JUDGMENT OF THE COURT (Ninth Chamber)

4 October 2024 (*)

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(Appeal – Plant protection products – Implementing Regulation (EU) 2020/2087 – Non-renewal of approval of the active substance mancozeb – Regulation (EC) No 1107/2009 – Implementing Regulation (EU) No 844/2012 – Action for annulment)

In Case C-262/23 P,

APPEAL under Article 56 of the Statute of the Court of Justice of the European Union, brought on 24 April 2023,

UPL Europe Ltd, established in Warrington (United Kingdom),

Indofil Industries (Netherlands) BV, established in Amsterdam (Netherlands), represented by C. Mereu, avocat,

appellants,

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the other party to the proceedings being:

European Commission, represented by A. Dawes and M. ter Haar, acting as Agents,

defendant at first instance,

THE COURT (Ninth Chamber),

composed of O. Spineanu-Matei, President of the Chamber, S. Rodin and L.S. Rossi (Rapporteur), Judges,

Advocate General: N. Emiliou,

Registrar: A. Calot Escobar,

having regard to the written procedure,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 By their appeal, UPL Europe Ltd and Indofil Industries (Netherlands) BV seek to have set aside the judgment of the General Court of the European Union of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74; ‘the judgment under appeal’), by which the General Court dismissed their action for annulment of Commission Implementing Regulation (EU)

2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, 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 2020 L 423, p. 50; 'the implementing regulation at issue').

Legal context

Regulation (EC) No 1107/2009

2 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, p. 1), states, in recitals 12 and 14 thereof:

'(12) In the interest of predictability, efficiency and consistency, a detailed procedure should be laid down for assessing whether an active substance can be approved. The information to be submitted by interested parties for the purposes of approval of a substance should be specified. In view of the amount of work connected with the approval procedure, it is appropriate that the evaluation of such information be performed by a Member State acting as a rapporteur for the Community. To ensure consistency in evaluation, an independent scientific review should be performed by the European Food Safety Authority [EFSA] … It should be clarified that [EFSA] performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active substance. Provisions should be included to ensure the transparency of the evaluation process.

…

(14) To speed up the approval of active substances, strict deadlines should be established for the different procedural steps.'

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3 Article 1 of that regulation, entitled 'Subject matter and purpose', provides, in paragraph 2 thereof, that that regulation lays down, inter alia, rules for the approval of active substances which plant protection products contain. Paragraph 3 thereof states that the purpose of that regulation is, inter alia, to ensure a high level of protection of both human and animal health and the environment. According to paragraph 4 of that article, the provisions thereof 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.

4 Chapter II of that regulation contains a Section 1, entitled 'Active substances', made up of three subsections, the first of which relates to 'requirements and conditions for approval'. Article 4 of that regulation, entitled 'Approval criteria for active substances', which is included in that Subsection 1, provides:

'1. An active substance shall be approved in accordance with Annex II if it may be expected, in the light of current scientific and technical knowledge, that, taking into account the approval criteria set out in points 2 and 3 of that Annex, plant protection products containing that active substance meet the requirements provided for in paragraphs 2 and 3.

The assessment of the active substance shall first establish whether the approval criteria set out in points 3.6.2 to 3.6.4 and 3.7 of Annex II are satisfied. If these criteria are satisfied the assessment shall continue to establish whether the other approval criteria set out in points 2 and 3 of Annex II are satisfied.

…

3. A plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use, shall meet the following requirements:

(a) it shall be sufficiently effective;

(b) it shall have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health, directly or through drinking water (taking into account substances resulting from water treatment), food, feed or air, or consequences in the workplace or through other indirect effects, taking into account known cumulative and synergistic effects where the scientific methods accepted by [EFSA] to assess such effects are available; or on groundwater;

(c) it shall not have any unacceptable effects on plants or plant products;

(d) it shall not cause unnecessary suffering and pain to vertebrates to be controlled;

(e) it shall have no unacceptable effects on the environment …

…

5. For approval of an active substance, paragraphs 1, 2 and 3 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

…

7. By way of derogation from paragraph 1, where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger but not exceeding five years even if it does not satisfy the criteria set out in points 3.6.3, 3.6.4, 3.6.5 or 3.8.2 of Annex II, provided that the use of the active substance is subject to risk mitigation measures to ensure that exposure of humans and the environment is minimised. …

This derogation shall not apply to active substances which are or have to be classified in accordance with Regulation (EC) No 1272/2008 [of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1)] as carcinogenic category 1A, carcinogenic category 1B without a threshold, or toxic for reproduction category 1A.

…’

5 Subsection 2 in Chapter II, Section 1 of Regulation No 1107/2009, entitled ‘Approval procedure’, contains Articles 7 to 13 thereof.

6 Under Article 7(1) of that regulation:

‘An application for the approval of an active substance or for an amendment to the conditions of an approval shall be submitted by the producer of the active substance to a Member State, (the rapporteur Member State), together with a summary and a complete dossier as provided for in Article 8(1) and (2) or a scientifically reasoned justification for not providing certain parts of those dossiers, demonstrating that the active substance fulfils the approval criteria provided for in Article 4.

A joint application may be submitted by an association of producers designated by the producers for the purpose of compliance with this Regulation.

The application shall be examined by the Member State proposed by the applicant, unless another Member State agrees to examine it.'

7 Under Article 9 of that regulation, the admissibility of the application is assessed by the rapporteur Member State under the conditions and within the periods established therein.

8 Article 11(1) of that regulation provides:

'Within 12 months of the date of the notification provided for in the first subparagraph of Article 9(3), the rapporteur Member State shall prepare and submit to the Commission, with a copy to [EFSA], a report, referred to as the "draft assessment report", assessing whether the active substance can be expected to meet the approval criteria provided for in Article 4.'

9 Article 12 of Regulation No 1107/2009, entitled 'Conclusion by [EFSA]', provides, in paragraphs 1 and 2 thereof:

'1. '[EFSA] shall circulate the draft assessment report received from the rapporteur Member State to the applicant and the other Member States at the latest 30 days after its receipt. …

[EFSA] shall make the draft assessment report available to the public, after giving the applicant two weeks to request, pursuant to Article 63, that certain parts of the draft assessment report be kept confidential.

[EFSA] shall allow a period of 60 days for the submission of written comments.

2. [EFSA], where appropriate shall organise a consultation of experts, including experts from the rapporteur Member State.

Within 120 days of the end of the period provided for the submission of written comments, [EFSA] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents available at the time of application on whether the active substance can be expected to meet the approval criteria provided for in Article 4 and shall communicate it to the applicant, the Member States and the Commission and shall make it available to the public. In the event of a consultation as provided for in this paragraph, the 120-day period shall be extended by 30 days.

…'

10 Article 13 of that regulation, entitled 'Approval Regulation', states, in paragraph 1 thereof:

'Within six months of receiving the conclusion from [EFSA], the Commission shall present a report, referred to as "the review report", and a draft Regulation to the Committee referred to in Article 79(1), taking into account the draft assessment report by the rapporteur Member State and the conclusion of [EFSA].

The applicant shall be given the possibility to submit comments on the review report.'

11 Article 14(1) of that regulation, entitled 'Renewal of approval', provides, in paragraph 1 thereof:

'On application the approval of an active substance shall be renewed where it is established that the approval criteria provided for in Article 4 are satisfied.

Article 4 shall be deemed to be satisfied where this has been established with respect to one or more representative uses of at least one plant protection product containing that active substance.

…'

12 Article 20 of that regulation, entitled 'Renewal Regulation', provides, in paragraph 1 thereof:

‘A Regulation shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), providing that:

(a) the approval of an active substance is renewed, subject to conditions and restrictions where appropriate; or

(b) the approval of an active substance is not renewed.’

13 Points 3.6.4 and 3.6.5 of Annex II to Regulation No 1107/2009 are worded as follows:

‘3.6.4 An active substance, safener or synergist shall only be approved if, on the basis of assessment of reproductive toxicity testing carried out in accordance with the data requirements for the active substances, safeners or synergists and other available data and information, including a review of the scientific literature, reviewed by [EFSA], it is not or has not to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible …

3.6.5 An active substance, safener or synergist shall only be approved if, on the basis of the assessment of Community or internationally agreed test guidelines or other available data and information, including a review of the scientific literature, reviewed by [EFSA], it is not considered to have endocrine disrupting properties that may cause adverse effect in humans, unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible …

By 14 December 2013, the Commission shall present to the Standing Committee on the Food Chain and Animal Health [(“the standing committee”)] a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties to be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 79(4).

Pending the adoption of these criteria, substances that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as carcinogenic category 2 and toxic for reproduction category 2, shall be considered to have endocrine disrupting properties.

In addition, substances such as those that are or have to be classified, in accordance with the provisions of Regulation (EC) No 1272/2008, as toxic for reproduction category 2 and which have toxic effects on the endocrine organs, may be considered to have such endocrine disrupting properties.’

14 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ 2018 L 101, p. 33, and corrigendum OJ 2018 L 111, p. 10), applicable as from 10 November 2018, added a fifth and a sixth paragraph to that point 3.6.5, which provide:

‘From 10 November 2018, an active substance, safener or synergist shall be considered as having endocrine disrupting properties that may cause adverse effect in humans if, based on points (1) to (4) of the sixth paragraph, it is a substance that meets all of the following criteria, unless there is evidence demonstrating that the adverse effects identified are not relevant to humans:

…’

Implementing Regulation (EU) No 844/2012

15 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 2012 L 252, p. 26), was the subject of various amendments before being repealed by Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 (OJ 2020 L 392, p. 20). The latter regulation nevertheless provided that Implementing Regulation No 844/2012 would continue to apply to procedures for the renewal of the approval of active substances for which the approval period either ends before 27 March 2024, such as the procedure concerned in the present case, or is extended until 27 March 2024 or a later date.

