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Environmental risk assessment of GMO: Lawfulness of a recital of a draft Commission Directive to adapt the Annexes to Directive 2001/18/EC of the Parliament and of the Council to technical progress

Legal opinion

commissioned by the German Federal Agency for Nature Conservation (BfN)

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I. Summary

1. Recital 9 of the Draft Commission Directive to amend the Annexes to Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMO) into the environment infringes the principle of institutional balance (Article 13 (2) TEU). The Commission exceeds its power to adapt the Annexes to the Directive to technical progress (Article 27 of Directive 2001/18/EC) and to state the reasons therefore (Article 296 (2) TFEU).

2. Recital 9 concerns the legal framework of the environmental risk assessment and thus the interpretation of a core element of a legislative act of the Parliament and of the Council. The Commission has no mandate to make such a statement of interpretation. Recital 9 has no relevance to the Commission's authorisation under Article 27 of Directive 2001/18/EC (adaptation to technical progress). In particular Recital 9 does not state a reason to a proposed amendment by the Commission to adapt the Directive to technical progress.

3. By proposing Recital 9 the Commission uses its empowerment to adopt delegated acts for a misleading statement as to the interpretation of the basic act. The power of the Commission to lay down recitals to a delegated act is restricted to giving reasons for the provisions in the proposed delegated act. It does not include the power to give isolated and unclear statements on the interpretation of legislative acts of the Parliament and of the Council.

4. According to Recital 9 of the Draft Commission Directive, the scope of the environmental risk assessment (ERA) of a genetically modified (GM) plant made tolerant to a herbicide should be consistent with Directive 2001/18/EC. The ERA of use of a plant protection product (PPP) on a GM plant would fall under the scope of PPP Regulation (EC) 1107/2009.

5. The statement in Recital 9 is not wrong but misleading. It suggests that the use of PPP on GM plants would not fall within the scope of the authorisation procedure of the GMO. In fact, according to Directive 2001/18/EC, the use of PPP on GM plants has to be considered of in the authorisation procedure of the GMO independently from whether or not it has been considered in a PPP authorisation procedure before. The main difference between the authorisation procedure of the GMO and of the PPP is the subject-matter of the authorisation, which is either the GMO or the PPP. If PPP are used on GM plants, the environmental effects of the combination have to be considered of in both authorisation procedures. Nevertheless, as far as available and appropriate, the results of the environmental risk assessment (ERA) in one procedure should be considered of in the other procedure as well.

6. Although Recital 9 may lead to a wrong interpretation of the scope and interplay of the GMO Directive 2001/18/EC and PPP Regulation (EC) No 1107/2009, it has no binding effect. It does not allow any restriction of the scope of the GMO authorisation procedure. The substantial provisions of the amendments of the Annexes to Directive 2001/18/EC proposed by the Commission must still be interpreted in a way that the use of PPP on GM HT plants has to be part of the environmental risk assessment (ERA) in the GMO authorisation procedure.

7. To exclude the effects on the environment of the use of PPP on GM plants from the scope of the ERA of Directive 2001/18/EC, the European Parliament and of the Council had to amend the Directive in a respective manner. The scope of the Directive is an essential element which shall not be restricted by a delegated act of the Commission. Furthermore, the restriction of the scope of the Directive would not be an adaptation to technical progress as required for an amendment by the Commission according to Article 27 of Directive 2001/18/EC.

II. Zusammenfassung

1. Erwägungsgrund 9 des Entwurfs der Kommissionsrichtlinie zur Änderung der Anhänge der Richtlinie 2001/18/EG über die absichtliche Freisetzung gentechnisch veränderter Organismen (GVO) in die Umwelt verletzt den Grundsatz des institutionellen Gleichgewichts (Art. 13 Abs. 2 EUV). Die Kommission überschreitet damit ihre Kompetenz zur Anpassung der Anhänge der Richtlinie an den technischen Fortschritt (Art. 27 der Richtlinie 2001/18/EG) und zur Begründung dieser Anpassungen (Art. 296 Abs. 2 AEUV).

2. Die Aussage in Erwägungsgrund 9 betrifft den rechtlichen Rahmen der Umweltverträglichkeitsprüfung und damit die Auslegung eines Kernbestandteils eines Gesetzgebungsaktes des Parlaments und des Rates. Zu einer solchen, die Auslegung steuernden Aussage ist die Kommission nicht befugt. Die Aussage in Erwägungsgrund 9 hat keinerlei inhaltlichen Bezug zu der Ermächtigung der Kommission nach Art. 27 der Richtlinie 2001/18/EG (Anpassung an den technischen Fortschritt). Insbesondere enthält Erwägungsgrund 9 keine Begründung für eine vorgeschlagene Änderung der Kommission zur Anpassung der Richtlinie an den technischen Fortschritt.

3. Mit Erwägungsgrund 9 nutzt die Kommission ihre Rechtssetzungsbefugnis für eine irreführende Aussage zur Auslegung des zu Grunde liegenden Rechtsakts. Die Ermächtigung der Kommission zur Festlegung von Erwägungsgründen eines delegierten Rechtsakts ist beschränkt auf die Begründung der Regelungen des vorgeschlagenen delegierten Rechtsakts. Sie beinhaltet nicht die Ermächtigung zu isolierten und unklaren Aussagen über die Auslegung von Gesetzgebungsakten des Parlaments und des Rates.

4. Nach Erwägungsgrund 9 des Entwurfs der Kommissionsrichtlinie sollte der Umfang der Umweltverträglichkeitsprüfung von Pflanzen, die zwecks Toleranz gegen ein Herbizid ge-

netisch verändert wurden, mit der Richtlinie 2001/18/EG in Einklang stehen. Die Umweltverträglichkeitsprüfung der Anwendung eines Pflanzenschutzmittels (PSM) beim Anbau einer gv-Pflanze falle in den Anwendungsbereich der PSM-Verordnung (EG) 1107/2009.

