Memorandum
Advice regarding Commission proposal COM(2018) 179 final regarding transparency

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Subject

Hereunder the proposal of the European Commission with reference COM(2018) 179 final[1] (hereafter: the proposal) will be analysed, where it concerns the main possible effects of the proposal on the transparency of information under the European food legislation. The proposal amends Regulation 178/2002[2] (hereafter the General Food Law (GFL) Regulation) and several related Regulations and Directives. There are some positive changes in the proposal where it concerns transparency. For example the new requirement that applications under food law will have to be submitted in a digital standardised format (new Article 39f of the GFL Regulation) and the explicit mention that some categories of information shall be made public by EFSA of its own motion, such as the agendas, minutes and scientific outputs of the Scientific Committee and the Scientific Panels, including minority opinions, and EFSA's scientific opinions and studies (proposed Article 38(1)(a)(b)(f) of the GFL Regulation). However, under the current transparency regime this information could already fall under the obligation to disclose information upon request. The analyses hereunder will focus on the possible negative effects of the proposal and on suggestions for the maintaining of the current transparency level.

Findings and conclusions

The Commission's proposal makes clear that all supporting data and information relating to applications for authorisations are to be made public by EFSA, save exceptions foreseen in the proposal. The proposal nevertheless leads to less transparency regarding authorisations related to food. The proposal creates in part a specific, more restrictive regime with regard to disclosure, deviating from the general rules for disclosure of information laid down in Regulations 1049/2001 and 1367/2006, the latter of these specifically covers environmental information. As a *lex specialis*, the new provisions that the Commission foresees to add to the existing food legislation regarding the disclosure and confidentiality of information will replace or amend in part the disclosure regime based on Regulation 1049/2001 with regard to information submitted under the food legislation.

The proposal introduces a new provision stating that the disclosure of scientific data and studies regarding applications for authorisations under food law, f.e. authorisations for GMOs or additives in food, 'shall be without prejudice to' 'any intellectual property right which may exist over documents or their content'. Further the proposal introduces a presumption with regard to categories of information that the disclosure of such information 'may be deemed to significantly harm commercial interests', where the general disclosure regime in Regulations 1049/2001 and 1367/2006 does not contain such a presumption, but even applies, where it concerns environmental information, a restrictive interpretation of that ground for refusing to disclose commercial information. Most of the existing food legislation, covering specific are-as, that the proposal

[1] Commission proposal of 11 April 2018, Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002, Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 2065/2003, Regulation (EC) No 1935/2004, Regulation (EC) No 1331/2008, Regulation (EC) No 1107/2009 and Regulation (EU) No 2015/2283, COM/2018/0179 final - 2018/088 (COD)

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety,OJ L 31, 1.2.2002, p. 1

amends contains lists of information that 'shall not be considered confidential'. These lists of non-confidential information - that should thus be made public under the current legislation – are in the Commission's proposal replaced in part by lists of information that may not be disclosed as disclosure of that information 'shall be deemed to significantly harm commercial interests'. The overall conclusion is that the proposal creates a regime that is not compliant with the Aarhus Convention.

Introduction

1. It is important to note the motives for the proposal as set out by the Commission in the proposal. The Commission sees as one of the main objectives of the proposal to 'tighten and clarify the rules on transparency', especially with regard to the scientific studies used as the basis for EFSA's risk assessments. And, according to the proposed 36e recital of the proposed new Regulation:

'To ensure that sectoral specificities with respect to confidential information are taken into account, it is necessary to weigh up the relevant rights of the public to transparency in the risk assessment process, including those flowing from the Aarhus Convention, against the rights of commercial applicants, taking into account the specific objectives of sectoral Union legislation as well as experienced gained'. With this observation the Commission expresses its concern that the protection of 'commercial applicants' would not be sufficiently ensured under the Aarhus Convention, and thus under the European legislation implementing the Aarhus Convention -Regulations 1049/2001[3] and 1367/2006[4]. In other words: The Commission's proposal would be meant to grant more protection to commercial parties than the Aarhus-legislation provides for.

2. From the following, it will become clear that the Commission indeed foresees to tighten – read: narrow – part of the transparency rules applying to information under the European food legislation.