16 Consequently, for the purposes of this dispute, Implementing Regulation No 844/2012 continues to apply. The application to renew the approval of mancozeb, submitted by the appellants in June 2013, was the subject of a draft renewal assessment report ('the RAR') by the United Kingdom of Great Britain and Northern Ireland, the initial rapporteur Member State ('the initial RMS'), on 27 September 2017. Accordingly, that draft was first adopted on the basis of the provisions of Implementing Regulation No 844/2012 in its original version. In January 2019, the United Kingdom submitted an update of that draft prepared pursuant to the provisions of Implementing Regulation No 844/2012, as amended by Commission Implementing Regulation (EU) 2018/1659 of 7 November 2018 (OJ 2018 L 278, p. 3). Indeed, as is apparent from recital 2 of Implementing Regulation 2018/1659, it introduced new scientific criteria for the determination of endocrine disrupting properties, which are to apply as of 10 November 2018 to applications for the renewal of the approval of active substances, including pending applications. In accordance with recital 3 of that regulation, the application for the renewal of the approval which the appellants submitted before 10 November 2018 is regarded as a pending application. The assessment of the application by the Hellenic Republic – which was initially the co-rapporteur Member State but which, following Brexit, succeeded the United Kingdom as rapporteur Member State as from 1 February 2020 ('the new RMS') – was carried out in accordance with Implementing Regulation No 844/2012, as amended by Commission Implementing Regulation (EU) 2019/724 of 10 May 2019 (OJ 2019 L 124, p. 32), since the latter regulation entered into force on 2 June 2019. However, the provisions of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2019/724, are not at issue in the present dispute, with the result that that dispute is governed by Implementing Regulation No 844/2012 in its original version and by that regulation as amended by Implementing Regulation 2018/1659.

17 Under the first subparagraph of Article 1(1) of Implementing Regulation No 844/2012, which was not amended by Implementing Regulation 2018/1659, the application for the renewal of the approval of an active substance is to be submitted by a producer of the active substance to the rapporteur Member State and the co-rapporteur Member State, designated in accordance with the annex to Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest (OJ 2012 L 200, p. 5).

18 Article 11 of Implementing Regulation No 844/2012, entitled 'Assessment by the rapporteur Member State and the co-rapporteur Member State', which was not amended by Implementing Regulation 2018/1659, provides:

'1. Where the application is admissible in accordance with Article 8(1), the rapporteur Member State shall, after consulting the co-rapporteur Member State, at the latest 12 months after the date referred to in Article 6(3), prepare and submit to the Commission, with a copy to [EFSA], a report assessing whether the active substance can be expected to meet the approval criteria, as provided for in Article 4 of Regulation (EC) No 1107/2009 ("the draft [RAR]").

2. The draft [RAR] shall also include the following:

(a) a recommendation with regard to the renewal of the approval;

…

3. The rapporteur Member State shall make an independent, objective and transparent assessment in the light of current scientific and technical knowledge. It shall take into account the supplementary dossiers,

and, where appropriate, the dossiers submitted for the approval and subsequent renewals of approval.

4. The rapporteur Member State shall first establish whether the approval criteria set out in points 3.6.2, 3.6.3, 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009 are satisfied.

Where those criteria are not satisfied, the draft [RAR] shall be limited to those parts of the assessment, unless Article 4(7) of Regulation (EC) No 1107/2009 applies.

…'

19 Article 12 of Implementing Regulation No 844/2012, entitled 'Comments on the draft [RAR]', which was not amended by Implementing Regulation 2018/1659, provides:

'1. [EFSA] shall circulate the draft [RAR] received from the rapporteur Member State to the applicant and to the other Member States at the latest 30 days after its receipt.

2. [EFSA] shall make the draft [RAR] available to the public …

3. [EFSA] shall allow a period of 60 days from the date the report is made available to the public for the submission of written comments. Such comments shall be communicated to [EFSA], which shall collate and forward those comments, including its own comments, to the Commission.

4. [EFSA] shall make the updated supplementary summary dossiers available to the public …'

20 Under Article 13 of Implementing Regulation No 844/2012, entitled 'Conclusion by [EFSA]':

'1. Within five months from the expiry of the period referred to in Article 12(3), [EFSA] shall adopt a conclusion in the light of current scientific and technical knowledge using guidance documents applicable at the date of the submission of the supplementary dossiers on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. [EFSA] shall, where appropriate, organise a consultation of experts, including experts from the rapporteur Member State and co-rapporteur Member State. [EFSA] shall communicate its conclusion to the applicant, the Member States and the Commission.

By way of derogation from the first subparagraph, the Commission may inform [EFSA] without delay after the period referred to in Article 12(3) has expired that a conclusion is not necessary.

…

3. Where [EFSA] considers that additional information from the applicant is necessary, it shall, in consultation with the rapporteur Member State, set a period not exceeding one month for the applicant to supply such information to the Member States, the Commission and [EFSA]. The rapporteur Member State shall, within 60 days from the date of receipt of the additional information evaluate the information received and send its evaluation to [EFSA].

…

5. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.'

21 Article 13 of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2018/1659, is drafted in terms identical to those set out in the preceding paragraph, except for the inclusion of a new paragraph 3a and a modified paragraph 5, which provide:

‘3a For the purposes of assessment of the approval criteria set out in point 3.6.5 … of Annex II to Regulation (EC) No 1107/2009 as amended by Commission Regulation (EU) 2018/605, in relation to applications submitted in accordance with Article 1 before 10 November 2018, for which the draft [RAR] has been submitted but the conclusion by [EFSA] is not yet adopted by that date, where the information available in the dossier is not sufficient for [EFSA] to conclude the assessment on whether these approval criteria are met, [EFSA] shall, in consultation with the Member States, request from the applicant the additional information to be submitted to the rapporteur Member State, the other Member States, the Commission, and [EFSA] in the form of an updated supplementary dossier including the additional information. [EFSA] shall, in consultation with the rapporteur Member State and the applicant, set a period for the submission of that information. Such period shall be at least of 3 months, shall not exceed 30 months, and shall be justified in relation to the type of information which has to be submitted.

…

Where additional information is submitted in accordance with the first … subparagraph within the period set for its submission, the rapporteur Member State shall, within 90 days from the date of receipt of the additional information evaluate the information received and send its evaluation to [EFSA] in the form of a revised draft [RAR]. [EFSA] shall conduct a consultation on the revised draft [RAR] with all the Member States and the applicant in accordance with Article 12. [EFSA] shall adopt the conclusion referred to in paragraph 1, within 120 days from the date of receipt of the revised draft [RAR] …

…

5. Information submitted by the applicant without having been requested, or provided after the expiry of the period set for its submission in accordance with the first subparagraph of paragraph 3 or in accordance with the first or third subparagraphs of paragraph 3a of this Article, shall not be taken into account, unless it is submitted in accordance with Article 56 of Regulation (EC) No 1107/2009.’

22 Article 14 of Implementing Regulation No 844/2012, entitled ‘Renewal report and renewal Regulation’, states, in paragraphs 1 and 2 thereof, which were not amended by Implementing Regulation 2018/1659:

‘1. The Commission shall present to the [Standing Committee on Plants, Animals, Food and Feed, established by Article 58 of 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), as amended by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 (OJ 2014 L 189, p. 1)], referred to in Article 79(1) of Regulation (EC) No 1107/2009 a renewal report and a draft Regulation within six months from the date of receipt of the conclusion of [EFSA] or in cases where there is no such conclusion of [EFSA], the expiry of the period referred to in Article 12(3) of this Regulation.

The renewal report and the draft Regulation shall take into account the draft [RAR] of the rapporteur Member State, the comments referred to in Article 12(3) of this Regulation and the conclusion of [EFSA], where such a conclusion has been submitted.

The applicant shall be given the possibility to submit comments on the renewal report within a period of 14 days.

2. On the basis of the renewal report and taking into account comments submitted by the applicant within the period referred to in the third subparagraph of paragraph 1, the Commission shall adopt a Regulation in accordance with Article 20(1) of Regulation (EC) No 1107/2009.’

Regulation No 1272/2008

23 Under Article 36(1)(d) of Regulation No 1272/2008, a substance that fulfils the criteria set out in Annex I thereto for dangers relating to ‘reproductive toxicity, category 1A, 1B or 2 (Annex I, section 3.7)’, is normally to be subject to harmonised classification and labelling in accordance with Article 37 of that regulation.

24 Article 37(4) of that regulation provides that the Committee for Risk Assessment (‘the RAC’) of the European Chemicals Agency (ECHA) is to adopt an opinion on any proposal submitted pursuant to paragraph 1 or 2 of that article within 18 months of receipt of the proposal, giving the parties concerned the opportunity to comment and that that agency is to forward that opinion and any comments to the European Commission. Under Article 37(5), where the Commission finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, it must, without undue delay, adopt delegated acts in order to amend Annex VI to that regulation so as to include that substance therein.

Background to the dispute

25 The background to the dispute is set out in paragraphs 2 to 50 of the judgment under appeal and can be summarised as follows.

26 The appellants produce and market, in the European Union, plant protection products containing the active substance mancozeb. Mancozeb is a fungicide used to combat a number of fungal pathogens affecting potato, carrot, onion, vine, pome fruit and tree fruit crops.

27 Mancozeb was approved in the European Union for a 10-year period as from 1 July 2006 by Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ 2005 L 279, p. 63), which added the active substance mancozeb to Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ 1991 L 230, p. 1).

28 In accordance with Regulation No 1107/2009, the active substances included in Annex I to Directive 91/414 were deemed to have been approved under that regulation. Since Regulation No 1107/2009 also repealed Directive 91/414, it was necessary, for the purpose of applying that regulation, to adopt another regulation containing the list of active substances included in that Annex I. That is the purpose of 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 2011 L 153, p. 1). The approval period of mancozeb was extended until 31 January 2021 in order to allow the procedure for the renewal of the approval of that substance to be completed before the expiry of the approval period of that substance.

29 The appellants sought the renewal of the approval of mancozeb, pursuant to Implementing Regulation No 844/2012.

30 In accordance with Implementing Regulation No 686/2012, the United Kingdom was designated as the initial RMS for the evaluation of mancozeb in the context of the renewal procedure for the approval of that active substance, the co-rapporteur Member State being the Hellenic Republic.