5. Die Aussage in Erwägungsgrund 9 des Entwurfs der Kommissionsrichtlinie ist nicht falsch, aber irreführend. Sie erweckt den Eindruck, als fiele die Anwendung von PSM beim Anbau von gv-Pflanzen nicht in den Anwendungsbereich des GVO-Genehmigungsverfahrens. Tatsächlich muss die Anwendung von PSM beim Anbau von gv-Pflanzen im GVO-Genehmigungsverfahren unabhängig davon berücksichtigt werden, ob sie bereits zuvor in einem PSM-Genehmigungsverfahren berücksichtigt wurde. Der wesentliche Unterschied zwischen den Genehmigungsverfahren für GVO und PSM ist der Gegenstand der Genehmigung, also entweder der GVO oder das PSM. Werden beide gemeinsam verwendet, müssen die dadurch bedingten Umweltauswirkungen in beiden Genehmigungsverfahren berücksichtigt werden. Unabhängig davon sollten die Ergebnisse der Umweltrisikoprüfung in einem Verfahren auch im anderen Verfahren berücksichtigt werden, soweit sie bereits vorliegen und dafür geeignet sind.

6. Obwohl Erwägungsgrund 9 zu einer Fehlinterpretation des Anwendungsbereichs und des Verhältnisses der Freisetzungsrichtlinie 2001/18/EG und der PSM-Verordnung (EG) Nr. 1107/2009 führen kann, hat er keine verbindliche Wirkung. Er erlaubt keinerlei Beschränkung des Gegenstandes des GVO-Genehmigungsverfahrens. Die materiell-rechtlichen Vorschriften der von der Kommission vorgeschlagenen Änderungen der Anhänge der Richtlinie 2001/18/EG müssen nach wie vor in der Weise ausgelegt werden, dass die Anwendung von PSM beim Anbau von gv-Pflanzen Teil der Umweltrisikoprüfung des GVO-Genehmigungsverfahrens sein muss.

7. Um die Umweltauswirkungen der Anwendung von PSM beim Anbau von gv-Pflanzen vom Anwendungsbereich der Umweltrisikoprüfung der Richtlinie 2001/18/EG auszuschließen, müssten das Europäische Parlament und der Rat die Richtlinie entsprechend anpassen. Der Anwendungsbereich der Richtlinie ist ein wesentliches Element, das nicht durch einen delegierten Rechtsakt der Kommission eingeschränkt werden darf. Außerdem wäre die Beschränkung des Anwendungsbereichs der Richtlinie keine Anpassung an den technischen Fortschritt, die Artikel 27 der Richtlinie 2001/18/EG für eine Änderung der Kommission voraussetzt.

III. Question

Directive 2001/18/EC of the European Parliament and of the Council[1] sets out requirements for the environmental risk assessment (ERA) of genetically modified organisms (GMOs).

Any person must, before undertaking a deliberate release of a GMO into the environment or placing a GMO on the market for the first time, submit a notification to the competent authority of a Member State.[2] The notification shall include a technical dossier supplying the information specified in Annex III and the ERA required in Annex II of the Directive.[3] ERA means the evaluation of risks the deliberate release or the placing on the market of GMOs may pose to human health and the environment, whether direct or indirect, immediate or delayed, and needs to comply with Annex II of Directive 2001/18/EC.[4] The notification and the included information are the basis for the assessment[5] and the final consent[6] of the competent authority.

Article 27 of Directive 2001/18/EC enables the Commission to adapt parts of the Annexes to technical progress by amending non-essential elements of the Directive, in accordance with the regulatory procedure with scrutiny laid down in Article 30 (3) of the Directive. In accordance with Article 3 of Directive (EU) 2015/412 of the European Parliament and of the Council[7] the Commission has to update the Annexes to Directive

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1 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.04.2001, p.1).

2 Article 5 and 6, 13 of Directive 2001/18/EC.

3 Article 6 and 13 of Directive 2001/18/EC.

4 Article 2 (8) of Directive 2001/18/EC.

5 Articles 4 (3), 5 (2) and 14 of Directive 2001/18/EC.

6 Articles 7 (3), 15 (3) and 19 of Directive 2001/18/EC.

7 Directive (EU) 2015/412 of the European Parliament and of the Council of 13 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member Stages to or pro-

2001/18/EC in accordance with Article 27 of that Directive as regards the ERA, with a view to incorporating and building upon the strengthened 2010 EFSA Guidance on the environmental risk assessment of genetically modified plants (EFSA ERA Guidance).[8]

To this end, the Commission prepared a Draft Commission Directive to amend the Annexes to Directive 2001/18/EC in 2017.[9] Recital 9 of the Draft Commission Directive reads as follows:

> *"Where the environmental risk assessment concerns a genetically modified plant made tolerant to a herbicide, its scope should be consistent with Directive 2001/18/EC. The environmental risk assessment of the use of a plant protection product, in-*

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hibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68, 13.03.2015, p. 1).

7 EFSA Panel on GMO, Guidance on the environmental risk assessment of genetically modified plants, Scientific Opinion, EFSA Journal 2010; 8(11):1879.

7 Commission Directive (EU) …./ … of xxx amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms, SANTE/11248/2016 Rev. 2, with Annex, Rev. 3, published in the comitology register, http://ec.europa.eu/transparency/regcomitology/index.cfm, search for document 50702 or for dossier CMTD (2017) 1126.

7 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p.1).

7 See comitology register, http://ec.europa.eu/transparency/regcomitology/index.cfm, search for for document 50702 or dossier CMTD (2017) 1126.restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ L 68, 13.03.2015, p. 1).

