Decision in case 952/2014/OV on the European Food Safety Authority's (EFSA) public consultation procedure for the renewal of the approval of the herbicide glyphosate

Decision
Case 952/2014/OV - **Opened on** 18/06/2014 - **Decision on** 18/11/2015 - **Institutions concerned** European Food Safety Authority (No maladministration found) | European Food Safety Authority (Settled by the institution) |

The complainant, GM-Free Cymru, a Welsh pressure group campaigning to keep Wales free of genetically-modified crops, wanted to participate in the public consultation organised by the European Food Safety Authority (EFSA) on the renewal of EU approval of the herbicide glyphosate (the active ingredient of the commercialised herbicide "Roundup"). Having complained to the EFSA about the complexity of the public consultation procedure, the complainant turned to the Ombudsman. It alleged that the public consultation procedure was not user friendly, since it imposed 1) the mandatory use of an electronic template, as well as 2) the signature of a disclaimer in order to obtain a copy of the Renewal Assessment Report of the Rapporteur Member State. The complainant argued that these requirements discouraged public participation and that EFSA's intention was to minimise, rather than maximise, public involvement.

The Ombudsman asked the EFSA for an opinion on the complaint. The EFSA thereupon took immediate measures to simplify the relevant public consultation procedure. In particular, the EFSA deleted the requirement to accept any terms or conditions before submitting comments and inserted clarifications on how to fill in the template (previously contained in a separate Guidance document) directly into the template itself.

The Ombudsman welcomed the measures taken by the EFSA and found that the EFSA had settled the issue of the signing of the disclaimer. As regards the mandatory use of the template, the Ombudsman found that the EFSA had shown flexibility, and she trusted that it would do likewise in the future.

The background to the complaint

1. This complaint, submitted by "GM-Free Cymru" ("the complainant"), a pressure group

campaigning to keep Wales free of genetically-modified crops, concerns the alleged complexity of the EFSA's public consultation procedure on the renewal of EU approval of the herbicide "glyphosate" (the active ingredient of the herbicide "Roundup").

2. The renewal procedure in question is set out in Regulations 1107/2009 [1] and 1141/2010 [2] : The applications for renewal of the approval are evaluated first by a rapporteur Member State and subsequently by means of a peer review carried out by the EFSA and other Member States. In summary, a producer of an active substance wishing to obtain a renewal of the authorisation must submit an application to the designated Rapporteur Member State (RMS) which then will submit to the EFSA a draft Renewal Assessment Report (RAR). The Report is peer reviewed by the EFSA (more particularly by its Pesticides Unit) in cooperation with the Member States. In this context, the EFSA can organise a public consultation on the Report. The EFSA then drafts a scientific report which is sent to the Commission. Taking into account the EFSA's conclusions, the Commission takes a decision on whether or not to renew the approval of the active substance. In the case of the renewal procedure of glyphosate, Germany was the Rapporteur Member State. After the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung - BfR) submitted the draft Renewal Assessment Report, the EFSA on 22 January 2014 initiated the peer review. On 12 March 2014 the EFSA launched on its website a public consultation on the draft Report. The deadline for participating in the public consultation was 11 May 2014 (two months).

3. The complainant - which considers that both glyphosate and Roundup pose serious threats to public health and the environment - wanted to participate in the public consultation. On 28 March 2014, it wrote to the EFSA expressing concerns with regard to the complexity of the public consultation procedure. The complainant referred to the link on EFSA's website which explained the procedure for participating in the public consultation [3] : Participants in the public consultation were required to submit comments via an electronic template available on the EFSA's website. In order to participate, participants first had to submit an online request form in order to receive an e-mail providing access to the Renewal Assessment Report and to the template. They were also required to sign a *disclaimer* . The complainant further pointed out that, by referring to glyphosate as the " *active substance* ", the EFSA implied that it would look at the risks linked to glyphosate only and not at those linked to Roundup or other products which contain not only glyphosate, but also other chemicals. The complainant asked whether it was possible to submit comments simply via e-mail.

