

ANNEX

Assessment of the request for internal review of Commission Implementing Regulation (EU) 2022/2364 of 2 December 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate

I. LEGAL FRAMEWORK

1. The Commission Regulation, which is subject to the present request for internal review, is based on Article 17, first subparagraph, of Regulation (EC) No 1107/2009¹ (the “PPP Regulation”). It therefore appears useful to analyse the text, context and telos of this provision.

1. Article 17 of the PPP Regulation

1.1 Wording of Article 17 of the PPP Regulation

2. Article 17, first subparagraph, of the PPP Regulation² provides:

“Where for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.”

3. This provision lays down two conditions for a decision extending the approval period of an active substance:
 - (a) the approval of an active substance can be expected to expire before a decision can be taken on the renewal of that approval; and
 - (b) the reasons for the delay of the renewal procedure are beyond the control of the applicant for renewal.
4. When both conditions are fulfilled, “a decision shall be adopted [...] postponing the expiry”. This means that the Commission is obliged to extend the duration of the active substance’s approval

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 L 309, 24.11.2009, p. 1.

² Article 17, second subparagraph, of the PPP Regulation concerns the specific situation where an applicant could not give the three years’ notice required under Article 15(1) of the PPP Regulation because the active substance expired before 14 June 2014, i.e. within less than three years of the date of application of the PPP Regulation.

period by means of an Implementing Regulation. In other words, the Commission has no discretion as to whether such decision must be taken. This reading was confirmed by the European Ombudsman in Case 687/2018/TE³. There is nothing in the text that suggests that the Commission is required to investigate the exact reasons for the delay beyond establishing that they were not attributable to the applicant.

5. The absence of any criteria indicating a choice of the Commission in this regard also means that the mandatory extension of an approval in accordance with Article 17 does not depend on factors relating to the type of active substance, such as whether it is potentially hazardous, a candidate for substitution, a low-risk active substance, etc. These factors only play a role in determining the duration of an initial approval or renewal of approval⁴. This reading was also confirmed by the European Ombudsman in Case 687/2018/TE⁵.
6. In addition, it is clear from the wording of Article 17 that the duration of this extension should be determined such that it ensures that it is “sufficient to examine the application”. Again, Article 17 does not indicate any typical or maximum duration of extensions based on the level of risk entailed in an active substance (as mentioned above, such factors rather play a role in determining the duration of an approval or renewal of approval⁶) or any other substantive criteria related to properties of an active substance. The text of Article 17 is solely concerned with the assessment of the time needed to conclude the procedure (rather than with the nature of the substance).

1.2. Context of Article 17 of the PPP Regulation

7. The PPP Regulation establishes rules for the approval, at EU level, of active substances used in plant protection products and for the authorisation, at Member State level, for the marketing and use of plant protection products in the respective Member State⁷.

³ “28. Article 17 of the Pesticides Regulation states that, where it is likely that, for reasons beyond the control of the applicant, the approval of an active substance will expire before a decision has been taken on the application to renew the approval, the Commission “shall” adopt a regulation extending the approval period for an active substance.

29. The wording “shall” implies that the Commission has, legally, no choice: it must extend the approval period in such situations.”

⁴ Cfr. Articles 5, 22 and 24 of the PPP Regulation.

⁵ “30. The Ombudsman also notes that Article 17 does not distinguish between approval periods granted for potentially hazardous or non-hazardous active substances. From a legal point of view, the Ombudsman therefore considers that the provision also applies to (potentially) hazardous active substances.”

⁶ Cfr. Articles 5, 22 and 24 of the PPP Regulation.

⁷ Cfr. Recital 1 and Article 1 of the PPP Regulation.

8. In order to understand the role of Article 17 of the PPP Regulation in its systematic context, it is worth considering the so-called “cyclical approach” of that Regulation. It can be derived from:
- first, the fact that the validity of approvals of active substances granted in accordance with the PPP Regulation is limited in time. The specific time periods foreseen in the PPP Regulation for the duration of an approval’s validity vary according to the degree of risk that an active substance may pose⁸;
 - second, the valid approval of an active substance can, upon application, be renewed for another limited period of time⁹.
 - third, in line with this cyclical approach for approvals, the authorisations of plant protection products are also issued for a limited period of time, which must not exceed one year after the expiry of relevant approvals of the active substances contained in those plant protection products¹⁰.
9. The cyclical approach provides for the regular re-assessment of an active substance’s properties as regards its effects on health and the environment in light of the latest scientific and technical knowledge. The duration of approval, and respectively authorisation, periods foreseen in the PPP Regulation aim at covering a period of time during which new scientific and technical knowledge may be developed that will be taken into account in the re-assessment of an active substance during its renewal procedure (and consequently the renewal of related authorisations, cfr. Article 43 of the PPP Regulation)¹¹.
10. As part of the cyclical approach, Article 15(1) of the PPP Regulation requires applicants for renewal of the approval of an active substance to submit their application no later than three years before the expiry of that approval. In setting this time limit, the legislator had to consider not only the necessity to adopt all decisions on approval and renewal of active substances on the basis of the latest scientific and technical knowledge, on the one hand, but also the time required to conduct the scientific assessments and administrative procedures leading to a decision on renewal, on the other hand.

