

On the admissibility of requests for internal review of Commission decisions which are based on Regulation 1829/2003

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Executive summary: The study examines, whether EU legislative or other measures which refer to the provision on "public health" in the Treaty on the Functioning of the European Union, can be considered to be part of "environmental law" under Regulation 1367/2006. It discusses in detail the provisions of the EU Treaties, the practice of the European Court of Justice and secondary environmental law. It concludes that the legal basis of a provision is not a decisive aspect and that the ECJ used the terms of "human health" and "public health" in an interchangeable way. As "environmental law", according to Article 191 TFEU, also includes measures which aim at the protection of human health, the mere fact that a legislative act - such as Regulation 1829/2003 - and measures which are adopted on its basis, have Article 168 TFEU as a legal basis, does not exclude such measures from the term "environmental law" in Regulation 1367/2006.

Table of content

Executive summary

Table of content

The problem	1 - 3
The arguments of the Commission and the legal controversy	4 - 11
The protection of "public health" and "human health" in EU law	12 - 29
Health and safety evaluations in Directive 2001/18 and Regulation 1829/2003	30 - 46
Conclusion	47

The problem

1. By letter of 16 November 2015, the Commission rejected almost completely the request for internal review, introduced by Gene Watch, United Kingdom and Testbiotech, Germany¹. The request had been based on Article 10 of Regulation 1367/2006² and asked to review the three Implementing Decisions 2015/686,

¹ Commission, letter of 16 November 2015, ARES (2015) 5145741 - 17/11/2015

2015/696 and 2015/698 of 24 April 2015, by which the Commission authorized genetically engineered soybeans MON 87769, MON 87705 and MON 30423.

2. The request had asked to re-examine the authorizations in view of the following aspects:

1. there was a lack of EFSA guidance for health impacts of genetically modified crops with significantly altered nutritional content;
2. the nutritional risk assessment was inadequate and inconsistent;
3. the labelling for genetically modified food with altered nutritional composition was inadequate and inconsistent;
4. the proposals for the post-marketing monitoring of genetically modified food and feed with altered nutritional composition were inadequate and inconsistent;
5. herbicide residues were not considered in the health impacts of genetically modified food and feed consumption;
6. there was an inadequate assessment of the unintended effects of Ribonucleic acid (RNA) interference.

3. In its letter of 15 November 2015, the Commission gave the following answer:

- "- Allegations 1 to 5 and part of allegation 6 are rejected as falling outside the scope of Article 10 of the Aarhus Regulation;
- Part of allegation 6 related to the environmental risk assessment does not justify the need to amend Commission Implementing Decision (EU) 2015/696 as a consequence of the Commission's review".

The arguments of the Commission and the legal controversy

4. The Commission argued that Regulation 1367/2006 dealt with *environmental* matters. Consequently, Article 10 of Regulation 1367/2006 only allowed for an internal review of a Commission decision, when the request concerned *environmental* law. Article 191 TFEU and Article 2(f) of Regulation 1367/2006 which mentioned that the objective of the EU environmental policy should be, among others, the protection of human health, could only "be interpreted as covering health issues other than those related to the state of the environment".

5. However, decisions of authorization on genetically modified food and feed addressing the health impacts of the consumption of products did not constitute Regulation 1367/2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to justice in Environmental matters to Community institutions and bodies, OJ2006, L 264 p.13.

environmental law. Under the TFEU, a specific provision was dedicated to the protection of public health (Article 168 TFEU). This provision constitutes, argued the Commission, a legal basis for veterinary and phytosanitary measures which have as the direct objective the protection of public health. The present Article 168 TFEU was also used for Regulation 1829/2003 on genetically modified food and feed which intended to cover health aspects that were not covered by Article 191 TFEU. If Article 191 TFEU were interpreted as related to any measure which concerned the protection of human health, Article 168(4) TFEU would be devoid of substance.