4. The EFSA's Pesticides Unit replied on 16 April 2014 that the public consultation procedure was laid down in Article 15(2) of Regulation 1141/2010 and insisted that comments had to be made via the electronic template, in order to ensure full transparency and to facilitate the internal process of gathering comments. The EFSA also referred to its Guidance document on the provision of comments in the course of its pesticides consultations [4] .

5. On 7 May 2014, the complainant wrote back to the EFSA formally complaining about the " *byzantine* " and " *kafkaesque* " consultation process. The complainant argued that the consultation process was designed to discourage citizens and NGOs from participating. The complainant alleged that the system was thus biased in favour of the industry. The complainant

also stated that the *disclaimer* which participants had to sign [5] in order to obtain a copy of the Renewal Assessment Report was unacceptable, since it gave to the EFSA the right to disregard anything it considered to be irrelevant.

6. On 8 May 2014, the EFSA replied that it was ready to improve its procedures, but that it had to follow some basic rules to guarantee fair treatment of all participants. The EFSA however sent to the complainant links to the Renewal Assessment Report on glyphosate (in 15 PDFs), the Guidance document and the electronic template for the submission of comments. The EFSA explained that, as all comments would be published as part of the peer review report, they needed to be collected in the format of a template. It underlined that a non-structured public consultation would take up too much of its resources. The EFSA stated that it looked forward to receiving the complainant's contribution in the template provided.

7. On 8 May 2014, three days before the public consultation deadline, the complainant sent its submission by e-mail, arguing that both glyphosate and Roundup should be banned as early as possible, since they constitute serious dangers for farm animals, human health and the environment. On 22 May 2014, not having received an acknowledgement of receipt of its submission, the complainant sent an e-mail to inform the EFSA that it would complain to the Ombudsman. On the same day, the EFSA replied that the complainant's comments had been received and would be sent, together with the comments from other stakeholders, to the German authorities for further consideration as part of the peer review process.

The inquiry

8. On 22 May 2014, the complainant submitted this complaint to the Ombudsman who opened an inquiry into the complainant's allegation that the EFSA's public consultation procedure for the renewal of the approval of glyphosate is not user friendly because it requires 1) the mandatory use of an electronic template (part 1 of the allegation), as well as 2) the signature of a disclaimer in order to obtain a copy of the Renewal Assessment Report (part 2 of the allegation).

9. The inquiry also included the complainant's claim that the EFSA should re-open the public consultation process and allow members of the public to submit comments in a timely and convenient way, and outside of the electronic system.

10. In relation to the complainant's allegation and related claim, the Ombudsman asked the EFSA to say how many contributions it had received through the electronic template, and how many contributions other than the complainant's one through different means, and whether it would be possible to accept contributions to the public consultation which are not entered into an electronic template. In this respect, the Ombudsman asked the EFSA to take into account the following three considerations:

First, there is nothing in Article 15(2) of Regulation 1141/2010 prescribing a specific system for consulting the public. In fact, Article 15(2) merely states that "[u] *pon request from any interested party, the Authority shall make the renewal assessment report available ...* ".

Second, although the EFSA had made available a Guidance document on how to participate in the public consultation [6] , the electronic template for comments remains **extremely complex** : The Guidance document explains that the template consists of 5 sections covering the sections of the Renewal Assessment Report. Each of the 5 sections has a separate header. In each header, the originator of the comments, the type of the assessment report, the name of the active substance and the date should be inserted. Each section then contains separate subsections with 4-column tables for comments relevant to that subsection. The first column serves as a numerical counter of the comments of each subsection. For any subsequent comments, additional rows should be added with corresponding numbers inserted in the first column.

Third, in most public consultations launched at the EU level, participants can send in their comments in the form and format they wish.

11. In the course of the inquiry, the Ombudsman received the opinion of the EFSA [7] on the complaint and, subsequently, the comments of the complainant in response to the EFSA's opinion. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.