Proposal in relation to Regulation 178/2002 on general food law (GFL)

The current transparency regime

3. Article 38 of the GFL Regulation provides that the European Food Safety Authority (EFSA) shall ensure that it carries out its activities with a high level of transparency. The provision enumerates information that shall be made public without delay, such as agendas and minutes of the Scientific Committee and the Scientific Panels and the opinions, the information where opinions are based on, without prejudice to Articles 39 and 41, and results of scientific studies.

4. Article 39(1) states that EFSA, by way of derogation from Article 38, shall not divulge to third parties confidential information for which confidential treatment has been re-quested and justified, except for information that must be made public if circumstances so require, in order to protect public health.

5. Two years after the entering into force of the GFL Regulation an amendment was adopted, leading to a new Article 41 in the Regulation providing that Regulation 1049/2001 shall apply to documents held by EFSA. Decisions taken by EFSA pursuant to Article 8 of Regulation 1049/2001 may form the subject of a complaint to the Ombudsman or an appeal before the European Court of

[3] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145 of 31.5.2011, p. 43

[4] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 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, OJ L 264, of 25.9.2006, p. 13

justice[5]. When adopting Regulation 1049/2001 the European Parliament, the Council and the Commission agreed in a joint declaration that the Community Agencies should apply the same rules as regards access to documents[6].

6. The European Court of Justice did not rule on the exact relation between the confidentiality rule of the current Article 39 of the GFL Regulation and the subsequently adopted Article 41, providing that the information that EFSA holds falls under Regulation 1049/2001. As the last provision has been adopted to 'apply the same rules' to EFSA as the rules regarding access to justice applying to the three institutions it could lead to the conclusion – together with the fact that confidentiality should be requested ánd justified – that the confidentiality rule of Article 39 should be interpreted within the framework of Regulation 1049/2001[7]. The conclusion is that the transparency rules laid down in the GFL Regulation probably are not creating a specific disclosure regime but should be interpreted in relation to Regulation 1049/2001. Through Regulation 1367/2006 the restrictive interpretation of specific grounds for refusal to disclose information applies to information submitted under de GFL Regulation as well as the emissions-rule laid down in Article 6(1) of Regulation 1367/2006.

7. Hereunder only the main proposed changes regarding transparency rules in the GFL Regulation will be discussed.

8. The list of information in the proposed Article 38(1) of the GFL Regulation that has to be made public is slightly extended and expands in addition to the current provision for example to agendas and minutes of Working Groups of the Scientific Panels and to all scientific outputs form EFSA, including results of consultations performed during the risk assessment. Where it concerns scientific data, studies and other information supporting applications for authorisation under European food law, including scientific opinions, the information is disclosed *'taking into account protection of confidential information' and personal data in accordance with the Articles 39 to 39f*, which clause will be discussed below. The Commission's proposal further provides in the disclosing of information where 'scientific outputs, including scientific opinions' are based on, *taking into account protection of confidential data and personal data in accordance with Articles 39 to 39f*. The proposed Article 38(1), second sentence, provides that the information listed in Article 38(1) shall be published on EFSA's Web-site.

9. The proposal adds a new paragraph 1a to Article 38 of the GFL Regulation providing that the disclosure of information such as scientific data, studies and information sup-porting applications for authorisation, 'shall be without prejudice to' 'any intellectual property right which may exist over documents or their content', and 'any provisions of Union food law protecting the investment by innovators ('data exclusivity rules').

10. According to the new Article 39 of the proposal EFSA shall not disclose the information listed in Article 38 'for which confidential treatment has been requested' under the conditions laid down in Article 39. Article 39(2) of the modified GFL Regulation contains a list of information that may be deemed, upon verifiable justification, to significantly harm commercial interests, information such as 'the method and other technical and industrial specifications' used to manufacture or produce the substances and foods for which EFSA's scientific reaction or opinion is requested, as well as information on commercial links between an applicant or authorization holder and producers or importers, other commercial information and 'quantitative composition' of the substance that is to be assessed by EFSA. According to the proposed Article 39(4) in case of 'urgent

[5] The modified Article 41 was adopted by Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003, OJ L 245, 29.9.2003, p. 4

[6] COM(2002)406 final, p. 3

[7] See for example Case T 729/15, 5 februari 2018 par. 127

action to protect human health or the environment' the confidential in-formation can be disclosed, as well as in case the information relates to 'foreseeable health effects'.