31 On 27 September 2017, the initial RMS submitted its draft RAR to EFSA in accordance with Article 11 of Implementing Regulation No 844/2012, in which it identified certain risks relating to the use of mancozeb in certain products or for certain uses, which could, however, be mitigated at Member State level. Therefore, the initial RMS considered that Article 4 of Regulation No 1107/2009 had been complied with and that that substance could be approved.

32 In February 2018, EFSA circulated the draft RAR of 27 September 2017, in particular, to the Member States and the appellants to allow them, pursuant to Article 12 of Implementing Regulation No 844/2012, to submit comments. The appellants submitted their comments on 26 April 2018.

33 On 4 July 2018, EFSA, pursuant to Article 13(3) of Implementing Regulation No 844/2012, asked the appellants to provide it with additional information within a period of one month. That request concerned 88 points, relating to, inter alia, the storage stability of mancozeb and metabolite ethylene thiourea (ETU), the intended use of the substance in cereals, the processing factors for mancozeb and the metabolite ETU for wheat and potato processed commodities, as well as the criteria for endocrine disruption.

34 On 3 August 2018, the appellants provided some of the information requested. On 19 October 2018, with the agreement of EFSA, they provided the additional information which had been requested on the endocrine disrupting properties of mancozeb.

35 In November 2018, the RAC of ECHA issued its opinion, according to which mancozeb should be classified as a toxic substance for reproduction category 1B, in accordance with Regulation No 1272/2008.

36 In January 2019, the initial RMS submitted an updated version of the draft RAR of 27 September 2017 to EFSA.

37 On 27 February 2019, the Commission adopted Implementing Regulation (EU) 2019/336 amending Regulation (EU) No 1141/2010 and Implementing Regulation (EU) No 686/2012 as regards the rapporteur Member State for the evaluation of 1-methylcyclopropene, famoxadone, mancozeb, methiocarb, methoxyfenozide, pirimicarb, pirimiphos-methyl and thiacloprid (OJ 2019 L 60, p. 8). In Annex I to that implementing regulation, it designated the Hellenic Republic as the new RMS for the evaluation of mancozeb. That designation was applicable as from 30 March 2019 or, in the event that a decision was taken to extend the two-year period referred to in Article 50(3) TEU, as from the day following that on which the legislation relating to plant protection products ceased to apply to and in the United Kingdom.

38 In March 2019, the initial RMS submitted to EFSA a further updated draft RAR (‘the updated draft RAR of March 2019’). The appellants received that draft on 22 March 2019. That draft proposed that mancozeb be found not to satisfy the conditions of approval laid down in Article 4 of Regulation No 1107/2009 for the following three reasons: (i) mancozeb was considered to be an endocrine disruptor in humans; (ii) there was a risk resulting from non-dietary exposure; and (iii) there was a risk to birds and mammals, non-target arthropods and soil organisms.

39 On 12 April 2019, the appellants sent a letter to EFSA reiterating the fact that the additional data on endocrine disruption they had submitted in October 2018 had not been taken into account. In that letter, the appellants also expressed their concerns about the legal and scientific bases upon which the endocrine disruption assessment of mancozeb had been conducted, principally because, in their view, undue influence had been accorded to ETU rather than to the substance itself.

40 On 12 June 2019, EFSA published its conclusions on the peer review of the pesticide risk assessment of mancozeb, in which it stated that that substance could not be expected to meet the approval criteria laid down in Article 4 of Regulation No 1107/2009.

41 On 20 June 2019, EFSA forwarded its conclusions to the Commission, which then invited the appellants to comment thereon, which they did on 16 July 2019.

42 By email of 18 September 2019, the initial RMS confirmed to the appellants that it was no longer attending meetings of the standing committee relating to mancozeb.

43 By email of 26 November 2019, the Hellenic Republic informed the Commission that, in view of its designation as incoming RMS, it would need until 30 July 2020 to ‘assess in detail the dossier’ on mancozeb and to ‘review in depth specific points raised by EFSA’.

44 In response, by email of 17 December 2019, the Commission informed the Hellenic Republic that it intended to prepare a renewal report and draft regulation based on the updated draft RAR of March 2019 and EFSA’s conclusions of 12 June 2019. The Commission explained that the initial RMS had conducted

its assessment, taking into account all available information and comments from the appellants. It also indicated that it intended to present a renewal report and draft regulation to the Member States at the 23 and 24 March 2020 meeting of the standing committee, and that the Hellenic Republic should complete its assessment and review in advance of that meeting.

45 On 16 January 2020, the Commission sent the appellants its draft renewal report, in which it proposed not to renew the approval of mancozeb. It also invited the appellants, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation No 844/2012, to submit comments on that draft report, which they did on 31 January 2020.

46 Following the withdrawal of the United Kingdom from the European Union, the Hellenic Republic officially became, on 1 February 2020, the new RMS.

47 Prior to the standing committee meeting of 23 and 24 March 2020, on an unspecified date, the new RMS circulated a document concerning mancozeb. According to that document, the appellants had 'informed [the new RMS] that several pieces of information regarding (eco)toxicology and (non)dietary risk assessment were not considered in the Renewal Assessment Report (RAR, 2019) drafted by the [initial RMS, the United Kingdom], due to Brexit, and as such they were not considered in the EFSA Peer Review process'. The document also stated that the new RMS had 'reviewed briefly the additional information claimed by the [appellants not to have been] considered and noted that a scientifically sound evaluation [would] only be possible if sufficient time [was granted to the new RMS] for assessment of all the points made by the [appellants] and all the available studies'.

48 The Commission's proposal for non-renewal of mancozeb was placed on the agenda for the standing committee meeting of 23 and 24 March 2020. On that occasion, the appellants requested a meeting with the Commission, which proposed to meet with them on 18 March 2020. That meeting was cancelled due to the pandemic, as was the standing committee meeting of 23 and 24 March 2020. The Member States were invited by the Commission to communicate their views on the non-renewal of mancozeb no later than 14 April 2020.

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49 After several meetings of the standing committee during which the issue of the non-renewal of mancozeb was discussed, on 2 September 2020, the new RMS submitted a further updated draft RAR ('the updated draft RAR of September 2020') to the Commission. It maintained the proposal of the initial RMS in its updated draft RAR of March 2019, namely, to conclude that mancozeb did not satisfy the conditions for approval laid down in Article 4 of Regulation No 1107/2009. It also stated that mancozeb was considered to be an endocrine disruptor for humans and non-target organisms and that there was a risk to birds, mammals and non-target arthropods. However, the new RMS found that, by altering the good agricultural practices (GAP) on cereals and using water-soluble bags, it was possible to find a use that was safe for human health (that is to say, for operators, workers and persons living nearby). The updated draft RAR of September 2020 was made available to EFSA, the other Member States and the appellants.

50 On 21 September 2020, the Commission sent the appellants an updated draft renewal report, in which it proposed not to renew the approval of mancozeb. The appellants submitted comments on the draft renewal report on 2 October 2020.

51 At a standing committee meeting of 23 October 2020, the Member States finalised the renewal report and issued, by qualified majority, an opinion in favour of the draft implementing regulation not renewing the approval of mancozeb.

52 On 14 December 2020, the Commission adopted the implementing regulation at issue, recitals 12 to 15 of which set out the reasons for the non-renewal of mancozeb as follows:

'(12) [EFSA] identified certain specific concerns. In particular, it concluded that mancozeb has been classified as toxic for reproduction category 1B and that the new criteria to identify endocrine disrupting properties are met for humans and most likely for non-target organisms. In addition, it

concluded that the non-dietary exposure estimates exceed the reference values for the representative uses in tomatoes, potatoes, cereals and grapevines. Therefore for the representative uses considered, non-dietary exposure to mancozeb also cannot be considered as negligible for the purposes of points 3.6.4 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009. Given the concerns identified the derogation provided for in Article 4(7) to Regulation (EC) No 1107/2009 cannot apply.

(13) The Commission invited the applicants to submit their comments on the conclusion of [EFSA] and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicants submitted their comments which have been carefully examined.

(14) However, despite the arguments put forward by the applicants the concerns regarding the active substance could not be eliminated.

(15) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance mancozeb.'

The procedure before the General Court and the judgment under appeal

53 By application lodged at the Registry of the General Court on 18 December 2020, the appellants brought an action for annulment of the implementing regulation at issue.

54 In support of their action, the appellants put forward five pleas in law, the first alleging infringement of essential procedural requirements; the second, infringement of their rights of defence; the third, infringement of the principle of sound administration; the fourth, manifest error of assessment; and the fifth, infringement of the principle of protection of legitimate expectations.

55 By the judgment under appeal, the General Court rejected those pleas and dismissed the action in its entirety.

Forms of order sought and procedure before the Court of Justice

56 The appellants claim that the Court of Justice should:

– set aside the judgment under appeal;

– annul the implementing regulation at issue or refer the case back to the General Court; and

– order the Commission to pay the costs at both instances or order the Commission to bear the costs of the present appeal and refer the case back to the General Court.

57 The Commission contends that the Court should:

– dismiss the appeal; and

– order the appellants to pay the costs.

The appeal

58 In support of their appeal, the appellants put forward five grounds of appeal. The first ground of appeal alleges various distortions of the evidence, infringement of the rights of the defence, failure to address

pleas and respond to arguments put forward at first instance, and various errors in law and/or of assessment concerning the provisions of Implementing Regulation No 844/2012. The second ground of appeal alleges a failure to state reasons in the judgment under appeal. The third ground of appeal alleges a distortion of the evidence and an error of assessment relating to the Commission's bias. The fourth ground of appeal alleges erroneous and contradictory reasoning in the judgment under appeal which breaches the principle of legal certainty as regards taking into account the RAC's opinion in the procedure for the renewal of mancozeb. The fifth ground of appeal alleges a distortion of the evidence and errors in law and of assessment relating to the principle of legitimate expectations.

The first ground of appeal, alleging various distortions of the evidence, infringement of the rights of the defence, failure to address pleas and respond to arguments put forward at first instance, and various errors in law and/or of assessment concerning the provisions of Implementing Regulation No 844/2012

59 The first ground, which comprises six parts, is directed against the assessments made by the General Court in paragraphs 75 to 117 of the judgment under appeal.