6. Furthermore, the Commission argued that Article 2(1)(d)(vi) of Regulation 1367/2006 confirmed this interpretation. Genetically modified organisms were mentioned in Article 2(1), but not by reference to their properties as food or as feed. Measures such as the nutritional characteristics of a food or a feed, are not, in Article 2(1), considered as "environmental information". It followed from this that the health impacts of the consumption of genetically modified food and feed did not constitute environmental law and therefore could not be subject of an internal review under Article 10 of Regulation 1367/2006. Consequently, decisions which were adopted under Regulation 1829/2003 had to be examined under a case-by-case basis, whether they referred to the environmental risk assessment, to the health impacts due to the release of GMOs in the environment, or to health impacts of the consumption of genetically modified food and feed which are deemed not to be covered by Regulation 1367/2006.

7. The Commission was of the opinion that in the case of genetically modified food and feed, the safety assessment of genetically modified food and feed and the environmental risk assessment of genetically modified organisms had to be distinguished. The safety assessment comes under Articles 5 and 17 of Regulation 1829/2003, whereas the environmental risk assessment was covered by Articles 5(5)(a) and 17(5) of Regulation 1829/2003. It followed from this that the health impacts of genetically food and feed through consumption did not constitute environmental law under Regulation 1367/2006. Such health impacts also concerned the nutritional assessment. Also, the labelling of the composition of genetically modified food and feed related to the characteristics of genetically modified food delivered to the final consumer for consumption, but had no link with the environmental risk assessment carried out for products. The same applied to the post-marketing monitoring which aims at the collection of data on the consumption of imported food in the Member States. Finally, the herbicide residues which might be present in genetically modified food and feed, also relate to the health impacts of the consumption of such food and feed, but not to the environment.

8. Article 10 of Regulation 1367/2006 reads as follows: "1. Any non-governmental organisation which meets the criteria set out in Article 11 is entitled to make a request for internal review to the Community institution or body that has adopted an administrative act under environmental law or, in case of an alleged administrative omission, should have adopted such an act. 2...."

9. It follows from that when a provision is part of a legislative act on environmental law, an internal review of that decision may be requested, when

the decision itself dealt with environmental law. Such law is defined, in Article 2 (f) of Regulation 1367/2006 as "Community legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of Community policy on the environment as set out in the Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources, and promoting measures at international level to deal with regional and worldwide environmental problems".

10. For the present examination, it is of particular relevance that EU environmental policy, as laid down in this Article 2(f) of Regulation 1367/2006 and, more generally, in Article 191(1) TFEU, aims at "protecting human health". It follows from Article 2(d)(vi) of Regulation 1367/2006 - a provision which defines "environmental information" as concerning, among others, as "the state of human health and safety, including the contamination of the food chain, where relevant" - that legislation which deals with the state of human health and safety, including the contamination of the food chain, constitutes environmental law in the sense of Regulation 1367/2006. Indeed, it would be contradictory to consider information on the contamination of the food chain and the state of human health as "environmental information", but consider the corresponding legislation as not being part of environmental law.

11. The Commission, though, is of the opinion that a difference has to be made between the protection of "human health" and the protection of "public health". It derives this differentiation from Article 168 TFEU which contains specific provisions on the protection of public health, among others also in the veterinary and phytosanitary field which have as their direct objective the protection of public health (Article 168 (4)(b) TFEU). Therefore, it has to be examined, whether there is indeed a differentiation to be made between "public health" and "human health" with the consequence that measures in the veterinary or phytosanitary fields are not covered by the term "environmental law" of Regulation 1367/2006.

The protection of "public health" and "human health" in EU law

12. The protection of health is, apart from Articles 168 and 191 TFEU, also mentioned in different other provisions of the TFEU. Article 36 TFEU allows Member States, in the absence of relevant EU measures, prohibitions or restrictions on the free circulation of goods on grounds of "the protection of health and life of humans, animals or plants". Article 114 (3) TFEU provides that the Commission, when it proposes measures for the achievement of the internal EU market, shall, in the areas of health, environmental protection and consumer protection "take as a base a high level of protection". Article 114(4) TFEU allows a Member State, after the adoption of an EU harmonization measure under Article 114 TFEU, to maintain, on certain conditions, national provisions concerning the protection of the health and life of humans, animals or plants, or the protection of the environment. Article 169 TFEU stipulates as one of the objectives of the EU consumer protection policy to "contribute to protecting health, safety and economic interest of consumers".

