Comments on the Commission proposal to amend Regulation178/2002

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Summary of the suggestions made

It is suggested to

(1) Add Article 192(1) TFEU as the legal basis;

(2) Provide for a larger amendment of Regulation178/2002;

(3) Redraft the precautionary principle provision;

(4) Insert a provision into Article 7 of Regulation 178/2002 which states: "The applicant for an authorization shall prove that his substance or product complies with Union health and environmental safety requirements";

(5) Provide for citizen participation - not only consultation - in the authorization procedures for substances, pesticides and GM products;

(6) Clarify that information on emissions, discharges and other releases into the environment cannot be kept confidential;

(7) Clarify that a decision on a request for confidentiality shall take into consideration all arguments and opinions which were submitted or are otherwise available;

(8) Specify that on request, all information relating to an application for an authorization which is in the possession of EFSA, shall also be made available to the European Parliament;

(9) Take appropriate measures to promote research that is not influenced or dependant on vested interest sources;

(10) Adopt more precise provisions on combined effects of substances in pesticide products and GM plants or animals;

(11) Allow EFSA to launch verification studies on its own initiative;

(12) Reconsider the present division of work according to which an active substance is authorized at EU level, while pesticide products are authorized by Member States;

(13) Provide for greater details concerning the risk assessment of GMOs (combined and cumulative effects, impact on the immunity system and on reproduction);

(14) Introduce a monitoring requirement for pesticide products;;

(15) Improve official controls in EU Member States concerning the use of authorized uses of pesticides and GMOs;

(16) Delete proposals which aim at having industry and farming representatives in the EFSA Management Board;

(17) Allow also civil society to submit proposals for the appointment of experts to the EFSA Scientific Panels;

(18) Ensure appropriate remuneration of scientific experts in EFSA Scientific Panels.

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In April 2018, the EU Commission submitted a proposal for a regulation to amend Regulation 178/2002[1]. The present observations are submitted as a comment on this proposal.

1. The legal basis of the proposal

1.1 The Commission proposal is based on Articles 43, 114 and 168(4)(b) TFEU. These provisions concern agricultural policy, the free circulation of goods and public health respectively.

It is suggested that Article 192(1) TFEU is added as a supplementary legal basis, as the proposal directly concerns (EU) environmental law. Indeed, Directive 2001/18 on the deliberate release into the environment of GMOs, Regulation 1829/2003 of GM food and feed, and Regulation 1107/2009 on plant protection products (pesticides) which are all to be amended by the future Regulation, directly concern the cultivation of plants, the use of pesticides on land[2] and in agricultural activities, and the authorization of putting GM products into circulation.

Transparency and the assessment of the risks (impacts) on the environment which stem from human activities are core requirements of the EU environmental policy, which underpin any activity which relates to the natural or man-made environment[3]. The authorization to cultivate or to put into circulation genetically

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1 Commission, Proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain, amending Regulation (EC) No.178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on genetically modified food and feed], Regulation (EC) No.1831/2003 [on feed additives], Regulation(EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation [EC] No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation [EC] No 1107/2009 [on plant protection products] and Regulation [EU] No 2015/2283 [on novel foods). COM (2018) 179 of 11 April 2018.

2 The EU legislature underlined the importance for the environment of pesticides by adopting a specific directive on the use of pesticides, see Directive 2009/128, OJ 2009 L 309, p.71.

3 See on transparency in particular Regulation 1367/2006, OJ 2006, L 264 p.13 which requests in particular in Article 5 an active policy by the EU institutions to promote transparency in environmental matters; Directive 2003/4, OJ 2003, L 41 p.26, which contains in Article5 the same requirement for Member States. As regards the environmental impact, see in particular Directive 2011/92, OJ 2012,L 26p.1 on the assessment of the effects of projects on the environment and Directive 2001/42, OJ 2001, L 197 p.30 on the assessment of the impact of plans and programmes on the environment

modified organisms, plants or animals as well as the authorization of active substances of pesticides has considerable impacts on the natural environment and on human health; the protection of human health forms part of the EU environmental policy (Article 191 (1)TFEU).

1.2 In substance, the authorization procedures for both pesticides and GMOs or GM food and feed - which include plants and animals - are committed, under existing EU legislation, to dedicate as much attention to the impact on the environment of the substance or the product in question as on human health. It is therefore arbitrary and not justifiable not to include the environmental protection provisions of the TFEU as the legal basis for the proposed Regulation.

The EU General Court recently again clarified that legislation on GMOs - Directive 2001/18 and Regulation 1829/2003 in particular- are part of environmental law[4]. Moreover, the Court of Justice clarified that "sustainable development" - which is already mentioned in Article 3 TEU - includes matters of environmental protection[5]. Finally, Article 11 TFEU requests the EU institutions to integrate environmental requirements in the elaboration and implementation of the different EU policies and activities. Therefore, as the proposed Regulation intends to deal with the sustainability of risk assessments, its relevance for the environment requires the reference also to Article 192(1) TFEU as the legal basis.