The first part of the first ground of appeal

– *Arguments of the parties*

60 The first part of the first ground alleges that the General Court distorted the evidence in the file in the course of rejecting the complaint alleging failure to take into consideration data on endocrine disruption.

61 In the first place, the appellants submit that the General Court wrongly considered, in paragraphs 75 to 77 of the judgment under appeal, that the initial RMS had, in the updated draft RAR of March 2019, made an updated assessment of the endocrine disruption linked to mancozeb. According to the appellants, it was apparent from the documents in the file, in particular a document (Annex B3) submitted by the Commission which records a comment from the new RMS, that, although they had provided that assessment in October 2018 at the request of EFSA, it had not been taken into account by the initial RMS. The appellants add, in their reply, that the part of the RAR referred to by the Commission in its response confirms that statement.

62 In the second place, the appellants claim that the General Court erred in finding, in paragraphs 78, 81 and 82 of the judgment under appeal, that some of their 'additional arguments' did not have to be taken into account because they had been submitted after the expiry of the time limit laid down in Article 13(5) of Implementing Regulation No 844/2012. The appellants submit that the 'additional arguments' had no relation to the assessment of mancozeb's endocrine disruption. Accordingly, they argue, the General Court used its misreading of the evidence available to justify its finding that the initial RMS had assessed the data relating to mancozeb's endocrine disruption.

63 The Commission contends that the first part of the first ground of appeal is unfounded.

– *Findings of the Court*

64 According to the case-law of the Court of Justice, there is distortion of the evidence where the General Court has manifestly exceeded the limits of a reasonable assessment of that evidence. That distortion must be obvious from the file, without there being any need to carry out a new assessment of the facts and the evidence. In that regard, it is not sufficient to show that a document could be interpreted differently from the interpretation adopted by the General Court (judgment of 5 March 2024, *Kočner* v *Europol*, C-755/21 P, EU:C:2024:202, paragraph 96 and the case-law cited).

65 In the first place, it should be noted that the General Court took into account, as is apparent from paragraph 73 of the judgment under appeal, the document produced by the new RMS on which the appellants base their claim that the initial RMS had not conducted an endocrine disruption assessment in

the updated draft RAR of March 2019 in response to the data which it had submitted on 19 October 2018 following EFSA's request of 4 July 2018.

66 It then found, in paragraph 76 of the judgment under appeal, that 'the draft RAR of March 2019 [had been] updated[,] following receipt of the [appellants'] replies', on the basis of an extract from the updated draft RAR of March 2019 stating that, 'following the peer review process, an updated [endocrine disruption] assessment [had] been provided by [the appellants] in two expert reports' and that those 'new expert reports [provided] no significant new information and [did] not change the conclusions reached by the [initial] RMS in this document before the peer review process'.

67 It follows that the appellants, who do not dispute the extract of that report from which it is apparent that the initial RMS had reviewed the data and the updated endocrine disruption assessment which they had provided, cannot claim that the assessment made by the General Court in paragraphs 75 to 77 of the judgment under appeal was based on a distortion of the evidence, irrespective of the interpretation of the document from the new RMS referred to in paragraph 73 of the judgment under appeal.

68 In the second place, the appellants criticise the General Court for taking the view, in paragraphs 78, 81 and 82 of the judgment under appeal, that some 'additional information' and 'additional arguments' did not have to be taken into account on the ground that they had been submitted after the expiry of the time limit, even though the material submitted was unrelated to the assessment of mancozeb's endocrine disruption.

69 It should, however, be noted that such an argument is ineffective. Indeed, irrespective of the purpose of those additional arguments or that additional information, the appellants do not allege that the General Court erred in law by finding, in paragraphs 80 and 81 of that judgment, that, in accordance with Article 13(3) and (5) of Implementing Regulation No 844/2012, for such arguments and information to be taken into consideration by the initial RMS, they should have been submitted before the expiry of the time limit set by EFSA in its request of 4 July 2018, which the appellants had not established having done.

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70 It follows that the first part of the first ground of appeal must be rejected as, in part, ineffective and, in part, unfounded.

The second part of the first ground of appeal

– *Arguments of the parties*

71 The appellants complain that the General Court failed to rule on their argument concerning the lack of assessment of certain data which they had submitted and which related to the assessment of mancozeb's risk to birds and mammals, non-target arthropods, soil organisms and toxicological reference values on the ground, set out in paragraph 84 of the judgment under appeal, that those data had been submitted after the expiry of the time limit set in Article 13(5) of Implementing Regulation No 844/2012.

72 The Commission contends that the second part of the first ground of appeal is unfounded.

– *Findings of the Court*

73 As recalled in paragraph 69 above, in accordance with Article 13(3) and (5) of Implementing Regulation No 844/2012, information which the applicant submits after the expiry of the period set for its submission is not taken into account.

74 In paragraph 84 of the judgment under appeal, the General Court found that the data on the risk to birds and mammals, non-target arthropods, soil organisms and toxicological reference values had been submitted by the appellants after the expiry of the time limit for the submission of the additional information requested by EFSA on 4 July 2018.

75 Accordingly, the General Court did not err in law when it held, in paragraph 85 of that judgment, that 'the Commission cannot be criticised for the initial RMS's failure to take account of that data during the procedure for renewal of the approval of mancozeb'.

76 The second part of the first ground of appeal must therefore be rejected as unfounded.

The third part of the first ground of appeal

– *Arguments of the parties*

77 The third part of the first ground of appeal alleges that the General Court erred in law when it declared inadmissible, on the ground that they were new, the appellants' arguments concerning the application of new criteria relating to endocrine disruptors from Implementing Regulation No 844/2012.

78 The appellants recall that, in their application initiating proceedings, they had submitted that mancozeb should have been assessed in the light of the interim criteria for endocrine disruption established in point 3.6.5 of Annex II to Regulation No 1107/2009. According to those criteria, mancozeb was not an endocrine disruptor. They also note that, at the hearing before the General Court, they argued that mancozeb had been assessed in the light of the new criteria, applicable as from 10 November 2018 and added to point 3.6.5 of Annex II to Regulation No 1107/2009, as amended by Regulation 2018/605, because the Commission had not complied with the time limits set by those regulations in their previous version.

79 The appellants maintain that the General Court, in paragraphs 86 to 92 of the judgment under appeal, incorrectly classified their arguments as 'new' and, therefore, wrongly declared inadmissible those arguments which alleged misapplication of procedural provisions concerning the new criteria relating to endocrine disruptors, applicable as from 10 November 2018, to which Article 13(3a) of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2018/1659, refers.

80 According to the appellants, those arguments constituted an amplification of their first plea in law put forward at first instance, alleging infringement of essential procedural requirements and referring to the procedural provisions and time limits laid down in Articles 11 to 14 of Implementing Regulation No 844/2012 both in its original version and in the version amended by Implementing Regulation 2018/1659.

81 Moreover, in so far as those arguments concerned the infringement of mandatory procedural guarantees, namely the opportunity to submit, following the new criteria relating to endocrine disruptors applicable as from 10 November 2018, comments or new studies within a period of 3 to 30 months, the General Court should have found that the appellants were entitled to rely on those arguments at any time and that it was obliged to take them into account of its own motion. In their reply, the appellants specify, first, that the essential procedural requirements laid down by Implementing Regulation No 844/2012, in its original version and in the version amended by Implementing Regulation 2018/1659, are, in particular, established to ensure that an applicant may submit comments on the assessment conducted by the authorities, that is to say, to preserve its rights of defence. Secondly, even if they had alleged an infringement of their rights of defence, respect for those rights is a fundamental principle, and such an infringement would be comparable to the infringement of an essential procedural requirement like the procedure provided for by Implementing Regulation No 844/2012 and its amended version.

82 The Commission contends that the third part of the first ground of appeal is unfounded.

– *Findings of the Court*

83 By the third part of the first ground of appeal, the appellants submit, first, that the General Court erred in finding, in paragraphs 86 to 92 of the judgment under appeal, that their arguments, put forward during the hearing before it, alleging non-compliance with the time limits laid down by Regulation No 1107/2009 and

Implementing Regulation No 844/2012, which led to the application of the new criteria relating to endocrine disruptors provided for in the fifth paragraph of point 3.6.5 of Annex II to Regulation No 1107/2009, as amended by Regulation 2018/605, were new and, therefore, inadmissible. Secondly, they claim that the General Court also, in the same paragraphs, wrongly declared inadmissible their arguments alleging non-compliance with the time limits set in Article 13(3a) of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2018/1659. Moreover, they claim that the General Court should have examined those arguments of its own motion.

84 It must be borne in mind that, according to Article 84(1) of the Rules of Procedure of the General Court, no new plea in law may be introduced in the course of proceedings unless it is based on matters of law or of fact which come to light in the course of the procedure. However, a plea or an argument which may be regarded as amplifying a plea put forward previously, whether directly or by implication, in the original application and which is closely connected therewith must be declared admissible (judgment of 29 February 2024, *Methanol Holdings (Trinidad)* v *Commission*, C-688/22 P, EU:C:2024:180, paragraph 54 and the case-law cited).

85 In the present case, it must be observed that the appellants' first ground of appeal, put forward in their application initiating proceedings, alleged non-compliance with the assessment procedure provided for in Articles 11 to 14 of Implementing Regulation No 844/2012, in its original version and in the version thereof amended by Implementing Regulation 2018/1659. As is apparent from paragraphs 104 to 108 of that application, they were of the opinion that, since that procedure was not complied with, the assessment which had been conducted of the active substance was incomplete. In paragraph 109 of that application, they had outlined the errors which, in their view, impacted the assessment procedure.

86 However, it should be noted that the fact that Article 13(3a) of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2018/1659, 'should not have been applied to them if the authorities involved in the procedure for the renewal of mancozeb had complied with the time limits applicable' to the assessment procedure provided for by Regulation No 1107/2009 and Implementing Regulation No 844/2012, is not among those 'errors'.

