment 325
Anne Sander

Proposal for a regulation
Article 6 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7a. The Commission may, after consulting the European Food Safety Authority and other Member States, make reasoned objections against the verification report, as regards compliance with the criteria set out in Annex I, within 20 days from the date of receipt of that report. Those reasoned objections shall refer only to the criteria set out in Annex I

and shall include a reasoned scientific opinion.

Or. fr

Amendment 326

Veronika Vrecionová

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

Amendment

8. *In the absence of any comments from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.* **deleted**

Or. en

Amendment 327

Martin Hlaváček

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

Amendment

8. *In the absence of any comments from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to* **deleted**

the Commission.

Or. en

Amendment 328

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any **comments** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Amendment

8. In the absence of any **reasoned scientific objections** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Justification

Coherence

Amendment 329

Daniela Rondinelli

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of **any comments** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision

Amendment

8. In the absence of **reasoned scientific objections** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification

declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. it

Amendment 330

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any *comments* from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision *without undue delay* to the requester, the other Member States and to the Commission.

Amendment

8. In the absence of any *reasonable objections* from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision *within 10 working days* to the requester, the other Member States and to the Commission.

Or. en

Amendment 331

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any *comments* from a Member State or the Commission,

Amendment

8. In the absence of any *reasoned objections* from a Member State or the

within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Amendment 332

Annie Schreijer-Pierik

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any *comments* from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Amendment

8. In the absence of any *reasoned objections* from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Amendment 333

Tom Vandenkendelaere

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any *comments* from a Member State or the Commission, within 10 working days from the expiry of

Amendment

8. In the absence of any *reasoned objections* from a Member State or the Commission, within 10 working days from

the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Amendment 334

Bert-Jan Ruissen

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any **comments** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Amendment

8. In the absence of any **reasoned objections** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Amendment 335

Daniel Buda, Dan-Ştefan Motreanu

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any **comments** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the

Amendment

8. In the absence of any **reasoned objection** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in

competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Amendment 336

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of any **comments from a Member State or** the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Amendment

8. In the absence of any **reasoned objections from** the Commission **or Member States**, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. en

Amendment 337

Herbert Dorfmann

Proposal for a regulation

Article 6 – paragraph 8

Text proposed by the Commission

8. In the absence of **any comments** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that prepared the

Amendment

8. In the absence of **reasoned objections** from a Member State or the Commission, within 10 working days from the expiry of the deadline referred to in paragraph 7, the competent authority that

verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

prepared the verification report shall adopt a decision declaring whether the NGT plant is a category 1 NGT plant. It shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.

Or. it

Amendment 338

Veronika Vrecionová

Proposal for a regulation

Article 6 – paragraph 9

Text proposed by the Commission

Amendment

9. In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the comment(s) to the Commission without undue delay. **deleted**

Or. en

Amendment 339

Martin Hlaváček

Proposal for a regulation

Article 6 – paragraph 9

Text proposed by the Commission

Amendment

9. In cases where a comment is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the comment(s) to the Commission without undue delay. **deleted**

Or. en

Amendment 340
Daniela Rondinelli

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **the comment(s) to** the Commission without undue delay.

Amendment

9. In cases where a **reasoned scientific objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **objections and their justifications to the Member States and** the Commission without undue delay.

Or. it

Amendment 341
Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where **a comment is** made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **the comment(s) to** the Commission without undue delay.

Amendment

9. In cases where **reasoned objections are** made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **the reasoned(s) objection (s) to the other Member States and** to the Commission without undue delay.

Or. en

Amendment 342
Annie Schreijer-Pierik

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **the comment(s)** to the Commission without undue delay.

Amendment

9. In cases where a **reasoned objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **reasoned objection(s)** to the **requester, other Member States and to** Commission without undue delay.

Or. en

Amendment 343
Herbert Dorfmann

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **the comment(s) to** the Commission without undue delay.

Amendment

9. In cases where a **reasoned objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **objections and their justifications to the Member States and** the Commission without undue delay.

Or. it

Amendment 344
Bert-Jan Ruissen

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made

Amendment

9. In cases where a **reasoned**

by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the **comment(s)** to the Commission without undue delay.

objection is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the the **reasoned objection(s)** to **the other Member States** and the Commission without undue delay.

Or. en

Amendment 345

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation

Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall **forward the the comment(s)** to the **Commission** without undue delay.

Amendment

9. In cases where a **reasoned objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall **upon request make the reasoned objections available** to the **other Member States** without undue delay.

Or. en

Amendment 346

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall

Amendment

9. In cases where a **reasonable objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification

forward the *the comment*(s) to the Commission *without undue delay*.

report shall forward the *reasonable objection*(s) to the Commission *within 10 working days*.

Or. en

Amendment 347

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a *comment* is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the *the comment*(s) to the Commission without undue delay.

Amendment

9. In cases where a *reasoned scientific objection* is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the *the objection*(s) to the Commission without undue delay.

Or. en

Justification

Coherence

Amendment 348

Daniel Buda, Dan-Ştefan Motreanu

Proposal for a regulation

Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a *comment* is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the *the comment*(s) to the Commission without undue delay.

Amendment

9. In cases where a *reasoned objection* is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the *the reasoned objection*(s) to the Commission without undue delay.

Amendment 349
Tom Vandenkendelaere

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission

9. In cases where a **comment** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **the comment(s)** to the Commission without undue delay.

Amendment

9. In cases where a **reasoned objection** is made by another Member State or by the Commission by the deadline referred to in paragraph 7, the competent authority that prepared the verification report shall forward the **reasoned objection(s)** to the Commission without undue delay.

Amendment 350
Asger Christensen
on behalf of the Renew Group
Emma Wiesner, Elsi Katainen, Ulrike Müller, Jan Huitema, Erik Poulsen

Proposal for a regulation
Article 6 – paragraph 9 a (new)

Text proposed by the Commission

Amendment

9 a. The national competent authority can decide to take the reasoned objection(s) into account in the verification report or decide to reject the objection(s) for not being based on justified and scientific grounds. If the national authority considers that a decision on the question is necessary, it may request a decision from the Commission and forward the reasoned objection(s) to the Commission.

Justification

To ensure efficient application of the verification procedure, reasoned objections from another Member State should not pr. default entail that the decision is transferred to the Commission. This would risk creating roadblocks of a political rather than scientific nature.

Amendment 351 **Daniela Rondinelli**

Proposal for a regulation **Article 6 – paragraph 10**

Text proposed by the Commission

10. The Commission, after having consulted the **European Food Safety Authority** (*'the Authority'*), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking **the latter** into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the Authority, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned scientific objections and their justifications**, taking **that information** into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. it

Amendment 352 **Veronika Vrecionová**

Proposal for a regulation **Article 6 – paragraph 10**

Text proposed by the Commission

10. The **Commission**, after having consulted the **European Food Safety Authority** (*'the Authority'*), shall **prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant** within 45 working days from the date of receipt of the **comment(s)**, **taking the latter into account**. The decision **shall be adopted in accordance with the procedure referred to in Article 28(2)**.

Amendment

10. The **competent authority** shall **adopt its decision based on the EFSA's opinion** within 20 working days from the date of receipt of the **EFSA's opinion**. **The competent authority shall transmit the decision without undue delay to the requester, the other Member States and to the Commission.**

Amendment 353
Martin Hlaváček

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The **Commission**, after having consulted the **European Food Safety Authority** (*‘the Authority’*), shall **prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant** within 45 working days from the date of receipt of the **comment(s)**, **taking the latter into account**. The decision **shall be adopted in accordance with the procedure referred to in Article 28(2)**.

Amendment

10. The **competent** authority shall **adopt its decision based on the EFSA’s opinion** within 20 working days from the date of receipt of the **EFSA’s opinion**. **The competent authority shall transmit the decision without undue delay to the requester, the other Member States and to the Commission**.

Amendment 354
Herbert Dorfmann

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the **European Food Safety Authority** (*‘the Authority’*), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking **the latter** into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the Authority, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objections and their justifications**, taking **that information** into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment 355

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **resoned scientific objection(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Justification

Coherence

Amendment 356

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Atidzhe Alieva-Veli, Ulrike Müller, Jan Huitema, Erik Poulsen

Proposal for a regulation

Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the **European Food Safety Authority ('the Authority')**, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the **latter** into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the Authority, shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **request of a decision from the competent authority**, taking the **reasoned objection(s)** into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 357

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos Ros Sempere

Proposal for a regulation

Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned(s) objection(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 358

Bert-Jan Ruissen

Proposal for a regulation

Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objection(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 359
Daniel Buda, Dan-Ștefan Motreanu

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment**(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objection**(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 360
Tom Vandenkendelaere

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment**(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objection**(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 361
Annie Schreijer-Pierik

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objection(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 362

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **comment(s)**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within 45 working days from the date of receipt of the **reasoned objections**, taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Amendment 363

Ulrike Müller, Martin Hlaváček, Elsi Katainen

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within **45** working days from the date of receipt of the comment(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Amendment

10. The Commission, after having consulted the European Food Safety Authority ('the Authority'), shall prepare a draft decision declaring whether the NGT plant is a category 1 NGT plant within **20** working days from the date of receipt of the comment(s), taking the latter into account. The decision shall be adopted in accordance with the procedure referred to in Article 28(2).

Or. en

Justification

As stated in recital 20 of the proposal, the verification of category 1 NGT plant status is of technical nature and does not involve any risk assessment or risk management considerations and the decision on the status is only declaratory. Hence, it should be ensured that comments by Member States do not trigger an unduly long procedure. As the Commission considers 20 days a sufficient period for Member States to prepare comments, the same period should be adequate for their assessment.

Amendment 364

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 6 a (new)

Text proposed by the Commission

Amendment

Article 6a

Verification procedure of category 1 NGT plant status prior to the deliberate release for any other purpose than placing on the market

A permit for the release of NGTs has to be applied for according to Directive 2001/18.

Or. en

Amendment 365

Sandra Pereira

Proposal for a regulation
Article 7.º

Text proposed by the Commission

Amendment

[...]

deleted

Or. pt

Amendment 366
Anja Hazekamp

Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 367
Tom Vandenkendelaere

Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

No benefit in the installation of two different verification procedures. If the Member State can perform the verification for deliberate releases such as field trials, it can also do so for plants and plant products that are intended for placing on the market.

Amendment 368
Maria Noichl

Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 369
Veronika Vrecionová

Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

Merged with Article 6. Moreover: (i) We prefer a simple, effective, and harmonized verification procedure of NGT plant status at national level in order to reduce administrative burden and increase available access for SMEs. (ii) The outcome of the procedure should be strictly based on scientific opinion. (iii) The verification of NGT plant status should be carried out in a uniform procedure regardless of the use of these plants (for deliberate release into the environment or placing on the market). (iv) This can be achieved by merging Articles 6 and 7 and the proposed amendments.

Amendment 370
Benoît Biteau
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 7

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.

Amendment 371

Bert-Jan Ruissen

Proposal for a regulation

Article 7 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products

Amendment

Verification procedure of category 1 NGT plant status ***for requests submitted*** prior to the placing on the market of NGT products

Or. en

Amendment 372

Annie Schreijer-Pierik

Proposal for a regulation

Article 7 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products

Amendment

Verification procedure of category 1 NGT plant status ***for requests submitted*** prior to the placing on the market of NGT products

Or. en

Amendment 373

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero, Marcos

Ros Sempere

Proposal for a regulation
Article 7 – title

Text proposed by the Commission

Verification procedure of category 1 NGT plant status prior to the placing on the market of NGT products

Amendment

Verification procedure of category 1 NGT plant status ***for request submitted*** prior to the placing on the market of NGT products

Or. en

Amendment 374

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Jan Huitema, Erik Poulsen

Proposal for a regulation

Article 7 – paragraph 2 – point c

Text proposed by the Commission

(c) a description of the trait(s) and characteristics which have been introduced or modified;

Amendment

(c) a description of the trait(s) and characteristics which have been introduced or modified ***including information on the technique(s) used to obtain the trait(s)***;

Or. en

Justification

Inclusion of techniques in line with the wording on the database

Amendment 375

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 7 – paragraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the proof that:

(i) there are no patents or exclusive rights covering the process used to develop the plant;

(ii) there are no patents or exclusive rights covering the plant or parts thereof;

(iii) no application has been tabled for such patents or exclusive rights to be granted;

Or. en

Justification

Patentability of plants is not linked to the GMO legislation, but to the European Patent Convention, and secondarily, to Directive 98/44/EC (so-called Biotech directive), which is not modified by this proposal. Therefore, most or all NGT plants will be patentable if their promoters choose to apply for a patent. Patented material should be subject to the most thorough rules available concerning traceability and labelling, in order to allow farmers, breeders and consumers to make informed choices in full knowledge of the rules and liability linked to this form of Intellectual Property.