The allegation that the public consultation procedure is not user-friendly and the related claim

Arguments presented to the Ombudsman

12. The **complainant** argued that the EFSA was discouraging the public from participating and that its intention was to minimise, instead of maximise, public involvement. The system was designed for the EFSA's own administrative convenience, to further the interests of the pesticides and biotechnology industries and to ignore the public health concerns of EU citizens. In the complainant's view, the electronic process for participating in the public consultation was the same as the one used for the "peer review" involving stakeholders like the pesticides industry and the Member States' scientific advisers.

13. In its opinion, the **EFSA** stated that, upon receiving the complaint, it had decided to review and simplify the contested requirements. The EFSA proactively changed the relevant page of its website, i) by deleting the requirement to accept any terms or conditions before submitting comments, ii) by simplifying the text and process explaining how to submit comments, and iii) by deleting the separate Guidance document and inserting directly into the template clarifications on how to fill in the template. The EFSA further stated that, on 16 July 2014, it opened a public consultation on a staff working paper entitled " *Transformation to an Open EFSA* ", in which it set out a "roadmap" on how to further increase the level of openness and transparency in the EFSA.

14. The EFSA described the legal framework for the public consultation procedure. It argued that the principles of openness and transparency had been implemented in the EFSA's legal framework to ensure that it undertakes its risk assessments in an independent, objective, open and transparent manner and that it takes into consideration technical and scientific considerations only.

15. Regarding the present case, the EFSA stated that the procedure for the renewal of the approval of the active substance glyphosate was set out in Regulation 1141/2010. However, Article 15 of the Regulation does not provide for an explicit public consultation phase. It simply obliges the EFSA to gather and forward the comments from Member States' authorities and to make available the Renewal Assessment Report upon request. The EFSA also argued that, apart from the right to be heard, the EFSA and the EU Code of Good Administrative Behaviour do not specify any obligation to consult with the public when a scientific body is drawing up a scientific or technical document. However, because of the importance of the principles of openness and transparency, the EFSA decided to go beyond its legal obligation and to give interested parties the opportunity to comment on the Renewal Assessment Reports. The EFSA Unit responsible for the pesticides peer review process developed *Guidelines* to assist interested parties in the submission of comments.

16. The EFSA acknowledged that, at the time the complainant wanted to submit its comments, it had in place a system that required i) the mandatory use of an electronic template as well as ii) the signature of a disclaimer. As explained by the EFSA in its e-mails to the complainant, these requirements were put in place to facilitate the consultation process and to optimise the use of the EFSA's limited human resources.

17. The EFSA stated that the Ombudsman had already decided in previous cases (1151/2008/ANA and 2558/2009/DK) that the precise manner by which participatory democracy is made effective in any given circumstances depends on the specific nature of the Union action in question and that this is especially so in areas which are technically complex. In this case, according to the EFSA, it had decided to ask contributors to the consultation to formulate their comments in a standardised way using a template which should be completed in line with the EFSA's Guidelines.

18. As regards the prior signing of a disclaimer, the EFSA stated that it was not imposing an undue procedural burden on participants, since they simply needed to flag a box to proceed further. The text of the disclaimer makes clear to the prospective contributors that only relevant comments will be taken into account by the EFSA. The EFSA said if found it difficult to understand how the flagging of a short disclaimer would make it impossible for interested individuals to participate in the public consultation. Also, the complainant's argument that many people were intimidated and discouraged was not supported by any verifiable evidence.

19. The EFSA underlined that one should also consider the sheer size of the documents and data frequently submitted for public consultation by the EFSA's Pesticides Unit. Contrary to the average documents put out for public consultation by other EU institutions, each Renewal Assessment Report is composed of hundreds or even thousands of pages of a highly technical

nature. The use of a template is required to allow the correct insertion of comments to the relevant part of the document. By requiring prospective contributors to insert each comment on a specific part of the document under consultation, the EFSA encourages interested parties to actually read the document and send only comments that are relevant. Furthermore, the use of an electronic system to help the institutions in structuring comments received from the public on consultations is widespread at Union level. It also facilitates the EFSA's work in processing the comments. Ultimately, this contributes to the overall transparency of the consultation process. Obliging the EFSA to accept unstructured contributions would only increase its discretion.