13. Article 168 TFEU which is entitled "public health", provides for EU competence in matters concerning the quality and safety of organs and substances of human origin, blood and blood derivatives, measures in the veterinary and phytosanitary fields and measures setting high standards for the quality and safety for medicinal products and devices for medical use (Article 168(4) TFEU).

14. Neither "health" nor "health for humans", "human health", "consumer health" or "public health" are defined in the TFEU. In case 272/80, though, the Court of Justice had to give a preliminary decision on a Dutch legislation which restricted the use of a pesticide. The Court held³ that "it is not disputed that the national rules in question are intended to protect public health and that they therefore come within the exception provided for by Article 36 [now Article 36 TFEU]". In this case, the Court of Justice apparently considered that the present Article 36 TFEU which aims at the protection of life of humans, is a provision which also aims at the protection of public health.

15. The Court of Justice reached a similar conclusion in the interpretation of a provision of secondary EU law. In case C-293/97, it was asked to interpret provisions of Directive 91/676 on water pollution from nitrates⁴. That Directive was adopted on the environmental legal basis of the present Article 192 TFEU. Its Recital six stated that measures against water pollution were necessary, "in order to protect human health and living resources and aquatic ecosystems"⁵. The term "public health" does not appear in the whole text of Directive 91/676. However, the Court of Justice held that the permitted nitrates levels in the Directive were established in order to protect public health⁶.

16. A careful reading of the relevant paragraph 34 of the judgment in case C-293/97 reveals that the terms "public health" and "human health" used by the Courts are interchangeable. The same interchangeable use of terms resorts from the Court's findings in case C-48/14, when the Court discussed the terms of "protecting human health" of Article 191 TFEU and "protection of the health of the general public", used in Article 30 of the Euratom Treaty.⁷

3 Court of Justice, case 272/80, *Biologische Producten*, ECLI:EU:C:1981:312, paragraph 13.

4 Directive 91/676 concerning the protection of waters against pollution caused by nitrates from agricultural sources, OJ 1991, L 375 p.1.

5 *Ibidem*, Recital 6.

6 Court of Justice, case C-293/97, *Standley*, ECLI:EU:C:1999:215, paragraph 34: "The fact that the level for the concentration of nitrates taken into account when identifying waters was set by reference to that laid down in Directive 75/440, shows that requirements of public health protection determined the maximum concentration of nitrates of whatever origin permissible in waters for human consumption, nitrate pollution being harmful to human health..."

7 Court of Justice, case C-48/14, *European Parliament v. Council*, ECLI:EU:C:2015:91.

17. When the General Court discussed positions adopted by the European Medicines Agency, it declared that the Agency "has as its main responsibility the protection of public and animal health"⁸, though Regulation 726/2004 which established the Agency⁹ concerns the authorization and supervision of medicinal products "for human and veterinary use". Apparently, the General Court borrowed, in its statement, from the wording of Article 36 TFEU mentioned above ("protection of health of humans, animals and plants"). Again, it seems that the General Court did not see a decisive difference between "public health" and "human health".

18. EU health-related legislation confirms that no differentiation is made between "human health" and "public health". Even those EU legislative measures, where the provision of the present Article 168 TFEU is, together with other provisions, taken as a legal basis for the legislative act, the term "public health" does not appear. For example, Regulation 178/2002¹⁰ only mentions "human health", in its recitals¹¹ and in its substantive articles¹². The European Agency for Food Safety which is established by that Regulation, is to ensure a "high level of protection of human life and health" (Article 22(3)) and Member States are given the possibility to take emergency measures, where they see a risk for human life (Article 53). The protection of the environment as objective of the Regulation is explicitly mentioned in Article 3.

19. Another example is Regulation 1107/2009 on pesticides¹³ which again does not use the term "public health" but refers to "human health": Article 1(3) provides that it is the purpose of the Regulation to provide for a high level of protection of both human and animal health, whereas Article 4(3)(b) establishes that plant protection products should have "no harmful effect on humans health,

8 General Court, case T-718/15R PTC Therapeutic International v. EMA, ECLI:EU:T:2016:426, paragraph 1; in the same sense T-729/15R MSD Animal Health Innovation v. EMA, ECLI:EU:T:2016:435, paragraph 1.

9 Regulation 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004, L 136 p.1. Also Articles 57 and 58 of that Regulation which describe the tasks of the Agency, refer to "medicinal products for human use".