⁸ Cfr. Articles 5, 22 and 24 of the PPP Regulation.

⁹ Article 14(2) of the PPP Regulation.

¹⁰ Article 32 of the PPP Regulation.

¹¹ See Recital 15 of the PPP Regulation.

1.3. Objectives of Article 17 of the PPP Regulation

11. The PPP Regulation is based on Articles 37(2), 95 and 152(4)(b) TEC (now Articles 43(2), 114 and 168(4)(b) TFEU). In line with this three-pronged legal basis, the purpose of the PPP Regulation is manifold: ensuring a high level of protection of human and animal health as well as the environment (Articles 114 and 168(4)(b) TFEU, respectively), improving the functioning of the internal market by harmonising the rules for the placing of plant protection products on the market (Article 114 TFEU), and improving agricultural production (Article 43(2) TFEU)¹².
12. As a consequence of the particular relevance which the protection of health and the environment plays among its objectives, the provisions of the PPP Regulation are underpinned by the precautionary principle¹³.
13. In order to pursue the objectives set out above and, where necessary, to find a balance between them with due regard to the precautionary principle, the EU legislator, through the PPP Regulation, established a comprehensive and rigorous framework for the approval of active substances as well as for the authorisation of plant protection products, making conscious and deliberate choices.
14. Although the recitals and legislative history of the PPP Regulation are silent on the specific purpose of Article 17, it is apparent from the overall objectives of the PPP Regulation as such, that – in adopting this provision – the legislator has balanced the various relevant interests when a renewal procedure cannot be concluded before the expiry of an approval. Article 17 is an expression of the balance found by the legislator between, on the one hand, the necessity to complete the renewal assessment procedure to ensure the high level of protection of health and the environment required by Article 114 TFEU and by the precautionary principle and, on the other hand, the need to respect legal certainty and protect legitimate expectation on the side of the applicant for renewal (who submitted all required data in time) in these cases. At the same time, in striking this balance, the legislator has evidently had particular regard to the precedence of the objective of a high level of protection of health and the environment, as Article 17 maintains the principle that all decisions under the PPP Regulation are based on robust scientific assessments as regards the effects of substances on health and the environment, even at the risk of extending – for a limited amount of time – an approval that later cannot be renewed.

¹² See also Recital 1 and Article 1 of the PPP Regulation.

¹³ See Recital 8 and Article 1(4) of the PPP Regulation.

1.4. Practical considerations in the application of Article 17

15. The Commission can generally ascertain well in advance of the expiry of the approval whether above-mentioned condition (a) of Article 17, that “it appears that the approval is likely to expire before a decision has been taken on renewal”, is fulfilled. This is in particular due to the knowledge of various consecutive steps required in a renewal procedure and their expected duration.

16. Thus it is useful to recall the main steps of the renewal procedure as set out in the Renewal Regulation:

- *A producer of an active substance must submit an application for renewal of that active substance to a Member State designated by the Commission, no later than three years before the expiry of the approval of that active substance.*
- *The Rapporteur Member State checks the application received and informs the applicant, the co-Rapporteur Member State, the Commission and the European Food Safety Authority (EFSA) if it has been submitted by the required date and contains all the required elements.*
- *Where the application has been submitted by the required date but one or more required elements are missing, the Rapporteur Member State requests the applicant to submit the missing elements.*
- *The applicant subsequently submits the supplementary dossiers containing all technical and scientific information required as set out in Article 7 of Commission Implementing Regulation (EU) No 844/2012 (the Renewal Regulation)¹⁴.*
- *The Rapporteur Member State assesses whether the supplementary dossiers have been submitted within the deadline and contain all the required information and informs the applicant, the co-Rapporteur Member State, the Commission and EFSA of the date of receipt of the supplementary dossiers and of the admissibility of the application.*

¹⁴ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation No 1107/2009, OJ L 252, 19.9.2012, p. 26.

- *Where the supplementary dossiers have been submitted by the required date but one or more required elements are missing, the Rapporteur Member State within one month requests the applicant to submit the missing elements within 14 days.*
- *The Rapporteur Member State then assesses the supplementary dossiers in order to determine if the approval criteria, which also apply to the renewal of an approval, can be expected to be fulfilled.*
- *During its assessment, the Rapporteur Member State may request additional information from the applicant and may also consult EFSA and request additional technical or scientific information from other Member States.*
- *As a result of its assessment, the Rapporteur Member State submits its Draft Renewal Assessment Report to the Commission and EFSA. EFSA circulates the Draft Renewal Assessment Report to the other Member States, the applicant and the public for comments.*
- *EFSA and the Member States then proceed to determine whether the approval criteria can be expected to be fulfilled by the substance subject to the application for renewal which may involve a consultation of experts ('peer review'), including in particular also experts from the Rapporteur Member State and co-Rapporteur Member State.*
- *When EFSA considers that additional information from the applicant is necessary, it requests after consultation with the Rapporteur Member State, the applicant to supply such information within a period that cannot exceed one month.*
- *EFSA communicates the conclusion of its assessment to the applicant, the Member States and the Commission.*
- *The Commission, on the basis of the information presented in the Draft Renewal Assessment Report and in EFSA's Conclusion, considers the risk management options and within 6 months from the adoption of the EFSA Conclusion presents a draft renewal report to the Standing Committee on Plants, Animals,*

Food and Feed (the “PAFF Committee”) and a draft Regulation on renewal (or non-renewal) of the approval of the active substance concerned.