11. The proposed Articles 39a and 39b provide that a request for confidentiality can be submitted. The request shall be accompanied by 'verifiable justification' demonstrating how disclosure will significantly harm the commercial interests concerned. EFSA will then adopt a reasoned decision on the confidentiality request. Such decisions may be appealed before the European Court of Justice, as is the case under the current GFL Regulation, as it foresees in the application of the general disclosure Regulation 1049/2001, which provides in an administrative re-examination of a decision regarding the (non-)disclosure of information as well as in legal remedy through appeal be-fore the European Court of Justice.

12. A new paragraph 3 is replacing the current paragraph 3 of Article 40, stating that EF-SA shall publish all its scientific output, in accordance with the confidentiality rules in Articles 38 and 39 to 39f of the proposal. Furthermore, the proposal foresees in adding to Article 41, which refers to Regulation 1049/2001, a sentence stating that Article 6 and 7 of Regulation 1367/2006 will apply to environmental information.

Discussion of the Commission's proposal regarding the GFL Regulation

13. The proposed changes to the GFL Regulation are creating a specific confidentiality regime for commercial parties and thus for applicants for authorisations under Euro-pean food law, a regime that derogates in part from the general disclosure regime laid down in Regulation 1049/2001. The new provision of Article 39b in the proposed GFL demonstrates that the general regime of Regulation 1049/2001, which foresees in the possibility to appeal decisions regarding disclosure, may not apply after entrance into force of the proposed amendments. This new provision in Article 39b regarding the right of appeal also raises the question whether this right is also guaranteed for the public with regard to EFSA's decisions on confidentiality requests of applicants for authorisations.

14. The new Article 38(1a) lays down a new, specific, ground for refusing to disclose in-formation based on the protection of intellectual property rights. The provision says that the disclosure of scientific data and studies held by EFSA will be 'without prejudice to any intellectual property right which may exist over documents or their con-tent'. However intellectual property rights are protected under Article 4(2) of Regulation 1049/2001 where the disclosure of information would realistically be expected to 'undermine' the protection of these rights. Further, Regulation 1049/2001 foresees in the protection of intellectual property rights, unless there is an overriding public interest in disclosure, whereas an overriding public interest in disclosure cannot put aside the protection of intellectual property rights based on Article 38(1a) of the modified GFL Regulation.

15. The proposed Article 39 provides a strong presumption of confidentiality with regard to the data listed in the second paragraph of it. Further, the new Article 39 derogates from the new Article 38 that lists information that should be made public, without de-lay. Article 39(4) provides to disclose the confidential information listed in Article 39 only in case of 'urgent action to protect human health or the environment' as well as in case the information relates to 'foreseeable health effects'. There is no exception to confidentiality based on the fact that 'an overriding public interest in disclosure' exists.

16. Finally, the new Article 41 of the GFL Regulation specifically provides that the Articles 6 and 7 of Regulation 1367/2006 apply to environmental information, under the GFL Regulation. As the proposed Article 41 does not mention other provisions of Regulation 1367/2006, such as Article 2

of the Regulation, containing the definition of environmental information, there is a risk that the rest of the provisions of Regulation 1367/2006 does not apply to information under the GFL.

[...]

Proposed changes to Directive 2001/18

Current transparency regime under Directive 2001/18[8] and proposed changes

20. Article 25 of Directive 2001/18 on the deliberate release of genetically modified organisms contains confidentiality provisions applying to information under that Directive. The Court of Justice ruled in Case 552/07 that Directive 2001/18 'established exhaustive rules relating to the right of public access in the area considered and the existence of any exceptions to that right' (par. 47).

21. Article 25(1) of the Directive provides that no confidential information shall be divulged, and the Commission and competent authorities shall protect intellectual property rights relating to the data received under the Directive. Based on the second para-graph of Article 25 a notifier under the Directive may request confidentiality, but only based on 'verifiable justification'. It is the competent authority that shall take a decision on such a request, based on Article 25(3).

22. Finally, Article 25(4) of Directive 2001/18 lists data that in 'no case may be kept confidential'. It concerns the description of the GMO – genetically modified organism – , name and address of the notifier, purpose of the release of GMOs, the intended uses, methods and plans for monitoring and for emergency response, and the environmental risk assessment.