10 Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Agency and laying down procedures in matters of food safety, OJ 2002, L 31 p.1.

11 See for example Recitals 2, 10, 60 and 62.

12 See for example Article 1 ("high level of protection of human health"), Article 5, 6 and 10.

13 Regulation 1107/2009 concerning the placing of plant protection products on the market, OJ 2009, L 309 p.1.

including vulnerable groups, or animal health, directly or through drinking water"¹⁴. Regulation 1107/2009 replaced Directive 91/414¹⁵, but that Directive likewise only referred to the protection of human health, not to the protection of public health¹⁶. Both Regulation 1107/2009 - in Article 1(3) - and Directive 91/414 - in Recital 4 - mention the protection of the environment as one of the objectives of the measure.

20. Not even Regulation 396/2005 on pesticide residues¹⁷ confirms the Commission's opinion of a differentiation between public health and human health-related issues. Recital 5 states that "public health should be given priority over crop production, thus it is necessary to ensure that such residues should not be present at level presenting an unacceptable risk to humans and, where relevant, to animals". Here again the terms "public health" and "human health" appear interchangeable. In the following, public health is only once mentioned in relation to food export (Article 3(g)), whereas everywhere else, mentioning is made of "human health" or "consumer health".

21. There are numerous other EU legislative acts which refer to the protection of human health which is to be protected. Only a few will be mentioned here. Directive 98/83 on drinking water contains, among others, a maximum level of pesticide residues in drinking water (Article 5 and Annex I, section B), though its objective is to "protect human health from any adverse effects of any contamination of water intended for human consumption"¹⁸.

22. Directive 2009/128 contains provisions on the restricted use of pesticides, with the purpose "to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticides use on human health and the environment"¹⁹.

¹⁴ See furthermore Recitals 7, 8, 10, and 14 which all mention "human health".

¹⁵ Directive 91/414 concerning the placing of plant protection products on the market, OJ 1991, L 230 p.1.

¹⁶ See for example Recitals 4, 9 and 10, and Articles 4, 5, 7 and 11.

¹⁷ Regulation 396/2005 on maximum residue levels of pesticides in food or feed of plant and animal origin, OJ 2005, L 70 p.1.

¹⁸ Directive 98/83 on the quality of water intended for human consumption, OJ 1998, L 330 p.32, Article 1. The Directive is based on the environmental provision of the present Article 192 TFEU .

¹⁹ Directive 2009/128 establishing a framework for Community action to achieve the sustainable use of pesticides, OJ 2009, L 309 p.1, Article 1. The Directive is based on the environmental provision of the present Article 192 TFEU.

23. Directive 2001/18 on the release of genetically modified organisms (GMOs)²⁰ refers to the risk of GMOs throughout its provisions²¹. The term "public health" does not appear in the text. In contrast, the protection of the environment is laid down in Article 1 as one of the Directive's objectives.

24. Regulation 1829/2003 on genetically modified food and feed²² refers exclusively to the protection of human health²³. The term "public health" does not appear. In contrast, the protection of the environment is mentioned in Article 1 as one of the objectives of the Regulation.

25. The result of this examination of the Courts' practice and of EU legislation is the following: no legal consequence can be derived from the fact that some EU legislation also used the present Article 168 TFEU on public health as a legal basis. Rather, the purpose of the legislation in question, which was examined, is to protect humans against undesired or unauthorized substances which might be contained in food or feed. "Public health" and "human health" are, to a large extent, interchangeable. Some EU legislation - Directive 98/83 on drinking water and Directive 2009/128 on the use of pesticides - explicitly used the environmental provision of Article 192 TFEU as a legal basis. But also, when the environmental provisions of the TFEU are not explicitly mentioned as a legal basis, this does not mean that the environment is not one of the objectives of the legislative acts. Indeed, the settled case-law of the European Court of Justice stipulates that when a Treaty objective - such as the environment - only is of secondary or tertiary relevance for the adoption of the act, the legal basis of this secondary or tertiary objective need not be mentioned²⁴. The protection of the environment is explicitly mentioned in all the above-discussed legislative acts - with the exception of Regulation 396/2005, though - as one of the objectives of the legislation.