20. On the question of whether the EFSA could accept contributions to the public consultation which are not entered into an electronic template, the EFSA stated that this was indeed possible and that in this case, the complainant (and another participant) had actually been allowed to do so. The EFSA pointed out that it had received in total 28 contributions, two of which (including the complainant's) were received in formats different from those required by the EFSA. However, because of the breadth, scope and complexity of the documents put out for consultation, it would be extremely impractical to allow this on a systematic basis. Moreover, the EFSA provided the complainant with the consultation documents notwithstanding the fact that it had not signed the disclaimer.

21. As regards the complainant's argument that the system is designed to further the interests of the pesticides and biotechnology industry, the EFSA stated that the use of a mandatory template does not suggest any kind of bias. What matters for the EFSA is that unqualified and unscientific concerns find no place in its mission or tasks.

22. In reply to the three concerns expressed by the Ombudsman, the EFSA made the following comments:

i) The EFSA stated that there is indeed nothing in Article 15(2) of Regulation 1141/2010 prescribing a specific system for the consultation of interested parties. In fact, the EFSA goes well beyond the participatory requirements set out in the Regulation;

ii) The EFSA acknowledged that the Guidance document on the provision of comments could be perceived as being relatively complex. However, this perception has to be put in the context of the complexity of the subject matter and documents on which EFSA is seeking input, as demonstrated by the annexes enclosed with EFSA's opinion. Against this background, requiring potential interested parties to submit their comments by filling in a pre-formatted table cannot, and should not, be considered as a complex task. The EFSA is simply asking contributors to indicate the identity, the reference to the report, the name of the substance and the date of submission. Although the template could be simplified, the EFSA believes that the level of complexity is not such as to discourage prospective contributors. Nevertheless, following this complaint, the EFSA proactively took the three steps described above which have already been implemented.

iii) The EFSA acknowledged that although in some public consultations at EU level on general or political topics (such as the European Ombudsman's own consultation on the composition of

European Commission's expert groups), participants may contribute in the format they wish, due account should however be taken of each institution and body's mission and tasks, as well as of the nature of deliverables and underlying documents.

23. On the basis of the above, the EFSA concluded that it committed no maladministration and that it showed the appropriate level of flexibility by providing the complainant with the documents and accepting its comments.

24. In reply to the complainant's **claim** , the EFSA stated that the consultation was over by now and could not be re-opened, since otherwise the consultation phase would unduly delay the entire process and harm the legitimate interests of the applicant and of the EFSA's institutional partners involved in the procedure.

25. In its observations, the **complainant** contested that, after receiving its complaint, the EFSA had " *proactively changed* " the relevant page of its website. The complainant noted that the EFSA's argument that, because the consultation matters are highly complex, comments should be made through an electronic template so that only "relevant" comments are submitted, is the root of the problem insofar as it is the EFSA which determines which comments are relevant. In the complainant's view, the possible re-approval of glyphosate is a major health issue for the citizens of Europe. That their concerns were valid was also borne out by the fact that, on 2 April 2015, the German Federal Institute for Risk Assessment (BfR) announced that it was not recommending the re-approval of glyphosate, in the light of the findings of the IARC [8] and other concerns [9] . This showed that the EFSA should, from the beginning, have encouraged a much more flexible and widespread comments system, so as to enable a comprehensive examination of health/toxicity concerns.

26. In further observations sent in August 2015, the complainant pointed out that the Commission, acting upon the EFSA's advice, on 10 August 2015 had refused a request for access to the glyphosate file made by a German NGO, on the grounds that disclosure at this stage of the process would seriously undermine the EFSA's ongoing decision-making process [10] . The complainant argued that this reinforced its view of on-going maladministration by the EFSA in ignoring its own guidelines and commitments to stakeholder involvement.