23. In the Commission's proposal Article 25 is replaced by a new version of the provision. In paragraphs 1 and 2 the right for a notifier to make a confidentiality request is laid down, as well as the fact that the competent authority will decide on the request. Further, according to the new provision, the Articles 39-39f of the proposed modified GFL Regulation apply, so that the criteria of 'verifiable justification' for a confidentiality request would apply to requests under Article 25 of the Directive. The list of non-confidential information in Article 25(4) of Directive 2001/18 is removed and has been replaced in the proposal by a list of information 'the disclosure of which may be deemed, upon verifiable justification, to significantly harm' the commercial interests concerned. The list mentions DNA sequence information, breeding patterns and strategies.

Conclusion and suggestions regarding the proposal for the modification of Directive 2001/18

24. The proposal gives no explanations as to why the list of information that 'in no case may be kept confidential' in Article 25(4) of the Directive should be replaced by a list of information that is deemed to harm the commercial interests concerned and there-fore may be kept confidential.

25. The current Directive foresees in the obligation to disclose the basic information regarding a GMO and its risk assessment, as GMOs spread in the environment, for ex-ample as a consequence of field trials. Further, it is not necessary to provide that the DNA sequence information that has been put on this confidentiality list in the new Article 25(4) shall be kept confidential, as it can may be kept confidential when necessary upon request by the notifier and 'justified verification' under the proposed Article 25(1).

[8] 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, 17.4.2001, p. 1

26. To maintain the current level of transparency it is necessary to annul the list of confidential documents in the proposed Article 25(2) and to maintain the list of information that should be released enumerated in the current Article 25(4) of Directive 2001/18.

27. As the proposed Article 25(1) refers to the proposed Articles 39 to 39f of the GPL Regulation it would add to the transparency under Directive 2001/18 if these provisions will be amended as proposed above.

Proposed changes to Regulation 1829/2003

Current transparency regime under Regulation 1829/2003 and proposed changes

28. Regulation 1829/2003[9] on genetically modified food and feed provides in several pro-visions regarding the application for an authorization and the publishing of EFSA's opinion on the application that the confidentiality rules laid down in Article 30 of the Regulation apply.

29. Article 29(1) of Regulation 1829/2003 on 'Public access' provides that the application for authorisations of genetically modified food and feed, information from the applicant, opinions from the competent authorities, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public. According to the second paragraph EFSA 'shall apply the principles of Regulation 1049/2001' 'when handling applications for access to documents'.

30. Article 30(1) and (2) of Regulation 1829/2003 foresees in the possibility for applicants for an authorization to ask for confidentiality upon 'verifiable justification'. The pro-visions do not seem to create a specific confidentiality regime in derogation with Regulation 1049/2001. Article 30(3) contains a – quite extensive – list of information that 'shall not be considered confidential', mentioning information such as – in short – name and composition of the GMO food or feed, indication of the substrate and the micro-organism, a general description of the GMO, name and address of the authorisation-holder, physico-chemical and biological characteristics of the GMO food or feed, effects on human and animal health and on the environment, effects on the characteristics of animal products and its nutritional properties, methods for detection and identification and information on waste treatment and emergency response.

31. Relevant is that the proposal foresees in a new version of Article 6(7) of Regulation 1829/2003, making reference to Article 38(1) of the amended GFL Regulation, containing the list of information that EFSA shall make public. The Regulation foresees in Article 31 in data protection, providing that the scientific data and other information in the application dossier may not be used for the benefit of another applicant for a period of 10 years, unless agreement between the new applicant and the authorisation-holder.

32. The proposal modifies Article 5(3)(l) of Regulation 1829/2003 by introducing a reference to a modified Article 30 of Regulation 1829/2003 and the modified Article 39 of the GFL Regulation. Article 29(1) of Regulation 1829/2003 on 'Public access' is re-placed in the Commission's proposal, limiting access to the application for authorization and underlying information and to scientific opinions, by referring to the new Articles 38, 39 to 39f and 40 of the GFL Regulation. The new second paragraph of Article 29 provides that EFSA shall apply Regulation 1049/2001 when handling applications for access to documents.

[9] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p. 1

33. Article 30 is completely replaced in the proposal. Article 30(1) provides the right for the applicant for authorization to request for confidentiality upon 'verifiable justification'. The list of information that 'shall not be considered confidential' in Article 30(3) of Regulation 1829/2003 is replaced by a reference in Article 30(2) to the list of information that 'may be deemed to significantly harm commercial interests' in the new Article 39(2) of the GFL Regulation, adding to that a list of additional information that 'may be deemed, upon verifiable justification, to significantly harm commercial interests, including DNA sequence information and information on breeding patterns and strategies.