- *The applicant must be given the possibility to submit comments on the draft renewal report.*
- *Once the PAFF Committee has delivered a favourable opinion on the renewal or non-renewal proposed by the Commission, the Commission adopts an Implementing Regulation renewing or not renewing the approval of the active substance concerned.*
- *In case the PAFF Committee does not deliver an opinion, the Commission can refer the draft Regulation to the Appeal Committee for further deliberation.*

17. Secondly, the above-mentioned condition (b) of Article 17, that the reasons for the expected delays in the assessment of an application for renewal of an active substance are “beyond the control of the applicant”, can in practice be met for various reasons. Such delays may, for example, be due to the complexity of the assessment to be conducted by the Rapporteur Member State or EFSA, a need for more in-depth exploration of specific aspects of the risk assessment, etc.
18. Finally, in applying the requirement of Article 17 that the postponement should be “for a period sufficient to examine the application”, the Commission needs to estimate how much more time will be required to conclude the procedure for the assessment of the application for renewal and the subsequent decision-making (for the individual steps entailed in such procedure, see above under paragraph 16).
19. The Commission’s extensions of approval periods on the basis of Article 17 were usually limited to one year. The Commission, in its extension decisions, opted for extension for relatively short periods of time that could be extended again if necessary, rather than single longer extension periods. In addition, as also stated in a standard recital in all Implementing Regulations extending the expiry of an approval¹⁵, the extension period will be rescinded immediately if and when a conclusive decision can be made on the renewal (or non-renewal, respectively).¹⁶

¹⁵ See for example Recital 7 of the Commission Regulation.

¹⁶ See for example Commission Implementing Regulation (EU) 2021/1450 of 3 September 2021 amending Implementing Regulation (EU) No 540/2011 as regards the approval periods of the active substances acrinathrin and prochloraz, OJ L 313, 6.9.2021, p. 25.

20. Since January 2023, the Commission, taking into account past experience, has chosen to extend approval periods based on a more exact calculation of the minimum estimate of time needed for the completion of all procedures instead of repetitive yearly extensions. The main reason is that, in most cases one-year extensions appeared not sufficient and the Commission was obliged to extend the approval periods of many active substances repeatedly over consecutive years¹⁷. Therefore, the extensions after January 2023 have been based on estimates more closely based on the available evidence in terms of past experience of the usual duration of the various stages of the assessment and decision-making processes.
21. However, in cases where there are clear indications that the approval criteria cannot be fulfilled, the Commission also endeavours to conclude the renewal procedure as soon as possible, including by limiting the scope of the risk assessment to those aspects that would preclude the possibility of a renewal. This approach was, for example, applied to the non-renewal of the active substances chlorpyrifos¹⁸ and chlorpyrifos-methyl¹⁹ due to the critical nature of concerns identified in the risk assessment.

II. FACTS AND PROCEDURE

22. Glyphosate-based pesticides are used as herbicides in agriculture, horticulture and in some non-cultivated areas. Glyphosate has been thoroughly assessed by Member States, the European Chemicals Agency and the European Food Safety Authority (EFSA) in recent years. It was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2001/99/EC. Upon the entry into force of the PPP Regulation, glyphosate was therefore deemed to have been approved under that Regulation and was

¹⁷ This is particularly the case for applications submitted before 10 November 2018, many of which were (or still are) are subject to an additional “stop the clock” period in accordance with Article 13(3a) of the Renewal Regulation to complete the assessment of endocrine-disrupting properties in light of new scientific criteria established in 2018.

¹⁸ Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 7, 13.1.2020, p. 14.

¹⁹ Commission Implementing Regulation (EU) 2020/17 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 7, 13.1.2020, p. 11.

consequently listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011²⁰.

23. In 2017, its approval has been renewed for a period of five years and it was listed in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011. Thus the expiry date of the renewed approval was set to 15 December 2022.
24. Due to the large amount of data to be assessed and in order to guarantee maximum transparency, instead of one rapporteur Member State and one co-rapporteur Member State, the task of assessing the next renewal application was attributed to a group of four Member States, representing different zones, as co-rapporteur Member States: France, Hungary, the Netherlands and Sweden, referred to as the Assessment Group on Glyphosate (“AGG”).
25. In December 2019, the application for the second renewal of approval was submitted by a consortium of several companies²¹, referred to as the Glyphosate Renewal Group (“GRG”). On 8 June 2020, the GRG submitted the supplementary dossiers containing the required set of scientific studies and literature data, and published these on its website²².
26. The AGG carried out an admissibility check of the application and the supplementary dossiers followed by an assessment of all available information and confirmed the admissibility of the supplementary dossiers in August 2020.
27. On 15 June 2021, the AGG submitted its draft assessment report to EFSA and a proposal for harmonised classification and labelling to ECHA.
28. On 23 September 2021, EFSA and ECHA launched public consultations on the draft assessment report and proposal for harmonised classification delivered by the AGG, which ended on 22 November 2021.
29. The AGG together with EFSA and ECHA considered the comments received during the public consultation and the reactions of the GRG to them. Based on an initial analysis of the comments

²⁰ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, OJ L 153, 11.6.2011, p. 1.