26. This means that, contrary to what the Commission argues in its letter of 16 November 2015, nothing for the interpretation of "environmental law" in Regulation 1367/2006 can be deduced from the presence or the absence of the terms "public health" in EU environmental legislation, nor from the legal basis on which a legislative act or another measure of EU law is based.

27. This result is confirmed by the definition of "environmental law" in Regulation 1367/2006 which explicitly states that this term covers EU legislation

20 Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, OJ 2001, L 106 p.1. The Directive is based on the internal market provision of the present Article 114 TFEU.

21 See, for example, Articles 1, 2 no.8, and 4(1),(2) and (3).

22 Regulation 1829/2003 on genetically food and feed, OJ 2003, L 268 p.1.

23 See, for example, Articles 1 and 4, Recitals 1, 2 and 3.

24 This is the co-called "centre of gravity"-doctrine, see Court of Justice, joined cases C-164/97 and C-165/97 European Parliament v. Council, ECLI:EU:C:1999:99; settled case-law.

"irrespective of its legal basis"²⁵. As long as EU legislation has the objective - be it among other objectives - to contribute to the pursuit of the environmental objectives of Article 191 TFEU which are taken up by Article 2(1)(f) of Regulation 1367/2006, the legislation or other EU measure concerns "environmental law". And explicitly or implicitly, the EU legislation which undertakes to protect human health, contributes to the protection of human health, one of the objectives of Article 191 TFEU, and thus to the protection of the environment.

28. If one were to follow the Commission's opinion, this would have as a consequence that an internal review for Commission decisions regarding the presence of pesticide residues in drinking water would be admissible under Regulation 1367/2006; the same would apply to requests for internal review of pesticide residues in plants that were not genetically modified, as in such cases, Regulation 1829/2003 would not apply. In contrast, as soon as Regulation 1829/2003 becomes applicable, the request for internal review concerning the presence of pesticide residues would become inadmissible.

29. This example shows that the Commission's opinion is not consistent, as it would lead to different results for the review of food and feed products that are or are not genetically modified. EU legislation does not contain any indication that such a differentiation was intended.

Health and safety evaluations in Directive 2001/18 and Regulation 1829/2003

30. The Commission also argued that Directive 2001/18 is limited to those aspects which concern the environmental effect of GMO products. In contrast, Regulation 1829/2003 deals with the health aspects of GMO food and feed; and Regulation 396/2005 which deals with pesticide residues on food or feed refers back, as regards the health aspects, to Regulation 1829/2003. Therefore, when health aspects of food or feed products are in question, environmental legislation does not come into play. For this reason, legal aspects which concern the health and safety of genetically modified food and feed, do not constitute "environmental law" under Regulation 1367/2006. The consequence of this is that a request for internal review under Regulation 1367/2006 of decisions concerning such health aspects is, according to the Commission, inadmissible.

31. From what was stated above, it is already doubtful, whether the premise that Regulation 1829/2003 does not constitute "environmental law", is correct. Indeed, Article 1 of the Regulation states that the "objective of this Regulation.. is to.. provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed..." No differentiation is made in Article 1, nor indeed elsewhere, between environmental and health aspects of the Regulation. Rather, the wording of Article 1 only allows the conclusion that the whole of Regulation aims at contributing to the protection human health and the environment and thus constitutes "environmental law" in the sense of Regulation 1367/2006.

25 Regulation 1367/2006 (fn.2, above) Article 2(1) (f).

32. Also, it is one of the premises of an authorization under Regulation 1829/2003 that the characteristics of the genetically modified food or feed are not different from those of its conventional counterpart²⁶. It would be very strange to consider that the legislation concerning pesticide residues in and on food of conventional nature constitutes "environmental law" in the sense of Regulation 1367/2006, but that the legislation on genetically modified food and feed, the characteristics of which are not different, should not be considered "environmental law". No provision in Regulation 1829/2003 provides for or allows such a differentiation.

33. This result is confirmed by a closer look at the provisions of Regulation 1829/2009. The definition of "environmental risk assessment" in Article 2 no.4 explicitly refers to the definition which was given to that term in Directive 2001/18. This term will be closer examined below.