Conclusion and suggestions regarding the proposed modification of Regulation 1829/2003

34. Regulation 1829/2003 foresees in the obligation to disclose the basic information regarding GMO food and feed as GMOs can present risks to human and animal health and GMO food is intended for human consumption as are the products of animals consuming GMO feed. The obligation to give access to this list of essential environmental information disappeared from the modified Regulation and a list of confidential in-formation was added. Further, as has been set out, the proposed Articles 29 and 30 are aimed at creating a specific disclosure regime in deviation from the general disclosure regime under Regulation 1049/2001.

[...]

Proposal regarding Regulation 1831/2003

Current transparency regime and proposed changes

37. Regarding Regulation 1831/2003[10] on feed additives the main change consists of the replacing of Article 18 of the Regulation. Article 18 of Regulation 1831/2003 provides in its paragraph 1 and 2 that the applicant for an authorisation can indicate the information he wishes to be treated as confidential on the ground that its disclosure might significantly harm his competitive position. Verifiable reasons must be given in such cases. The Commission decides upon such a request. Article 18(3) of Regulation 1831/2001 lays down a list of information that 'shall not be considered confidential', including information on the name and composition of the feed additive and indication of the production strain, physicochemical and biological data, conclusions of studies on effects on human and animal health and on the environment and on the characteristics of animal products and its nutritional properties, methods for detection and identification of the feed additive and monitoring requirements and a summary of results of monitoring.
38. EFSA shall apply the principles of Regulation 1049/2001 when handling access to documents requests under Regulation 1831/2003.

39. In the proposal Article 18 of the Regulation is replaced by a new Article 18. The first paragraph of which Article states that EFSA shall make public the authorisation and relevant supporting information, as well as scientific opinions in accordance with the new proposed provisions of Article 38, 30 to 39f and 40 in the GFL Regulation. The second paragraph provides that the applicant for authorisation can request the confidentiality of information upon verifiable justification. EFSA shall take a decision on such a request. The list of information that has to be made public in Article 18(3) of Regulation 1831/2003 is replaced by a reference to the list of information that may be deemed confidential based on the new Article 39(2) of the GFL Regulation. A new list of information with regard to which EFSA may also accept to provide

[10] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 268, 18.10.2003, p. 29

confidential treatment, the disclosure of which may be deemed, upon verifiable justification, to significantly harm commercial interests is added, regarding information such as studies demonstrating the efficacy of feed additives and specifications of the impurities of the active substance in a feed additive.

40. The confidentiality list comprised information that under the current regime could qualify as information on emissions into the environment and that as a consequence may not be kept confidential.

Conclusion and suggestions regarding the proposed modification of Regulation 1831/2003

41. Regulation 1829/2003 foresees in the obligation to disclose the basic information regarding feed additives, as these substances could potentially contaminate the food chain and pose risks to human health and the environment. The obligation to give access to a quite extensive list of essential environmental information disappeared from the modified Regulation and a list of confidential information was added. Further, the new Article 18 is aimed at creating a specific disclosure regime in deviation from the general disclosure regime under Regulation 1049/2001.

[...]

Proposal regarding Regulation 2065/2003

Current transparency regime and proposed changes

44. Article 7 of Regulation 2065/2003[11] on smoke flavourings lists the information that should be submitted to obtain the inclusion of a product under the Regulation. Article 14 provides that applications for authorisations of some flavourings, information from the applicant, opinions from the competent authorities, monitoring reports and information from the authorisation holder, excluding confidential information, shall be made accessible to the public. According to the second paragraph EFSA 'shall apply the principles of Regulation 1049/2001' 'when handling applications for access to documents'.

45. Confidentiality provisions are laid down in Article 15 of Regulation 2065/2003. Article 15(1) provides that an applicant may indicate which information submitted under Article 7 should be treated as confidential because disclosure may significantly harm his or her competitive position. Verifiable justification must be given. Article 15(3) lists the information that 'shall not be considered confidential', including the name and address of the applicant and the name of the product, information of direct relevance to the assessment of the safety of the product and information on the analytical method.