1.3 The omission to also take Article 192(1)TFEU as a legal basis for the proposal as well as for Regulation 178/2002, manifests itself also in later provisions, in particular in Articles 5 to 8 of Regulation 178/2002 which deal with the general principles of food law: Article 5 states that food law shall aim at "a high level of protection of human life and health and the protection of consumer interests". This provision does not aim at a high level of environmental protection which is explicitly mentioned in Article 114 and Article191 TFEU, and is explicitly aimed at by Regulation 1107/2009, Article 1(3), Directive 2001/18, Articles 1 and 4, and Regulation 1829/2003, Article1(a). It cannot seriously be denied that Regulation 1107/2009 on pesticides which the Commission proposal intends to amend, also aims at the protection of land, soil and water as well as of fauna and flora and the natural environment. The same applies to the deliberate release of genetically modified organisms and the cultivation and/or marketing of genetically modified food and feed, where EU law even provides for a specific environmental risk assessment. It is therefore too short to declare that food law only aims at the protection of human health and consumer interests.

The same omission occurs in the present Article 6 of Regulation 178/2002, which provides for a risk analysis "in order to achieve a high level of protection of human health and life". The environment is not mentioned at all despite the fact that Directive 2001/18 as well as Regulation 1829/2003 on GMOs explicitly require an environmental risk assessment and lay the basis for a full risk analysis.

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4 General Court, case T-33/16, Testbiotech v. Commission, ECLI:EU:T:2017:115.

5 Court of Justice, Opinion 2/15 (Free Trade Agreement with Singapore), ECLI:EU:C:2017:376, paragraphs 138 to 150.

Article 7 of Regulation178/2002 allow the taking of precautionary measures when "harmful effects on health" appear possible. Such measures must also be possible, when harmful effects on the environment cannot be excluded.

Article 8 of Regulation 178/2002 intends to protect consumers' economic interests. It appears more than arbitrary to protect these interests, but to completely ignore the protection of the environment.

1.4 In conclusion, there is a need to insert Article 192(1) TFEU as a supplementary legal basis and to align the general principles of food law - Articles 5 to 8 of the present Regulation 178/2002- to also deal with the protection of the environment.

2. The limited amendments foreseen by the proposal

2.1 The Commission proposal only addresses some aspects of the current legislative framework, i.e. the provisions on risk communication[6], transparency[7] and the effectiveness of EFSA[8].

There is no reason whatsoever to limit the legislative discussions to these three elements. Indeed, the discussions during the last twenty years showed that there are other aspects of food law which require amendments. This applies in particular to the relationship between food production and the protection of the environment. These aspects are in particular relevant in the above-mentioned legislative acts on GMOs (Directive 2001/18 and Regulation 1829/2003), pesticides (Regulation 1107/2009) and novel foods (Regulation 2015/2283). The following comments will, next to Regulation 178/2002, concentrate on this legislation.

2.2 Even with regard to these pieces of legislation, not all aspects of concern to the public will be raised by these comments. For example, research in the area of pesticides and of GMOs is strongly dependent on industry and other economic operators; this is justified with the argument that industry has the burden of proof that a specific substance or product is safe. However, this consideration does not take away the problems which the dependency of industry-sponsored or -financed research has, as the interest of human health and of environmental protection must prevail over economic interests.

It should be considered in due time, whether it is not necessary to set up a body which organizes research that is not dependent - de iure or de facto - of industry and its financing. The difficulties of any such approach are not easy to overcome. But the present situation is simply too largely in favour of economic interests, though also problems of human health and environmental protection are at stake.

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6 Commission proposal (fn.1, above), Recitals 3 to 8.

7 Commission proposal (fn.1, above), Recital 9.

8 Commission proposal (fn.1, above), Recitals 10 to 21.

Furthermore, the approach to re-assess the renewal of authorized substances or products will have to be reorganized. At present, the re-examination of the risk to health and the environment is often rather poor (no or few new studies; no real re-assessment of earlier studies). Other areas which require attention are the consideration by legislative measures concerning cumulative effects of several pesticides, pesticides and GM products, mixtures of pesticides, and residues of pesticides, in particular on products which are imported.

3. The precautionary principle

3.1 The Commission proposal does not provide for an amendment of Article 7 of Regulation 178/2002 which deals with the precautionary principle. Article 7 provides the possibility for the EU to adopt, provisional measures which are necessary to ensure a high level of health protection. Such measures shall be reviewed within a reasonable period of time. The precautionary principle is also declared as a basic principle in Directive 2001/18, Article 1 and in Regulation 1107/2009), Article1(4); Regulation 1829/2003 refers in its Article1 to the general principles of Regulation 178/2002, thus also to its Article 7.