34. Article 5(3) (for food) and Article 17(3) (for feed) lay down a number of documents which must accompany any application for the authorization of genetically modified food or feed. This documentation includes studies which have been carried out to demonstrate that the GMO food or feed has no adverse effects on human health, animal health or the environment, as well as an analysis showing that the characteristics of the food or feed are not different from those of its conventional counterpart. This documentation shall have to be analyzed and evaluated by the European Food Safety Authority (EFSA) and by the Commission as the authorizing authority. These provisions clearly and undoubtedly refer to the environment as well as to human health.

35. The environmental risk assessment was defined, in Directive 2001/18 as follows²⁷: "the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose and carried out in accordance with Annex II". Article 2 no.4 of Regulation 1829/2003 declared that for the purposes of that Regulation "the definitions of... 'environmental risk assessment' referred to in Directive 2001/18/EC shall apply". It will therefore be examined, whether the environmental risk assessment under Directive 2001/18 is limited to environmental aspects, but excludes human health aspects.

36. Directive 2001/18, Annex II defined the terms of "direct effects", "indirect effects", and "immediate effects". Of interest here is the definition of "delayed effects" which explicitly referred to human health issues²⁸. Furthermore, Annex II stated²⁹: "A general principle for environmental risk assessment is also that an analysis of the 'cumulative long-term effects' relevant to the release and the

26 See Regulation 1829/2003 (n.22, above), Articles 6(3)(e) and 18(3)(e).

27 Directive 2001/18 (n.20, above), Article 2 no.8.

28 Directive 2001/18 (n.20, above), Annex II, Introduction: "'delayed effects' refers to effects on human health or the environment which may not be observed during the period of release of the GMO, but become apparent as a direct or indirect effect either at a later stage or after termination of the release".

29 Directive 2001/18 (n.20, above), Annex II, introduction.

placing on the market is to be carried out. 'Cumulative long-term effects' refers to the accumulated effects of consents on human health and the environment, including inter alia... the feed/food chain.. and resistance problems to antibiotics". These words clarify that the environmental risk assessment is not limited to examine the effects of the GMO on the environment, but that it also includes the food chain; and the effects of herbicide residues in the food chain are at least "indirect effects"³⁰ of the genetic modification.

37. This finding - that the environmental risk assessment is not limited to examining the effects of the GMO on the natural environment, but also includes the effects on human health - is confirmed by a considerable number of statements in Annex II: indeed, this Annex provided that the risk assessment has to include, among others, effects concerning:

- "disease to humans including allergenic or toxic effects"³¹;
- "compromising prophylactic or therapeutic medical.. treatments, for example by transfer of genes conferring resistance to antibiotics used in human.. medicine"³²;
- "possible immediate and/or delayed effects on human health resulting from direct and indirect interactions of the GMO and persons working with, coming into contact with or in the vicinity of the GMO release(s)"³³;
- "possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any product derived from it, if it is intended to be used as animal feed"³⁴;
- "possible immediate and/or delayed effects on human health resulting from potential direct and indirect interactions of the genetically modified higher plant and persons working with, coming into contact with or in the vicinity of the genetically modified higher plant release(s)"³⁵;

30 Directive 2001/18 (n.20, above) Annex II, Introduction: "'indirect effects' refers to effects on humans or the environment occurring through a causal chain of events, through mechanisms such as interactions with other organisms, transfer of genetic material, or changes in use or management".

31 Directive 2001/18 (n.20, above), Annex II C.2 no.1 first indent.

32 Directive 2001/18 (n.20, above), Annex II C.2 no,1, 5th indent.

33 Directive 2001/18 (n.20, above), Annex II D1, no.6; this indent applies to GMOs other than higher plants.

34 Directive 2001/18 (n.20, above), Annex II D.1 no.7; this indent applies to GMOs other than higher plants.

35 Directive 2001/18 (n.20, above), Annex II, D.2 no.6.

- "possible immediate and/or delayed effects on animal health and consequences for the feed/food chain resulting from consumption of the GMO and any products derived from it, if it is intended to be used as animal feed"³⁶.

38. Also Annex III B to Directive 2001/18 pointed into the same direction. This Annex concerns "Information required in notifications concerning releases of genetically modified higher plants (GMHP) (Gymnospermae and Angiospermae)". The notifier who intended to release a GMO into the environment had, under this Annex, to supply information "on any toxic allergenic or other harmful effects on human health arising from the genetic modification", as well as information "on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genes modification, where the GMHP is intended to be used in animal feedstuffs"³⁷.