²¹ Current members: Albaugh Europe SARL, Barclay Chemicals Manufacturing Ltd., Bayer Agriculture bvba, Ciech Sarzyna S.A., Industrias Afrasa S.A., Nufarm GMBH & Co.KG, Sinon Corporation and Syngenta Crop Protection AG.

²² <https://www.glyphosate.eu/>

and the reactions, EFSA - in consultation with the AGG - requested additional information from the GRG in accordance with the Renewal Regulation.

30. Given the volume of new information received through the public consultation, the number of action points identified for the AGG following the evaluation of those comments, and the need to evaluate additional information that was requested from the GRG by EFSA, the AGG indicated that more time was needed to provide an updated draft renewal assessment report (dRAR).
31. On 10 May 2022, EFSA and ECHA announced²³ that, due to the expected later delivery of the updated dRAR by the AGG and in order to complete the peer review process, there would be a delay in delivering the EFSA Conclusion, estimating that the Conclusion would become available only in July 2023.
32. On 30 May 2022, ECHA's Committee for Risk Assessment (RAC) agreed that the current harmonised classification of glyphosate should be retained (i.e. as causing serious eye damage and being toxic to aquatic life). Based on a wide-ranging review of the available scientific evidence, RAC concluded²⁴, as in 2017, that classifying glyphosate as a carcinogen is not justified.
33. In the light of the delay announced by EFSA and ECHA, the Commission had to extend the approval period of glyphosate, originally expiring on 15 December 2022, in order to allow for the completion of the scientific risk assessment process. The Commission therefore adopted Commission Implementing Regulation 2022/2364²⁵, which extended the period of approval until 15 December 2023.

III. ASSESSMENT OF THE GROUNDS FOR REVIEW

1. The requestor's grounds for review

34. In its request for internal review, the requestor puts forward four main grounds for review:
 - (a) First, the requestor claims that Article 17 could not have been applied as the extension of the deadline for EFSA's conclusion has no basis in the procedural rules and, therefore, the

²³ <https://www.efsa.europa.eu/en/news/glyphosate-efsa-and-echa-update-timelines-assessments>

²⁴ <https://echa.europa.eu/-/glyphosate-no-change-proposed-to-hazard-classification>

²⁵ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32022R2364>

Commission should have decided without an EFSA conclusion (Section B.II.4(a) of the request).

- (b) Second, the requestor claims that Article 17 could not have been applied as the reasons for the delay were not beyond the control of the applicant and, therefore, one of the conditions for its application was not met (Section B.II.4(b) of the request).
 - (c) Third, the requestor claims that Article 17 could not be applied due to data gaps and gaps in the risk assessment (Section B.III of the request).
 - (d) Fourth, the requestor submits that, even if Article 17 is applicable, its application by the Commission was contrary to EU law because the Commission did not carry out a proper balancing exercise and should have applied the precautionary principle (Section B.IV of the request).
35. The Commission will first provide general comments addressing a number of overarching issues raised across the different grounds for review (Subsection III.2). Then the Commission will examine each of these grounds in turn (Subsections III.3).

2. General comments

2.1. Risk assessment v. risk management

36. In different parts of the request, the requestor refers to risk assessment and risk management without clearly distinguishing them. The Commission would like to clarify that they are not just subsequent stages in terms of timing, but notably distinct types of assessments/decisions as to their content, nature, criteria, methods and even participants.
37. According to Article 3(11) of Regulation (EU) No 178/2002 laying down the general principles and requirements of food law (the “GFL Regulation”)²⁶, risk assessment means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation.
38. Pursuant to Article 3(12) of the GFL Regulation, risk management means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering

²⁶ 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.

risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options.

39. The Renewal Regulation provides *inter alia*, first, in Chapter 1, provisions on the conditions for the admissibility of an application for renewal (Articles 1 to 10) and, second, in Chapter 2, provisions on the assessment of such an application (Articles 11 to 14).
40. When adopting Implementing Regulations concerning the approval or renewal of approval of an active substance under the PPP Regulation, the Commission acts as risk manager as defined in Article 3(12) of the GFL Regulation. Following the risk assessment carried out by a Rapporteur Member State and EFSA, it acts in close consultation with risk managers from the Member States represented in the PAFF Committee.
41. The Commission, as risk manager, must take its risk management decisions on the basis of the risks explored and identified in the scientific assessment²⁷. The scientific assessments [of risks entailed with the use of an active substance contained in PPP] which the Commission must take into account include, notably, the draft renewal assessment report prepared by the Rapporteur Member State and the EFSA conclusion. In addition, under the GFL Regulation, the Commission may turn to EFSA for any clarification that it considers necessary for taking its risk management decision, in particular where it sees the need to increase scientific certainty. These statements become also part of the risk assessment on which the Commission bases its decision. While the Commission is bound to take the scientific assessments into account, these do not predetermine the outcome of its risk management decision, in particular because they do not represent the only factor to be considered and because they contain an assessment of risks, not a decision on managing risks.