Article 7 needs a thorough redrafting. In its present version, it directly contradicts the interpretation of the precautionary principle as defined by the Court of justice. It also is in contradiction with the very purpose of Regulation 178/2002.

3.2 The Court of Justice of the EU (CJEU) interpreted the precautionary principle in a much broader way than laid down in Article 7. In case C-180/96 it declared[9]: "where there is uncertainty as to the existence of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those measures become fully apparent". In case C-441/17 it stated[10]: "the precautionary principle [which] is one of the foundations of the high level of protection aimed at by EU policy on the environment as provided for in the first paragraph of Article 191(2) TFEU, and in the light of which EU legislation on environmental protection has to be interpreted". There is thus no reason to limit the taking of measures on the basis of the precautionary principle to provisional measures[11].

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9 CJEU, case C-180/96 United Kingdom v. Commission, ECLI:EU:C:1998:192, paragraph 99: see also case C-157/96 National Farmers' Union, ECLI:EU:C:1998:191, paragraph 63.

10 CJEU (Grand Chamber), case C-441/17R, Commission v. Poland, ECLI:EU:C:2017:877, paragraph 42.

11 Admittedly, the Rio Principles provide, in Principle 15, for the taking of provisional precautionary steps. However, this formulation which was inserted at the insistence of the United States - which also opposed the term "precautionary principle" and insisted on the term "precautionary approach"- cannot determine the interpretation of the precautionary principle under EU law which is mentioned in Article 191(2) TFEU. The Rio Principles are not binding.

3.3 The provisional character of measures on the basis of the precautionary principle contradicts very clearly the basic approach adopted by Regulation 178/2002 which the Commission itself formulated as follows[12]: "Current procedures are based on the principle that it is for the applicant to prove that the subject matter of an authorisation procedure complies with Union safety requirements given the scientific knowledge in its possession. This principle is based on the premise that public health is better protected when the burden is on the applicant to prove that a particular food of feed is safe prior to its placing on the market, instead of the public authorities having to prove that it is unsafe".

Following this basic approach, in cases of technical, scientific or other uncertainty, the EU institutions are not obliged to only take provisional measures. Rather, they should protect the environment - which includes the protection of human health - by not authorizing the substance or product in question. It is then up to the applicant to dissipate any doubt by introducing new information. Only this procedure is in line with the precautionary principle. It is not either necessary to review the EU measure which had been taken, at regular intervals. Indeed, if the applicant has new studies, facts or other information to submit, he may ask for a new EU decision on his application. If he has no such new information, a revision is not appropriate.

The precautionary principle thus requires that in cases of any reasonable scientific, technical, factual or other doubt, the authorization of a substance or a product is not granted, unless and until the applicant complies with his burden of proof and eliminates any doubt as to the harmfulness of the substance or product. There is no reason to maintain the present drafting of Article 7 and review ex officio the refusal of an authorization which was based on precautionary reasons,

Also the practical application of the precautionary principle requires reconsideration and a more precise drafting of Article 7. At present, authorizations of active substances for pesticides are regularly given with specific indications to Member States to consider the environmental impact of the substance; sometimes these indications are formulated as a legal obligation, sometimes as a mere recommendation (**3.3.1**). Furthermore, frequently the comments which accompany the authorization of an active substance reveal that the authorization was granted, though scientific or other uncertainties continued to exist; this openly and flagrantly contradicts the precautionary principle (**3.3.2**).

3.3.1 As regards indications, the publication of the approving decisions on the one hand regularly refers to a decision of a Commission Committee which gave its agreement to the authorization[13]. However, these decisions are not publicly available. It cannot be checked, what kind of conditions the Committee has approved for the specific active substance.

12 Commission, Proposal (fn.1, above), p.2 and 3, and Recitals 16 and 22.

13 In Commission Implementing Regulation 540/2011, OJ 2011,L 153 p.1, which listed 353 active substances which were authorized at the time of the Regulation, and in subsequent implementing regulations the reference is made to the "Standing Committee on the Food Chain and Animal Health".

The written observations accompanying the approval of an active substance mainly refer to the protection of the environment. They normally address the Member States which have to authorize the pesticide product that contains the active substance which had been approved by the EU. An examination of the first 150 active substances of the list of 353 active substances in Regulation 540/2011 shows that in 49 cases that "Member States should pay attention to the protection of aquatic plants, aquatic organisms, birds, mammals, arthropods, but also to operators, bystanders, "groundwater under vulnerable conditions" or applications "in regions with vulnerable soil and/or climatic conditions"[14]. In 83 other cases the decision on an active substance formulated that "Member States must (shall) pay particular attention" to one or several of the above-mentioned environmental assets.