Amendment 376

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Article 7 – paragraph 3

Text proposed by the Commission

3. The Authority shall acknowledge receipt of the verification request to the requester ***without delay***, stating the date of receipt. It shall make available the verification request to the Member States and to the Commission ***without undue delay*** and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of

Amendment

3. The Authority shall acknowledge receipt of the verification request to the requester ***within 5 working days*** stating the date of receipt. It shall make available the verification request to the Member States and to the Commission ***within 10 working days*** and make public the verification request, relevant supporting information and any supplementary information supplied by the requester, in accordance with article 38(1) of Regulation (EC) No 178/2002, after omission of any information identified as confidential in accordance with Articles 39 to 39e of

Regulation (EC) No 178/2002 and Article 11 of this Regulation.

Regulation (EC) No 178/2002 and Article 11 of this Regulation.

Or. en

Justification

Aligning the wording with article 6 on the time-limit and changing 'without delay' to 5 days as to align with the principle of predictability.

Amendment 377

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Atidzhe Alieva-Veli, Irène Tolleret, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Article 7 – paragraph 4

Text proposed by the Commission

4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission ***without undue delay*** of the inadmissibility of the verification request and shall provide the reasons of its decision.

Amendment

4. If the verification request does not contain all the necessary information, it shall be declared inadmissible by the Authority within 30 working days within the date of receipt of a verification request. The Authority shall inform the requester, the Member States and the Commission ***within 10 working days*** of the inadmissibility of the verification request and shall provide the reasons of its decision.

Or. en

Amendment 378

Annie Schreijer-Pierik

Proposal for a regulation

Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7a

Free movement of category 1 NGT plants

and category 1 NGT products

Member States shall not prohibit, restrict or impede the deliberate release or the placing on the European single market of category 1 NGT plants and products produced from or by such plants.

Or. en

Justification

It is essential for the functioning of the internal market and the free movement of NGT plants across the EU, that the deliberate release of NGT plants and placing on the market of NGT products are based on harmonised requirements and procedures laid down in this Regulation, leading to a decision uniformly applicable to all Member States. It is important that Member States do not unilaterally derogate from those provisions in a way that would restrict, prohibit or hinder the free movement, placing on the market and deliberate release of NGT plants or related products within the EU territory.

Amendment 379

Daniel Buda, Dan-Ştefan Motreanu

Proposal for a regulation

Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7a

Free movement

Member States shall not prohibit or restrict the deliberate release or placing on the market of type 1 NGT plants and related products referred to in Article 3 through requirements that are specific to type 1 NGT plants or related products.

Or. en

Amendment 380

Tom Vandenkendelaere

Proposal for a regulation

Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7a

A plant that is the result of a conventional cross between two verified category 1 NGT plants and in which the introduced modifications are maintained is not considered a new NGT plant and automatically maintains category 1 NGT status.

Or. en

Justification

It is very useful to clarify the category 1 NGT status of plants that are the result of a conventional cross between two verified category 1 NGT plants.

Amendment 381
Herbert Dorfmann

Proposal for a regulation
Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7a

Free movement

Member States shall not prohibit or restrict the deliberate release or placing on the market of Category 1 NGT plants or Category 1 NGT products.

Or. it

Amendment 382
Daniela Rondinelli

Proposal for a regulation
Article 7 a (new)

Text proposed by the Commission

Amendment

Article 7a

Free movement

Member States shall not prohibit or restrict the deliberate release or placing on the market of Category 1 NGT plants or Category 1 NGT products.

Or. it

Amendment 383
Sandra Pereira

Proposal for a regulation
Article 8.º

Text proposed by the Commission

Amendment

Article 8

deleted

8 The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this Title.

The Commission shall set up and maintain an electronic system for the submission of verification requests in accordance with Articles 6 and 7 and the exchange of the information under this Title.

Or. pt

Amendment 384
Benoît Biteau
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 8

Text proposed by the Commission

Amendment

Article 8

deleted

System of exchange of information

*between Member States, the Commission
and the Authority*

***The Commission shall set up and
maintain an electronic system for the
submission of verification requests in
accordance with Articles 6 and 7 and the
exchange of the information under this
Title.***

Or. en

Justification

NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.

**Amendment 385
Anja Hazekamp**

**Proposal for a regulation
Article 8 – paragraph 1**

Text proposed by the Commission

Amendment

***The Commission shall set up and
maintain an electronic system for the
submission of verification requests in
accordance with Articles 6 and 7 and the
exchange of the information under this
Title.***

deleted

Or. en

**Amendment 386
Veronika Vrecionová**

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

Text proposed by the Commission

Amendment

Member States shall not prohibit, restrict or impede the deliberate release or the placing on the market of category 1 NGT plants and related products, which comply with the requirements of this Regulation.

Or. en

Amendment 387
Sandra Pereira

Proposal for a regulation
Article 9.º

Text proposed by the Commission

Amendment

Article 9

deleted

Database of decisions declaring the category 1 NGT plant status

1.

The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6).

The database shall contain the following information:

- (a) name and the address of the requester;***
- (b) the designation of the category 1 NGT plant;***
- (c) a summarised description of the technique(s) used to obtain the genetic modification;***
- (d) a description of the trait(s) and characteristics which have been introduced or modified;***
- (e) an identification number, and***

(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.

2. The database shall be publicly available.

Or. pt

Amendment 388
Anja Hazekamp

Proposal for a regulation
Article 9

Text proposed by the Commission

Amendment

Article 9

deleted

*Database of decisions declaring the
category 1 NGT plant status*

1.

The Commission shall establish and maintain a database listing the decisions declaring the category 1 NGT plant status adopted in accordance with Article 6(8) and (10) and Article 7(6).

The database shall contain the following information:

(a) name and the address of the requester;

(b) the designation of the category 1 NGT plant;

(c) a summarised description of the technique(s) used to obtain the genetic modification;

(d) a description of the trait(s) and characteristics which have been introduced or modified;

(e) an identification number, and

(f) the decision referred to in Article 6(8) or (10), and Article 7(6), as appropriate.

2. The database shall be publicly available.

Amendment 389

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 9

Text proposed by the Commission

Amendment

Article 9

deleted

***Database of decisions declaring the
category 1 NGT plant status***

1.

***The Commission shall establish and
maintain a database listing the decisions
declaring the category 1 NGT plant status
adopted in accordance with Article 6(8)
and (10) and Article 7(6).***

***The database shall contain the following
information:***

(a) name and the address of the requester;

***(b) the designation of the category 1 NGT
plant;***

***(c) a summarised description of the
technique(s) used to obtain the genetic
modification;***

***(d) a description of the trait(s) and
characteristics which have been
introduced or modified;***

(e) an identification number, and

***(f) the decision referred to in Article 6(8)
or (10), and Article 7(6), as appropriate.***

**2. The database shall be publicly
available.**

Justification

NGT plants, by definition, could not occur naturally. The process of creating a NGT plant

leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.

Amendment 390

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 9 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. a description of a risk assessment according to Directive 2001/18.

Or. en

Justification

Article 114 § 3 TFEU states that the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Already, many problems have been documented for NGTs. For example, CRISPR applications have turned out to cause toxicity and mosaicism, whereas the impact and adverse effects on non-target and unintentionally exposed organisms are yet unknown. Such knowledge is only generated when risk assessments are required and in place, and both the impact and the uncertainties are estimated and acknowledged.

Amendment 391

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 9 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1 b. a description of methods for sampling and detection identification of the NGT plant

Justification

Article 114 § 3 TFEU states that the Commission will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Already, many problems have been documented for NGTs. For example, CRISPR applications have turned out to cause toxicity and mosaicism, whereas the impact and adverse effects on non-target and unintentionally exposed organisms are yet unknown. Such knowledge is only generated when risk assessments are required and in place, and both the impact and the uncertainties are estimated and acknowledged.

Amendment 392**Anne Sander****Proposal for a regulation****Article 10***Text proposed by the Commission**Amendment**Article 10**deleted*

10 Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Amendment 393**Anja Hazekamp**

Proposal for a regulation
Article 10

Text proposed by the Commission

Amendment

Article 10

deleted

***Labelling of category 1 NGT plant
reproductive material, including breeding
material***

***Plant reproductive material, including for
breeding and scientific purposes, that
contains or consists of category 1 NGT
plant(s) and is made available to third
parties, whether in return for payment or
free of charge, shall bear a label
indicating the words ‘cat 1 NGT’,
followed by the identification number of
the NGT plant(s) it has been derived from.***

Or. en

Amendment 394

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation
Article 10

Text proposed by the Commission

Amendment

Article 10

deleted

***Labelling of category 1 NGT plant
reproductive material, including breeding
material***

***Plant reproductive material, including for
breeding and scientific purposes, that
contains or consists of category 1 NGT
plant(s) and is made available to third
parties, whether in return for payment or
free of charge, shall bear a label
indicating the words ‘cat 1 NGT’,
followed by the identification number of
the NGT plant(s) it has been derived from.***

Or. en

Justification

NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.

Amendment 395

Annie Schreijer-Pierik

Proposal for a regulation

Article 10

Text proposed by the Commission

Amendment

Article 10

deleted

***Labelling of category 1 NGT plant
reproductive material, including breeding
material***

***Plant reproductive material, including for
breeding and scientific purposes, that
contains or consists of category 1 NGT
plant(s) and is made available to third
parties, whether in return for payment or
free of charge, shall bear a label
indicating the words 'cat 1 NGT',
followed by the identification number of
the NGT plant(s) it has been derived from.***

Or. en

Justification

Labelling, of for example seed bags, for verified conventional-like NGT plants is discriminatory. This extra requirement is creating an unjustified distinction and administrative burden. Information about the use of NGTs should be made publicly available (through public databases), however, the additional labelling provisions and the prohibition for organic production creates a third category of plant products in between conventional and GMOs. This is not in line with approaches already taken in other countries and will create

trade issues.

Amendment 396
Bert-Jan Ruissen

Proposal for a regulation
Article 10

Text proposed by the Commission

Amendment

Article 10

deleted

***Labelling of category 1 NGT plant
reproductive material, including breeding
material***

***Plant reproductive material, including for
breeding and scientific purposes, that
contains or consists of category 1 NGT
plant(s) and is made available to third
parties, whether in return for payment or
free of charge, shall bear a label
indicating the words ‘cat 1 NGT’,
followed by the identification number of
the NGT plant(s) it has been derived from.***

Or. en

Amendment 397
Peter Jahr, Lena Düpont, Christine Schneider, Marlene Mortler

Proposal for a regulation
Article 10

Text proposed by the Commission

Amendment

Article 10

deleted

***10 Plant reproductive material, including
for breeding and scientific purposes, that
contains or consists of category 1 NGT
plant(s) and is made available to third
parties, whether in return for payment or
free of charge, shall bear a label
indicating the words ‘cat 1 NGT’,
followed by the identification number of
the NGT plant(s) it has been derived from.***

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Or. de

Justification

The labelling of category 1 NGT plant reproductive material, including breeding material, is discriminatory. Such material should be conventionally treated. Transparency and consumer choice can be fully ensured by making information about the use of NGTs publicly available. The additional provisions on the labelling of seed bags, however, create a third category of plant products. This is not in line with the approaches taken in other countries and will create trade issues.