2.2. Admissibility v. data gaps

42. Another pair of notions that needs to be distinguished is admissibility and data gaps. In Section II of the request the requestor claims that they are somehow interlinked – the initial incompleteness of the dossier resulted in data gaps which in consequence led to a delay in the renewal procedure (p. 19 for instance).
43. It is incumbent on the applicant for renewal to submit supplementary dossiers to support the application for renewal in accordance with Article 7 of the Renewal Regulation, which comply with

²⁷ Article 14(1), second subparagraph, of the Renewal Regulation sets out that the Commission “*shall take into account*” these outcomes when making a risk management decision on the renewal of an active substance.

the data requirements for these dossiers, as set out in Commission Regulations (EU) No 283/2013²⁸ and 284/2013²⁹. Article 7(1) of the Renewal Regulation lists what is required to be included in the supplementary dossiers.

44. As set out in Article 8(1) of the Renewal Regulation, where the supplementary dossiers have been submitted by the required date and contain all the elements provided for in Article 7, the Rapporteur Member State must, within a period of one month, inform the applicant, the co-Rapporteur Member State, the Commission and EFSA that the application is admissible.
45. The admissibility of an application does not, however, preclude that either the Rapporteur Member State or EFSA, when performing their role as risk assessors, may find during the assessment that the submitted data does not allow to conclude whether the approval criteria are met in substance. In this case, the Rapporteur Member States or EFSA may require the submission of additional data within specific time periods or ultimately set a data gap in that regard, in order to facilitate their risk assessment. Therefore, a “data gap” is a point in the assessment for which there is not sufficient information available and thus the assessing authority cannot conclude, based on the available data, whether there is a risk (of which kind, which extent etc) or not. Such data gaps may apply to all or only some of the representative uses described in the supplementary dossiers. The European Court of Justice has confirmed the distinction between admissibility and data gap in Case C-374/20 P, stating that any other interpretation would undermine the provisions of the PPP Regulation and the Renewal Regulation.³⁰
46. Moreover, data gaps as such do not necessarily lead to the non-approval (or non-renewal of approval) of an active substance. The scope, the extent and the importance of data gaps are weighed by the Commission as risk manager in the light of the overall findings of the risk assessors, and it is the Commission that ultimately decides whether the existence of such gaps put in question

²⁸ Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013, p. 1.

²⁹ Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, OJ L 93, 3.4.2013, p. 85.

³⁰ Judgment of 9 December 2021, *Agrochem-Maks v Commission*, C-374/20 P, EU:C:2021:990, para. 76: “It therefore follows from all of those provisions that, contrary to what the appellant claims, once the rapporteur Member State has declared the application for renewal of an active substance admissible, within the meaning of Articles 7 and 8 of Implementing Regulation No 844/2012, EFSA is entitled to call into question the completeness of the information provided by the applicant at the merits stage of its application for renewal. Any other interpretation would undermine the provisions of Regulation No 1107/2009 and of Implementing Regulation No 844/2012.”

the findings on a possible safe representative use in accordance with Article 4 of the PPP Regulation, also taking into account the Member States' role in authorising products subsequently.

2.3. The precautionary principle

47. Section IV of the request is based on an alleged breach of the precautionary principle. Thus, it is important to recall its place in Regulation 1107/2009 and the interpretation given by the ECJ.
48. Article 1(4) of the PPP Regulation states that its provisions are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. Furthermore, recital 8 of the PPP Regulation states that, as an expression of the precautionary principle, this Regulation should ensure that industry must demonstrate that substances or products produced or placed on the market have neither harmful effect on human or animal health nor any unacceptable effects on the environment.
49. It follows from Article 13(2) of the PPP Regulation that the Commission approves an active substance on the basis of the review report, other factors relevant to the matter under consideration and the precautionary principle.
50. In its judgment *Blaise and Others*³¹, the Court held that the EU legislature ought to establish a normative framework that ensures that the competent authorities have available to them, when they decide on an authorisation and an approval, sufficient information in order adequately to assess, in accordance with the requirements of the precautionary principle, the risks to health resulting from the use of those active substances and those plant protection products.
51. In particular, the Court held that the applicant's obligation to adduce evidence that the active substance or plant protection product that is the subject of an application for approval or authorisation respectively, fulfils the relevant criteria laid down by the PPP Regulation contributes to achieving compliance with the precautionary principle by ensuring that there is no presumption that active substances and plant protection products have no harmful effects³².
52. In the context of applying the precautionary principle, the Commission has to acquaint itself with all of the relevant information before giving a decision on the application for renewal of the active substance in question. The fact that the burden of proof is borne by the applicant does not relieve

³¹ Judgment of 1 October 2019, *Blaise and Others*, C-616/17, EU:C:2019:800, para. 47.

³² Judgment of 1 October 2019, *Blaise and Others*, C-616/17, EU:C:2019:800, para. 80.

the Commission of its obligation to take account of all of the relevant elements in the exercise of its discretion.

53. Lastly, only where there are margins of appreciation and discretion, the precautionary principle also plays a role in the application and implementation of the PPP Regulation, even if in balancing with other applicable general principles of EU law. When acting under the PPP Regulation, the Commission may recur to the precautionary principle while respecting the proportionality principle, as confirmed by the Court³³.