8 EFSA Panel on GMO, Guidance on the environmental risk assessment of genetically modified plants, Scientific Opinion, EFSA Journal 2010; 8(11):1879.

9 Commission Directive (EU) …./ … of xxx amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms, SANTE/11248/2016 Rev. 2, with Annex, Rev. 3, published in the comitology register, http://ec.europa.eu/transparency/regcomitology/index.cfm, search for document 50702 or for dossier CMTD (2017) 1126.

cluding its use on a genetically modified plant, falls under the scope of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[10] and will be carried out at Member State level to take into account specific agricultural conditions."

According to the Federal Agency for Nature Conservation (BfN) the impacts on biodiversity of the application of herbicides on herbicide tolerant GMOs (HT GM plants) have to be considered in the GMO authorisation procedure, since these impacts are consequences of the genetic modification and specific to each GMO. Environmental risks of the combination of GMO and herbicide application are not assessed on a case-by-case basis in the authorisation procedure of a plant protection product.

For this reason the question is, whether Recital 9 meets the legal requirements or whether it has to be deleted, since such an amendment may not be adopted in accordance with the regulatory procedure with scrutiny and would be no adaptation to technical progress (see V. below). If Recital 9 has to be deleted, we need to clarify in which way one may implement an amendment to restrict the ERA of the application of PPP to GM HT plants to the PPP authorisation procedure (VI.).

The Draft Commission Directive was accepted by the regulatory committee according to Article 5a of Council Decision 1999/468/EC on 13 October 2017.[11] The vote of the Parliament according to Article 5a (3)(b) of Council Decision 1999/468/EC is pending.

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[10] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directive 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p.1).

[11] See comitology register, http://ec.europa.eu/transparency/regcomitology/index.cfm, search for document 50702 or dossier CMTD (2017) 1126.

IV. Regulatory framework

To give an answer to the questions above, the following sub-sections need to be assessed: (1.) the legal requirements for and effects of recitals, (2.) the scope of the ERA of HT GM plants according to Directive 2010/18/EC, and (3.) the Commission's power to amend the Annexes to the Directive according to Article 27 of the Directive.

1. Legal requirements for and effects of recitals

The recitals are the part of a legal act which contains the statement of reasons for its adoption.[12] It is a specific obligation of Article 296 (2) TFEU to state the reasons on which a legal act is based upon.

According to the European Court of Justice (ECJ), the statement of reasons is an essential part of a legal act. They constitute an indivisible whole. It must appear in the legal act itself and it must be adopted by the author of the act.[13]

Nevertheless, the preamble to a legal act including the recitals has no binding legal force and cannot be relayed on as a ground for derogating from the actual provisions of the act in question.[14]

According to settled case-law a statement of reasons for an EU measure must clearly and unequivocally show the

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[12] See European Union, Joint practical guide of the European Parliament, the Council and the Commission for persons involved in the drafting of European Union legislation, 2015, p. 31 et seq.

[13] ECJ, judgment of 21 January 2003, Commission v Parliament, C-378/00, ECLI:EU:C:2003:42, paragraph 66; judgment of 15 June 1994, Commission v BASF, C-137/92 P, ECLI:EU:C:1994:247, paragraph 67; judgment of 23 February 1998, UK v Council, 131/86, ECLI:EU:C:1988:86, paragraph 37 .

[14] ECJ, judgment of 19 November 1998, Nilsson, C-162/9, ECLI:EU:C:1998:554, paragraph 54 and the case-law cited.

reasoning of the author of the measure in question, so as to enable the persons concerned to ascertain the reasons for the measure and to enable courts to exercise their power of review. The question whether the obligation to provide a statement of reasons has been satisfied must be assessed with reference not only to the wording of the measure but also to its context and the whole body of legal rules governing the matter in question.[15]

In particular, the reasons given for a measure are sufficient if that measure was adopted in a context known to the institution concerned, and thus able to understand the scope of the measure adopted.[16]

The obligation to provide a statement of reasons is an essential procedural requirement, as distinct from the question whether the reasons given are correct which goes to the substantive legality of the contested measure.[17]

If a legal act establishes exemptions from general rules, which constitute an essential part of the policy in a specific area, and the statement of reasons does not give reasons for this exemption, it does not provide any legal justification for the contested provisions, so that the legal act in question is not valid.[18]

The legal effect of a recital is that by stating the reason of a substantial provision of the related act, it

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[15] ECJ, judgment of 16 June 2015, Gauweiler, C-62/14, ECLI:EU:C:2015:400, paragraph 70; judgment of 19 November 2013, Commission v Council, C-63/12, ECLI:EU:C:2013:752, paragraph 98 et seq. and the case-law cited.

[16] ECJ, judgment of 19 November 2013, Commission v Council, C-63/12, ECLI:EU:C:2013:752, paragraph 99 and the case-law cited.

[17] ECJ, judgment of 17 March 2011, AJD Tuna, C-221/09, ECLI:EU:C:2011:143, paragraph 60 and the case-law cited; judgment of 2 April 1998, Commission v Sytraval et al., C-367/95 P, ECLI:EU:C:1998:154, paragraph 67.

[18] ECJ, judgment of 7July 1981, REWE, 158/89, ECLI:EU:C:1981:163, paragraph 26 et seq.

shows the purpose of that provision. The purpose and the wording of a provision are the main factors for the interpretation of legal acts by its addressees and the jurisprudence.

2. Scope of the ERA of herbicide tolerant GMOs

According to Recital 9 of the Draft Commission Directive the ERA of the use of a Plant Protection Product (PPP), including its use on a genetically modified plant, falls under the scope of Regulation (EC) No 1107/2009 and will be carried out at Member State level to take into account specific agricultural conditions.