46. The Commission's proposal consists of inserting in Article 7(2) of Regulation 2065/2003 a reference to Articles 14 and 15 of the Regulation to 'ensure public access to the application and supporting information. The new proposed Article 14(1) of the Regulation states that EFSA shall make public authorisations, underlying information and scientific opinions in accordance with the proposed Articles 38, 39 to 39f and 40 of the modified GFL Regulation. As has been set out, the proposed Article 38(1a) contains a specific and extensive ground for refusing to disclose information regarding copy rights and the new Article 39 provides that EFSA shall not disclose the information listed in Article 38 'for which confidential treatment has been requested' under the conditions laid down in Article 39. Follows a list of information in Article 39(2) of the proposed

[11] Regulation 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods, OJ L309 of 26.11.2003, p. 1

GFL Regulation, that is deemed to significantly harm commercial inter-est. The Commission's proposal further replaces Article 15 of Regulation 2065/2003 by a confidentiality clause that refers to Articles 39 to 39f of the modified GFL Regulation, stating that the applicant may request for confidentiality of certain information, accompanied by verifiable justification. EFSA shall decide on such a request. The list of information that shall not be considered confidential has been removed from Article 15.

Conclusion and suggestions regarding the proposed modification of Regulation 2065/2003

47. Regulation 2065/2003 provides that a list of information that has been considered by the legislator of importance for the public may not be kept confidential, as smoke flavouring products could have effects on human health through consumption. The obligation to give access to this list of information disappeared from the modified Regula-tion and was replaced by reference to provisions of the modified GFL Regulation, *inter alia* modified Articles 38 and 39, containing in Article 38(1a) a new provision regarding the protection of copy rights and in Article 39(2) a list of information 'the dis-closure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned'. Further, the new Article 15 is aimed at creating a specific disclosure regime and does not refer to Regulation 1049/2001.

[...]

Amendments to Regulation 1935/2004

Current transparency regime and proposed changes

50. According to Article 19(1) of Regulation 1935/2004[12] on food contact materials EFSA makes the applications for authorisation, supplementary information and opinions from EFSA, excluding confidential information, accessible to the public in accordance with the Articles 38, 39 and 41 of the GFL Regulation.

51. Article 20(1) of Regulation 1935/2004 foresees in the right to submit an application for confidentiality for part of the information submitted under the Regulation, upon verifiable justification. The Commission takes a decision on such a confidentiality re-quest (proposed Article 20(3)). Paragraph 2 of Article 20 contains a list of information that 'shall not be considered confidential', such as name and address of the applicant and the chemical name of the substance concerned, information of direct relevance to the assessment of the safety of the substance, the analytical method.

52. The new Article 19(1) provides that the application for authorisation, relevant supporting information and supplementary information submitted, as well as EFSA's scientific opinions shall be made public in accordance with the new Articles 38, 39 to 39f and Article 40 of the amended GFL Regulation and the new Article 20 of Regulation 1935/2004. In the proposal, Article 20 is to be replaced by a complete new provision, providing in its first paragraph that a confidentiality request can be submitted by the applicant in accordance with the new Articles 39 to 39f of the GFL Regulation, which means that a specific disclosure regime applies, with the presumption that the disclosure of information listed in Article 39(2) may significantly harm commercial interests. This confidentiality list contains information on methods and other technical specifications, meanwhile under the current regime the analytic methods are part of the information that shall not be

[12] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, OJ L 338, 13.11.2004, p. 4

considered confidential. Furthermore, a supplementary list of confidential data is added in the proposed Article 20(2), including descriptions of starting substances, composition of preparations, the manufacturing methods, and impurities and specific procedural rules in the sense of Article 5(1)(n) of the Regulation.

Conclusion and suggestions regarding the proposed modifications

53. Regulation 1935/2004 provides in Article 20(2) that there is an obligation to disclose certain information regarding applications for food contact materials. The reason therefore lays in the fact that these materials that are in contact with food can pose risks to human health and to the environment. The obligation in Article 20(2) to give access to this list of information was removed from the modified Regulation 1935/2004 and a list of confidential information was added. It should be noted that the general list of – in principle – public information laid down in Article 38(1) of the modified GFL Regulation does not cover the information in the list to be removed from Article 20(2) of Regulation 1935/2004. Therefor the reference in the proposed Article 19(1) of Regulation 1935/2004 to Article 38 does not cover the current list of non-confidential information. Further, as has been set out, will the information, sub-mitted to EFSA under Regulation 1935/2004, fall under the new transparency regime in the GFL Regulation through the new Article 19(1), with reference to Articles 38, 39 to 39f and 40 of the GFL Regulation and through the new Article 20 with reference to the Articles 39 to 39f of the modified GFL Regulation. The information held by EFSA under Regulation 1935/2004 will as a result of the proposal fall under a specific dis-closure regime in deviation from the general disclosure regime under Regulation 1049/2001.