Amendment 398

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 10 – title

Text proposed by the Commission

Labelling of category 1 NGT plant reproductive material, including breeding material

Amendment

Labelling of category 1 NGT plant reproductive material, including breeding material. ***NGT plant for food and feed use, NGT product and produced from an NGT plant.***

Or. en

Justification

Consumer rights are fundamental EU rights and should be safeguarded to ensure confidence in the NGT products. Therefore, freedom of choice for consumers and traceability along the entire food and feed value chain are required for all NGTs. These requirements do not represent a particular hardship for industry, as these are part of responsible sourcing of goods.

Amendment 399
Veronika Vrecionová

Proposal for a regulation
Article 10 – title

Text proposed by the Commission

Amendment

Labelling of category 1 NGT plant reproductive material, including breeding material

Transparency of category 1 NGT plant reproductive material, including breeding material

Or. en

Amendment 400
Sandra Pereira

Proposal for a regulation
Article 10.^o – title

Text proposed by the Commission

Amendment

Labelling of **category 1** NGT plant reproductive material, including breeding material

Labelling of NGT plant reproductive material, including breeding material

Or. pt

Amendment 401
Asger Christensen
on behalf of the Renew Group
Emma Wiesner, Elsi Katainen, Irène Tolleret, Erik Poulsen

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

Amendment

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’,

deleted

followed by the identification number of the NGT plant(s) it has been derived from.

Or. en

Justification

Information related to the use of NGTs in breeding Category 1 NGT plants is already foreseen in the Common Catalogue and a public registry. Physically labelling the seed bags does not provide any additional value to farmers or consumers, and results in additional costs and administrative burden.

Amendment 402

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

Amendment

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

deleted

Or. en

Justification

If conventional-like NGT plants are to be treated conventionally, this requirement creates unjustified administrative burden. Transparency and consumer choice is ensured by making information about the use of NGTs publicly available in databases.

Amendment 403

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

Amendment

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

deleted

Or. en

Justification

Cat 1 NGT plants should be treated conventionally, this extra requirement is creating unjustified distinctions and administrative burden. Furthermore, the additional seed bag labelling provisions would create a third category of plant products between conventional and GMOs.

Amendment 404

Daniel Buda, Dan-Ştefan Motreanu

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

Amendment

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

deleted

Or. en

Justification

Category 1 NGT plants are considered equivalent to conventional plants and this extra requirement is discriminatory, creating unjustified distinctions and administrative burden. Transparency can be ensured by making the database public. Furthermore, creating labelling requirements for a third category of plant reproductive material, between conventional and GMOs, would have a negative impact on trade.

Amendment 405

Veronika Vrecionová

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a **label** indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Amendment

Plant reproductive material, including for breeding and scientific purposes, that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a **mention in national variety register automatically transmitted in the EU common register provided for in PRM/FRM** indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Or. en

Amendment 406

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 10 – paragraph 1

Text proposed by the Commission

Plant reproductive material, including for breeding and scientific purposes, **that contains or consists of category 1 NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the words ‘cat 1 NGT’, followed by the identification number of the NGT plant(s) it has been derived from.**

Amendment

Plant reproductive material, including for breeding and scientific purposes, **NGT plant for food and feed use, NGT product and produced from an NGT plant shall fulfill the labelling requirements as set out in Directive 2001/18 and Regulation (EC) No 1830/2003.**

Or. en

Justification

Consumer rights are fundamental EU rights and should be safeguarded to ensure confidence in the NGT products. Therefore, freedom of choice for consumers and traceability along the entire food and feed value chain are required for all NGTs. These requirements do not represent a particular hardship for industry, as these are part of responsible sourcing of goods.

Amendment 407 **Sandra Pereira**

Proposal for a regulation **Article 10.º – paragraph 1**

Text proposed by the Commission

Plant reproductive material, including for breeding and scientific purposes, ***that contains or consists of category 1*** NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the ***words ‘cat 1*** NGT’, followed by the identification number of the NGT plant(s) it has been derived from.

Amendment

Plant reproductive material, ***its descendants and derived products,*** including for breeding and scientific purposes, ***containing or consisting of*** NGT plant(s) and is made available to third parties, whether in return for payment or free of charge, shall bear a label indicating the ***abbreviation ‘NGT’***, followed by the identification number of the NGT plant(s) it has been derived from.

Or. pt

Amendment 408 **Asger Christensen** on behalf of the Renew Group **Emma Wiesner, Elsi Katainen, Jan Huitema, Erik Poulsen**

Proposal for a regulation **Article 10 – paragraph 1 a (new)**

Text proposed by the Commission

Amendment

It shall be prohibited to label consumer products as containing NGT products or having been developed using NGT. It shall furthermore be prohibited to use ‘negative labelling’ by labelling products as not containing or not having been

developed using NGT.

Or. en

Justification

It is important to ensure that there will not be any labelling on consumer products - also 'negative labelling' as described. Such labelling is discriminatory and misleading towards consumers as the knowledge of plant breeding techniques is not widespread and is traditionally never labelled.

Amendment 409

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 10 a (new)

Text proposed by the Commission

Amendment

Article 10a

Cultivation

During the authorisation procedure of a given category 1 NGT or during the renewal of consent/authorisation, a Member State may demand that the geographical scope of the written consent or authorisation be adjusted to the effect that all or part of the territory of that Member State is to be excluded from cultivation, according to article 26b of Directive 2001/18/EC.

Or. en

Justification

The so-called opt-out clause (article 26b of Directive 2001/18/EC) was adopted to allow Member states to adapt the cultivation of specific GM plants to their local conditions, notably: specific environmental challenges, % of organic farmers on the territory, specific economic interests, etc... This clause was widely used by Member states and will be also useful for NGTs. Member states should be able to decide for each NGTs if the potential benefits outweigh the social and economic risks.

Amendment 410

Proposal for a regulation
Article 11.º

Text proposed by the Commission

Amendment

Article 11

deleted

Confidentiality

1.

2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.

3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:

(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;

(b) DNA sequence information; and

(c) breeding patterns and strategies.

4. The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.

5. Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.

6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply *mutatis mutandis*.

7. In the event of a withdrawal of the verification request by the requester,

Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

Or. pt

Amendment 411

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 11

Text proposed by the Commission

Amendment

Article 11

deleted

Confidentiality

1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this Title as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.

2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.

3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to

potentially harm its interests to a significant degree:

(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;

(b) DNA sequence information; and

(c) breeding patterns and strategies.

4. The competent authority or the Authority, as appropriate, shall, after consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.

5. Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.

6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.

7. In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

Or. en

Justification

NGT plants, by definition, could not occur naturally. The process of creating a NGT plant leaves specific alterations that can always be identified through a whole-genome PCR analysis, even if the trait obtained can be similar to one that could occur in nature, and have similar DNA on the targeted site. There is no link between the fact that the trait developed could also occur in nature and the absence of risks. Additionally, there is no history of safe use for NGTs, which was the focus point of 2018 ECJ ruling. NGTs should have obligations

that are proportional to their risks, which can only be determined by a case-by-case impact assessment (as stated in the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law). The proposed categorisation of NGT has no link to actual risk factors as they are usually considered by risk assessors. This is why we propose to delete the specific rules dedicated to category 1 NGTs.

Amendment 412

Anja Hazekamp

Proposal for a regulation

Article 11

Text proposed by the Commission

Amendment

Article 11

deleted

Confidentiality

1. The requester referred to in Articles 6 and 7 may submit a request to the Member State competent authority or to the Authority, as appropriate, to treat certain parts of the information submitted under this Title as confidential, accompanied by verifiable justification, in accordance with paragraphs 3 and 6.

2. The competent authority or the Authority, as appropriate, shall assess the confidentiality request referred to in paragraph 1.

3. The competent authority or the Authority, as appropriate, may grant confidential treatment only with respect to the following items of information, upon verifiable justification, where the disclosure of such information is demonstrated by the requester to potentially harm its interests to a significant degree:

(a) items of information referred to in points (a), (b) and (c) of Article 39(2) of Regulation (EC) No 178/2002;

(b) DNA sequence information; and

(c) breeding patterns and strategies.

4. The competent authority or the Authority, as appropriate, shall, after

consultation with the requester, decide which information is to be treated as confidential and shall inform the requester of its decision.

5. Member States, the Commission and the Authority shall take the necessary measures to ensure that confidential information notified or exchanged under this Chapter is not made public.

6. The relevant provisions of Articles 39e and 41 of Regulation (EC) No 178/2002 shall apply mutatis mutandis.

7. In the event of a withdrawal of the verification request by the requester, Member States, the Commission and the Authority shall respect the confidentiality as granted by the competent authority or the Authority in accordance with this Article. Where the withdrawal of the verification request takes place before the competent authority or the Authority has decided on the relevant confidentiality request, Member States, the Commission and the Authority shall not make public the information for which confidentiality has been requested.

Or. en

Amendment 413
Sandra Pereira

Proposal for a regulation
Chapter III – title

Text proposed by the Commission

III *Category 2* NGT plants and
category 2 NGT products

Amendment

III NGT Plants and NGT products

Or. pt

Amendment 414
Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation
Chapter III – title

Text proposed by the Commission

Amendment

III **Category 2** NGT plants and
category 2 NGT products

III NGT plants and NGT products

Or. en

Amendment 415
Sandra Pereira

Proposal for a regulation
Article 12.^o – title

Text proposed by the Commission

Amendment

Status of **Category 2** NGT plants and
category 2 NGT products

Status of NGT plants and NGT products

Or. pt

Amendment 416
Benoît Biteau
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 12 – title

Text proposed by the Commission

Amendment

Status of **Category 2** NGT plants and
category 2 NGT products

Status of NGT plants and NGT products

Or. en

Amendment 417
Maria Noichl

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

The rules which apply to GMOs in Union legislation *in so far as they are not derogated from by this Regulation*, shall apply to *category 2* NGT plants and *category 2 NGT* products.

Amendment

The rules which apply to GMOs in Union legislation shall apply to NGT plants and *their* products.

Or. en

Amendment 418

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Chapter III – Section 1 – title

Text proposed by the Commission

1 Deliberate release of *category 2* NGT plants for any other purpose than for placing on the market

Amendment

1 Deliberate release of NGT plants for any other purpose than for placing on the market

Or. en

Amendment 419

Sandra Pereira

Proposal for a regulation

Chapter III – Section 1 – title

Text proposed by the Commission

1 Deliberate release of *category 2* NGT plants for any other purpose than for placing on the market

Amendment

1 Deliberate release of NGT plants for any other purpose than for placing on the market

Or. pt

Amendment 420

Maria Noichl

Proposal for a regulation

Article 13 – paragraph 1 – introductory part

Text proposed by the Commission

As regards the deliberate release of a category 2 NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(1) of Directive 2001/18/EC shall include:

Amendment

To obtain an authorisation for the release of NGTs, authorisation must be requested in accordance with Directive 2001/18.