According to BfN, the impacts on biodiversity of the application of herbicides on herbicide tolerant GMOs have to be considered in the GMO authorisation procedure, since these impacts are consequences of the genetic modification specific to each GMO,[19] and environmental risks of the combination of GMO and herbicide application are not assessed on a case-by-case basis in the authorisation procedure of a PPP.

These statements do not exclude each other. Both of them are correct:

First of all, the requirements for the authorisation for placing on the market of a PPP include the assessment of risks to the environment. Regulation (EC) No 1107/2009 requires that a PPP shall have no unacceptable effects on the environment, having particular regard to, inter alia, its impact on biodiversity and the ecosystem, where the scientific methods accepted by EFSA to assess such ef-

[19] See https://www.bfn.de/themen/agro-gentechnik/umweltrisikopruefung/aus-marginalspalte/herbizidresistenz-und-landwirtschaftliche-anwendungen.html.

fects are available.[20] Second, there is no exception for the use of PPP on GMOs, so that the scope of the risk assessment of a PPP in principle includes its use on a GM plant. Third, the authorisation procedure for a PPP has to be conducted at Member State level.[21] Fourth, compliance with the requirements for the authorisation shall be established by tests and analyses carried out under agricultural and environmental conditions relevant to the use of the PPP in question and representative of the conditions prevailing in this zone where the product is intended to be used.[22] In particular, specific agricultural conditions in each of the three geographical zones of the EU (North, Centre and South) defined in Article 3 (17) and Annex I of Regulation (EC) No 1107/2009, have to be taken into account.

On the other hand, it is also correct, as BfN states, that the impacts on biodiversity of the application of herbicides on HT GM plants have to be considered in the GMO authorisation procedure.

The ERA of GMOs includes the evaluation of indirect and delayed risks to the environment, which the placing on the market of GMOs may pose (Article 2 (8) of Directive 2001/18/EC).

According to Annex II of the Directive in force ‘indirect effects’ refers to effects, inter alia, through changes in use or management.[23] Furthermore, it is a general principle for ERA that an analysis has to be carried out of the ‘cumulative long-term effects’ relevant to the release and the placing on the market. ‘Cumulative long-

[20] Article 29 (1)(e) in combination with Article 4 (3)(e)(iii) of Regulation (EC) No 1107/2009.

[21] Article 33 (1) of Regulation (EC) No 1107/2009.

[22] Article 29 (3) of Regulation (EC) No 1107/2009.

[23] Annex II paragraph 2 second indent of Directive 2001/18/EC:

term effects' refers to the accumulated effects of concerns on human health and the environment, including, inter alia, flora and fauna and biological diversity.[24] Adverse effects may occur directly or indirectly through mechanisms which may include, inter alia, changes in management, including, where applicable, in agricultural practices.[25]

According to this, changes of management practices including changes in the use of PPP, and their effects on the environment have to be considered in the GMO authorisation procedure.

The 2010 EFSA ERA Guidance confirms this. The Guidance describes specific considerations for GM HT plants. The

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24 Annex II paragraph 3 of Directive 2001/18/EC. See also 3.4 of the Annex to Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 200, 30.07.2002, p. 22).

24 Section C.2.1. paragraph 3 indent 5 of Annex II to Directive 2001/18/EC.

24 EFSA, Guidance on the environmental risk assessment of genetically modified plants, EFSA Journal 2010; 8 (11):1879, p. 78.

24 Scientific Panel on GMO, Minutes of the 94th Plenary meeting of the Scientific Panel on GMO, held on 2-4 December 2014, Parma, section 8.2, page 5, http://www.efsa.europa.eu/sites/default/files/event/141203b-m.pdf.

24 EFSA Journal 2012(10) 6 :2753, p. 35 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2753/epdf.

24 EFSA Journal (2009) 1137, p. 23 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2009.1137/pdf.

24 EFSA Journal 2011 ;9(11):2428, p. 59 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2428/epdf.

24 EFSA Journal 2011 ;9(12):2480, p. 32 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2480/epdf.Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 200, 30.07.2002, p. 22).

25 Section C.2.1. paragraph 3 indent 5 of Annex II to Directive 2001/18/EC.

EFSA GMO panel considers that the novel use of herbicides on GM HT plants will change agricultural practices and as a result this requires an ERA. Therefore, the applicant is requested to describe the potential herbicide regimes to be applied to the GM HT crop under consideration, specify under what circumstances the potential herbicide regimes likely to be adopted for the GM plant may lead to greater, similar or lower adverse environmental effects than the current management systems they are likely to replace, and consider the consequences of the assessment on the impact of the herbicide treatments on biodiversity in fields and the implications of this for wider biodiversity within farming regions, integrated pest and disease management and the functioning of agriculture ecosystems.[26]

In 2014, in the context of early discussions of the Draft Commission Directive, the Scientific Panel on GMO described the interplay between ERA of GMOs and associated pesticides as follows:

> *"The GMO Panel agreed that the consequences to possible changes in crop management practices, including the herbicide treatments, should remain as an integral part of the ERA of GMOs. Members of the GMO Panel confirmed their scientific responsibility to consider environmental effects of herbicide tolerant systems such as reductions in arable plants, insects and bird-food, and expressed doubts that any proper environmental risk assessment could be concluded if such considerations were excluded. The Chair of the GMO Panel provided evidence for his view that there was no current alternative regulatory process within the*

[26] EFSA, Guidance on the environmental risk assessment of genetically modified plants, EFSA Journal 2010; 8 (11):1879, p. 78.