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87 The General Court therefore correctly found, in essence, in paragraphs 90 to 92 of the judgment under appeal, that the arguments alleging non-compliance with the time limits set by Regulation No 1107/2009 and Implementing Regulation No 844/2012, by the authorities involved in the procedure for the renewal of mancozeb, were not sufficiently closely connected with that first plea in law, with the result that they could not be regarded as amplifying that plea within the meaning of the case-law cited in paragraph 84 above.

88 In addition, contrary to what the appellants claim, non-compliance with those time limits is not an infringement of essential procedural requirements which must be raised by the General Court of its own motion.

89 As the Court has held, only procedural time limits, such as the time limit for bringing proceedings laid down in Article 263 TFEU, are a matter of public policy, compliance with which must be examined by the EU judicature of its own motion. Since those time limits have been laid down with a view to protecting public interests, inter alia that of ensuring clarity and legal certainty, they are not within the discretion of either that judicature or the parties before it (see, to that effect, judgment of 8 November 2012, *Evropaïki Dynamiki* v *Commission*, C-469/11 P, EU:C:2012:705, paragraph 50 and the case-law cited).

90 However, the time limits laid down in Articles 11 to 13 of Implementing Regulation No 844/2012 are regulatory time limits laid down in the interest of the applicant to allow it, where appropriate, to provide EFSA – and the RMS in particular – with additional information for the assessment of the approval criteria. Accordingly, those time limits, and also the time limit laid down in the third subparagraph of Article 14(1) of that regulation, cannot be classified as a matter of public policy. Consequently, the General Court was not required to raise potential non-compliance with those time limits of its own motion.

91 It follows that the third part of the first ground of appeal must be rejected as unfounded.

The fourth part of the first ground of appeal

– *Arguments of the parties*

92 By the fourth part of their first ground of appeal, the appellants claim that the General Court failed to examine their argument alleging misapplication, as from November 2018, of the provisions and procedural guarantees, and also of time limits concerning the new criteria for endocrine disruption, provided for in paragraph 13(3a) of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2018/1659. They also submit that, in so doing, the General Court infringed its obligation to state reasons for its decisions.

93 The Commission contends that this part is unfounded.

– *Findings of the Court*

94 For the same reasons as those set out in paragraphs 85 to 87 above, the General Court was justified in finding that the argument put forward during the hearing before it, alleging non-compliance with the time limit of 3 to 30 months laid down in Article 13(3a) of Implementing Regulation No 844/2012, as amended by Implementing Regulation 2018/1659, was new and, therefore, inadmissible. Consequently, since the General Court was not required to raise of its own motion the failure to comply with such a time limit, which was laid down in the interest of the applicant, it did not have to give reasons for rejecting that argument or, a fortiori, examine its substance.

95 It follows that the fourth part of the first ground of appeal must be rejected as unfounded.

The fifth part of the first ground of appeal

– *Arguments of the parties*

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96 The fifth part of the first ground of appeal alleges that the General Court distorted the evidence and erred in law when interpreting Article 12 of Implementing Regulation No 844/2012.

97 In that regard, the appellants recall that, under Article 12(3) of Implementing Regulation No 844/2012, the draft RAR of the RMS must be subject to a public consultation.

98 In the present case, the General Court considered that EFSA had not needed to make the updated draft RAR of September 2020, which was prepared by the new RMS, subject to such a consultation, on the ground, set out in paragraph 96 of the judgment under appeal, that ‘Implementing Regulation No 844/2012 … [did] not contain any provision concerning the conduct of [the] stages [of the procedure] in the event of the appointment of a new RMS during that procedure’.

99 The appellants claim that that assessment lacks any legal basis and infringes essential procedural requirements. The report of the new RMS, they argue, which was the only final assessment which had to be made available to the public, should have been made subject to a public consultation, contrary to the view taken by the General Court in paragraph 109 of the judgment under appeal. The fact, noted by the General Court in paragraph 104 of the judgment under appeal, that the new RMS reached the same conclusion as the initial RMS in its updated draft RAR of March 2019, cannot, in the appellants’ opinion, excuse the procedural irregularities on the part of the Commission. Those irregularities are even less excusable since, according to the appellants, the conclusions of the two RMS only appear similar. Indeed, in contrast with the conclusion which the initial RMS reached, the new RMS had noted the existence of a safe use by relying on the endocrine disruption data which had not been reviewed by the initial RMS. According to the appellants, the obligation to consult is a mandatory procedural guarantee, the infringement of which should have been censured by the General Court.

100 The Commission contends that the fifth part of the first ground of appeal must be rejected as, in part, inadmissible and, in part, unfounded.

– *Findings of the Court*

101 By the fifth part of the first ground of appeal, the appellants submit that the General Court, by finding, in paragraph 109 of the judgment under appeal, that 'the Commission could choose to continue with the procedure for the renewal of mancozeb without submitting the new RMS's assessment to public consultation and without ensuring that EFSA would produce its conclusions on that assessment', distorted the evidence and erred in law when interpreting Article 12 of Implementing Regulation No 844/2012. In so doing, they argue, it also disregarded the fact that the absence of that assessment deprived the appellants of a procedural right and infringed essential procedural requirements.

102 In that regard, it must be recalled at the outset that, in accordance with Article 11 of Regulation No 1107/2009 and Article 11 of Implementing Regulation No 844/2012, the draft RAR prepared by the RMS assesses, as requested by the applicant, whether the active substance in question can be expected to meet the approval criteria provided for in Article 4 of Regulation No 1107/2009.

103 That draft is communicated to EFSA, which, pursuant to the first subparagraph of Article 12(1) of Regulation No 1107/2009 and Article 12(1) of Implementing Regulation No 844/2012, forwards it, inter alia, to the applicant.

104 In accordance with the second and third subparagraphs of Article 12(1) of Regulation No 1107/2009 and Article 12(2) and (3) of Implementing Regulation No 844/2012, EFSA makes the draft RAR available to the public and allows a period of 60 days for the submission of written comments. Under Article 12(3) of that implementing regulation, such written comments are to be communicated to EFSA, which is to collate and forward those comments, including its own comments, to the Commission.

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105 Those provisions merely state, as the General Court found, in essence, in paragraph 98 of the judgment under appeal, that only the draft RAR needs to be submitted to EFSA and made available to the public by the latter.

106 In the present case, as follows from paragraphs 9, 10, 18 and 21 of the judgment under appeal, the draft RAR of the initial RMS of September 2017, from which it was apparent that Article 4 of Regulation No 1107/2009 had been complied with and that mancozeb could be approved, was made available to the public in February 2018, in accordance with the provisions of Article 12 of Implementing Regulation No 844/2012. Subsequently, in March 2019, the initial RMS adopted the updated draft RAR of March 2019, which proposed concluding that mancozeb did not satisfy the conditions for approval laid down in Article 4 of Regulation No 1107/2009. That draft was the subject of EFSA's conclusions on 12 June 2019, according to which mancozeb did not satisfy the conditions for approval laid down in Article 4 of the regulation and on which the appellants submitted comments on 16 July 2019.

107 It follows that the draft RAR of the initial RMS was indeed made available to the public, in accordance with the second and third subparagraphs of Article 12(1) of Regulation No 1107/2009 and Article 12(2) and (3) of Implementing Regulation No 844/2012.

108 By contrast, as is apparent from paragraphs 100 to 110 of the judgment under appeal, following the replacement of the initial RMS with the new RMS on 1 February 2020, the updated draft RAR of September 2020, which the latter prepared and sent to EFSA, was never made available to the public by EFSA.

109 In that regard, it must be noted that, when interpreting Articles 12 to 14 of Implementing Regulation No 844/2012, the Court of Justice has held that the fact that, unlike an initial draft RAR, a revised assessment report has not been submitted to the various intervening parties for their comments does not mean that the latter report cannot be taken into account by the Commission in its renewal report for the

purpose of adopting an implementing regulation refusing to renew the approval of an active substance (see, to that effect, judgment of 9 December 2021, *Agrochem-Maks* v *Commission*, C-374/20 P, EU:C:2021:990, paragraph 103).

110 Admittedly, in the case that gave rise to the judgment of 9 December 2021, *Agrochem-Maks* v *Commission* (C-374/20 P, EU:C:2021:990), the author of the draft RAR and of the revised RAR was the same RMS.

111 However, that circumstance does not mean that the nature of the procedural obligation consisting in making a revised or updated RAR available to the public is different in a situation where, as in the present case, the draft RAR, which was communicated to the public, and the updated RAR, which was not, were prepared, in the context of a single procedure for the renewal of the same active substance, by different RMSs.

112 Moreover, having regard to the clear wording of the second and third subparagraphs of Article 12(1) of Regulation No 1107/2009 and to Article 12(2) and (3) of Implementing Regulation No 844/2012, it is also not for EFSA to make the updated draft RAR of March 2019, prepared by the initial RMS, available to the public.

113 Accordingly, the fact that the updated draft RAR of September 2020, submitted by the new RMS, was not made available to the public is not, contrary to what the appellants claim, an infringement of an essential procedural requirement which would lead to the annulment of the implementing regulation at issue, since making such a draft available to the public is not required.

114 The General Court was therefore right to hold, in paragraph 97 of the judgment under appeal, that, given that Implementing Regulation No 844/2012 is silent as to the conduct of the procedure for the renewal of an active substance in the event of the designation of a new RMS in the course of that procedure, such a designation cannot be regarded as requiring the procedure provided for in Articles 12 and 13 of that implementing regulation to be recommenced.

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115 Indeed, a contrary interpretation of the latter provisions would disregard the aim, recalled in recital 14 of Regulation No 1107/2009, of speeding up the approval procedure for active substances, which, in the present case, meant that, in accordance with Commission Implementing Regulation (EU) 2019/2094 of 29 November 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ 2019 L 317, p. 102), the procedure for the renewal of mancozeb had to be capable of being completed before the end of the approval period of that active substance, which had been extended until 31 January 2021.

116 Since there was no obligation to make the updated draft RAR of September 2020 available to the public, the complaints set out by the appellants as regards the General Court's assessment in paragraphs 101 to 109 of the judgment under appeal, concerning the comparative analysis of the conclusions reached by the initial RMS and those reached by the new RMS, are ineffective because they are directed against grounds that were included in that judgment purely for the sake of completeness.