Or. en

Amendment 421

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – paragraph 1 – introductory part

Text proposed by the Commission

As regards the deliberate release of a **category 2** NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(1) of Directive 2001/18/EC shall include:

Amendment

As regards the deliberate release of a NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(1) of Directive 2001/18/EC shall include:

Or. en

Amendment 422

Sandra Pereira

Proposal for a regulation

Article 13.^o – paragraph 1 – introductory part

Text proposed by the Commission

As regards the deliberate release of **a category 2** NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(1) of Directive 2001/18/EC shall include:

Amendment

As regards the deliberate release of **an** NGT plant for any other purpose than placing on the market, the notification referred to in Article 6(1) of Directive 2001/18/EC shall include:

Or. pt

Amendment 423
Sandra Pereira

Proposal for a regulation
Article 13.º – paragraph 1 – point c – point ii

Text proposed by the Commission

(ii) information relating to the *category*
2 NGT plant(s);

Amendment

(ii) information relating to the NGT
plant(s);

Or. pt

Amendment 424
Sandra Pereira

Proposal for a regulation
Article 13.º – paragraph 1 – point c – point iv

Text proposed by the Commission

(iv) information on the interactions
between the *category* 2 NGT plant(s) and
the environment;

Amendment

(iv) information on the interactions
between the NGT plant(s) and the
environment;

Or. pt

Amendment 425
Sandra Pereira

Proposal for a regulation
Article 13.º – paragraph 1 – point c – point v

Text proposed by the Commission

(v) a plan for monitoring in order to
identify effects of the *category* 2 NGT
plant(s) on human health or the
environment;

Amendment

(v) a plan for monitoring in order to
identify effects of the NGT plant(s) on
human health or the environment;

Or. pt

Amendment 426

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 13 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(d a) the proof that:

(i) there are no patents or exclusive rights covering the process used to develop the plant;

(ii) there are no patents or exclusive rights covering the plant or parts thereof;

(iii) no application has been tabled for such patents or exclusive rights to be granted;

Or. en

Justification

Patentability of plants is not linked to the GMO legislation, but to the European Patent Convention, and secondarily, to Directive 98/44/EC (so-called Biotech directive), which is not modified by this proposal. Therefore, most or all NGTs will be patentable if their promoters chose to apply. Patented material should be applied the most thorough rules available concerning traceability and labelling, in order to allow farmers, breeders and consumers to make informed choices in full knowledge of the rules and liability linked to this particular form of Intellectual property.

Amendment 427

Maria Noichl

Proposal for a regulation

Chapter III – Section 2

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 428

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Chapter III – Section 2 – title

Text proposed by the Commission

2 Placing on the market of **category 2**
NGT products other than food or feed

Amendment

2 Placing on the market of NGT
products other than food or feed

Or. en

Amendment 429

Sandra Pereira

Proposal for a regulation

Chapter III – Section 2 – title

Text proposed by the Commission

2 Placing on the market of **category 2**
NGT products other than food or feed

Amendment

2 Placing on the market of NGT
products other than food or feed

Or. pt

Amendment 430

Sandra Pereira

Proposal for a regulation

Article 14.^o – paragraph 1 – introductory part

Text proposed by the Commission

1. As regards the placing on the market of **category 2** NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:

Amendment

1. As regards the placing on the market of NGT products other than food and feed, the notification referred to in Article 13(2) of Directive 2001/18/EC, without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, shall contain:

Amendment 431
Sandra Pereira

Proposal for a regulation
Article 14.º – paragraph 1 – point b

Text proposed by the Commission

(b) designation and specification of the *category 2* NGT plant;

Amendment

(b) designation and specification of the NGT plant;

Amendment 432
Sandra Pereira

Proposal for a regulation
Article 14.º – paragraph 1 – point e

Text proposed by the Commission

(e) the environmental risk assessment carried out in accordance with the principles and criteria set out in *Parts 1 and 2 of* Annex II and with the implementing act adopted in accordance with Article 27, point (c);

Amendment

(e) the environmental risk assessment carried out in accordance with the principles and criteria set out in Annex II and with the implementing act adopted in accordance with Article 27, point (c).

Amendment 433
Sandra Pereira

Proposal for a regulation
Article 14.º – paragraph 1 – point h

Text proposed by the Commission

(h) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, *including a proposal for the*

Amendment

(h) where appropriate, a monitoring plan for environmental effects in accordance with Annex VII to Directive

time-period of the monitoring plan; this time-period may be different from the proposed period for the consent. If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the notifier considers that the NGT plant does not need a monitoring plan, the notifier may propose not to submit a monitoring plan;

2001/18/EC.

Or. pt

Amendment 434

Sandra Pereira

Proposal for a regulation

Article 14.^o – paragraph 1 – point j

Text proposed by the Commission

(j) proposed commercial names of the products and names of **category 2** NGT plants contained therein, and a proposal for a unique identifier for the **category 2** NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004⁽⁶⁰⁾. After the consent any new commercial names should be provided to the competent authority;

⁶⁰ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

Amendment

(j) proposed commercial names of the products and names of NGT plants contained therein, and a proposal for a unique identifier for the NGT plant, developed in accordance with Commission Regulation (EC) No 65/2004⁶⁰. After the consent any new commercial names should be provided to the competent authority;

⁶⁰ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

Or. pt

Amendment 435
Sandra Pereira

Proposal for a regulation
Article 14.^o – paragraph 1 – point l

Text proposed by the Commission

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. ***In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);***

Amendment

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant.

Or. pt

Amendment 436
Juozas Olekas, Carmen Avram, Paolo De Castro

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

Text proposed by the Commission

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, ***if duly justified by the notifier, the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and***

Amendment

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, ***the NGT plant should fall under category 1 as to Art 3 (7)(c)***

the guidance referred to in Article 29(2);

Or. en

Justification

NGT plants for which no unique identification method can be developed, should be regulated as Category 1 NGT plants, as they will be indistinguishable from conventionally-bred plants. Any other outcome will result in enforcement issues and create challenges for imports.

Amendment 437

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Article 14 – paragraph 1 – point l

Text proposed by the Commission

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the *modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);*

Amendment

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the *NGT 2 plant should be considered to fall under category 1 as to Article 3 (7) (ba);*

Or. en

Justification

Cat 2 plants for which no or only an adapted identification method can be developed –should logically be treated as Cat 1 NGT plants (conventional-like).

Amendment 438

Annie Schreijer-Pierik

Proposal for a regulation

Article 14 – paragraph 1 – point l

Text proposed by the Commission

Amendment

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the ***modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);***

(l) methods for sampling (including references to existing official or standardised sampling methods), detection, identification and quantification of the NGT plant. In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the notifier, the ***category 2 NGT plant should then be considered to fall under category 1 NGT plant as per Art 3 (7)(ba new);***

Or. en

Justification

The proposal suggests that for certain category 2 NGT plants no, or only an adapted, identification method can be developed. Although regulated as GMOs, these plants will not be fully distinguishable from conventional plants. This is a specific challenge for imports: if it is not possible to identify unauthorized NGTs with category 2 changes, it is discriminatory to require GM traceability and labelling of such products in the EU. Hence, category 2 plants for which no, or only an adapted, identification method can be developed, should logically be treated as category 1 NGT plants.

Amendment 439

Sandra Pereira

Proposal for a regulation

Article 14.º – paragraph 1 – point m

Text proposed by the Commission

Amendment

(m) samples of the ***category 2*** NGT plant and their control samples, and information as to the place where the reference material can be accessed;

(m) samples of the NGT plant and their control samples, and information as to the place where the reference material can be accessed;

Or. pt

Amendment 440

Sandra Pereira

Proposal for a regulation
Article 14.º – paragraph 2

Text proposed by the Commission

2. The notifier shall include in this notification information on data or results from releases of the same **category 2** NGT plant or the same combination of **category 2** NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.

Amendment

2. The notifier shall include in this notification information on data or results from releases of the same NGT plant or the same combination of NGT plants previously or currently notified and/or carried out by the notifier either inside or outside the Union.

Or. pt

Amendment 441
Benoît Biteau
on behalf of the Verts/ALE Group

Proposal for a regulation
Article 15

Text proposed by the Commission

Amendment

Article 15

deleted

Specific provisions on monitoring

The written consent referred to in Article 19 of Directive 2001/18/EC shall either specify monitoring requirements, as described in Article 19(3) point (f) or state that monitoring is not required. Article 17(2), point (b), of Directive 2001/18/EC shall not apply if monitoring is not required by the consent.

Or. en

Justification

NGT plants will cover a far wider range of species than transgenic plants did. This will multiply the risks of unintended impacts on the ecosystems, notably through crossing with wild plants. It is therefore necessary to maintain a monitoring, as currently outlined in the GMO legislation.

Amendment 442
Herbert Dorfmann

Proposal for a regulation
Article 16

Text proposed by the Commission

Amendment

Article 16

deleted

Labelling in accordance with Article 23

In addition to Article 19(3) of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.

Or. en

Amendment 443
Maria Noichl

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

Amendment

In addition to Article 19(3) of Directive 2001/18/EC, the written consent shall specify the labelling in accordance with Article 23 of this Regulation.

The labelling *must be clear and unambiguous using the term "genetic engineering" along the entire value chain.*

Or. en

Amendment 444
Sandra Pereira

Proposal for a regulation
Article 17.º

Text proposed by the Commission

Amendment

Article 17

deleted

Duration of the validity of the consent after renewal

1. The consent granted under Part C of Directive 2001/18/EC shall, after the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Article 17(6) or (8) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.

2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.

Or. pt

Amendment 445

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 17

Text proposed by the Commission

Amendment

Article 17

deleted

Duration of the validity of the consent after renewal

1. The consent granted under Part C of Directive 2001/18/EC shall, after the first renewal in accordance with Article 17 of Directive 2001/18/EC, be valid for an unlimited period, unless the decision referred to in Article 17(6) or (8) provides that the renewal is for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the consent.

2. The last sentence in Article 17(6) and (8) of Directive 2001/18/EC shall not apply.

Justification

It is not in line with the Precautionary principle, or with plain good sense, to deliver authorizations forever for products which can reproduce and interact with wild plants and the ecosystems. It is all the more problematic as the proposal does not contain any safeguard clause that would allow the Commission to withdraw an authorization in case a problem is detected.

Amendment 446**Sandra Pereira****Proposal for a regulation****Chapter III – Section 3 – title***Text proposed by the Commission*

3 Placing on the market of **category 2** NGT plants for food or feed use and of **category 2** NGT food and feed

Amendment

3 Placing on the market of NGT plants for food or feed use and of NGT food and feed

Or. pt

Amendment 447**Sandra Pereira****Proposal for a regulation****Article 18.º – paragraph 1 – point a***Text proposed by the Commission*

(a) **category 2** NGT plants for food use or for feed use;

Amendment

(a) NGT plants for food use or for feed use;

Or. pt

Amendment 448**Sandra Pereira****Proposal for a regulation****Article 18.º – paragraph 1 – point b**

Text proposed by the Commission

(b) food containing, consisting or produced from **category 2** NGT plants or containing ingredients produced from **category 2** NGT plants (**'category 2 NGT food'**);

Amendment

(b) food containing, consisting **of** or produced from NGT plants, or containing ingredients produced from NGT plants;

Or. pt

Amendment 449

Sandra Pereira

Proposal for a regulation

Article 18.^o – paragraph 1 – point c

Text proposed by the Commission

(c) feed containing, consisting or produced from **category 2** NGT plants (**'category 2 NGT feed'**).

Amendment

(c) feed containing, consisting **of** or produced from NGT plants;

Or. pt

Amendment 450

Sandra Pereira

Proposal for a regulation

Article 19.^o – paragraph 1 – introductory part

Text proposed by the Commission

1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a **category 2** NGT plant for food or feed use, or **category 2** NGT food or feed shall be accompanied by a copy of **the studies, including, where available,** independent, peer-reviewed studies, which have been carried out and any other

Amendment

1. By way of derogation from Articles 5(3), point (e), and 17(3), point (e), of Regulation (EC) No 1829/2003, and without prejudice to any additional information that may be required in accordance with Article 32b of Regulation (EC) No 178/2002, an application for authorisation of a NGT plant for food or feed use, or NGT food or feed shall be accompanied by a copy of independent, peer-reviewed studies, which have been carried out and any other available material to demonstrate that:

available material to demonstrate that:

Or. pt

Amendment 451

Sandra Pereira

Proposal for a regulation

Article 19.º – paragraph 1 – point b

Text proposed by the Commission

(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on ***a safety assessment*** of the food or feed carried out in accordance with the principles and criteria laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).

Amendment

(b) the food or the feed complies with the criteria referred to in Article 4(1) or Article 16(1) of Regulation (EC) No 1829/2003, respectively, based on ***an assessment of the risk to biodiversity and of the safety*** of the food or feed carried out in accordance with the principles and criteria laid down in Parts 1 and 3 of Annex II to this Regulation and with the implementing act adopted in accordance with Article 27, point (c).