EU that provided an appropriate assessment of such indirect herbicidal effects."[27]

Examples for ERAs of the use of PPP on GM HT plants are the EFSA scientific opinions on glyphosate tolerant GM soybean 40-3-2[28] as well as on the glyphosate tolerant GM maize events NK 603,[29] MON 88017[30] and GA 21.[31]

After all, the environmental risks of the combination of GM Plant and herbicide have to be considered both in the PPP authorisation procedure and in the GMO authorisation procedure. Both regulatory regimes aim at protecting the environment and therefore all environmental risks connected to the respective product have to be considered. The difference between these regimes is their subject-matter, the authorised product, not the risk assessed. Subject-matter of the PPP authorisation decision is only the placing on the market and the authorised uses of a PPP; only they can be restricted. By contrast, in the GMO authorisation procedure the subject-matter of the decision is only the placing on the market and the authorised use of the GMO. For this reason, environmental risks resulting from the combination of the cultivation of a GMO and the use of a herbicide on them have to be addressed in both procedures.

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27 Scientific Panel on GMO, Minutes of the 94th Plenary meeting of the Scientific Panel on GMO, held on 2-4 December 2014, Parma, section 8.2, page 5, http://www.efsa.europa.eu/sites/default/files/event/141203b-m.pdf.

28 EFSA Journal 2012(10) 6 :2753, p. 35 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2012.2753/epdf.

29 EFSA Journal (2009) 1137, p. 23 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2009.1137/pdf.

30 EFSA Journal 2011 ;9(11):2428, p. 59 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2428/epdf.

31 EFSA Journal 2011 ;9(12):2480, p. 32 et seq., http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2011.2480/epdf.

In accordance with this, the Council Conclusions on GMO 0f 4 December 2008 underlined the need to study potential consequences for the environment of changes in the use of herbicides caused by herbicide tolerant GM plants and emphasised the need for competent authorities for the GMO authorisation procedure and the procedures necessary for PPP authorisation, within the Commission and at national level, to co-ordinate their action as far as possible.[32]

Insofar it is clear that, if the PPP is authorised, in the authorisation procedure of a GM HT plant the assessment of the environmental risk of the herbicide itself should be based upon and should be consistent with the ERA of the herbicide in the PPP authorisation procedure. In the GM authorisation procedure only the special environmental impacts of the combination of the GM plant and the herbicide have to be considered. The same is true vice versa: If a GMO is already authorised, and the environmental risks of a PPP, which is likely to be applied on HT GM crops, have to be assessed in the PPP authorisation procedure, the assessment of the risk of the GMO and the combination of GMO and herbicide should be based upon and should be consistent with the ERA of the GMO in the GMO authorisation procedure. There should be a coordination of the two procedures which allows for coherent and sufficient conditions both in the authorisation of the GMO and in the authorisation of the PPP to avoid risks to health and the environment. Neither the GMO authorisation procedure nor the PPP authorisation procedure prevails each other, but both have to take account of each other.

3. Power of the Commission

As to the Commission’s empowerment, we first set out the general principle of institutional balance [a)]. Second,

[32] Council Conclusion on GMOs of 4 December 2008, paragraph 4, Council Document 16882/08 of 5 December 2008, page 3, http://register.consilium.europa.eu/pdf/en/08/st16/st16882.en08.pdf.

the empowerment to amend the Annexes to the Directive [b)] has to be distinguished from the empowerment to lay down the recitals to the amending Directive [c)].

a) Principle of institutional balance

As a general principle of EU law, the institutions of the Union may act only within the limits of the powers conferred upon them by the treaties (principle of institutional balance, Article 13 (2) TEU).[33]

Within the framework of these powers, the limits of which must be determined by reference amongst other things to the essential general aims of the legislation in question, the Commission is authorised to adopt implementing measures which are necessary or appropriate for the implementation of the basic legislation, provided that they are not contrary to it.[34] Therefore it must first be determined whether the Commission is acting within the limits of the powers given to it and, more particularly, it must be ascertained whether the Commission has exceeded the powers conferred on it by the enabling act, bearing in mind in particular that such a delegated power must in any event comply with the essential elements of the enabling act and come within the regulatory framework as defined by the basic legislative act.[35]

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[33] See ECJ, judgement of 1 April 2008, Parliament v Commission, C-14/06 et al., ECLI:EU:C:2008:176, paragraph 50 and the case-law cited, as to the former Article 7 (1) TEC; judgment of 13 June 1958, Meroni v High Authority, 9/56, ECLI:EU:C:1958:7.

[34] ECJ, judgment of 1 April 2008, Parliament v Commission, C-14/06 et al., ECLI:EU:C:2008:176, paragraph 52; judgment of 30 September 2003, Germany v Commission, C-239/01, ECLI:EU:C:2003:514, paragraph 55, and the case-law cited.

[35] ECJ, judgment of 11 May 2017, Dyson, C-44/16 P, ECLI:EU:C:2017:357, paragraph 53, as to the requirements of Article 290 TFEU.

b) Empowerment to amend the Annexes of Directive 2001/18/EC

Article 27 of Directive 2001/18/EC enables the Commission and Article 3 of Directive (EU) 2015/412 obliges the Commission to adapt parts of the Annexes to technical progress, by amending non-essential elements of Directive 2001/18/EC, in accordance with the regulatory procedure with scrutiny laid down in Article 30 (3) of Directive2001/18/EC in combination with Article 5a of Council Decision 1999/468/EC.[36]

The regulatory procedure with scrutiny was replaced by Article 290 TFEU, which establishes rules for delegated acts of the Commission.[37] Nevertheless it is still applicable for existing basic acts making reference to Article 5a of Decision 1999/468/EC,[38] which was based on Article 202 of the EC Treaty. The Commission proposed an amendment to adapt, inter alia, Directive 2001/18/EC to Article 290 TFEU[39] in accordance with the Interinstitutional Agreement of 13

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36 Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.07.1999, p. 23).

37 See 2.1 of the Communication of the Commission of 9 December 2009 on the implementation of Article 290 of the Treaty on the Functioning of the European Union, COM (2009) 673 final, p. 3, and ECJ, judgment of 18 March 2014, Commission v Parliament, C-427/12, ECLI:EU:C:2014:170, paragraph 36.