117 Accordingly, the fifth part of the first ground of appeal must be rejected as, in part, ineffective and, in part, unfounded.

The sixth part of the first ground of appeal

– *Arguments of the parties*

118 By the sixth part of the first ground of appeal, the appellants submit that the General Court erred in law by finding, in paragraphs 114 to 117 of the judgment under appeal, that the Commission had complied with the renewal procedure even though it had adopted its renewal report in January 2020, that is to say, before the new RMS had completed its assessment.

119 They submit that the General Court infringed Article 4 of Regulation No 1107/2009, which requires that the active substance in question be assessed in the light of current scientific and technical knowledge. The fact that the Commission submitted an updated version of the renewal report in October 2020, following the submission of the updated draft RAR of September 2020, is, in the appellants' opinion, irrelevant to that infringement.

120 The Commission contends that the sixth part of the first ground of appeal is, principally, inadmissible and, in the alternative, unfounded.

– *Findings of the Court*

121 In paragraphs 115 and 116 of the judgment under appeal, the General Court rejected the appellants' argument that the Commission had sent an updated renewal report without taking account of the assessment conducted by the new RMS. It observed that the Commission had adopted the updated version of its draft renewal report following the submission, by the new RMS, of the updated draft RAR of September 2020. In so doing, it found that the Commission did not adopt its report before the new RMS completed the risk assessment.

122 By the sixth part of the first ground of appeal, the appellants claim, in essence, that the General Court erred in law by finding that the Commission was allowed to adopt its draft renewal report in January 2020 before the new RMS had even completed the risk assessment.

123 That argument must be rejected.

124 In accordance with Article 14(1) of Implementing Regulation No 844/2012, the Commission must present a renewal report within six months from the date of receipt of the conclusion of EFSA, taking into account the draft RAR of the RMS, that conclusion and also the comments referred to in Article 12(3) of that regulation.

125 However, since, as is apparent from paragraph 21 of the judgment under appeal, EFSA forwarded its conclusions to the Commission on 20 June 2019 and the appellants submitted their comments thereon on 16 July 2019, compliance with the time limit laid down in Article 14(1) of that regulation required that the Commission adopt its draft report within six months, which it indeed did in January 2020.

126 Contrary to what the appellants claim, the fact that that draft was adopted before the new RMS had 'completed' its assessment is inconsequential since, in any event, the Hellenic Republic did not officially become the new RMS until 1 February 2020.

127 Moreover, as the General Court noted in paragraph 116 of the judgment under appeal, it is common ground that, once the new RMS was designated and its assessment had been conducted, the Commission adopted an updated version of the draft renewal report which incorporated, inter alia, the appellants' comments.

128 It follows that the sixth part of the first ground of appeal must be rejected as unfounded.

129 Since none of the parts of the first ground of appeal has been upheld, that ground must be rejected as, in part, inadmissible and, in part, unfounded.

The second ground of appeal, alleging a failure to state reasons in the judgment under appeal

– *Arguments of the parties*

130 By their second ground of appeal, alleging infringement of Article 36 of the Statute of the Court of Justice of the European Union, the appellants claim that the General Court, in paragraph 118 of the judgment under appeal, did not provide an adequate statement of reasons for rejecting its second plea in law at first instance concerning infringement, by the Commission, of the rights of the defence. In that regard, the

appellants submit that the alleged analogy between the arguments of the first and second pleas put forward at first instance is not sufficient to allow the General Court to reject that second plea without an adequate assessment or statement of reasons. They state that the General Court justified rejecting that plea in paragraph 118 of that judgment by referring to the assessment made in paragraph 111 thereof even though the latter concerns only the argument relating to the lack of public consultation and not the argument relating to the infringement of the appellants' rights of defence.

131 The Commission contends that that ground of appeal is unfounded.

– *Findings of the Court*

132 According to settled case-law, the statement of the reasons on which the judgment under appeal is based must clearly and unequivocally disclose the General Court's thinking, so that the persons concerned can be apprised of the justification for the decision taken and the Court of Justice can exercise its power of review (judgment of 29 April 2021, *Achemos Grupė and Achema* v *Commission*, C-847/19 P, EU:C:2021:343, paragraph 60 and the case-law cited).

133 The obligation on the General Court to state reasons for its decisions, under Article 36 and the first paragraph of Article 53 of the Statute of the Court of Justice of the European Union, does not require it to provide an account that follows exhaustively and one by one all the arguments put forward by the parties to the dispute. The General Court's reasoning may therefore be implicit, on condition that it enables the persons concerned to know the grounds of the General Court's decision and provides the Court of Justice with sufficient material for it to exercise its power of review (judgment of 9 November 2023, *Global Silicones Council and Others* v *ECHA*, C-559/21 P, EU:C:2023:842, paragraph 114 and the case-law cited).

134 It must also be borne in mind that the obligation of the General Court to state reasons, pursuant to Article 36 of the Statute of the Court of Justice of the European Union, read in conjunction with Article 53 thereof, is an essential procedural requirement that must be distinguished from the question whether the reasoning is well founded (judgment of 5 May 2022, *Commission* v *Missir Mamachi di Lusignano*, C-54/20 P, EU:C:2022:349, paragraph 69 and the case-law cited).

135 In paragraph 118 of the judgment under appeal, the General Court rejected the appellants' argument, which alleged an infringement of their rights of defence in that they were not given an opportunity to comment, in accordance with Article 12(1) of Implementing Regulation No 844/2012, on the updated draft RAR of September 2020. It found that that argument, which it examined in paragraphs 95 to 111 of the judgment under appeal, was essentially the same as the argument relating to how the procedure following the preparation of that updated draft RAR was conducted and, more specifically, to the lack of public consultation about that draft which allegedly infringes the requirements of Article 12 of Regulation No 1107/2009.

136 Accordingly, contrary to what the appellants claim, paragraph 118 of the judgment under appeal, which does not merely refer to paragraph 111 of that judgment, is not vitiated by any failure to state reasons.

137 Admittedly, the appellants claimed, in their second plea put forward at first instance, that their rights of defence had been infringed because they had not been given an opportunity to submit properly their comments on the updated draft RAR of September 2020.

138 It is true that the General Court referred, in paragraph 118 of the judgment under appeal, to paragraphs 95 to 111 thereof, which essentially concerned the fact that the updated draft RAR of September 2020, prepared by the new RMS, was not made available to the public.

139 However, it is unambiguously apparent from paragraph 99 of the judgment under appeal that the General Court also examined the appellants' claim that, as applicants for the renewal of the approval of mancozeb, their right to submit comments on that draft RAR had been infringed.

140 In that regard, the General Court rejected that claim on the ground that the appellants had already had the opportunity to submit comments, on 16 July 2019, on the updated draft RAR of March 2019 of the initial RMS and on EFSA's conclusions of 12 June 2019, thus making use of their rights under Article 12(3) of Implementing Regulation No 844/2012, since mancozeb's risk assessment process had been formally completed before the designation of the new RMS on 1 February 2020.

141 However, the appellants do not allege, in support of their second ground of appeal, that that assessment is vitiated by an error of law or by a distortion of the facts and/or the evidence.

142 Moreover, as is apparent from paragraph 40 of the judgment under appeal, it is common ground that the appellants were indeed able to submit their comments on the updated draft renewal report of the Commission.

143 Accordingly, the second ground of appeal must be rejected as unfounded.

The third ground of appeal, alleging a distortion of the evidence and an error of assessment relating to the Commission's bias

– *Arguments of the parties*

144 By their third ground of appeal, the appellants claim that the General Court distorted the evidence and made an error of assessment by finding, in paragraphs 125 and 126 of the judgment under appeal, that the Commission was not biased even though it had adopted the implementing regulation at issue on the basis of a procedure which had not taken into account the final risk assessment by the new RMS and the final conclusions of EFSA. The General Court, they argue, also failed to examine whether the Commission had rectified its proposal for non-renewal of mancozeb once the new RMS had completed its assessment. According to the appellants, the mere fact, stated in paragraph 125 of that judgment, that the final decision of the Commission was adopted after the assessment of mancozeb by the new RMS, even though the Commission's proposal for non-renewal preceded that assessment by several months, is irrelevant and shows that the General Court obstinately sought to justify the Commission's decision to ban mancozeb by relying on its own biased views rather than on the objective final report of the new RMS. In that regard, the appellants recall that the new RMS noted the existence of a safe use of that substance by relying on the endocrine disruption data which had not been reviewed by the initial RMS and had accordingly not confirmed the latter's conclusion.

145 The Commission contends that the third ground of appeal should be rejected as inadmissible.

– *Findings of the Court*

146 In the first place, it must be observed that the appellants' argument that the General Court failed to examine whether the Commission had rectified its proposal of non-renewal of mancozeb once the new RMS had completed its assessment is based on a misinterpretation of the Commission's obligations under Article 14(1) of Implementing Regulation No 844/2012. According to that provision, the renewal report and the draft implementing regulation need only take into account the draft RAR of the RMS.

147 In paragraph 125 of the judgment under appeal, the General Court stated that it was apparent from 'the dossier' before it that the implementing regulation at issue had been adopted after the new RMS's assessment had been completed and after the Commission had adopted the updated version of its draft renewal report 'in order to take account of the new RMS's assessment'. It was therefore not for the General Court, contrary to what the appellants claim, to ascertain whether the draft renewal report and the draft implementing regulation at issue prepared by the Commission had been 'rectified' following the updated draft RAR of the new RMS. In any event, it is apparent from paragraph 127 of that judgment that the General Court examined and rejected, on the merits, the appellants' arguments that the Commission had not made any substantive change to its updated renewal report after the updated draft RAR of September 2020 which was prepared by the new RMS.