3. Assessment of the individual grounds for review

3.1. Article 17 of the PPP Regulation could be applied regardless of the delay in the delivery of EFSA's conclusion (Section B.II.4(a) of the request)

54. In Section B.II.4(a) of the request, the requestor submits that Article 17 of the PPP Regulation could not have been applied in the case at hand and that the Commission should have decided on the renewal without awaiting EFSA's conclusion. According to the requestor, *"the extension of the deadline for EFSA's conclusion has no basis in the procedural rules"*. Therefore, the requestor submits, *"following EFSA's notification of the delay (of 10 May 2022), it was the Commission's responsibility, as part of risk management, to decide on the renewal of the approval of the active substance"*. The requestor also submits that Article 14(1) of the Renewal Regulation *"explicitly provides that the Commission may decide on renewal even in the absence of EFSA's conclusion"*.
55. First, the Commission points out that Article 17 of the PPP Regulation obliges the Commission to extend the approval of an active substance whenever the two conditions laid down in Article 17 are met (see paragraphs 2-4 above). These two conditions do not require that EFSA's conclusion is delivered within a certain timeframe. Accordingly, a delay in the delivery of EFSA's conclusion does not prevent the application of Article 17 (quite to the contrary, see next paragraph). It should be noted that the Commission has not taken any decision *"extending EFSA's deadline"*, but a decision to postpone the expiry of the approval (which is the subject of the current review procedure).
56. Second, the Commission would point out that the very existence of Article 17 of the PPP Regulation proves that the timelines during the renewal procedure are not absolute and their exceedance is possible when needed. Indeed, the purpose of Article 17 is precisely to provide sufficient time for

³³ Judgment of 6 May 2021, *Bayer Crop Science and Bayer v Commission*, C-499/18 P, EU:C:2021:367, paras. 79, 80 and 166.

the conclusion of the risk assessment by the Member States and EFSA, and to allow for a well-substantiated decision to be taken on the renewal or the non-renewal of an approval, before the expiry of that approval. The requestor in fact also admits the importance of the risk assessment stage in its request, noting that “*EFSA’s technical expertise should also be essential to review the assessment report in the light of the latest scientific and technical knowledge and to assess any remaining doubts as to the fulfilment of the approval criteria*” and that “*a Commission decision without a prior, closed EFSA risk assessment would be problematic*” (both on page 20).

57. Third, as regards Article 14(1) of the Renewal Regulation, which indeed foresees the possibility for the Commission to decide without an EFSA conclusion, the Commission notes that this scenario concerns cases where the Commission decides, pursuant to Article 13(1), second subparagraph, of the Renewal Regulation, that an EFSA conclusion is not necessary because the latest scientific and technical information required to take the decision on (non-)renewal is already at the disposal of the Commission. It does not imply that the Commission could take any decisions on renewal or non-renewal without gathering the relevant information from scientific assessments of the substance in question. No such decision was appropriate in the present case. Where a scientific risk assessment by EFSA, summarised in EFSA’s Conclusion, is considered necessary and has been requested, as is the case for glyphosate, it must be taken into account in the risk management decision to be taken by the Commission.
58. Lastly, it should be noted that the European Ombudsman in her Decision in Case 687/2018/TE³⁴ has confirmed that the Commission is obliged to extend the approval of active substances if the reassessment is not completed in time, provided that it is not the applicant that causes the delay.

3.2. Article 17 was not incorrectly applied because the reasons for the delay were in fact beyond the control of the applicant (Section B.II.4(b) of the request)

59. In Section B.II.4(b) of the request, the requestor submits that the second condition of Article 17, that the reasons for the delay were beyond the control of the applicant, would not have been met in the present case. The requestor claims that the reasons for the delay “*are actually the responsibility of the applicant*” and puts forward several arguments supporting this view:

³⁴ “29. The wording “shall” implies that the Commission has, legally, no choice: it must extend the approval period in such situations. The Ombudsman also notes that Article 17 does not distinguish between approval periods granted for potentially hazardous or non-hazardous active substances. From a legal point of view, the Ombudsman therefore considers that the provision also applies to (potentially) hazardous active substances.”

- (a) **The applicant did not provide a complete dossier in the beginning of the renewal procedure:** In various parts of the application, the requestor claims that the renewal dossier was not complete when submitted: *“This application was incomplete: for example, it did not yet contain any sufficient timetable for the expected completion of ongoing studies and justification of their necessity”* (page 11), therefore it was declared inadmissible initially. The requestor also claims that all the necessary data had to be submitted with the initial dossier, without waiting for the competent authorities to request additional data: *“The necessary evidence that the active substance is safe must, in principle, be available at the start of the approval procedure”* (page 16). Further in Section B.II.4(b), the requestor develops its argumentation by stating that *“in accordance with the relevant procedural rules (see above, 1. and III.1.) the applicant shall demonstrate that the approval criteria have been met by submitting complete documentation (application and dossier) at the first stage of the approval procedure”* (page 21).
- (b) **The applicant is responsible for the identified data gaps:** In the same Section B.II.4(b) the requestor claims that the delay might be caused by data gaps for which the applicant is responsible: *“The reasons given further in support of the extension – an evaluation of the high number of opinions in the consultation process and discussions by experts – may well be due to gaps in the dossier originally submitted by the applicant and in other data gaps”* (page 21).
- (c) **The applicant failed to provide all the relevant scientific information that was available at the time of the renewal application:** The requestor also submits it is the responsibility of the applicant to submit all scientific information at the time of the application: *“The same applies to the assessment of information obtained from the public consultation but which could have been submitted and processed earlier by the applicant (e.g. on the impact on aquatic habitats and on biodiversity and the lack of data on residues in products). In this respect, it seems important to determine whether the scientific evidence was already available at the time of the application and could therefore have been taken into account by the applicant”* (page 32).
- (d) **The applicant provided too much information:** *“it also falls within the applicant’s responsibility, for example, if the assessment of the data submitted by it requires a considerable amount of staff and time, with the result that the prescribed deadlines cannot be met”* (page 32)