38 See Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

39 See Commission, Point 139 of the Annex to the Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union of 10.1.2017, COM (2016) 799 final/2, p. 274.

April 2016 on Better Law-Making.[40] The proposal is currently discussed by Parliament and Council in the ordinary legislative procedure.[41]

According to Article 27 of Directive 2001/18/EC the power of the Commission to amend the Annexes to Directive 2001/18/EC is limited to amend non-essential elements of the Directive for the purpose of adaptation to technical progress.

First of all, the Commission's power to amend a legislative act to adapt its provisions to technical progress has to be distinguished from the power to supplement and the authority to interpret the basic act.

The delegation of a power to "amend" a legislative act aims to authorise the Commission to modify or repeal non-essential elements laid down by the legislature in that act by a formal amendment to that act. By contrast, the delegation of a power to "supplement" a legislative act is meant to authorise the Commission to flesh out that act. It empowers the Commission to develop in detail non-essential elements of the legislation in question that the legislator has not specified. For reasons of regulatory clarity and transparency of the legislative process, the Commission may not, in the context of the exercise of a power to "supplement" a legislative act, add an element to the actual text of that act. Such an incorporation would be liable to create confusion

[40] Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

[41] See Procedure file 2016/0400 (COD) of the European Parliament.

as to the legal bases of that element.[42] For this reason the empowerment of the Commission to amend the annexes of Directive 2001/18/EC is restricted to such formal amendments of that Directive and does not allow to supplement the Directive by more detailed regulations.

Furthermore, the Commission is not empowered to interpret the legislative act by binding delegated or implementing acts. This is, first of all, the consequence of the Court's exclusive power to interpret the Treaties and the acts of the institutions of the Union (Article 267 (1) TFEU, Article 19 (1) TEU). According to the Treaties the function of the Commission is to oversee the application of union law under the control of the Court of Justice of the European Union (Article 17 (1) TEU). Therefore the empowerment of the Commission to amend or supplement basic legislative acts by delegated acts does not cover the empowerment to supply binding interpretations of the basic legislative acts.

The legal requirements for an amendment with the purpose to adapt a basic act to technical progress have not yet been further clarified by case-law.[43] According to the wording and the purpose of Article 27 of Directive 2001/18/EC an adaptation to technical progress requires, at least, that sufficient technical or scientific progress was reached, with the conse-

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[42] ECJ, judgment of 17 March 2016, Parliament v Commission, C-286/14, ECLI:EU:C:2016:183, paragraphs 40 et seq., 52 et seq. See also No. 2.3 of the Communication of the Commission of 09.12.2009 on the implementation of Article 290 of the Treaty on the functioning of the European Union., COM (2009) 673 final, p.4.

[43] For case-law concerning the discretionary power of the Commission when adapting a basic act to technical progress see ECJ, judgment of 21 July 2011, Nickel Institute, C-14/10, ECLI:EU:C:2011:503, paragraph 59 et seq. and the case-law cited.

quence that the existing provisions are outdated and thus an amendment of the basic act is justified.[44]

c) Empowerment to lay down recitals

The empowerment to lay down the recitals of a legal act is a consequence of the obligation to state the reasons of the act in accordance with Article 296 (2) TFEU, as shown above (IV.1.).

As a consequence of the principle of conferral of powers, the empowerment to lay down recitals is also restricted by the purpose to state the reasons for the proposed amendments.

In particular the Commission is not empowered to set out interpretations of basic acts in the recitals of a delegated act, unless such an interpretation is a necessary condition to state the reasons for a proposed amendment.

As a further consequence of the function of recitals to state the reasons of the act they are connected to, the recitals of a delegated act of the Commission are no appropriate means for the interpretation of the basic act.
They only may be consulted to assess the purpose of the Commission by enacting the provisions of the delegated act. As regards the purpose of the basic act of the Parliament and of the Council, only the recitals of the basic act and the recitals of its amendments by the Parliament and the Council itself have the authority to show the reasons of the basic act as a basis for the interpretation of its provisions.

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[44] See ECJ, judgment of 21 July 2011, Nickel Institute, C-14/10, ECLI:EU:C:2011:503, paragraph 91 et seq.

V. Lawfulness of Recital 9

Before examining whether Recital 9 is lawful the effects of the Recital have to be clarified.

1. Effects of Recital 9 of the Draft Commission Directive

Although the proposed Recital 9 of the Draft Commission Directive is not wrong in a strict sense, as shown above, it is nonetheless misleading in several aspects:

First of all, Recital 9 may lead to the impression, that the ERA of the use of PPP on GM HT plants has to be considered in the authorisation procedure of the PPP only, because Recital 9 stresses the scope of the ERA of the PPP authorisation procedure but does not mention the need to consider this combination in the GMO authorisation procedure as well. Therefore Recital 9 suggests that the use of PPP on GM HT plants may not be within the scope of the authorisation procedure of the GM plant.

As shown above, according to the Annexes to Directive 2001/18/EC in force, the environmental impacts of the use of PPP on GM HT plants have to be considered in the authorisation procedure of the GM plant as well as in the PPP authorisation procedure (IV.2.). Insofar the substantial provisions in Annex II and III of Directive 2001/18/EC according to the proposed Draft Commission Directive do not differ from the provisions in Annex II and III of Directive 2001/18/EC already in force. In particular, potential changes in agriculture practices and management of the GM plant resulting from the genetic modification and the adverse environmental effects thereof are still part of the ERA of GM plants.[45] Since changes in

[45] See Annex II Section C.3.(1)(d) indent 5, Section D.2.(5), Annex III B Section I.A.3.(e) and Section II.B.4.(e) of the Directive as proposed in the Annex to the Draft Commission Directive.

herbicide treatment are an important change of agricultural management practices as a consequence of cultivation of GM HT plants, it is clear that they have to be considered in the future as well as they had to be considered in the past.