148 In the second place, as regards the considerations set out by the appellants concerning the content of the updated draft RAR of September 2020, it must be recalled that, in accordance with Article 256(1) TFEU and the first paragraph of Article 58 of the Statute of the Court of Justice of the European Union, an appeal lies on points of law only. The General Court has exclusive jurisdiction to find and appraise the relevant facts and to assess the evidence. The appraisal of those facts and the assessment of that evidence is not, therefore, save where they have been distorted, a point of law which is subject, as such, to review by the Court of Justice on appeal (judgment of 19 October 2023, *QB* v *Commission*, C-88/22 P, EU:C:2023:792, paragraph 29 and the case-law cited).

149 However, in spite of the heading of the third ground of appeal, the appellants in no way claim or, a fortiori, show that the General Court vitiated the findings in paragraph 127 of the judgment under appeal by distorting the facts and/or the evidence.

150 It follows that the third ground of appeal must be rejected as, in part, inadmissible and, in part, unfounded.

The fourth ground of appeal, alleging erroneous and contradictory reasoning in the judgment under appeal which breaches the principle of legal certainty as regards taking into account the RAC's opinion in the procedure for the renewal of mancozeb

Arguments of the parties

151 By their fourth ground of appeal, the appellants claim that the reasons set out in paragraphs 140 to 157 of the judgment under appeal are erroneous and contradictory.

152 First of all, they indicate that the General Court correctly found, in paragraphs 138 and 141 of the judgment under appeal, that mancozeb was formally classified as a toxic substance for reproduction category 2 for developmental toxicity and that the RAC's opinion on mancozeb's classification as a toxic substance for reproduction category 1B, issued in a separate harmonised classification and labelling procedure for an active substance under Regulation No 1272/2008, was merely a recommendation. However, in their submission, the General Court could not hold, in paragraph 142 of that judgment, that the existence of a formal classification of an active substance was not decisive for the purposes of its approval under Regulation No 1107/2009 and that the Commission could, on that basis, take the RAC's opinion into consideration, without the judgment under appeal being vitiated by an error in law and by contradictory reasoning.

153 Next, the appellants submit that, while, in paragraph 144 of the judgment under appeal, the General Court correctly set out their argument that the RAC's opinion was not based on the latest scientific advances for the purposes of classifying mancozeb as a toxic substance, and rightly found, in paragraph 145 of that judgment, that the Commission always had to take account of the latest scientific and technical knowledge, its reasoning in paragraphs 149 and 150 of that judgment is contradictory and erroneous.

154 First, in so far as the General Court held, in paragraph 149 of the judgment under appeal, that the complaints alleging that the RAC's opinion was not well founded had to be examined in the classification and labelling procedure for mancozeb and could not be relied on in order to call into question the lawfulness of the implementing regulation at issue, the appellants claim that that reasoning is inconsistent and applies 'double standards', thus infringing their rights of defence, since the General Court allowed the Commission to rely on that opinion of the RAC in the course of adopting the implementing regulation at issue.

155 Secondly, the appellants dispute the General Court's statement, in paragraph 150 of the judgment under appeal, that the RAC's opinion showed the most recent scientific knowledge concerning the classification of mancozeb as a toxic substance. In that regard, the appellants submit that the General Court acknowledged that that opinion, which is based on a study from 1980, relied on outdated data. Furthermore, they argue, it was apparent from various documents that the initial RMS did not share that

opinion, which was going to be re-examined at the request of another Member State, namely the Republic of Malta.

156 Lastly, in addition to the considerations set out above concerning the reasoning in paragraph 149 of the judgment under appeal, reiterated by the General Court in paragraph 154 of that judgment, the appellants complain that the General Court failed to give reasons for the statements it made in paragraphs 155 and 157 of that judgment, respectively, that metabolites are relevant in the assessment of mancozeb and that it is common ground that mancozeb is a metabolised substance.

157 The Commission contends that that ground of appeal is, in part, inadmissible and, in part, unfounded.

158 As regards, first, the complaints directed against paragraph 142 of the judgment under appeal, the Commission submits that the General Court set out the legal basis on which it relied, namely point 3.6.4 of Annex II to Regulation No 1107/2009, which provides that an active substance is approved only if it 'is not' or 'has not to be' classified as toxic for reproduction category 1A or 1B, in accordance with the provisions of Regulation No 1272/2008. In other words, the existence of an official classification of an active substance under Regulation No 1272/2008 is not decisive for the purposes of its approval under Regulation No 1107/2009 and the question whether it should be classified as such is also relevant. Furthermore, the Commission states that the appellants disregarded the grounds of the judgment under appeal, by which the General Court stated that the fact that the RAC's opinion was not legally binding did not diminish its scientific value and did not prevent it from being taken into consideration in the application of Regulation No 1107/2009.

159 Secondly, the Commission claims that the appellants had sought not to rely on the RAC's opinion, but, on the contrary, to dispute it. However, since they were of the opinion that the classification of mancozeb as a toxic substance for reproduction category 1B in the procedure provided for by Regulation No 1272/2008 was erroneous, they should have disputed it in the course of that procedure. Failing that, the Commission and the General Court were entitled to take that opinion into account in the procedure provided for by Regulation No 1107/2009.

160 Thirdly, in the Commission's view, the complaint directed against the General Court's factual assessment that the RAC's opinion could be regarded as showing the most recent scientific knowledge is inadmissible. The argument that the initial RMS did not share the opinion of the RAC is also, it argues, inadmissible in so far as the appellants first presented it at the appeal stage.

161 Fourthly, the Commission claims that the mere fact that a Member State, namely the Republic of Malta, notified its intention to submit a new classification dossier for the active substance in question under Regulation No 1272/2008 was not a new scientific datum. In addition, the Commission indicates that that Member State withdrew its notification in February 2022.

162 Fifthly, the Commission is of the opinion that the General Court was correct, in paragraph 155 of the judgment under appeal, to refute the appellants' argument, which was put forward at first instance and summarised in paragraph 131 of that judgment, that it is clear from point 32 of Article 3 of Regulation No 1107/2009 that metabolites are not to be a decisive factor in the renewal procedure for an active substance.

163 Sixthly and lastly, in the Commission's opinion, the appellants' complaints directed at paragraph 157 of the judgment under appeal, which states, in particular, that 'it is common ground that mancozeb is a metabolised substance', are merely intended to dispute factual findings and are therefore inadmissible at the appeal stage.

Findings of the Court

164 As is apparent from paragraphs 142, 144, 149 and 150 of the judgment under appeal, the General Court found that, in the procedure for renewal of the approval of mancozeb, EFSA and the Commission could

rely on the RAC's opinion classifying mancozeb as a toxic substance for reproduction category 1B, which is a non-legally binding opinion issued under Regulation No 1272/2008, even though that substance had been formally classified as toxic for reproduction category 2 for developmental toxicity when the implementing regulation at issue was adopted.

165 The General Court justified that finding by holding, in paragraph 142 of the judgment under appeal, first, that, despite not being legally binding, the RAC's opinion had scientific value and, secondly, that 'the existence of a formal classification of an active substance [was] not decisive for the purposes of its approval under Regulation No 1107/2009' and that point 3.6.4 of Annex II to that regulation provided that an active substance is approved only if it 'is not' or 'has not to be' classified as toxic for reproduction category 1A or 1B, in accordance with the provisions of Regulation No 1272/2008.

166 Furthermore, the General Court, while recognising, in paragraph 140 of the judgment under appeal, that the elements emerging from the harmonised classification and labelling procedure for an active substance, governed by Regulation No 1272/2008, could have a substantive impact on the approval of that substance under Regulation No 1107/2009, noted, in paragraph 141 of that judgment, that the procedures set out by both regulations '[were] separate' and each 'organised according to its own rules'. It inferred from that, in paragraph 149 of that judgment, that 'any complaint alleging that that classification by the RAC [was] not well founded [had to] be examined solely in the light of the rules laid down in Regulation No 1272/2008' and that the appellants 'may not rely on an alleged material infringement occurring in that procedure in order to call into question the lawfulness of the [implementing regulation at issue]'. Consequently, it rejected their complaint that the RAC's opinion was based on an old study. However, in paragraph 150 of that judgment, the General Court held that that opinion 'could be regarded as a document showing the most recent scientific knowledge concerning the classification of mancozeb as a toxic substance', in so far as it was prepared before EFSA's conclusions were adopted in the procedure for the renewal of that substance.

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167 In the first place, as the General Court observed in paragraph 46 of the judgment under appeal, the RAC's opinion was issued in November 2018 in accordance with the provisions of Regulation No 1272/2008 on the classification and labelling of active substances, more specifically Article 37 thereof.

168 It is apparent from Article 37(5) of that regulation that, following the RAC's opinion which it receives, the Commission adopts 'without undue delay' a delegated act if it finds that the harmonisation of the classification and labelling of the substance concerned is appropriate, to amend Annex VI by including that substance together with the relevant classification and labelling elements in that annex. However, in the light of that obligation, the fact that the Commission did not adopt any delegated act concerning the classification procedure for mancozeb following the RAC's opinion must, in principle, mean that, on the date of adoption of the implementing regulation at issue, which was more than two years after the date on which that opinion was issued, the Commission did not find that the harmonisation of the classification of that substance was appropriate, for the purposes of that Article 37(5).

169 Accordingly, as the General Court stressed in paragraph 138 of the judgment under appeal, on the date of adoption of the implementing regulation at issue, that is to say, 14 December 2020, no delegated act concerning the classification procedure for mancozeb as a toxic substance for reproduction category 1B had yet been adopted, since mancozeb was formally classified as a toxic substance for reproduction category 2 for developmental toxicity.

170 Therefore, the General Court could not infer solely from the non-legally binding opinion of the RAC that the approval of mancozeb was precluded on the ground that, in accordance with point 3.6.4 of Annex II to Regulation No 1107/2009, only an active substance which 'is not' or 'has not to be' classified as toxic for reproduction category 1A or 1B, in accordance with the provisions of Regulation No 1272/2008, may be approved. Indeed, while it is admittedly true that, under that provision, a substance which is not yet formally classified as a toxic substance for reproduction category 1A or 1B, but which should be, is precluded from being approved under Regulation No 1107/2009, the fact remains that there is, in the present case, a formal classification of mancozeb. Consequently, the General Court could not, without

erring in law, find, in the absence of any duly reasoned justification from the Commission, that a non-legally binding opinion was sufficient for rejecting that formal classification of mancozeb or showing that that active substance could not be approved on that ground that it 'had' to be classified as toxic for reproduction category 1B, within the meaning of point 3.6.4 of Annex II of Regulation No 1107/2009.