The Ombudsman's assessment

Preliminary remark concerning the scope of the inquiry

27. The Ombudsman notes that, in its further observations of 10 April and 18 August 2015, the complainant made specific comments with regard to the safety of glyphosate and Roundup, arguing that the EFSA should not recommend the renewal of the approval. However, the present complaint does not concern the substance of the EFSA peer review of the Renewal Assessment Report on glyphosate, but only the procedural aspects of the EFSA's relevant public consultation procedure. The Ombudsman is nevertheless aware that the complaint is set

against a background of increased public concerns with regard to the safety of glyphosate and Roundup. More particularly, on 30 July 2015, the EFSA itself announced [11] that - as part of its ongoing peer review - it was going to assess the findings of a report by the IARC which concluded that glyphosate is " *probably carcinogenic to humans* " [12] (the EFSA's conclusions are due in November 2015). Also, on 15 September 2015, the European Parliament's Committee on the Environment, Public Health and Food Safety voted against the extension of the approval period of glyphosate.

28. It is against this background that the present complaint needs to be assessed. In particular, in view of the public concerns with regard to the safety of glyphosate, the duty to carry out a proper public consultation, before the decision on the renewal of the approval is taken, becomes particularly relevant.

29. The Ombudsman also notes that, in its further observations, the complainant pointed out that the Commission had refused public access to a German NGO to a report on glyphosate. This issue is not covered by the present inquiry. However, the issue could be submitted to the Ombudsman in a complaint, after having exhausted the procedures set out in Articles 6 to 8 of Regulation 1049/2001 (namely an initial and confirmatory application for public access).

30. At this point, the public consultation has now been closed and the EFSA peer review was finalised with the publication of EFSA's conclusions on 12 November 2015 [13] . In these circumstances, the Ombudsman accepts the EFSA argument that the public consultation procedure should not be re-opened. On the question of the EFSA'S insistence that participants in the consultation should use the electronic template, this is no longer an issue in the present case. The EFSA has accepted the complainant's submission even though it was sent by email and not by way of the template. The complainant's individual case has now been resolved. However, the more general question concerning the procedures for participation in the EFSA's public consultations under Regulation 1141/2010 remains to be answered.

Assessment

31. Article 1 of the Treaty on European Union (TEU) provides that the Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, " *in which decisions are taken as openly as possible and as closely as possible to the citizen* ". The Lisbon Treaty introduced in the TEU the Title " *Provisions on Democratic Principles* " (Articles 9-12). Article 10(3) TEU states that every citizen shall have the right to participate in the democratic life of the Union and reiterates that "[d] *ecisions shall be taken as openly and as closely as possible to the citizen* ". Article 11(1) and (2) TEU provide that the EU institutions shall, by appropriate means, give citizens and representative associations **the opportunity to make known and publicly exchange their views in all areas of Union action,** and that the institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society. Article 11(3) TEU provides that the Commission shall carry out broad consultations with parties concerned.

32. As regards specifically the EFSA, Regulation 178/2002 [14] (known as "the EFSA founding Regulation") provides in Article 42 that "[t] *he Authority shall develop effective contacts with consumer representatives, producer representatives, processors and any other interested parties* ". Article 9 (" *Public consultation* "), which is part of the Section on " *Principles of Transparency* " provides that "[t] here shall be open and transparent public consultation *, directly or through representative bodies, during the* preparation, evaluation and revision of food law *, except where the urgency of the matter does not allow it* ". Since the EFSA's mission, according to Article 22(2) of Regulation 178/2002, is to " *provide scientific* advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety ", it is clear that the reference to open and transparent public consultation in Article 9 should be understood as being also relevant for the EFSA's activities, in particular when it comes to risk analysis [15] .

33. Regulation 1141/2010 - which lays down the procedure applicable to the renewal of the approval of active substances like glyphosate - does not provide explicitly for a public consultation as part of the renewal procedure. Article 15(2), to which the EFSA referred, merely provides that "[u] *pon request from any interested party, the Authority shall make the renewal assessment report available* ...". It was thus the EFSA's own (and very commendable) initiative to organise a public consultation procedure within the renewal procedure of Regulation 1141/2010. [16]

34. The Ombudsman notes that the EFSA, following this complaint, introduced the following three measures: 1) First, the EFSA deleted the requirement to accept any terms or conditions before submitting comments (the "disclaimer"); 2) second, the EFSA simplified the text and process explaining how to submit comments; and 3) the EFSA removed the Guidance document and inserted clarifications on how to fill in the electronic template directly into the template. The Ombudsman welcomes these three steps, which make the public consultation procedure less cumbersome. In addition, the Ombudsman also welcomes the added function on the EFSA's website which allows for receiving e-mail alerts on upcoming public consultations. [17] This suggests that the EFSA takes a genuine interest in its public consultations.