Legally, such formulations have a limited sense. Where the term "should" is used, the relative phrase does not constitute more than a recommendation. Where "must" or "shall" is used, the legally binding character is hardly stronger: paying attention does not necessarily mean that there is an obligation to take measures in order to prevent damage to the environment.

Also, a phrase such as "conditions of use shall include risk mitigation measures, where appropriate" or "risk mitigation measures shall be adopted, where appropriate" which are found in many authorization decisions for active substances, are meaningless, as they do not limit in any way the discretion of national authorities to act or not to act.

In all these cases, the use of such phrases indicates, however, that there is a certain risk for the environment which remained even after the authorization of the active substance was decided. This contradicts, the Commission's argument that the applicant for an authorization shall prove - and not only make likely - the safe character of the substance.

Independently of these observations, the question has to be raised who monitors compliance with the comments made by the EU. Under Regulation 178/2002 or Regulation 1107/2009, no monitoring system for pesticides is provided for. It is thus left at the discretion of each Member State, whether the comments which accompany the authorization decision, are complied with or not, when a pesticide product is authorized. This also applies to the later use of the authorized pesticide: it appears that no monitoring whatsoever is foreseen to examine, whether indeed the observation made by the EU were followed or not.

The practice of addressing comments to Member States, while authorizing an active substance, did not stop with Regulation 540/2011, as later Commission implementing regulations for specific active substances demonstrate[15].

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14 "Groundwater under vulnerable conditions" is not legally defined. Every Member State may understand something different of that term. The same observation applies to "vulnerable climatic conditions".

15 Commission Implementing Regulations 2015/553, OJ 2015, L 92 p.56; 2015/543, OJ 2015, L 90 p.1; 2015/51, OJ 2015, L 9 p.22; 1334/2014, OJ 2014, L 360 p.1; 890/2014, OJ 2014, L 243 p.42; 496/2014, OJ 2014, L143p.1, and

Overall, the comments made by the EU at the moment of authorizing an active substance demonstrate that, when such comments are made, the full evidence that a specific substance is safe for humans and the environment, has not been made. Under the precautionary principle, the substance should then not have been authorized.

3.3.2 The same conclusion has to be drawn from the requests for further information which accompany the authorization of a number of active substances for pesticides. Here, Member States are asked to request the applicant to submit further information - or "confirmatory information" - concerning, for example (for a random number of active substances):

- the acceptability of the long-term risk to birds and mammals[16];

- the potential for causing endocrine disrupting effects on birds and fish; the potential to contaminate surface waters; the risk from secondary poisoning for birds and mammals[17];

- studies on rotational crops residues and relevant information to confirm the risk assessment for birds, mammals, aquatic organism and non-target plants[18];

- the risk of inhalation and the risk assessment for non-target organisms and for soil and waste[19];

- the risk assessment for birds and mammals[20];

- the long-term risk assessment for birds and for potential groundwater contamination, in particular concerning metabolite R35140[21];

- the acceptability of the long-term risk to small granivorous birds and small herbivorous and frugivorous mammals concerning the use in apple and pear orchards[22]

193/2014, OJ 2014 L 59 p.25.

16 Commission Implementing Regulation 890/2014 (f.15, above) (Metobromuron).

17 Commission Implementing Regulation 193/2014,OJ 2014, L 59 p.25 (Amisulbrom).

18 Regulation 540/2011(fn.13, above) (Aclonifen, No 215).

19 *Ibidem*, (Tribasic copper sulphate, No 277)

20 *Ibidem* (Chlorpyrifos, no.111; Mancozeb no 114; Metiram no 115; Cyprodinil, no.130)

21 *Ibidem* (Pirimicarb, no 124)

22 Commission Implementing Regulation 496/2014 (fn.15, above)(Acequinocyl).

- confirming the risk assessment for granulate in acidic soils, birds and mammals and earthworms[23];

- address the potential endocrine disrupting properties within two years after the publication of international Test Guidelines for such studies[24];

- the risk assessment for mammals and non-target arthropods in apple orchards[25];

- which allows a comprehensive aquatic risk assessment to be made, taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures[26].

All such information is to be sent to the Commission within a specific time-span. The content of these requests and the fact that the information is due within a specific time, indicate without any doubt that the risk assessment which had been made, has not definitely proven the safety of the active substance in question, but that there remain doubts. According to the own principles of the Commission which were mentioned above, the active substance should therefore not have been authorized.

Moreover, with regard to GMO risk assessment, numerous requests from experts of Member States can be found in EFSA´s register of questions that were not taken into account in EFSA´s final opinions and in the decision of the EU Commission.