60. The Commission considers that none of arguments listed above show that the delay in the risk assessment procedure in this case was under the control of the applicant.
61. First, as regards points (a), (b) and (c) above, it should be noted that a distinction must be made between the requirements under the provisions relating to the conditions of admissibility of an application for renewal or of the supplementary dossiers and those requirements relating to the substantive assessment of the application, as explained in section 2.2. When a Rapporteur Member State has established the admissibility of an application for renewal and the supplementary dossiers, this implies that the applicant has submitted a complete application in time. Delays that occur later in the process for other reasons cannot be attributed to an application that has been held to be complete and in time and, therefore, admissible. Requests for additional information are a normal part of any renewal procedure, notably during the risk assessment³⁵. A request for additional information does not imply that the application for renewal was incomplete or otherwise inadmissible, as these requests are only made after the admissibility of an application has been established and on the basis of findings of the risk assessment conducted so far.
62. Second, as regards point (d) above, the circumstance that the applicant provided a lot of information, requiring “considerable staff and time” from the authorities, cannot be considered a circumstance under the control of the applicant. The applicant simply provided information as required by the PPP Regulation and the Renewal Regulation, including all studies necessary to comply with the data requirements (Regulations (EU) No 283/2013 and 284/2013) as well as the summaries and results of scientific peer-reviewed open literature, as referred in Article 8(5) of the PPP Regulation. It is true that, in the case of glyphosate, the volume of open literature is unprecedented compared to other active substances. However, the fact that the applicant provided a lot of data and information shows – if anything – that it acted diligently and in line with the legal requirements. Indeed, delays due to the complexity of the assessment to be conducted by the Rapporteur Member State or EFSA, are one of the most common situations where the delay is beyond the control of the applicant.
63. Lastly, the Commission notes that the requestor in fact admits that the delay is caused by the AGG and by EFSA, as these did not comply with the procedural timelines set out in the Renewal

³⁵ The PPP Regulation and the Renewal Regulation therefore explicitly provides the Member States and EFSA the power to request such additional information. See, for example, Articles 11(3) and 12(3) of the PPP Regulation and Articles 11(5) and 13(3) of the Renewal Regulation.

Regulation³⁶. In doing so, the requestor contradicts its own argument that the delay is attributable to the applicant.

3.3. Data gaps and gaps in the risk assessment are not relevant for the application of Article 17 (Section B.III of the request)

64. In Section B.III of the request, the requestor claims that the risk assessment conducted by the AGG showed “*significant data gaps and incompleteness*”. As a result, according to the requestor, “*certain relevant risks could not be investigated*”. The requestor refers to the data gaps identified by the AGG in its initial assessment as well as to additional alleged risks that, in its view, should have been taken into account. According to the requestor, these “*gaps in the risk assessment*” fall within the applicant’s responsibility. As a result, according to the requestor, “*there is no scope for an extension under Article 17*”. The requestor also asks the Commission to review whether “*the data gaps identified in the RAR and the resulting gaps in the risk assessment and delays*” fall under the responsibility of the applicant, whether there are “*any other data gaps and gaps in the risk assessment*” that fall within the applicant’s responsibility, *whether “it is justified and acceptable to clarify the methodological issues identified in the RAR (e.g. to assess the impact on biodiversity) in this renewal process (e.g. through expert consultations) and to extend the approval for this purpose” and “whether the risks to bees, bumble bees and other insects mentioned [...] can be adequately assessed on the basis of the methods used in the risk assessment”*. Furthermore, according to the requestor, “*if these risks have not yet been assessed or if the methods used do not cover these aspects, the question also arises as to whether the extension of approval to resolve such open methodological questions is justified and permissible and whether such open methodological questions ultimately come at the expense of the applicant*”.
65. First, the Commission reiterates that Article 17 of the PPP Regulation obliges the Commission to extend the approval of an active substance whenever the two conditions laid down in Article 17 of the PPP Regulation are met (see paragraphs 2-4 above). There are no other criteria which could be added to the test laid down by the legislator, in Article 17 – neither does the Commission have a choice not to act as prescribed when both conditions are fulfilled. The potential existence of data gaps or even alleged “*gaps in the risk assessment*” are not relevant for the fulfilment of these conditions. It is inherent in the notion of a delayed renewal procedure that this procedure could not yet be concluded, which implies that not all gaps may have been filled. Accordingly, the

³⁶ See pages 12, 13, 17 and 18 of the request.

allegation of data gaps or of “*gaps in the risk assessment*” in a pending renewal procedure does not prevent, but rather confirms, the applicability of Article 17.