Furthermore, the Draft Commission Directive does not incorporate the special considerations on GM HT plants in the EFSA ERA Guidance 2010, although the Commission is explicitly obliged to incorporate and build upon this Guidance by Article 3 of Directive 2015/412. One may interpret this omission as an indicator that the combination of PPP and GM HT plants should, according to the Commission´s view and in contrast to EFSA´s view, no longer be considered of in a GMO authorisation procedure.

As shown above, the Commission’s empowerment to amend Annexes II and III of Directive 2001/18/EC is restricted to amending these Annexes and does not include the Commission’s empowerment to supplement these Annexes. Therefore the missing implementation of the special considerations of the EFSA ERA Guidance for GM HT plants does not mean that the Commission rejects EFSA’s view. It is just the result of the limited powers of the Commission to amend the Annexes to Directive 2001/18/EC.

As a result, Recital 9 does not state the reason to a proposed amendment. Instead, it is misleading insofar, as it may only be appropriate to state the reasons for a restriction of the scope of the ERA of the GMO authorisation procedure. In fact such a restriction of the scope of the ERA is not provided for in the regulatory part of the proposed amendment. The Commission would even not be empowered to such a restriction of the scope of the basic act (see VI below).

Second, Recital 9 is misleading insofar as the impacts of the use of a PPP on GM crops are not necessarily considered of in the PPP authorisation procedure.

The uniform principles for evaluation and authorization of PPP (Commission Regulation (EU) No 546/2011[46]) as well as the data requirements for active substances (Commission Regulation (EU) No 283/2013[47]) and PPPs (Commission Regulation (EU) No 284/2013[48]) include neither specific requirements to consider the combination of the use of a PPP on GM plants nor specific requirements to assess the impacts of such a combined use on biodiversity. Specific data requirements only cover ecotoxical studies on specified plants and animals,[49] but no data requirements to assess the effects on biodiversity comparable to the data requirements set out in EFSA ERA Guidance 2010 to assess the environmental risks of the use of PPP on GM plants.[50] In accordance with this the Chair of the GMO Panel provided evidence that there was no current alternative reg-

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46 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.06.2011, p. 127).

47 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 03.04.2013, p. 1).

48 Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 93, 03.04.2013, p. 85).

49 Part I B 2.5.2 of the Annex to Commission Regulation (EU) No 546/2011, Part A section 8 of the Annex to Commission Regulation (EU) No 283/2013, Part A section 10 of the Annex to Commission Regulation (EU) No 284/2013.

50 See EFSA ERA Guidance 2010, p. 78, cited above (page 13 with footnote 26).

ulatory process within the EU that provided an appropriate assessment of such indirect herbicidal effects. [51]

To some extent data requirements concerning the application of the PPP such as details of intended use and number and timing of applications and duration of protection[52] may depend on the usage of the PPP on GM crops, but there are no particular data requirements regarding an intended use on GM crops. Furthermore, if a GM crop is not authorised before the approval of the active substance and the authorisation of the PPP, it is very unlikely and not required by law to examine mere hypothetical impacts of the use of a PPP on a GM HT plant under field conditions which cannot be specified if the cultivation of the GM HT plant has not been authorised first.

Therefore it depends on the individual ERA in the approval procedure of an active substance or in the authorisation procedure of a PPP, if possible impacts on biodiversity of the use of the active substance or the PPP on a specific GM HT plant have in fact been considered. If these impacts have been considered, the results of the assessment of the PPP procedure have to be considered in the GMO authorisation procedure as well, and it has to be checked if, according to the outcome of the ERA in the GMO authorisation procedure, complementary or additional restrictions for the use of the GMO have to be put in place in the GMO authorisation. If the use of PPP on the GM HT plant has not been considered of in the ERA of the PPP, the risks of a combined use must be managed by the GMO authorisation alone. Otherwise the authorisation had to be denied until the PPP authorisation would be updated

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51 Scientific Panel on GMO, Minutes of the 94th Plenary meeting of the Scientific Panel on GMO, held on 2-4 December 2014, Parma, section 8.2, page 5, http://www.efsa.europa.eu/sites/default/files/event/141203b-m.pdf, see IV.2. above.

52 Part A sections 3.3 and 3.6 of the Annex to Commission Regulation (EU) No 284/2013.

to ensure that the use of PPP on GM HT plant would meet the requirements to protect the environment.

Furthermore, Recital 9 is also misleading as regards the ERA of PPP at Member State level.

First of all, Recital 9 does not mention that the most important ingredient of a PPP, the active substance, is approved by a Commission Regulation at EU level on the basis of an ERA and an assessment report of EFSA.[53] Second, both the requirements of the ERA of active substances and the requirements of the ERA of PPP have to be evaluated in the light of EU-wide uniform principles.[54] Third, the competence of the Member States to take into account specific agricultural conditions is, in principle, restricted to take into account the specific agricultural conditions of one of the three zones according to Annex 1 of Regulation (EC) No 1107/2009 (north, centre and south of the EU). Member States of the same zone shall grant or refuse authorisations accordingly on the basis of the conclusions of the assessment of the one Member State who is examining the application for all the Member States in the same zone.[55] Member States have only limited power to restrict or refuse an authorisation to take account of their own specific environmental or agricultural circumstances.[56]

Therefore, although PPP authorisations are granted at Member State level, the ERA and the authorisation princi-

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53 Articles 4 to 21 of Regulation (EC) No 1107/2009.

54 Articles 4 (4) and 29 (6) of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products (OJ L 155, 11.06.2011, p. 127).