3.4 With regard to GMOS, the risk assessment which is made, hardly ever requests an examination of the combined effects of pesticides (herbicides) and the GM plants, or the effects of the GM plant on the immunity system and on procreation. In particular, the assessment of the interrelationship between herbicides and herbicide-resistant GM plants is frequently made, when the assessment of the herbicide is not even yet available.

The problem that research which is independent of vested interests is often not available, should lead to a very strict assessment of the studies and data that were submitted by the applicant -which is at present not always the case. While the decisions concerning an authorization of a GM plant under Directive 2001/17 and Regulation 1829/2003 do not contain similar comments to those which were mentioned above for pesticides, the scientific rigour of the assessments frequently could be improved. This also refers to the quality of the studies and data that are submitted which should be critically examined.

The publication of data, studies and other information which support an application for authorization (proposed new Article38(1)) is welcome. However, it

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23 Regulation 540/2011 (fn.13, above)(Oxamyl, No.116).

24 *Ibidem* (Flusilazole, No 143).

25 *Ibidem* (Glufosinate, No.215).

26 *Ibidem* (Fluoxastrobin, No. 166).

should also be mentioned that a partial publication shall be made, when parts of the materials falls under the provisions of Articles 39 to 39f. More observations on this issue will be made in the section on confidentiality, below.

3.5 In conclusion, a strict and vigorous scientific assessment of the risk assessment for pesticides and GMOs will help to make the precautionary principle (more) operational.

Therefore, it is suggested to incorporate the Commission's statement on the burden of proof, made in the explanatory memorandum of the proposal, into Article 7 of Regulation 178/2002. This phrase could, for example, be formulated as follows: "The applicant for an authorization shall prove that his substance or product complies with Union health and environment safety requirements".

4. Consultation of the public

4.1 The Commission proposal does not provide for an amendment of Article 8 of Regulation 178/2002 which concerns public consultation. The Commission does not either propose to amend Article 6(7) of Regulation 1829/2003 which allows the public to send, within 30 days, comments to the Commission on EFSA's opinion concerning the application for a GM food or feed, or of Article 24 of Directive 2001/18 which allows the public to comment, within 30 days, on the national assessment report concerning a GMO. As regards Regulation 1107/2009 on pesticides, not even a consultation of the public is foreseen, when an active substance is to be authorized. Article 10 only provides that public authorities have to make available to the public a summary of an application for authorizing an active substance; and Article 42 requires Member States to hold a register on applications for pesticide products. Article 63 finally states that some information is normally to be kept confidential, though it is added that this is "without prejudice to Directive 2003/4 on access to environmental information". These provisions are incompatible with existing EU law and should be amended.

4.2 As regards GMOs and GM products, the EU ratified the Aarhus Convention[27] including its amendment on GMOs[28]. This amendment provides that provisions on "early and effective information and public participation prior to making decisions on whether to permit the deliberate release and placing on the market" of GMOs shall be introduced in the national legislation. This requires more measures than allowing the public to comment, within 30 days, on the national assessment report (Directive 2001/18) or to comment to the Commission on EFSA's assessment within 30 days (Regulation 1829/2003). EFSA normally takes more than a year and frequently even several years, to make its assessment of an application concerning a GM plant and send it to the Commission. There is no

27 Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matter, of June 1998. The EU ratified the Convention by Decision 2005/370, OJ 2005, L 124, p.1; the Convention is published as an annex to the Decision.

28 The EU ratified the amendment by Decision 2006/957, OJ 2006, L 386 p.46.

reason, why the public should not be allowed to give comments on an application, all the more as the Commission now proposes to facilitate access to studies which accompany an application (proposal to insert Article 32b into Regulation 178/2002). The new proposal presupposes, though, that the documents which accompany an application, be also made available to the public, and not only, as at present "a summary in a standardised form[29].

The delay of 30 days for comments is much too short. The Commission itself, when it proceeds to consultations, normally provides for a time period of 12 weeks. It must be taken into consideration that normally the members of the public, including environmental or consumer protection organizations, obtain for the first time knowledge of a file, once they are asked to comment on a Member State's or EFSA's assessment opinion; and they neither have access to the correspondence between the applicant and the Member State (or EFSA), nor do they have at their disposal the different studies, data, reports and other documents which are essential to assess the opinion. The present system is thus neither effective nor does it provide for an early information and participation of the public.

The Aarhus Convention amendment, accepted by Council Decision 2006/957, provides for an early and effective "participation". Participation is different from consultation. The consultation just provides that the consulted public sends in its comments, opinions or objections, but leaves it to the receiving authority to decide, if and to what extent it takes these comments into consideration. In contrast to that, participation is a bilateral procedure: the public authority enters into a dialogue with the public concerned, by way of hearing or other appropriate form. It is obliged to weigh up the opinions which are submitted. And when a decision is taken, the public authority has to explain it and clarify why and to what extend or why not the opinions of the public were taken into consideration[30].