[...]

Amendments to Regulation 1331/2008

Current transparency regime and proposed changes

56. Articles 11 and 12 of Regulation 1331/2008[13] on the common authorisation procedure for food additives, food enzymes and food flavourings are laying down rules regarding transparency and confidentiality under the Regulation. Article 11 provides that EFSA shall ensure the transparency of its activities in accordance with Article 38 of Regulation (EC) No 178/2002 and that it shall in particular make its opinions public without delay. Article 12 of Regulation 1331/2008 contains the provision regarding confidentiality under the Regulation. According to the first paragraph of this provision confidential treatment may be given to information the disclosure of which might significantly harm the competitive position of the applicant for an authorisation under the Regulation. Information relating to the following shall not, in any circumstances, be regarded as confidential: the name and address of the applicant; the name and a clear description of the substance; the justification for the use of the substance in or on specific foodstuffs or food categories, information that is relevant to the assessment of the safety of the substance and the analysis method(s). Under Article 12(2) of Regulation 1331/2008 the applicants shall indicate which of the information provided they wish to be treated as confidential. Verifiable justification must be given in such cases. The Commission shall decide which information can remain confidential. According to Article 12(5) of the Regulation the Commission, EFSA and the Member States shall,

[13] Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p. 1

in accordance with Regulation (EC) No 1049/2001, take the necessary measures to ensure appropriate confidentiality of the information received by them under the Regulation, except for information which must be made public if circumstances so require in order to protect human health, animal health or the environment.

57. In the proposal Article 11 is replaced. The new provision states that, where the Com-mission requests on opinion under Article 3(2) of Regulation 1331/2008 EFSA shall make public the application for authorisation, supporting information and scientific opinions in accordance with the new provisions of the modified GFL Regulation, Articles 38, 39 to 39f and 40. The proposal replaces Article 12 on Confidentiality. Article 12(1) provides the applicant with a right to request for confidentiality upon verifiable justification, whereas the new Articles 12(2) and 12(3) provide that it is for EF-SA, in case an opinion in the sense of Article 3(2) is requested, and for the Commis-sion in case such opinion is not requested to decide on the confidentiality request. The extensive list in Article 12(2) of information that shall not, in any case, be regarded as confidential, has been removed in Commission's proposal.

[...]

Proposed changes to Regulation 1107/2009

Current transparency regime under Regulation 1107/2009 and proposed changes

60. The Articles 10 and 16 of Regulation 1107/2009[14] foresee in public access to information submitted by an applicant for the approval of an active substance under the Regulation and to information regarding the renewal of approval, by referring to Article 63 of Regulation 1107/2009.

61. Article 63(1) of Regulation 1107/2009 provides that a person, requesting that information submitted under the Regulation is to be treated confidential shall provide verifiable evidence to show that the disclosure of the information might undermine his commercial interests, or the protection of privacy and the integrity of the individual. According to Article 63(2) of Regulation 1107/2009 disclosure of the information listed there shall normally be deemed to undermine the protection of the commercial interests or of privacy and the integrity of the individuals concerned. The list contains information such as the method of manufacture, the specification of impurity of the active substance, results of production batches, methods of analysis for impurities, relevant links between a producer or importer and the applicant or the authorisation holder, information on the complete composition of a plant protection product, names and addresses of persons involved in testing on vertebrate animals.

62. It concerns for a large part the same or comparable categories of information that are listed in Article 39(2) of the Commission proposal for the modification of the GFL Regulation. Article 63(3) of Regulation 1107/2009 provides that Article 63 is 'without prejudice to Directive 2003/4'. The Court of justice of the European Union for that reason held in its Judgment of 23 November 2016 in Case C-442/14 that Article 63 applies without prejudice to Directive 2003/4. The Court further held:

"Accordingly, it does not in any way follow from that article that the information referred to therein could not be classified as 'information on emissions into the environment' or that that data could never be disclosed pursuant to that directive." (Case C-442/14, par. 101).