Or. pt

Amendment 452

Sandra Pereira

Proposal for a regulation

Article 19.º – paragraph 2 – subparagraph 2

Text proposed by the Commission

In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in

Amendment

deleted

accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

Or. pt

Amendment 453

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2);

deleted

Or. en

Justification

Category 2 NGT plants are clearly defined as GM plants in the regulation. Exemptions from the obligation to develop detection methods must be rejected. This will make it difficult or impossible to detect contamination. At the same time, the developers will not be interested in developing detection methods if they are not mandatory. Organic food and/or GMO-free food are premium products. Consumers expect these products to be free of genetic engineering. In terms of legal certainty for the food industry, detection methods are necessary for all category 2 NGT plants.

Amendment 454

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 19 – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or concluded by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 during the procedure referred to in Article 20(4), the modalities to comply with analytical method requirements shall be adapted as specified in the implementing act adopted in accordance with Article 27, point (e) and the guidance referred to in Article 29(2); **deleted**

Or. en

Justification

Several studies have outlined the conditions under which analytical testing could be feasible for all products obtained by targeted mutagenesis and cisgenesis. See notably Yves Bertheau (2019), New Breeding Techniques: Detection and Identification of the Techniques and Derived Products and Ribarits, A. et al. (2021): Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework.

Amendment 455
Sandra Pereira

Proposal for a regulation
Article 19.º – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of **category 2** NGT plants or food or feed containing or consisting of **category 2** NGT plants, the application shall also be accompanied by:

3. By way of derogation from Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, in the case of NGT plants or food or feed containing or consisting of NGT plants, the application shall also be accompanied by:

Or. pt

Amendment 456

Sandra Pereira

Proposal for a regulation

Article 19.º – paragraph 3 – point b

Text proposed by the Commission

(b) *where appropriate*, a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan. This duration may be different from the duration of the authorisation. *If, based on the results of any release notified in accordance with Section 1, the findings of the environmental risk assessment, the characteristics of the NGT plant, the characteristics and scale of its expected use and the characteristics of the receiving environment, in accordance with the implementing act adopted in accordance with Article 27, point (d), the applicant considers that the NGT plant does need a monitoring plan, the applicant may propose not to submit a monitoring plan.*

Amendment

(b) a monitoring plan for environmental effects in accordance with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; This duration may be different from the duration of the authorisation.

Or. pt

Amendment 457

Sandra Pereira

Proposal for a regulation

Article 21.º

Text proposed by the Commission

Amendment

Article 21

deleted

21 By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of

the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.

By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.

Or. pt

Amendment 458

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 21

Text proposed by the Commission

Amendment

Article 21

deleted

Duration of the validity of the authorisation after renewal

By way of derogation from Article 11(1) and Article 23(1) of Regulation (EC) No 1829/2003, after the first renewal, the authorisation shall be valid for an unlimited period, unless the Commission decides to renew the authorisation for a limited period, on justified grounds based on the findings of the risk assessment carried out pursuant to this Regulation and on experience with the use, including results of monitoring, if so specified in the authorisation.

Or. en

Justification

It is not in line with the Precautionary principle, or with plain good sense, to deliver authorizations forever for products which can reproduce and interact with wild plants and the ecosystems. It is all the more problematic as the proposal does not contain any safeguard clause that would allow the Commission to withdraw an authorization in case a problem is detected.

Amendment 459

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 21 a (new)

Text proposed by the Commission

Amendment

Article 21a

Safeguard clause

1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a NGT as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental

risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

2. Within 60 days of the date of receipt of the information transmitted by the Member State, a decision shall be taken on the measure taken by that Member State in accordance with the regulatory procedure referred to in Article 30(2).

For the purpose of calculating the 60-day period, any period of time during which the Commission is awaiting further information which it may have requested from the notifier or is seeking the opinion of the Scientific Committee or Committees which has or have been consulted shall not be taken into account. The period of time during which the Commission is awaiting the opinion of the Scientific Committee or Committees consulted shall not exceed 60 days. Likewise, the period of time the Council takes to act in accordance with the regulatory procedure referred to in Article 30(2) shall not be taken into account.

Or. en

Justification

If we lessen the obligations on some NGTs due to a lesser risk profile, it is all the more important to have a solid process in order to suspend or terminate their placing on the market in case serious issues are detected. It is fundamental that the public authorities keep that possibility for NGTs, as they have for other GMOs. This will benefit all stakeholders, including the petitionaries.

Amendment 460
Sandra Pereira

Proposal for a regulation
Chapter III – Section 4 – title

Text proposed by the Commission

Amendment

4 Common provisions for **category 2**
NGT plants and **category 2** NGT products

4 Common provisions for NGT
plants and NGT products

Or. pt

Amendment 461

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 22

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Justification

Consumers will find it very difficult to know whether these product claims reflect the reality. This form of greenwashing could confuse consumers, who take a primarily critical view of genetically modified products, and lead to a conflict of interests. Therefore, scientific proof is necessary. And there is no reason to give incentives for CAT2 based on predictions of sustainability. A bargaining to lower risk assessment requirement versus alleged sustainability conflicts with EU General food law.

Amendment 462

Maria Noichl

Proposal for a regulation

Article 22

Text proposed by the Commission

Amendment

[...]

deleted

Or. en

Amendment 463

Bert-Jan Ruissen

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Part 1 of Annex III** and it does not have any traits referred to in Part 2 of *that* Annex.

Amendment

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Article 52(1) of Regulation (EU) .../... [reference to the Regulation on the production and marketing of plant reproductive material]** and it does not have any traits referred to in Part 2 of Annex **III**.

Or. en

Amendment 464
Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation
Article 22 – paragraph 1

Text proposed by the Commission

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Part 1 of Annex III** and it does not have any traits referred to in Part 2 of that Annex.

Amendment

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **article 52(1) of Regulation (EU) .../... (reference to Plant Reproductive Material)** and it does not have any traits referred to in Part 2 of that Annex.

Or. en

Justification

For the sake of consistency, the sustainability assessment should be in line with the Regulation of Plant Reproductive Material, which establishes the sustainability requirements for all types of Plant Reproductive Material.

Amendment 465

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Part 1 of Annex III** and it does not have any traits referred to in Part 2 of that Annex.

Amendment

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **article 52(1) of Regulation (EU) .../... (of Plant Reproductive Material)** and it does not have any traits referred to in Part 2 of that Annex.

Or. en

Justification

The sustainability assessment should be in line with Regulation of Plant Reproductive Material, which establishes the sustainability requirements for all types of Plant Reproductive Material.

Amendment 466

Annie Schreijer-Pierik

Proposal for a regulation

Article 22 – paragraph 1

Text proposed by the Commission

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **Part 1 of Annex III** and it does not have any traits referred to in Part 2 of that Annex.

Amendment

1. The incentives in this Article shall apply to category 2 NGT plants and category 2 NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in **the Regulation on Plant Reproductive Material** and it does not have any traits referred to in Part 2 of that Annex.

Or. en

Justification

For the sake of consistency, the sustainability assessment should be in line with the Regulation on Plant Reproductive Material, which establishes the sustainability requirements for all types of Plant Reproductive Material.

Amendment 467

Sandra Pereira

Proposal for a regulation

Article 22.º – paragraph 1

Text proposed by the Commission

1. The incentives in this Article shall apply to **category 2** NGT plants and **category 2** NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in **Part 2 of** that Annex.

Amendment

1. The incentives in this Article shall apply to NGT plants and NGT products, where at least one of the intended trait(s) of the NGT plant conveyed by the genetic modification is contained in Part 1 of Annex III and it does not have any traits referred to in that Annex.

Or. pt

Amendment 468

Sandra Pereira

Proposal for a regulation

Article 22.º – paragraph 2 – point a

Text proposed by the Commission

(a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within **4** months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);

Amendment

(a) by way of derogation from Article 20(1), subsection (1) of this Regulation, the Authority shall deliver its opinion on the application within **6** months from the receipt of a valid application, unless the complexity of the product requires application of the time limit referred to in Article 20(1). The time limit shall be extendable under the conditions set out in Article 20(1), subsection (2);

Or. pt

Amendment 469
Sandra Pereira

Proposal for a regulation
Article 22.^o – paragraph 8 – point b

Text proposed by the Commission

(b) the Commission shall conduct an up-to-date scientific literature review of the impact on environmental, social and economic sustainability of the trait(s) it intends to add to or delete from the list in Annex III;

Amendment

(b) the Commission shall conduct an up-to-date scientific literature review of the impact on environmental, social and economic sustainability, ***as well as the impact on health***, of the trait(s) it intends to add to or delete from the list in Annex III;

Or. pt

Amendment 470
Maria Noichl

Proposal for a regulation
Article 23

Text proposed by the Commission

Article 23

Labelling of authorised category 2 NGT products

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.

Amendment

deleted

Amendment 471
Sandra Pereira

Proposal for a regulation
Article 23.º – title

Text proposed by the Commission

Amendment

Labelling of authorised **category 2** NGT products

Labelling of authorised NGT products

Or. pt

Amendment 472
Herbert Dorfmann

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Amendment

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.

deleted

Or. en

Amendment 473
Theresa Bielowski, Maria Noichl

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Amendment

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s) conveyed by the genetic modification, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.

deleted

Or. en

Justification

In the EU, no definition of sustainability exists. Specific regulations for "green claims" are currently being negotiated at EU level to avoid greenwashing. Information on the property conferred by the genetic modification under this regulation is therefore obsolete. Any additional food label should be based on clear methodology, baselines, define who is assessing the claims and how they can challenge.

Amendment 474
Colm Markey

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission

Amendment

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s)

In addition to the labelling requirements referred to in Article 21 of Directive 2001/18/EC, Articles 12, 13, 24 and 25 of Regulation (EC) No 1829/2003, and Article 4(6) to (7) of Regulation (EC) No 1830/2003, and without prejudice to the requirements under other Union legislation, the labelling of authorised category 2 NGT products may also mention the trait(s)

conveyed by the **genetic modification**, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.

conveyed by the **NGT**, as specified in the consent or the authorisation pursuant to Sections 2 or 3 of Chapter III of this Regulation.

Or. en

Justification

Category 2 NGT products should not be labelled as GMOs, but as category 2 NGT products.

Amendment 475

Maria Noichl

Proposal for a regulation

Article 24 – title

Text proposed by the Commission

Amendment

Measures to avoid the unintended presence of **category 2** NGT plants

Measures to avoid the unintended presence of NGT plants

Or. en

Amendment 476

Sandra Pereira

Proposal for a regulation

Article 24.^o – title

Text proposed by the Commission

Amendment

Measures to avoid the unintended presence of **category 2** NGT plants

Measures to avoid the unintended presence of NGT plants

Or. pt

Amendment 477

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 24 – paragraph 1

Text proposed by the Commission

Amendment

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

The Commission shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003, ***only in the event that the category 2 NGT plants are able to be detected, identified and quantified by analytical method. These provisions shall not apply to category 1 NGT plants and products produced from or by such plants. The burden of proof of the unintended presence shall not be put on the NGT2 producer.***

Or. en

Amendment 478

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Article 24 – paragraph 1

Text proposed by the Commission

Amendment

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003. ***These provisions shall not apply to category 1 NGT plants and products produced from or by such plants.***

Or. en

Justification

Given the fact that NGT Cat 1 are conventional-like, no coexistence measures are needed.

Amendment 479

Annie Schreijer-Pierik

Proposal for a regulation

Article 24 – paragraph 1

Text proposed by the Commission

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

Amendment

Member States shall take appropriate measures to avoid the unintended presence of category 2 NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003. ***These provisions shall not apply to category 1 NGT plants and category 1 NGT products.***

Or. en

Justification

Given the fact that Category 1 NGT are conventional-like, and in line with the current situation between conventional and organic farming, no coexistence measures are needed.

Amendment 480

Maria Noichl

Proposal for a regulation

Article 24 – paragraph 1

Text proposed by the Commission

Member States shall take appropriate measures to avoid the unintended presence of **category 2** NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

Amendment

Member States shall take appropriate measures to avoid the unintended presence of NGT plants in products not subject to Directive 2001/18 or Regulation 1829/2003.