As regards pesticides, it was already mentioned that no participation and not even a consultation if foreseen in Regulation 1107/2009. This ignores the fact that "public authorities hold environmental information in the public interest"[31]. In one way or the other, Regulation 1107/2009 should provide that the public obtains access to the file which Member States compile under Article 39 of Regulation 1107/2009, as soon as an application is introduced. Also as regards active substances, the application with its accompanying documents should be made available to the public.

5. Confidentiality

5.1 The Commission proposal provides for a new wording of Article 39 of Regulation 178/2002. Transparency is of overriding importance with regard to

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29 Regulation 1829/2003 on genetically modified food and feed, OJ 2003, L 268 p.1, Article 5 (3)(l).

30 See for details of the participation procedure Aarhus Convention (fn.27, above), Article 6 and Regulation 1367/2006 (fn.3, above), Article 9.

31 Aarhus Convention (fn.27, above), Recital 17.

pesticides, GMOs and GM products, as these products will enter the environment. As the environment is not the property of pesticide or GMO manufacturers, the interests of those groups of persons in keeping information confidential must be held secondary to the interest of the public to know which substances and products enter the environment. It is for this reason that EU legislation gives everybody a right of access to information on emissions, discharges and other releases into the environment[32]. The CJEU has recognized this right of the public to know: with regard to pesticides, it acknowledged that there was a right to have access to information regarding the nature, composition, quantity as well as the date and place of emission of a substance or product[33].

Though the Commission announces that its proposal will increase transparency, the proposed new Article39 is rather restrictive. It allows producers to request, without restriction, confidentiality, and allows EFSA, among other things, to give confidential treatment to the "quantitative composition of the subject matter of the request for a scientific output, including a scientific opinion". This somehow opaque provision risks to run counter to the judgment in case C-673/13P, mentioned before. As the outputs of EFSA may easily be qualified as "scientific output" or "scientific opinion", the provision risks of keeping all applications concerning substances or products, for which EFSA is asked to make an assessment or give an opinion, to be kept confidential as regards the composition, impurities, additives and other substances.

Also, the wording of the proposed Article 39 should clarify that confidentiality cannot be granted on simple request by the applicant. Rather, the applicant's request must first have been examined and then accepted by EFSA.

5.2 Therefore, the future Article 39 of Regulation 178/2002 should contain a provision which states that "information on emissions, discharges and other releases into the environment may not be kept confidential". This would ensure consistency with existing EU law and would clarify that, as regards the substances and products which enter the environment, the interests of producers in confidentiality do not prevail over the right of the public in transparency (right to know). This result could also be reached, if there were added a letter (c) to Article 39(4) which reads "information on emissions, discharges and other releases into the environment".

Moreover, Article 39 should clarify that also a partial publication or disclosure of information is possible. this may best be realized by taking up the model of Article4(6) of Regulation 1049/2001 on access to documents[34] and formulate, for example: "If only parts of a requested document are covered by a justified

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32 Regulation 1367/2006 (fn.3, above) Articles 1(1)(a) and 2(1)((d)(ii); Directive 2003/4 onpublic accessto environmental information, OJ2003, L 41p.26, Articles 1 and 2(1)(b).

33 CJEU case C-673/13P, Commission v. Stichting Greenpeace Nederland,ECLI:EU:C:2016:889, paragraph 79.

34 Regulation 1049/2001, OJ 2001, L 145 p.43

exception of confidentiality or the protection of personal data, the remaining parts of the document in question shall be made public".

5.3 The proposed new Article39b provides under (d) that EFSA, when taking a decision on the request for confidentiality, shall take "into account the observations of the applicant". However, EFSA should also be obliged to take into account other observations which plead against the confidentiality.

The decision of EFSA under Article 39b, last paragraph, may be subject to an action under Articles 263 and 278 TFEU. This provision does not clarify that also the decision by EFSA to grant confidentiality may be subject to such action before the CJEU.

The proposed new Article 39d(1) provides that EFSA shall make available, "upon request", to the Commission and the Member States "all information in its possession relating to an application for an authorisation". This provision should be complemented that such information shall have to be made available, upon request, also to the European Parliament. Consequently, the European Parliament should also be mentioned in Article39d(2).

The Commission proposes changes in the Directive 2001/18 (Article 25) and Regulation 1829/2003 (Article 30). It proposes that confidential treatment may be accepted with respect to the following information: (a) DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event; and (b) breeding patterns and strategies.