35. In particular, in relation to part 2 of the allegation (see paragraph 8 above) the Ombudsman welcomes the removal of the disclaimer since that disclaimer only repeated some obvious points, namely that the EFSA would disregard comments not related to the risk assessment or which were received after the deadline. The Ombudsman therefore considers that the disclaimer served simply as an additional and unnecessary formality and that its removal is therefore fully justified. By removing the disclaimer, the EFSA has thus settled part 2 of the allegation.

36. As regards part one of the allegation and the related claim, namely whether the mandatory use of an electronic template is appropriate for the public consultation, the Ombudsman notes that EFSA's website contains two different links to the electronic template, namely http://dar.efsa.europa.eu/dar-web/consultation [Link] and the link contained in http://www.efsa.europa.eu/en/pesticides/pesticidesconsultations [Link]. The Ombudsman assumes that it is the second of those two links which is now the one to be used, since the

template contains track changes with comments explaining how to fill it in. This appears to correspond to the measure announced by the EFSA that the Guidance document was removed and that the clarifications on how to fill in the electronic template have now been inserted directly into the template (the third measures announced by the EFSA). It would thus be appropriate for the EFSA to remove the other link from its website, since it is no longer up-to-date and serves no obvious purpose.

37. As regards the question whether the mandatory use of the electronic template is appropriate, it is clear that the first two paragraphs of Article 11 TEU seek to ensure that the Union's policies are shaped by means of a pluralistic input which includes the views of citizens, representative associations and civil society. Participation in the democratic life of the Union, however, is not unlimited but must take place " *by appropriate means* ". In order to fulfil their duties in this area, the EU institutions must therefore determine " *the appropriate means* " by which citizens and representative associations are given the opportunity to make known and publicly exchange their views. The Ombudsman understands that the precise manner by which participatory democracy is made effective depends on the specific nature of the Union action in question and the established procedures in place. In this regard, the EU institutions have a margin of discretion, especially in areas which are technically complex. However, they should always ensure that they can justify objectively how they exercise that margin of discretion [18] .

38. In the present case, the Ombudsman notes that the template is a complex and long document. Even with the clarifications on how to fill in the template that have now been added by the EFSA, it is still not a straightforward procedure.

39. It appears, however, that the EFSA has good reasons for the use of the template. First, the Ombudsman notes that the relevant context of the EFSA's peer review also needs to be taken into account in this respect: The Renewal Assessment Reports on which the public is consulted are in themselves highly complex and technical documents of a scientific nature. In the present case, it appears from the annexes to the EFSA's opinion that the Renewal Assessment Report on glyphosate and its annexes comprise a total of 3945 pages.

40. Second, when organising a public consultation on this type of document, the EFSA needs to carry out a balancing exercise between, on the one hand, the complexity of the documents on which it wishes to consult the public, and on the other hand, the real possibility for as many members of the public as possible to effectively participate in the public consultation. It is definitely useful for the EFSA - in order to easily process them afterwards - to receive comments which are structured in such a way that they follow the sections of the Report itself. The use of the template is thus clearly an efficient tool for organising the public consultation and for gathering and processing comments from the public.

41. There would obviously be concerns if the use of the template was mandatory in every case, because the mandatory use of the template could under certain circumstances become an impediment to participation by citizens, representative associations and civil society.

42. In the present case however, the EFSA has demonstrated commendable flexibility. In this

case, of the 28 contributions received and taken into account, two contributions (including that of the complainant) were not submitted through the electronic template. The Ombudsman therefore takes the view that there has been no maladministration by the EFSA with regard to the first part of the allegation.