Or. en

Amendment 481

Ivan David

Proposal for a regulation

Article 24 a (new)

Text proposed by the Commission

Amendment

Article 24 a

Protection of breeders' intellectual property

(1) NGT category 1 plants, as well as plants and varieties that may arise and occur naturally or may arise through conventional breeding or are considered to be conventional plants, should not be the subject of a patent.

(2) The procedure laid down in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, as amended, shall be applicable for the purposes of protecting the intellectual property of breeders of NGT category 1 plants, as well as plants and varieties that may arise and occur naturally or may arise through conventional breeding or are considered to be conventional plants.

Or. cs

Justification

NGT category 1 plants, as well as plants and varieties that may arise and occur naturally or may arise through conventional breeding or are considered to be conventional plants, should not be the subject of a patent but of a plant variety right that allows the use of the so-called breeder's exemption, thereby supporting innovation and creation of new varieties. EU plant variety law is a highly effective and widely used system for the protection of new varieties. It enables the protection of the breeder's intellectual property, license fees are a significant source of refinancing the expensive breeding process. Unlike a patent, it enables the use of a protected variety for research and breeding of other varieties without the consent of the holder of the breeding certificate, thus supporting innovation in breeding. In addition, EU plant variety law maintains a farm exemption that allows small farms and small farmers to use part of the harvest as seed the following year. EU plant variety law makes it impossible for the patent holder to force the farmer to commit to selling the entire crop back to the patent holder when signing the seed sales contract. Such practices are often abused in third countries to exploit farmers and cause monopolization of the market for agricultural commodities.

Amendment 482
Sandra Pereira

Proposal for a regulation
Article 25.º

Text proposed by the Commission

Amendment

Article 25

deleted

25 Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.

Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.

Or. pt

Amendment 483

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Article 25

Text proposed by the Commission

Amendment

Article 25

deleted

Cultivation

Article 26b of Directive 2001/18/EC shall not apply to category 2 NGT plants.

Or. en

Justification

The so-called opt-out clause (article 26b of Directive 2001/18/EC) was adopted to allow Member states to adapt the cultivation of specific GM plants to their local conditions, notably: specific environmental challenges, % of organic farmers on the territory, specific economic interests, etc... This clause was widely used by Member states and will be also useful for NGTs. Member states should be able to decide for each NGTs if the potential benefits outweigh the social and economic risks.

Amendment 484

Anna Zalewska, Krzysztof Jurgiel

Proposal for a regulation

Article 25 – paragraph 1

Text proposed by the Commission

Amendment

Article 26b of Directive 2001/18/EC shall **not** apply to category 2 NGT plants.

Article 26b of Directive 2001/18/EC shall apply to category 2 NGT plants.

Or. pl

Justification

Member States should retain the right to prohibit the cultivation of category 2 NGT plants in their territory, in accordance with Article 26b of Directive 2001/18.

Amendment 485

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Article 25 – paragraph 1

Text proposed by the Commission

Article 26b of Directive 2001/18/EC shall not apply to **category 2** NGT plants.

Amendment

Article 26b of Directive 2001/18/EC shall not apply to NGT plants.

Or. en

Justification

Since Category 1 NGT plants are equivalent to conventional ones, no opt-out from cultivation of these products should be needed.

Amendment 486

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Article 25 – paragraph 1

Text proposed by the Commission

Article 26b of Directive 2001/18/EC shall not apply to **category 2** NGT plants.

Amendment

Article 26b of Directive 2001/18/EC shall not apply to NGT plants.

Or. en

Justification

Given the fact that NGT CAT 1 are conventional-like, and in line with the current situation, no opt-out from cultivation of these products should be allowed.

Amendment 487

Theresa Bielowski, Maria Noichl

Proposal for a regulation
Article 25 – paragraph 1

Text proposed by the Commission

Amendment

Article 26b of Directive 2001/18/EC shall
not apply to category 2 NGT plants.

Article 26b of Directive 2001/18/EC shall
apply to category 2 NGT plants.

Or. en

Justification

Article 26b of Directive 2001/18 allows the total or partial exclusion of the cultivation of genetic engineering on the territory of the respective member state. In the sense of subsidiarity of the member states, this possibility is also to be maintained extensively for NGT plants.

Amendment 488
Theresa Bielowski, Maria Noichl

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission

Amendment

1. The power to adopt the delegated acts is conferred on the Commission subject to the conditions laid down in this Article. **deleted**

Or. en

Justification

The definitions of NGT are the core of the legislations and cannot not changed via delegated acts as defined in Art 290 TFEU only non-essential elements can be amended via delegated acts.

Amendment 489
Theresa Bielowski, Maria Noichl

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

Text proposed by the Commission

Amendment

(a) the information required to demonstrate that a plant is a NGT plant; *deleted*

Or. en

Justification

It should be clear for all stakeholders what the regulation will look like before it enters into force in order to have clarity for them. With this delegated act, stakeholders are left in the dark about the extent to which changes will be made regarding categorization and labelling. However, as these points are crucial for the implementation of the proposal, these answers would need to be available before a vote by the Member States and the Parliament

Amendment 490

Theresa Bielowski, Maria Noichl

Proposal for a regulation

Article 27 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) the methodology and information requirements for the environmental risk assessment of category 2 NGT plants and the safety assessments of category 2 NGT food and feed, in accordance with the principles and criteria laid down in Annex II; *deleted*

Or. en

Justification

The Regulation does not provide for any limitations, and therefore simplifications of the requirements are also possible. It should be clear for all stakeholders what the Regulation will look like before it enters into force, in order to have clarity for all stakeholders. With this implementing act, stakeholders are left in the dark about the extent to which changes will be made regarding categorization and labelling. However, as these points are crucial for the implementation of the proposal, these answers would need to be available before a vote by the Member States and the Parliament.

Amendment 491

Ulrike Müller, Atidzhe Alieva-Veli, Martin Hlaváček, Elsi Katainen

Proposal for a regulation

Article 30 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. No later than 2026, the Commission shall present a report to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the role and impact of patents on breeders' and farmers' access to varied plant reproductive material, as well as on innovation and particularly on the opportunities for SME. Where appropriate to ensure breeders' and farmers' access to plant reproductive material, seed diversity and affordable prices, as well as the ongoing promotion of innovation, particularly with a view to opportunities for SME, the report shall be accompanied by a roadmap to address necessary adjustments in the intellectual property framework.

Or. en

Amendment 492

Sandra Pereira

Proposal for a regulation

Article 31.º

Text proposed by the Commission

Amendment

Article 31

deleted

31 With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to this Regulation.

With regard to category 2 NGT plants, references in other Union legislation to Annex II or Annex III to Directive 2001/18/EC shall be construed as references to Parts 1 and 2 of Annex II to

this Regulation.

Or. pt

Amendment 493
Bert-Jan Ruissen

Proposal for a regulation
Article 31 a (new)

Text proposed by the Commission

Amendment

Article 31a

Exclusion from patentability

NGT plant material shall not be patentable.

Or. en

Amendment 494
Bert-Jan Ruissen

Proposal for a regulation
Article 33 a (new)

Text proposed by the Commission

Amendment

Article 33a

Amendments to Directive (EU) 98/44/EC

Article 4 of Directive (EU) 98/44/EC is amended as follows:

In paragraph 1, the following points (c) and (d) are added:

'(c) NGT plant material as defined in Regulation (EU) .../... [insert reference to this Regulation].

(d) plant material that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex IB of that directive'

Or. en

Justification

Technical alignment in relation to the exclusion of the plant material from patentability.

Amendment 495

Sandra Pereira

Proposal for a regulation

Annex I

Text proposed by the Commission

Amendment

Criteria of equivalence of NGT plants to conventional plants ***deleted***

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

(1) substitution or insertion of no more than 20 nucleotides;

(2) deletion of any number of nucleotides;

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

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

(5) any other targeted modification of 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 496

Benoît Biteau

on behalf of the Verts/ALE Group

Proposal for a regulation

Annex I

Text proposed by the Commission

Amendment

Criteria of equivalence of NGT plants to conventional plants

deleted

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

(1) substitution or insertion of no more than 20 nucleotides;

(2) deletion of any number of nucleotides;

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

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

(5) any other targeted modification of 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.

Justification

There is no scientific basis to support the allegation that the criteria proposed in this annex guarantee a lower level of risks. There is, in particular, no mention in any scientific publication, or list of criteria backed by risk assessors, of lower risks linked to a substitution or insertion of no more than 20 nucleotides. Additionally, the deletion of nucleotides can lead to major changes in the functioning of the cell, and it does not present less risks than substitution or insertion per se. Only a case-by-case impact assessment can evaluate the risks of a genetic modification.

Amendment 497

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it ***differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.***

Amendment

A NGT plant is considered equivalent to conventional plants when it ***does not include foreign genetic material from outside the breeder's gene pool.***

Amendment 498

Annie Schreijer-Pierik

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it ***differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by***

Amendment

A NGT plant is considered equivalent to conventional plants when it ***does not include foreign genetic material from outside the breeder's gene pool.***

bioinformatic tools.

Or. en

Justification

The Commission study highlighted that “there are implementation and enforcement challenges, in particular related to the detection and differentiation of NGT products that do not contain any foreign genetic material.” This is a problem for enforcement authorities, operators and applicants. The current criteria are complex and only partly solve this problem. Logically, Annex I should focus on those criteria that solve the enforcement and detection and identification problems as identified by the Commission study for NGT products that do not contain any foreign genetic material.

Amendment 499

Bert-Jan Ruissen

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it ***differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.***

Amendment

A NGT plant is considered equivalent to conventional plants when it ***does not include foreign genetic material from outside the breeders' gene pool.***

Or. en

Amendment 500

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it ***differs from the recipient/parental plant by no more than 20 genetic modifications of the types***

Amendment

A NGT plant is considered equivalent to conventional plants when it ***does not include foreign genetic material from outside the breeders' gene pool.***

referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Or. en

Justification

The Commission study highlighted that “there are implementation and enforcement challenges, in particular related to the detection and differentiation of NGT products that do not contain any foreign genetic material.” This is a problem for enforcement authorities, operators and applicants. The current criteria are complex and only partly solve this problem. Logically, Annex I should focus on those criteria that solve the enforcement and detection and identification problems as identified by the Commission study for NGT products that do not contain any foreign genetic material.

Amendment 501

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, ***in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.***

Amendment

A NGT plant is considered equivalent to conventional plants ***when it contains only genetic modifications referred to in points 1 to 5 and*** when it differs from the recipient/parental plant by no more than 20 genetic modifications, ***excluded off target modifications,*** of the types referred to in points 1 to 4, ***in the targeted site or sites in the monoploid genome.***

Or. en

Amendment 502

Veronika Vrecionová

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

Amendment

A **NGT** plant is considered equivalent to conventional **plants** *when* it differs from the recipient/parental plant by **no more than 20** genetic modifications of the types referred to in points 1 **to 5, in any DNA sequence sharing sequence similarity with the targeted site that** can be **predicted by bioinformatic tools**.

A plant **prepared by new genomic techniques** is considered equivalent to a conventional **plant** *if* it differs from the recipient/parental plant **only** by genetic modifications of the types referred to in points 1 **and 2 which** can be **combined with each other**.

Or. en

Justification

The current wording of the Annex I disproportionately restricts breeders using NGT compared to conventional breeding practices. They are forced to work with only a maximum of 20 genetic modification which is not equivalent to conventional breeding. Therefore, we suggest not to limit the number of genetic modification or to refer this number per monoploid genome so that European breeders are not disadvantaged compared to breeders from third countries, who will not be restricted in any way.

Amendment 503 **Daniela Rondinelli**

Proposal for a regulation **Annex I – paragraph 1**

Text proposed by the Commission

A NGT plant is considered equivalent to conventional **plants** when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 **to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools**.

Amendment

A NGT plant is considered equivalent to **plants obtained by means of** conventional **selection methods when it contains only the genetic modifications referred to in points 1 to 5 and** when it differs from the recipient/parental plant by no more than 20 genetic modifications, **excluding off-target modifications**, of the types referred to in points 1, **2 and 4, in the targeted site or sites in the monoploid genome**.