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

63. The Commission's proposal does not foresee in the removing of Article 63(3) of the Regulation stating that the provision is without prejudice to Directive 2003/4. But the proposal adds a new reference in Article 63(2) to the confidentiality list in Article 39(2) of the new GFL Regulation which will lead to the application of the confidentiality regime as laid down in that provision. The proposed Article 39(2) of the GFL Regulation is not 'without prejudice to Directive 2003/4'.

64. Further the new Article 63(2) of Regulation 1107/2009 'in addition to' Article 39(2) of the modified GFL Regulation states that 'confidential treatment may be accepted with respect to information, the disclosure of which may be deemed, upon verifiable justification, to significantly harm commercial interests. The list contains information regarding the specification of impurity, methods of analysis, results of production batches and information on the complete composition of a plant protection product.

Conclusion and suggestions regarding the proposed modification of Regulation 1107/2009

65. The replacing of the references to Article 63 of Regulation 1107/2009 in the Articles 10 and 16 of the Regulation by a reference to the new articles 38, 39 to 39f and 40 of the proposed GFL Regulation and the reference to these same provisions in the pro-posed new Article 63(2) of Regulation 1107/2009 creates a specific, less transparent regime than under the current Regulation. The proposal of the Commission therefore seems to set aside – at least in part – the Judgements of the Court of Justice of 23 November 2016 in case C-442/14 and C-673/13 P, where the Court held that information from the application dossier and information on impurities and the composition of batches may fall[15] under the concept of 'information on emissions into the environment' as laid down in the Articles 4(2) of Directive 2003/4 and 6(1) of Regulation 1367/2006. Information on emission into the environment cannot be withheld from the public.

66. These are serious consequences given the possible adverse effects of active substances and plant protection products for human health and the environment. Article 39 of the proposed GFL Regulation does not even foresee in a clause permitting the disclosure of confidential information, outside of urgent situations, in case of an overriding public interest, such as risks to health, as foreseen in Article 4(2), second sentence of Regulation 1049/2001.

[...]

Proposed amendments to Regulation 2015/2283

Current transparency regime and proposed changes

68. Regulation 2015/2283[16] on novel foods comprises a confidentiality provision in Article 23. According to paragraphs 1 and 2 applicants may request confidential treatment of certain information submitted under this Regulation where disclosure of such in-formation may harm their competitive position, upon verifiable justification. The Commission takes a decision on the request.

69. Article 23(4) of Regulation 2015/2283 contains a list of information to which 'confidentiality shall not apply'. It concerns information such as name and address of the applicant, name and description of the novel food, proposed conditions of use, a summary of the studies submitted, the results of the studies carried out to demonstrate the safety of the food, analytic method(s), and information on any prohibition or restriction by a third country.

[15] Case C-673/13 P has been referred back to the General Court for re-examination of the relevant facts in relation to the ruling of the Court of Justice in appeal (See Case T-545/11 RENV)

[16] Case C-673/13 P has been referred back to the General Court for re-examination of the relevant facts in relation to the ruling of the Court of Justice in appeal (See Case T-545/11 RENV)

70. In the proposal Article 23 of Regulation 2015/2283 is to be replaced, starting in para-graph 1 of the replacing provision with the obligation for EFSA to make public the application for authorisation, supporting information and scientific opinions in accordance with Articles 38, 39 to 39f and Article 40 of the modified GFL Regulation. The general list of information laid down in the proposed Article 38(1) of the GFL Regulation does not completely cover the detailed information listed in the current list of non-confidential information in Article 23(4) of Regulation 2015/2283, specifically in-formation on the analytic methods.

Conclusion and suggestions regarding the proposed modifications

71. Regulation 2015/2283 foresees in the obligation to disclose some information regarding applications for novel foods as these can present risks to human health. The obligation to give access to a specific list of information was removed from the modified Regulation and a list of confidential information was added. As has been noted above, the general list of – in principle – public information laid down in Article 38(1) of the modified GFL Regulation does not completely cover the removed list with information that shall not be considered confidential. Further, as has been set out, the pro-posed Article 23, by its reference to the provision in the modified GFL Regulation, leads to the information concerned falling under a specific disclosure regime, deviating in part from the general disclosure regime under Regulation 1049/2001.

[...].

Overall conclusion

Notwithstanding the changes with a positive effect on transparency in the proposal, it is necessary to amend the Commission's proposal for the maintaining of the current level of transparency under European Union food law with regard to several categories of information.

Note: Options for amendments were proposed in the original document. They have been removed as they are now out dated. In total, 16 paragraphs have been removed.