43. The Ombudsman trusts that the EFSA will adapt a similar flexibility with regard to the use of the template for future public consultations. It will indeed always be the case that a small minority of prospective contributors to the public consultation will find the mandatory use of the template overly cumbersome and therefore discouraging. This could lead to a situation where certain people who wish to participate in the public consultation may be forced to abstain.

44. The Ombudsman therefore particularly welcomes the statements made by the EFSA that it envisages additional short-term changes to its system, such as offering a generic comment section and a dedicated e-mail address. The Ombudsman thus understands that the EFSA is willing to take a more pragmatic approach and to take into consideration comments from the public even where they have not been submitted using the electronic template made available for that purpose.

Conclusions

On the basis of her inquiry into this complaint, the Ombudsman closes it with the following conclusion:

There has been no maladministration by the EFSA with regard to part 1) of the allegation and the claim.

Part 2) of the allegation has been settled by the EFSA.

The complainant and the EFSA will be informed of this decision.

Emily O'Reilly

Strasbourg, 18/11/2015

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21

October 2009 concerning the placing of plant protection products on the market and repealing

Council Directives 79/117/EEC and 91/414/EEC, OJ 2009 L 309, 1.

[2] Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council

Directive 91/414/EEC and establishing the list of those substances (OJ 2010 L 322, p. 10), as amended by Commission Implementing Regulation (EU) No 380/2013 of 25 April 2013 amending Regulation

(EU) No 1141 /2010 as regards the submission of the supplementary complete dossier to the

Authority, the other Member States and the Commission (OJ 2013 L 116, p. 4).

[3] http://dar.efsa.europa.eu/dar-web/consultation [Link]: The link, which contains a Guidance document and a template, no longer mentions glyphosate for which the public consultation is now terminated.

[4] http://www.efsa.europa.eu/en/pesticides/pesticidesconsultations.htm [Link]

[5] The disclaimer stated " *By sending the request I acknowledge that EFSA has the right to disregard any comments not related to risk assessment or received after the deadline set for the selected advice substance. I also accept that comments have to be submitted electronically to the email address given in the general instruction by using the template* " and " *I agree with the terms as stated above* ".

[6] http://www.efsa.europa.eu/en/praperconsultations/docs/prapergdconsultation.pdf [Link]

[7] The opinion and annexes in total comprise 7300 pages.

[8] The International Agency for Research on Cancer (IARC) of the World Health Organisation (WHO).

[9] The BfR statement states the following: " *The BfR recommends emphatically that all those involved in the assessment of glyphosate, WHO panels, IARC and JMPR (Joint FAO/WHO Meeting on Pesticide Residues), as well as the competent EU-authorities EFSA and ECHA, should discuss the current disputable issues, with the aim of resolving the discrepancies, before the EU-Commission makes a decision on the further approval of glyphosate* " (http://www.bfr.bund.de/cm/349/bfr-contribution-to-the-eu-approval-process-of-glyphosate-is-finalised.pdf [Link]).

[10] https:// www.testbiotech.org/en/node/1326 [Link]

[11] http://www.efsa.europa.eu/en/press/news/150730

[12] http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf

[13] http://www.efsa.europa.eu/en/press/news/151112

[14] 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 2002 L 31, p. 1.

[15] In this respect, Article 6 ("Risk analysis") of Regulation 178/2002 provides that " *1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis 2. Risk* assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner *. 3.* Risk management shall take into account the results of risk assessment, and in particular, the opinions of the [EFSA *]* " (emphasis added).

[16] http://dar.efsa.europa.eu/dar-web/consultation [Link]. Ongoing public consultations are mentioned on the link http://www.efsa.europa.eu/en/pesticides/pesticidesconsultations

[17] http://www.efsa.europa.eu/en/news/alerts?type=consultations

[18] See the Ombudsman's decision of 9 July 2013 on complaint 1151/2008/ANA, paragraph 71 (http://www.ombudsman.europa.eu/cases/decision.faces/en/50818/html.bookmark).