55 Articles 33 (1), 35 and 36 (2) of Regulation (EC) No 1107/2009.

56 Article 36 (3) of Regulation (EC) No 1107/2009; see also Article 40 et seq. of Regulation (EU) No. 1107/2009 as to the mutual recognition of authorisations.

ples are designed to avoid differences of the authorisations carried out by different Member States as far as possible.

As a result, although Recital 9 is not wrong in a strict sense, it is misleading as regards

- the scope of the GMO authorisation procedure as to the ERA of the use of PPP on GM HT plants,
- the actual consideration of the use of a PPP on GM HT plants in the PPP authorisation procedure and
- the Member States' power to take into account individual agricultural conditions in a PPP authorisation procedure.

Therefore Recital 9 has, in accordance with a correct interpretation of the substantial provisions, no legal effect at all. The substantial provisions of the proposed amendments must still be interpreted in a way that the use of PPP on GM HT plants has to be part of the ERA in the GMO authorisation procedure. In particular, the proposed Recital 9 of the Draft Commission Directive does not lead to a restriction of the scope of the GMO authorisation procedure as regards the ERA of the use of PPP on GM HT plants.

2. Lawfulness of Recital 9

The lawfulness of Recital 9 depends on the limits of the power conferred to the Commission.

As shown above, the empowerment of the Commission to lay down Recital 9 depends on whether the content of Recital 9 is a necessary or appropriate means to state the reasons of a provision of the Draft Commission Directive (Article 296 (2) TFEU in combination with Article 27 of Directive 2001/18/EC).

In fact, the Draft Commission Directive does not contain a provision for which Recital 9 would state the reasons.

Like in the Annexes to Directive 2001/18/EC in force, there is no reference to the interplay of the Directive to the PPP Regulation (No) 1107/2009 in the proposed amendments of the Draft Commission Directive. Moreover, as shown above, there is no change in the provisions which require an analysis of adverse effects on biological diversity by changes in management, including changes in agricultural practices.[57]

As a consequence, Recital 9 is an isolated statement relating to Parliament and Council Legislation. It does not state reasons to the proposed substantial provisions of the Draft Commission Directive, but invites for a misleading interpretation of the basic acts of the Parliament and of the Council. It does not clarify by stating reasons, but it is rather revealing the Commission´s intentions.

As a result, Recital 9 infringes the principle of conferral of powers according to Article 7 TFEU, since neither Article 27 of Directive 2001/18/EC nor Article 296 (2) TFEU confer the power to the Commission to give statements concerning the interpretation of the scope of Directive 2001/18/EC in a delegated act. The Commission exceeds her limits of conferred power by misusing the recital of a delegated act for a misleading statement which only relates to the interpretation of legislative acts of the Parliament and of the Council but does not state a reason to an amendment to adapt the Directive to technical progress.

VI. Lawful method to restrict the scope of the ERA of GM plants

Finally, it has to be clarified in which way an amendment to restrict the ERA of the application of PPP to GM HT plants to the PPP authorization procedure had to be invented.

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[57] See above, IV.2 (p. 12) and V.1. (p. 18 et seq.).

First of all, the Commission's power to amend the Annexes to Directive 2001/18/EC is limited to adapt them to technical progress. A limitation of the scope of the ERA would be no adaptation to technical progress, but a substantial change of the scope of the Directive as a whole.

Second, the essential elements of an area are reserved for the legislative act and accordingly shall not be the subject of a delegation of power (Article 290 (2) TFEU).[58] Provisions which require political choices falling within the responsibilities of the EU legislature, in order to be adopted cannot be delegated by the legislator. Accordingly, implementing measures adopted by the Commission cannot amend essential elements of basic legislation or supplement it by new essential elements.[59] Identifying the elements of a matter which must be categorized as essential must be based on objective factors amenable to judicial review, and requires account to be taken of the characteristics and particular features of the field concerned.[60]

As regards Directive 2001/18/EC a restriction of the scope of the ERA to adjust the interplay between Directive 2001/18/EC and Regulation (EU) No 1107/2009 evidently requires political choices falling within the responsibilities of the EU legislature. It would require an adjustment of two legislative acts of the Parliament and of the Council. The adjustment would raise principle questions such as whether a restriction of the scope of Directive 2001/18/EC would require changes in the regulation of PPP, e.g. an additional possibility to set out additional conditions to authorised PPP in case of the authorisation of a GM HT crop which has not been considered

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58 See ECJ, judgment of 5 September 2012, Parliament v Council, C-355/10, ECLI:EU:C:2012:516, paragraph 64 et seq. and the case-law cited.

59 Judgement of 22 June 2016, DK Recycling und Roheisen, C-540/14 P, ECLI:EU:C:2016:469, paragraph 47 and the case-law cited.

60 Judgement of 22 June 2016, DK Recycling und Roheisen, C-540/14 P, ECLI:EU:C:2016:469, paragraph 48 and the case-law cited.

of in the PPP authorisation procedure to avoid loopholes in the overall environmental risk assessment. Furthermore, the political question has to be answered whether risk management decisions on the use of PPP on GM crops should be taken on EU or Member State level. Finally, the scope of the ERA determines whether Member States are allowed to take decisions as to national safeguard measures or national restrictions of the cultivation of a GMO (opt out) on the basis of Article 23 and Article 26 b of Directive 2001/18/EC for the reason of negative effects of the use of PPP on GM HT plants.

As a result, the scope of the ERA of GM HT plants must not be restricted by a Commission Directive or Regulation at all. Neither Article 27 of Directive 2001/18/EC nor any other provision of the Directive confers the power to the Commission to restrict or to interpret the scope of the ERA as set out by the Directive. Even if such an empowerment would exist, it would infringe the principle that the essential elements of an area are reserved for the legislative act and accordingly shall not be the subject of a delegation of power (Article 290 (2) TFEU).