Or. it

Amendment 504 **Martin Hlaváček**

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A **NGT** plant is considered equivalent to conventional **plants when** it differs from the recipient/parental plant by **no more than 20** genetic modifications of the types referred to in points 1 to 5, **in any DNA sequence sharing sequence similarity with the targeted site that** can be **predicted by bioinformatic tools**.

Amendment

A plant **prepared by new genomic techniques** is considered equivalent to a conventional **plant if** it differs from the recipient/parental plant **only** by genetic modifications of the types referred to in points 1 to 4 **which** can be **combined with each other**.

Or. en

Amendment 505

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Elsi Katainen, Ulrike Müller, Erik Poulsen

Proposal for a regulation

Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than **20** genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Amendment

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than **30** genetic modifications **per haploid genome** of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Or. en

Justification

As described in recital 14a, plants have a different number of haploid genomes, so in order not to discriminate the limit should apply per haploid genomes. Furthermore, the limitation should be raised from 20 to 30 as 20 unnecessarily limits the possibilities of its use. We want to ensure that we fully benefit from the potential of NGTs including improving the environmental footprint of agriculture and increase food safety.

Amendment 506
Anne Sander

Proposal for a regulation
Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Amendment

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5 ***per haploid***, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Or. fr

Amendment 507
Herbert Dorfmann

Proposal for a regulation
Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Amendment

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5 ***per haploid***, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

Or. en

Amendment 508
Daniel Buda, Dan-Ştefan Motreanu

Proposal for a regulation
Annex I – paragraph 1

Text proposed by the Commission

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, ***in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.***

Amendment

A NGT plant is considered equivalent to conventional plants ***when it contains only genetic modifications referred to in points 1 to 5 and*** when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 4, ***in the targeted site or sites in the monoploid genome.***

Or. en

Justification

The criteria to establish equivalence with conventional plants should allow plants with complex genomes (polyploids) to benefit from NGTs in the same way as diploid crops. Point 5 of Annex I refers to genetic changes existing in the breeders gene pool and therefore it would be counterproductive for such changes to be counted in the verification that the threshold of 20 genetic modifications is met.

Amendment 509

Veronika Vrecionová

Proposal for a regulation

Annex I – paragraph 1 – indent 1 (new)

Text proposed by the Commission

Amendment

– ***Criteria specific for the use of targeted mutagenesis on the condition that the number of modification events per any protein-coding sequence does not exceed 3:***

Or. en

Justification

It is very unlikely that plants produced by conventional breeding have multiple mutations in a single protein-coding sequence, so to come closer to really meeting the equivalence criteria, we suggest to limit the number of modifications allowed per any single protein-coding sequence.

Amendment 510

Martin Hlaváček

Proposal for a regulation
Annex I – paragraph 1 – point 1 (new)

Text proposed by the Commission

Amendment

(1) Criteria specific for the use of targeted mutagenesis on the condition that the number of modifications per any gene cannot exceed 3:

Or. en

Amendment 511
Martin Hlaváček

Proposal for a regulation
Annex I – paragraph 1 – point 2 (new)

Text proposed by the Commission

Amendment

(2) Criteria specific for the use of cisgenesis on the condition that only one modification can occur per one genome site:

Or. en

Amendment 512
Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation
Annex I – point 1

Text proposed by the Commission

Amendment

(1) substitution or insertion of no more than 20 nucleotides; **deleted**

Or. en

Amendment 513
Bert-Jan Ruissen

Proposal for a regulation
Annex I – point 1

Text proposed by the Commission

Amendment

(1) *substitution or insertion of no more than 20 nucleotides;* *deleted*

Or. en

Amendment 514
Annie Schreijer-Pierik

Proposal for a regulation
Annex I – point 1

Text proposed by the Commission

Amendment

(1) *substitution or insertion of no more than 20 nucleotides;* *deleted*

Or. en

Amendment 515
Anne Sander

Proposal for a regulation
Annex I – point 1

Text proposed by the Commission

Amendment

(1) substitution or insertion of no more than 20 nucleotides; (1) substitution or insertion of no more than 20 nucleotides *per haploid*;

Or. fr

Amendment 516
Herbert Dorfmann

Proposal for a regulation
Annex I – point 1

Text proposed by the Commission

Amendment

(1) substitution or insertion of no more than 20 nucleotides;

(1) substitution or insertion of no more than 20 nucleotides ***per haploid***;

Or. en

Amendment 517

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation

Annex I – point 1

Text proposed by the Commission

Amendment

(1) substitution or insertion of no more than 20 nucleotides;

(1) ***targeted*** substitution or insertion of no more than 20 nucleotides;

Or. en

Amendment 518

Daniela Rondinelli

Proposal for a regulation

Annex I – point 1

Text proposed by the Commission

Amendment

(1) substitution or insertion of no more than 20 nucleotides;

(1) ***targeted*** substitution or insertion of no more than 20 nucleotides;

Or. it

Amendment 519

Bert-Jan Ruissen

Proposal for a regulation

Annex I – point 2

Text proposed by the Commission

Amendment

(2) ***deletion of any number of nucleotides;***

deleted

Amendment 520
Annie Schreijer-Pierik

Proposal for a regulation
Annex I – point 2

Text proposed by the Commission

Amendment

(2) *deletion of any number of
nucleotides;* *deleted*

Amendment 521
Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation
Annex I – point 2

Text proposed by the Commission

Amendment

(2) *deletion of any number of
nucleotides;* *deleted*

Amendment 522
Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation
Annex I – point 2

Text proposed by the Commission

Amendment

(2) deletion of any number of
nucleotides; (2) ***targeted*** deletion of any number of
nucleotides;

Amendment 523

Daniela Rondinelli

**Proposal for a regulation
Annex I – point 2**

Text proposed by the Commission

(2) deletion of any number of nucleotides;

Amendment

(2) ***targeted*** deletion of any number of nucleotides;

Or. it

**Amendment 524
Veronika Vrecionová**

**Proposal for a regulation
Annex I – point 2 – indent 1 (new)**

Text proposed by the Commission

Amendment

– ***Criteria specific for the use of cisgenesis on the condition that the genetic modification does not create a chimeric protein that is not already present in a species from the breeders' gene pool:***

Or. en

Justification

Generation of a gene encoding a chimeric protein is possible by repeated insertion or substitution of parts of coding sequence together with regulatory elements in/to the same target locus. Each inserted/substituted sequence will be “continuous and existing in the breeders' gene pool”, so technically the plant would be verified as NGT1, but it may be genetically equivalent to a plant generated by intra-genesis. That is why we included the condition that the modification cannot create a chimeric protein. Since deletion and other modifications that can easily knockout a gene are allowed for NGT1, interruption of an endogenous gene does not have to be forbidden. The same conditions can be applied also for inversions and translocations (point 4), so it would also make sense to include point (4) as point (3c) to simplify the text.

**Amendment 525
Juozas Olekas, Carmen Avram, Paolo De Castro**

Proposal for a regulation
Annex I – point 3

Text proposed by the Commission

Amendment

(3) on the condition that the genetic modification does not interrupt an endogenous gene: **deleted**

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 526
Bert-Jan Ruissen

Proposal for a regulation
Annex I – point 3

Text proposed by the Commission

Amendment

(3) on the condition that the genetic modification does not interrupt an endogenous gene: **deleted**

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 527
Annie Schreijer-Pierik

Proposal for a regulation

Annex I – point 3

Text proposed by the Commission

Amendment

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

deleted

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 528

Martin Hlaváček

Proposal for a regulation

Annex I – point 3 – introductory part

Text proposed by the Commission

Amendment

(3) on the condition that the genetic modification does not interrupt an endogenous gene:

(3) on the condition that the genetic modification does not interrupt an endogenous gene *or that the resulting DNA sequences context in the recipient plant already occurs in a species from the breeders' gene pool:*

Or. en

Amendment 529

Daniel Buda, Dan-Ștefan Motreanu

Proposal for a regulation

Annex I – point 3 – introductory part

Text proposed by the Commission

Amendment

(3) on the condition that the genetic modification does not *interrupt an*

(3) on the condition that the genetic modification does not *create an intragenic*

endogenous gene:

plant:

Or. en

Justification

As long as the insertion does not result in the creation of an intragenic plant, introductions or interruptions of endogenous genes by cisgenes should not be excluded as these applications enable opportunities for developing beneficial traits in category 1 (e.g. introduction of multiple disease resistant cisgenes to ensure resistance as highlighted in the JRC report on 'Economic and environmental impacts of disease-resistant crops developed with cisgenesis'). Category 1 plants can contain multiple cisgenes at one location but should not create an intragenic plant by resulting in the production of new proteins by fusion of the cisgenic sequences with endogenous coding sequence.

Amendment 530

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Annex I – point 3 – point a

Text proposed by the Commission

Amendment

(a) ***targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;*** ***deleted***

Or. en

Amendment 531

Tom Vandenkendelaere

Proposal for a regulation

Annex I – point 3 – point a

Text proposed by the Commission

Amendment

(a) ***targeted*** insertion of a contiguous DNA sequence existing in the breeder's gene pool;
(a) insertion of a contiguous DNA sequence ***other than the ones mentioned under (1)*** existing in the breeder's gene pool;

Or. en

Justification

This point 3 is about cisgenesis, though cisgenesis does not necessarily have to result from a targeted intervention. Cisgenes can also result from random insertions and there is no reason to state that the latter should not qualify as a category 1 NGT plant.

Amendment 532 **Herbert Dorfmann**

Proposal for a regulation **Annex I – point 3 – point a**

Text proposed by the Commission

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool;

Amendment

(a) targeted insertion of a contiguous DNA sequence existing in the breeder's gene pool ***for breeding purposes***;

Or. en

Amendment 533 **Daniela Rondinelli**

Proposal for a regulation **Annex I – point 3 – point a**

Text proposed by the Commission

(a) ***targeted*** insertion of a contiguous DNA sequence existing in the breeder's gene pool;

Amendment

(a) insertion of a contiguous DNA sequence existing in the breeder's gene pool;

Or. it

Amendment 534 **Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton**

Proposal for a regulation **Annex I – point 3 – point a**

Text proposed by the Commission

(a) ***targeted*** insertion of a contiguous DNA sequence existing in the breeder's

Amendment

(a) insertion of a contiguous DNA sequence existing in the breeder's gene

gene pool;

pool;

Or. en

Amendment 535

Veronika Vrecionová

Proposal for a regulation

Annex I – point 3 – point a

Text proposed by the Commission

Amendment

(a) ***targeted*** insertion of a ***contiguous*** DNA sequence existing in the breeder's gene pool;

(a) insertion of a ***continuous*** DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 536

Martin Hlaváček

Proposal for a regulation

Annex I – point 3 – point a

Text proposed by the Commission

Amendment

(a) ***targeted*** insertion of a contiguous DNA sequence existing in the breeder's gene pool;

(a) insertion of a contiguous DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 537

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Annex I – point 3 – point b

Text proposed by the Commission

Amendment

(b) ***targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the***

deleted

breeder's gene pool;

Or. en

Amendment 538

Tom Vandenkendelaere

Proposal for a regulation

Annex I – point 3 – point b

Text proposed by the Commission

(b) **targeted** substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Amendment

(b) substitution of an endogenous DNA sequence with a contiguous DNA sequence ***other than the ones mentioned under (1)*** existing in the breeder's gene pool

Or. en

Justification

This point 3 is about cisgenesis, though cisgenesis does not necessarily have to result from a targeted intervention. Cisgenes can also result from random insertions and there is no reason to state that the latter should not qualify as a category 1 NGT plant.