39. It is clear from these requirements that an environmental risk assessment under Directive 2001/18 also includes direct and indirect effects which a genetically modified plant may have on human health. This includes, of course, the increased tolerance to herbicides which a genetically modified plant has as a consequence of the genetic modification and, subsequently, the presence of increased levels of herbicide residues in or on the plant. As Regulation 1829/2003 declared that the environmental risk assessment under that Regulation shall be the same as the environmental risk assessment under Directive 2001/18, these findings also fully apply to genetically modified food and feed.

40. It follows from this that the Commission's opinion that the environmental risk assessment under Directive 2001/18 is limited to assess the direct and indirect effects of a GMO on the environment, but does not cover the effects on human health, does not find any support in the wording of either Directive 2001/18 or Regulation 1829/2003.

41. A further consideration confirms this finding: when Directive 2001/18 was adopted in 2001 after a long public and political discussion in favour or against the technique of genetically modified organisms and their release, Regulation 1829/2003 did not yet exist; it was only adopted in 2003. If one were following the Commission's opinion, this would mean that Directive 2001/18 did not cover the most important aspect of the discussion on GMOs, namely their short, medium and long-term effect on human health. This omission would then only have been remedied by the adoption of Regulation 1829/2003 and only as regards genetically modified food and feed. In view of the high sensitivity of the public all over the EU which existed at the time of the discussion and adoption of Directive 2001/18, it is inconceivable that the EU legislator chose not to deal with the human health aspects of the release of a GMO.

42. According to its Article 43, Regulation 1829/2003 amended Directive 2001/18 on several points. However, the provisions on the environmental risk assessment were not amended. Without such an amendment, though, it is not possible to

36 Directive 2001/18 (n.20, above), Annex II, D.2 no.7.

37 Directive 2001/18 (n.20, above), Annex III B, D no.7 and no 8.

argue that the later adoption of a legislative act implicitly amended several of the core provisions of Directive 2001/18 by excluding the effects of GMOs on human health.

43. This understanding is confirmed by the text of Regulation 1829/2003 itself. First, it follows from Articles 6(3)(b) (for food) and 18(3)(b) (for feed) that a safety assessment of genetically modified food or feed is not even mandatory: EFSA *may* ask a national authority to carry out a safety assessment of the food or feed in question, but is not obliged to do so. And nothing in Article 6 or 18 of Regulation 1829/2003 obliges EFSA to make such a safety assessment itself, if it does not consult a national authority.

44. Second, Article 6(4) for food and Article 18(4) for feed stipulate that in the case of food or feed, "the environmental safety requirements referred to in Directive 2001/18/EC shall apply to the evaluation to ensure that all appropriate measures are taken to prevent the adverse effects on human and animal health and the environment which might arise from the deliberate release of GMOs". Articles 6(4) and 18(4) clearly show that the different assessment measures under Directive 2001/18 are sufficient for allowing EFSA to evaluate the application for the release of a GMO. As *all* appropriate measures must be assessed, this also includes the residues of herbicides which might remain on a plant that was genetically modified.

45. For these reasons, it is legally necessary to follow the interpretation given above, according to which Directive 2001/18 intended to - and did indeed - cover *all* direct and indirect, immediate, delayed and cumulative effects which a release of a GMO might have on humans and the environment.

46. Directive 2001/18 is undoubtedly legislation which aims at the protection of human health and constitutes therefore "environmental law" in the sense of Regulation 1367/2006. The same conclusion applies to Regulation 1829/2003 which also has the objective, as laid down in its Article 1(a) "to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed.." and which refers, in its decisive parts - the environmental risk assessment, the evaluation by EFSA - back to Directive 2001/18.

Conclusion:

47. Regulation (EC) No. 1829/2003, alone or in conjunction with Regulation 396/2005, constitutes "environmental law" in the sense of Regulation 1367/2006. For this reason, an internal review against Commission decisions that are based on Article 1829/2003, is admissible.

Madrid, 25. August 2016
Prof. Dr. L. Günther