66. Indeed, the considerations regarding data gaps and gaps in the risk assessment set out in Section B.III of the request might be relevant for the renewal procedure and the assessment of the legality of a decision taken on the renewal, but they are irrelevant for the current review procedure of the extension under Article 17. Any considerations concerning the scientific risk assessment itself, its compliance with the procedural rules and its completeness are outside the scope of a decision on the application of Article 17, such as the contested Extension Regulation.
67. Second, contrary to what the requestor submits, data gaps and gaps in the risk assessment are not the “*responsibility of the applicant*”. As already explained in paragraph 61 above, in response to the requestor’s ground under Section B.II.4(b), such circumstances are beyond the control of an applicant who submitted an admissible application in time.
68. Third, the new elements and data submitted by the requestor in his request in relation to the risk assessment of glyphosate are irrelevant in the present internal review procedure. The requestor had the possibility to submit any relevant scientific information during the public consultation on the draft renewal assessment report and the harmonised classification and labelling report launched by EFSA and ECHA respectively, during the renewal procedure.³⁷ The present internal review does not relate to that renewal procedure, however, but rather concerns, solely and specifically, the reviewed measure, which is the decision to postpone the expiry of the approval of glyphosate in accordance with Article 17 of the PPP Regulation. As already set out above, this provision does precisely not prescribe or allow any scientific assessment of the active substance subject to a delayed renewal procedure.

3.4. The balancing exercise and the precautionary principle were taken into account by the legislator when adopting Article 17 (Section B.IV of the request)

69. In Section B.IV of the request, the requestor argues that, even if Article 17 is applicable, “*the extension of the approval by the Commission was contrary to EU law*” because the Commission did not carry out a proper “*balancing exercise*” and should have applied the precautionary principle. According to the requestor, it follows from such balancing exercise and from the precautionary principle that extensions under Article 17 “*must be limited to exceptional cases and limited in time*”

³⁷ <https://www.efsa.europa.eu/en/news/glyphosate-efsa-and-echa-launch-consultations>

to a few months". The requestor concludes, on that basis, that *the "extension of the authorisation up to 15.12.2023, i.e. for a period of up to 12 months, cannot be justified"*.

70. First, as regards a supposedly required "balancing exercise", the Commission notes that, as set out in paragraph 14 above, in adopting Article 17, the legislator has balanced the various relevant interests when a renewal procedure cannot be concluded before the expiry of an approval. Article 17 is an expression of the balance found by the legislator between, on the one hand, the necessity to complete the renewal assessment procedure to ensure the high level of protection of health and the environment required by Article 114 TFEU and by the precautionary principle and, on the other hand, the need to respect legal certainty and protect legitimate expectation on the side of the applicant for renewal (who submitted all required data in time). At the same time, in striking this balance, the legislator has evidently had particular regard to the precedence of the objective of a high level of protection of health and the environment, as Article 17 maintains the principle that all decisions under the PPP Regulation are based on robust scientific assessments as regards the effects of substances on health and the environment, even at the risk of extending – for a limited amount of time – an approval that later cannot be renewed. It is precisely because the legislator has balanced the relevant interest at stake itself, that there is no further room given to the Commission to carry out another balancing exercise. Instead, Art 17 provides for no discretion and obliges the Commission to act in a specific way when its two conditions are fulfilled.
71. Second, as regards the precautionary principle specifically, the Commission notes, as explained in paragraphs 47-53 above, that this principle actually obliges the Commission to take into account the results of the risk assessment before taking a decision whenever there is a choice to be made by the Commission. The precautionary principle has found many expressions in the PPP Regulation, including in Article 17 of the PPP Regulation, by ensuring that a thorough scientific risk assessment, required by that principle, can be carried out before a substantive decision on the (non-)renewal of an approval is taken, even when there are delays in the renewal procedure.
72. Third, as regards the requestor's claims that the period of 12 months for which the extension was granted was not justified, the Commission would also like to note that by requiring the Commission to postpone the expiry of an approval "*for a period sufficient to examine the application*", the legislator has provided for an assessment by the Commission as regards the appropriate length of an extension. In other words, the Commission has discretion as to how (long) it extends an approval, mostly based on its estimate of the time required to conclude the renewal procedure concerned (see paragraphs 18-20 above). In the specific case of glyphosate, that period is reasonable in the light of the announcement by EFSA that its conclusion on the risk assessment

would become available in July 2023, thus allowing for another 5 months for the Commission to complete the decision-making process. Furthermore, if it later turned out that the renewal procedure could still not be concluded during that time period of one year, the Commission would be obliged by Article 17 of the PPP Regulation to extend the approval period again.

73. Fourth, it is not clear why the requestor refers to the maximum approval period under Article 14(2) of the PPP Regulation. The purpose of Article 17 of the PPP Regulation is exactly to extend these approval/renewal periods “for the time sufficient to examine the application”. Furthermore, the PPP Regulation does not contain an absolute maximum of the time periods during which an active substance could have been approved following its initial approval, renewal and/or extensions.
74. Lastly, the considerations of the requestor concerning the need for further extension under Article 17 due to the “*expected delay*” in the risk management procedure are speculative and not supported by any evidence.

IV. CONCLUSION

75. For the reasons set out above, the Commission considers that the Commission Regulation fully complies with the legal requirements set out in the PPP Regulation and, accordingly, does not contravene EU environmental law.