These amendments are contrary to the general principle that all information which is relevant for the risk assessment shall be made public: The DNA sequences are highly relevant for risk assessment. If the sequences are not disclosed, experts cannot assess the risks independently from industry and authorities.

The DNA sequences have direct implications for the biological quality of the intended gene products, such as Bt toxins: These toxins as expressed in the plants are not produced from a DNA that is identical to the native variants as found in soil bacteria. In most cases, the DNA is truncated or changed in its structure to render it more efficient.

Furthermore, the DNA sequences of the gene constructs and the structure of the DNA at the site of insertion are also very relevant for risk assessment of unintended gene products: For example, natural genes can be interrupted by the insertion of the additional DNA. Further, open reading frames can emerge unintentionally that can give rise to unintended gene products. These unintended gene products can be proteins as well as non-coding miRNAs.

Breeding patterns are equally relevant for GMO risk assessment. Once again, if they are not disclosed, experts cannot assess the risks independently from industry and authorities.

EU regulation requests that the comparator for GMO risk assessment is chosen from a similar genetic background. In order to get a proper understanding of why a certain plant or organism is chosen as comparator or reference line, the breeding pattern has to be known.

6. Risk assessment

6.1 It is first referred to the comments made above in the section on the precautionary principle, which demonstrate that frequently the risk assessment on active substances is incomplete.

6.2 Generally, it has to be underlined that the research on the risk of pesticides and GMOs on humans or on the environment is too strongly influenced by vested interests. It is recognized that when industry has to prove the safety of its products in order to obtain an authorization, its studies will normally have a preponderant influence on the public body which is called to assess the risk - and subsequently on the risk-management body. In order to reduce and counterbalance this influence, research that is independent from vested interest should be promoted, as far as any possible. As in the field of pharmaceutical products for human use, research should be favoured that generates independent studies and objective facts. It is admitted that this suggestion faces cost problems and other serious obstacles. However, the EU institutions should not leave out of sight the basic requirement of independent research which alone is capable of establishing and maintaining the confidence of the public in the decision-making process in this area.

The existing provisions on the risk assessment which precede the authorization of active substances for pesticides as well as for GMOs need a revision and sharpening, in order to take into consideration the requirements of the precautionary principle.

6.3 For both pesticides and GMOs, the transparency of data should urgently be improved. The proposed increased publication of all studies which were made in order to prepare the application for the authorization of a substance or a product, discussed above, may be a first step. However, few data are available on combined effects, on mixtures, or on additives. And the combined effects of pesticides and GMOs are hardly ever the subject of empirical studies.

The newly proposed Article 32e of Regulation 178/2002 gives the Commission the possibility to request EFSA "in exceptional circumstances" to commission scientific studies "with the objective of verifying evidence used in its risk assessment process". This procedure is very heavy and clumsy. The need to launch further scientific studies is first of all a scientific, not a political request. Therefore, it should be possible for EFSA to commission such studies on its own initiative. Under the present proposal, EFSA does not even have the freedom to suggest to the Commission to mandate it with verification studies. As in future, all Member States shall be represented in the EFSA Management Board - see the proposed amendment of Article 25 - there is no need to leave the initiative on

verification studies exclusively with the Commission. Rather, it is sufficient that the launching of such studies be approved by the EFSA Management Board.

6.4 As regards pesticides, it is already questionable, whether the differentiation that active substances are authorized at EU level, but pesticides products then at the level of Member States, should be maintained. The effect of such differentiation is that substances which are added to an active substance, in order to generate a pesticide product, are often enough not thoroughly examined as to their harmful properties and their cumulative effects with the active substance. The practice in Member States varies widely and safety criteria for the added substances lack. Also, no provisions exist how to assess the risk, when one pesticide contains several active substances or when several additives are added to a mixture of several active substances.

6.5 The risk assessment for GMOs according to Directive 2001/18 is also affected by the incomplete risk assessment for pesticides. There lack empirical studies on combining effects between pesticides and GM plants. Often enough the authorization for a GMO is given without sufficient data for the risk assessment of pesticides being available. A quality control of the data which are submitted, frequently lacks. The effects of the genetic modification, alone or in combination with a pesticide, on the immunity system and the reproduction is often not sufficiently examined. A GMO should definitely only be authorized once all relevant data on the herbicides against which the plant is to become resistant, are available. Also a risk assessment for GMOs should always include the possible reaction of the plant on environmental concerns such as climate change or stress factors (drought, extreme weather conditions).

EFSA should be obliged to review the risk assessment methods at regular intervals, for example every five years, taking fully into account comments, observations and suggestions from the Member States and from scientific experts. It should give a reasoned explanation of amendments which it proposes. The final decision on the risk assessment guidelines should be with the Commission (comitology procedure). This would also allow the European Parliament to eventually voice concerns.