Amendment 539

Herbert Dorfmann

Proposal for a regulation

Annex I – point 3 – point b

Text proposed by the Commission

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Amendment

(b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool ***for breeding purposes***;

Or. en

Amendment 540

Veronika Vrecionová

Proposal for a regulation
Annex I – point 3 – point b

Text proposed by the Commission

(b) ***targeted*** substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the ***breeder's*** gene pool;

Amendment

(b) substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the ***breeders'*** gene pool;

Or. en

Amendment 541

Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation
Annex I – point 3 – point b

Text proposed by the Commission

(b) ***targeted*** substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Amendment

(b) substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 542

Martin Hlaváček

Proposal for a regulation
Annex I – point 3 – point b

Text proposed by the Commission

(b) ***targeted*** substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Amendment

(b) substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder's gene pool;

Or. en

Amendment 543

Veronika Vrecionová

Proposal for a regulation

Annex I – point 3 – point b – point i (new)

Text proposed by the Commission

Amendment

i) c) inversion or translocation of a continuous endogenous DNA sequence existing in the breeders' gene pool;

Or. en

Justification

In our opinion, the criteria for NGT category 1 are not uniform with regard to the permissibility of unplanned endogenous gene disruption. Moreover, the condition of targeted (intentional) modifications is not demonstrable and uniform as well. In respect of it, we propose simpler wording of the paragraph. We miss the presence of translocation in the annex, while it is mentioned in the Technical paper from the Commission that these translocations do occur in nature and conventional breeding. Therefore, it would be logical to include translocation under the requirement that it does not lead to creation of chimeric proteins.

Amendment 544

Martin Hlaváček

Proposal for a regulation

Annex I – point 3 – point b – point i (new)

Text proposed by the Commission

Amendment

i) translocation of a continuous endogenous DNA sequence existing in the breeders' gene pool;

Or. en

Amendment 545

Asger Christensen

on behalf of the Renew Group

Emma Wiesner, Irène Tolleret, Jérémy Decerle, Erik Poulsen

Proposal for a regulation

Annex I – point 3 a (new)

Text proposed by the Commission

Amendment

(3 a) On the condition that NGTs are not used with the purpose of developing herbicide tolerant plants;

Or. en

Amendment 546
Annie Schreijer-Pierik

Proposal for a regulation
Annex I – point 4

Text proposed by the Commission

Amendment

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

Or. en

Amendment 547
Bert-Jan Ruissen

Proposal for a regulation
Annex I – point 4

Text proposed by the Commission

Amendment

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

Or. en

Amendment 548
Juozas Olekas, Carmen Avram, Paolo De Castro

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 549

Veronika Vrecionová

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 550

Veronika Vrecionová

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.***

Or. en

Justification

The point (5) was merged with point (3) for simplification. The wording/meaning of the point (5) is already covered in points (1) – (3).

Amendment 551

Martin Hlaváček

Proposal for a regulation

Annex I – point 5

Text proposed by the Commission

Amendment

(5) any other targeted modification of 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. **deleted**

Or. en

Amendment 552

Annie Schreijer-Pierik

Proposal for a regulation

Annex I – point 5

Text proposed by the Commission

Amendment

(5) any other targeted modification of 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. **deleted**

Or. en

Amendment 553

Juozas Olekas, Carmen Avram, Paolo De Castro

Proposal for a regulation

Annex I – point 5

Text proposed by the Commission

Amendment

(5) any other targeted modification of 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. **deleted**

Amendment 554
Bert-Jan Ruissen

Proposal for a regulation
Annex I – point 5

Text proposed by the Commission

Amendment

(5) any other **targeted** modification of 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. **deleted**

Amendment 555
Elena Lizzi, Paola Ghidoni, Angelo Ciocca, Rosanna Conte, Gilles Lebreton

Proposal for a regulation
Annex I – point 5

Text proposed by the Commission

Amendment

(5) any other **targeted** modification of 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.

(5) any other modification of 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 **on the condition that the genetic modification does not interrupt an endogenous gene.**

Amendment 556
Herbert Dorfmann

Proposal for a regulation
Annex I – point 5

Text proposed by the Commission

(5) any other targeted modification of 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

(5) any other targeted modification of 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 gene pool **for breeding purposes**.

Or. en

Amendment 557

Sandra Pereira

Proposal for a regulation
Annex II – subheading 1

Text proposed by the Commission

Risk assessment of **category 2** NGT plants and **category 2** NGT food and feed

Amendment

Risk assessment of NGT plants and NGT food and feed

Or. pt

Amendment 558

Sandra Pereira

Proposal for a regulation
Annex II – paragraph 1

Text proposed by the Commission

Part 1 of this Annex describes the general principles to be followed to perform the environmental risk assessment of **category 2** NGT plants ***referred to in Article 13, points (c) and (d), Article 14(1), point (e), and Article 19(3), point (a), and the safety assessment of category 2 NGT food and feed referred to in Article 19(1), point (b).*** ***Part 2*** describes specific information for the environmental risk assessment of **category 2** NGT plants and ***Part 3*** describes specific information for the safety assessment of **category 2** NGT food

Amendment

This Annex describes the general principles to be followed to perform the environmental risk assessment of NGT plants.

and feed.

Or. pt

Amendment 559

Sandra Pereira

Proposal for a regulation

Annex II – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The type and amount of information necessary for the environmental risk assessment of NGT plants laid down in Annex III of Directive 2001/18/EC and for the food and feed safety assessment of NGT food and feed shall apply.

Or. pt

Amendment 560

Sandra Pereira

Proposal for a regulation

Annex II – Part 1

Text proposed by the Commission

Amendment

[...]

deleted

Or. pt

Amendment 561

Sandra Pereira

Proposal for a regulation

Annex III

Text proposed by the Commission

Amendment

Traits referred to in Article 22

deleted

1 Traits justifying the incentives referred to in Article 22:

Traits justifying the incentives referred to in Article 22:

(1) yield, including yield stability and yield under low-input conditions;

(2) tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;

(3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;

(4) more efficient use of resources, such as water and nutrients;

(5) characteristics that enhance the sustainability of storage, processing and distribution;

(6) improved quality or nutritional characteristics;

(7) reduced need for external inputs, such as plant protection products and fertilisers.

2 Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.

Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.

Or. pt

Amendment 562

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – introductory part

Text proposed by the Commission

Amendment

Traits justifying the incentives referred to in Article 22:

Traits justifying the incentives referred to in Article 22 ***are listed in article 52(1) of Regulation (EU) .../... (of Plant***

Reproductive Material).

Or. en

Justification

The sustainability assessment should be in line with Regulation of Plant Reproductive Material, which establishes the sustainability requirements for all types of Plant Reproductive Material. The following points (1 to 7) are deleted.

Amendment 563

Bert-Jan Ruissen

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – introductory part

Text proposed by the Commission

Traits justifying the incentives referred to in Article 22:

Amendment

Traits justifying the incentives referred to in Article 22 ***are listed in Article 52(1) of Regulation (EU) .../... [reference to Regulation on plant reproductive material].***

Or. en

Amendment 564

Annie Schreijer-Pierik

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – introductory part

Text proposed by the Commission

Traits justifying the incentives referred to in Article 22:

Amendment

Traits justifying the incentives referred to in Article 22 ***are listed in article 52(1) of Regulation (EU) .../... (of Plant Reproductive Material).***

Or. en

Justification

For the sake of consistency, the sustainability assessment should be in line with the Regulation of Plant Reproductive Material, which establishes the sustainability requirements

for all types of Plant Reproductive Material.

Amendment 565

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 1

Text proposed by the Commission

Amendment

**(1) yield, including yield stability and
yield under low-input conditions;** **deleted**

Or. en

Amendment 566

Annie Schreijer-Pierik

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 1

Text proposed by the Commission

Amendment

**(1) yield, including yield stability and
yield under low-input conditions;** **deleted**

Or. en

Amendment 567

Annie Schreijer-Pierik

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 2

Text proposed by the Commission

Amendment

**(2) tolerance/resistance to biotic
stresses, including plant diseases caused
by nematodes, fungi, bacteria, viruses and
other pests;** **deleted**

Or. en

Amendment 568

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 2

Text proposed by the Commission

Amendment

(2) *tolerance/resistance to biotic stresses, including plant diseases caused by nematodes, fungi, bacteria, viruses and other pests;* *deleted*

Or. en

Amendment 569

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) *tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;* *deleted*

Or. en

Amendment 570

Annie Schreijer-Pierik

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 3

Text proposed by the Commission

Amendment

(3) *tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;* *deleted*

Or. en

Amendment 571

Veronika Vrecionová

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 3

Text proposed by the Commission

(3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change;

Amendment

(3) tolerance/resistance to abiotic stresses, including those created or exacerbated by climate change ***conditions***;

Or. en

Amendment 572

Annie Schreijer-Pierik

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 4

Text proposed by the Commission

(4) ***more efficient use of resources, such as water and nutrients;***

Amendment

deleted

Or. en

Amendment 573

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 4

Text proposed by the Commission

(4) ***more efficient use of resources, such as water and nutrients;***

Amendment

deleted

Or. en

Amendment 574

Annie Schreijer-Pierik

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 5

Text proposed by the Commission

Amendment

(5) *characteristics that enhance the sustainability of storage, processing and distribution;* *deleted*

Or. en

Amendment 575

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 5

Text proposed by the Commission

Amendment

(5) *characteristics that enhance the sustainability of storage, processing and distribution;* *deleted*

Or. en

Amendment 576

Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation

Annex III – Part 1 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

(6) *improved quality or nutritional characteristics;* *deleted*

Or. en

Amendment 577

Annie Schreijer-Pierik

Proposal for a regulation
Annex III – Part 1 – paragraph 1 – point 6

Text proposed by the Commission

Amendment

(6) improved quality or nutritional characteristics; **deleted**

Or. en

Amendment 578
Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation
Annex III – Part 1 – paragraph 1 – point 7

Text proposed by the Commission

Amendment

(7) reduced need for external inputs, such as plant protection products and fertilisers. **deleted**

Or. en

Amendment 579
Annie Schreijer-Pierik

Proposal for a regulation
Annex III – Part 1 – paragraph 1 – point 7

Text proposed by the Commission

Amendment

(7) reduced need for external inputs, such as plant protection products and fertilisers. **deleted**

Or. en

Amendment 580
Clara Aguilera, Cristina Maestre Martín De Almagro, Inma Rodríguez-Piñero

Proposal for a regulation
Annex III – Part 2

Text proposed by the Commission

Amendment

2 ***Traits excluding the application of the incentives referred to in Article 22: tolerance to herbicides.*** ***deleted***

Or. en

Justification

Annex III, Part 2 excludes NGT plants featuring herbicide-tolerant traits from the regulatory incentives. Such an exclusion is further not consistent with recital (36) which clarifies that the proposed regulation is not intended to take specific measures on herbicide tolerant NGT plants.

Amendment 581

Anne Sander

Proposal for a regulation

Annex III – Part 2

Text proposed by the Commission

Amendment

Part 2 Part 2 ***deleted***

Or. fr

Amendment 582

Sandra Pereira

Proposal for a regulation

Annex III a (new)

Text proposed by the Commission

Amendment

ANNEX III a

Technological assessment:

A technological assessment will be introduced to evaluate the potential benefits of NGT plants in terms of reducing pesticides, adapting to climate change or other aspects of sustainability, in order to verify the potential advantages, also in comparison with conventional

reproduction. In addition, the technological assessment will also be implemented to address potential adverse effects that cannot be examined at the level of individual events, such as combinatorial, cumulative and long-term effects.

The technological assessment should address the characteristics of specific traits, as well as aspects that could, at an early stage, have an impact on future technological development in the field of NGT plants in general. The criteria to be taken into account in the technological assessment are: use of pesticides, greenhouse gas emissions, effects on biodiversity, effects on agroecology, interactions between genetically modified plants sharing the same environment, spatial and temporal control, less risky alternatives and reversibility of releases.

Or. pt

Amendment 583
Sandra Pereira

Proposal for a regulation
Annex III b (new)

Text proposed by the Commission

Amendment

Annex III b

Detection and traceability methods

In cases where it is not feasible to provide an analytical method that detects, identifies and quantifies, if duly justified by the applicant or decided on by the European Union Reference Laboratory referred to in Article 32 of Regulation (EC) 1829/2003 under the procedure referred to in Article 20(4), the modalities for the fulfilment of the requirements of the analytical method shall be adapted. Methods of documentation that do not rely on analysis but rather on

documentation should also be defined for relevant cases.

Or. pt