171 Consequently, the reasons which led the General Court to hold, in paragraph 143 of the judgment under appeal, that the Commission had not made a manifest error of assessment by taking into consideration only the non-legally binding opinion of the RAC on the classification of mancozeb as a toxic substance for reproduction category 1B, are vitiated by errors in law.

172 In the second place, the same is true of the ground, in paragraph 149 of the judgment under appeal, that 'any complaint alleging that [the] classification by the RAC is not well founded must be examined solely in the light of the rules laid down in Regulation No 1272/2008 with the result that the [appellants] may not rely on an alleged material infringement occurring in that procedure in order to call into question the lawfulness of the [implementing regulation at issue]'.

173 In that regard, the Court finds that, irrespective of the possibility of any interested party submitting comments on that opinion in accordance with Article 37(4) of Regulation No 1272/2008, the General Court's assessment in paragraph 149 of the judgment under appeal is based on the premiss, given that the RAC's opinion is preparatory and not legally binding, that: (i) the Commission adopted an act which may be the subject of an action for annulment, in particular a delegated act, in accordance with Article 37(5) of Regulation No 1272/2008; and (ii) the appellants were able to show that, in respect of that act, they satisfied the conditions laid down in the fourth paragraph of Article 263 TFEU.

174 However, as the General Court noted in paragraph 142 of the judgment under appeal, it is common ground that the Commission had not adopted such a delegated act by the date of adoption of the implementing regulation at issue.

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175 By ruling in that way, the General Court, in paragraph 149 of the judgment under appeal, completely denied the appellants the right to dispute the RAC's opinion, even though that opinion was one of the main pieces of evidence on which the Commission had based the non-renewal of the approval of mancozeb in the implementing regulation at issue. In so doing, it denied them all the guarantees attaching to the right to an effective legal remedy, which is a general principle of European Union law expressed in Article 47 of the Charter of Fundamental Rights of the European Union (see, to that effect, judgment of 28 February 2013, *Review of Arango Jaramillo and Others* v *EIB*, C-334/12 RX-II, EU:C:2013:134, paragraph 40 and the case-law cited), thus erring in law.

176 Moreover, the General Court engaged in contradictory reasoning when it held, on the one hand, that the RAC's opinion resembled scientific evidence which the Commission could take into account in the procedure for the renewal of mancozeb and, on the other, that the appellants could not dispute the merits of that opinion in that same procedure.

177 In those circumstances, the General Court was wrong simply to reject, in paragraph 149 of the judgment under appeal, the appellants' complaint alleging that the RAC's opinion was based on an old study, without examining the substance of the complaint alleging that the Commission had made a manifest error of assessment.

178 The same is true of the assessment in paragraph 154 of the judgment under appeal by which the General Court rejected, for the same reason as that set out in paragraph 149 of that judgment, the appellants' complaints concerning the fact that the Commission had, on the basis of the RAC's opinion, accorded 'undue influence' to the metabolite ETU rather than to the substance itself.

179 In addition, since the General Court did not examine the appellants' complaint that the study on which the RAC's opinion was allegedly based was old, it was wrong to find, in paragraph 150 of the judgment under appeal, that that opinion showed the most recent scientific knowledge. By ruling in that way, the General

Court also infringed the requirements of its own case-law, recalled in paragraph 145 of the judgment under appeal, as well as the case-law of the Court of Justice (judgment of 1 October 2019, *Blaise and Others*, C-616/17, EU:C:2019:800 paragraphs 66 to 69 and 88), that the decisions which the Commission is required to take in the context of Regulation No 1107/2009 must always take account of the latest scientific and technical knowledge.

180 It follows that the fourth ground put forward in support of the appeal must be upheld, without it being necessary to examine the other complaints submitted by the appellants in support of that ground.

The fifth ground of appeal, alleging a distortion of the evidence and errors in law and of assessment relating to the principle of legitimate expectations

Arguments of the parties

181 By their fifth ground of appeal, the appellants criticise the grounds set out in paragraphs 166 and 168 of the judgment under appeal by which the General Court rejected their argument that the Commission gave them precise and consistent assurances that it was prepared to reconsider the situation following the additional assessment by the new RMS.

182 First, according to the appellants, the General Court misread the Commission's letter of 10 June 2020, which was cited in the last sentence of paragraph 166 of the judgment under appeal. Indeed, contrary to what the General Court found in paragraph 166, that letter informed the appellants that, although, under normal circumstances, alterations of GAP on cereals are not taken into consideration, in the light of the special circumstances of the present case relating to the designation of a new RMS following the withdrawal of the initial RMS due to Brexit, the Commission committed to taking them into account.

183 Secondly, they argue, the General Court misunderstood, in paragraph 168 of the judgment under appeal, the appellants' argument, alleging infringement of the principle of protection of legitimate expectations, which was not that the new RMS should conclude in a manner favourable to the appellants but that the Commission, before adopting the implementing regulation at issue, should have taken into account the assessment and final conclusions of the new RMS.

184 The Commission contends that that ground of appeal is, principally, inadmissible and, in the alternative, unfounded.

Findings of the Court

185 According to settled case-law, the right to rely on the principle of protection of legitimate expectations presupposes that precise, unconditional and consistent assurances originating from authorised, reliable sources have been given to the person concerned by the competent authorities of the European Union. That right applies to any individual in a situation in which an institution, body or agency of the European Union, by giving that person precise assurances, has led him or her to entertain well-founded expectations (judgment of 25 April 2024, *CIMV* v *Commission*, C-366/23 P, EU:C:2024:351, paragraph 30 and the case-law cited).

186 In paragraphs 166 and 168 of the judgment under appeal, the General Court rejected the appellants' complaints that the Commission had given them such precise assurances, in particular in its letter of 10 June 2020, from which it was apparent that that institution had been prepared to reconsider the situation following the additional assessment by the new RMS.

187 As regards, in the first place, the appellants' complaint directed against the General Court's assessment made in the last sentence of paragraph 166 of the judgment under appeal concerning the letter of 10 June 2020, and, more specifically, the phrase 'normally such changes [to GAP on cereals][were] not permitted', it must be borne in mind that the General Court has exclusive jurisdiction to assess the evidence, save in the case of their distortion. Even though the appellants formally alleged such a distortion in the heading of

their fifth ground of appeal, it is clear that they are merely proposing their own interpretation of the passage from the letter of 10 June 2020, reproduced in paragraph 166 of the judgment under appeal, and of the adverb ‘normally’, which is used therein. Although distortion of the evidence may consist of an interpretation of a document contrary to the content of that document, it must be obvious from the file before the Court of Justice, and it presupposes that the General Court has manifestly exceeded the limits of a reasonable assessment of that evidence. In that regard, it is not sufficient to show that a document could be interpreted differently from the interpretation adopted by the General Court (judgment of 23 November 2023, *Ryanair and Airport Marketing Services*, C-758/21 P, EU:C:2023:917, paragraph 111 and the case-law cited).

188 It follows that that ground of appeal must be rejected as inadmissible.

189 In the second place, as regards the General Court’s finding in paragraph 168 of the judgment under appeal that ‘the Commission’s willingness, declared in its letter of 10 June 2020, to reconsider the situation when the new RMS had completed its assessment … cannot be interpreted as a precise assurance that it would change its position with regard to mancozeb’, and in respect of which the appellants submit that the General Court misinterpreted their argument put forward at first instance, it should be noted that it is apparent from paragraph 148 of the application initiating proceedings before the General Court that the appellants claimed therein that the letter of 10 June 2020 gave them the reasonable expectation both that the report of the new RMS, once available, would be taken into account by the Commission and that ‘the latter [would] change its position towards the [active substance]’. It follows that the General Court in no way misunderstood the appellants’ argument which was put forward at first instance in support of their fifth plea in law alleging infringement, by the Commission, of the principle of protection of legitimate expectations.

190 Accordingly, the fifth ground of appeal must be rejected as, in part, inadmissible and, in part, unfounded.

191 In the light of all those findings, the first, second, third and fifth grounds put forward in support of the appeal must be rejected and the fourth ground must be upheld.

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192 It follows that the judgment of the General Court must be set aside in so far as it found that the Commission could rely, in the implementing regulation at issue, on the RAC’s opinion on the classification of mancozeb as a toxic substance for reproduction category 1B.

The action before the General Court

193 In accordance with the first paragraph of Article 61 of the Statute of the Court of Justice of the European Union, if the Court of Justice quashes the decision of the General Court, it may itself give final judgment in the matter, where the state of the proceedings so permits.

194 In the present case, the General Court has failed to examine the whole of the fourth plea, in particular the substance thereof, put forward by the appellants in support of their action, alleging, in essence, a manifest error of assessment by the Commission as regards taking into account the RAC’s opinion on the classification of mancozeb as a toxic substance for reproduction category 1B.

195 Since the state of proceedings does not permit the Court of Justice to give final judgment in the matter, the case must be referred back to the General Court in order for it to rule on the fourth plea in law relied on before it.

Costs

196 Since the case has been referred back to the General Court, the costs must be reserved.

On those grounds, the Court (Ninth Chamber) hereby:

1. **Sets aside the judgment of the General Court of the European Union of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74), in so far as it found that the European Commission could rely, in Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of the approval of the active substance mancozeb, 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, on the opinion of the Committee for Risk Assessment of the European Chemicals Agency on the classification of mancozeb as a toxic substance for reproduction category 1B;**

2. **Dismisses the appeal as to the remainder;**

3. **Refers the case back to the General Court of the European Union in order for it to rule on the fourth plea in law relied on before it;**

4. **Reserves the costs.**

Spineanu-Matei Rodin Rossi

Delivered in open court in Luxembourg on 4 October 2024.

A. Calot Escobar O. Spineanu-Matei

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Registrar President of the Chamber

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* Language of the case: English.