7. Monitoring

7.1 It was already mentioned in the section on the legal basis, above, that it is rather doubtful to consider that Regulation 1107/2009 on pesticides and Directive2001/18 on GMOs (including Regulation 1829/2003 on GM food and feed) are "food law". Indeed, pesticides and GM plants or animals are released into the natural environment, before they become relevant in food and feed. This specificity requires a specific treatment of the relevant legislative acts, which manifests itself in particular in the requirement for a monitoring of pesticides and GMOs after their release into the environment. The reason for this lies in the fact that pesticides and GM plants or animals may cause damage to the natural environment, even though their effects might no longer be relevant in the final food or feed products.

As regards pesticides, Regulation 1107/2009 does not provide for any monitoring of pesticide use. It is remarkable that the Commission proposal does not even mention Directive 2009/128 which establishes a framework for Community action for the sustainable use of pesticides[35]. That Directive provides, among other things, for an obligation of Member States to develop national action plans for the use of pesticides and to lay down the conditions for the implementation of integrated pest management. These provisions should be strengthened and should in particular provide that the national action plans contain an effective monitoring plan concerning the use of pesticides. The Commission itself should assess the effectiveness of the monitoring plans and their implementation. The future Regulation178/2002 should explicitly provide for such a monitoring obligation of Member States and should provide for the possibility of the Commission to assess the effectiveness of Member States' monitoring activity for pesticides.

7.2 As regards Directive 2001/18 on GMOs, a post-authorization monitoring is foreseen for which, however, only general and vague rules are laid down. Directive 2001/18 should be amended and the monitoring requirements should be considerably strengthened and made binding; the present Decision 2002/811 only gives (non-binding) guidance to Member States which is or is not complied with. For the monitoring requirements which are laid down in the consent decision on the deliberate release, common criteria should be laid down which have to be inserted into each decision on the release. The monitoring reports according to Article 20(1) of the Directive should be made public on the internet. The present Article20(4) of Directive 2001/18 only requires the "results of the monitoring to be made publicly available which is not sufficient.

For both pesticides and GMOs, the Commission should be obliged to make full use of the possibilities provided for in Article 116 of Regulation 2017/625[36] which allows Commission controls in the Member States, investigations and audits in order to verify the practical application of EU legislation that is covered by that Regulation. The newly proposed Article 32d should explicitly refer to Article 116 of Regulation 2017/625.

8. EFSA Management Board

8.1 The Commission proposal that all Member States should be represented in the EFSA Management Board is welcome. Such an amendment will eliminate concerns that de facto the Management Board is influenced by large Member States and that smaller Member States have less influence. As the representation

35 Directive 2009/128, OJ 2009, L 128 p.71.

36 Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products[and amending and repealing several EU legislative acts], OJ 2017, L 95 p.1. This Regulation explicitly applies to pesticides and GMOs. It will be fully applicable as of 14 December 2019 (Article 167).

of all Member States is a common feature of the management boards of EU agencies, the proposal is consistent with the general lines of EU policy.

8.2 There are, however, objections to industry and farmers representatives being on the Management Board of EFSA (the newly proposed Article 25 (1a). This means to trust the cat to keep the cream: it is industry which normally requests the intervention of EFSA, in order to have its products authorized. The Management Board has a general function to ensure, in the general EU interest, EFSAs strict neutrality and objectivity. There is no reason, why industry should have a possibility to co-exercise such surveillance functions, together with public authorities. Industry and farmers representatives in the Board take away a good part of the credibility of EFSA in the eyes of the public. It would be more than sufficient to allow the Management Board to consult industry and farmers representatives in a specific case, if need there is.

There are, in contrast, no objections against the representation of consumer and environmental organizations in the Management Board. The difference to farmers and industry representatives is that farmers and industry represent vested interests, whereas consumer and environmental organizations defend the general interest; they do not make profit from the authorization of this or that substance or product, but have the interest of society as a whole in mind. This justifies a different treatment.

8.3 As regards the members of the Scientific Panels, the Commission proposal rightly identifies the need to recruit independent and highly qualified experts. However, it is too narrow to require that all proposals for experts shall be made by Member States only (Article28(5c)). This means that only experts who represent mainstream scientific thinking are likely to be proposed. There is no reason, why consumer and environmental organizations should not be able to propose experts. Also, EFSA itself should be allowed to make, next to Member States, a call for interest; the fact that the Management Board shall appoint the experts (Article28(5c) gives sufficient guarantees to avoid abuses.

8.4 The Regulation should provide for the remuneration of the members of the Scientific Panels. Details of a remuneration system might have to be elaborated later, but a remuneration which parallels that of members of the European Economic and Social Committee might be an appropriate option.

Madrid, 15 June 2018

Ludwig Krämer