JUDGMENT OF THE GENERAL COURT (Fifth Chamber)

29 October 2025 (*)

(Plant protection products – Active substance mancozeb – Non-renewal of approval – Regulation (EC) No 1107/2009 and Implementing Regulation (EU) No 844/2012 – Procedure for assessing the application for renewal of approval of an active substance – Manifest error of assessment – Procedure for harmonised classification and labelling – Regulation (EC) No 1272/2008)

In Case T-742/20 RENV,

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

Indofil Industries (Netherlands) BV, established in Amsterdam (Netherlands),

represented by C. Mereu and P. Parvati Martín Paredes, lawyers,

applicants,

v

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

defendant,

THE GENERAL COURT (Fifth Chamber),

composed, at the time of the deliberations, of J. Svenningsen, President, C. Mac Eochaidh (Rapporteur) and J. Laitenberger, Judges,

Registrar: S. Spyropoulos, Administrator,

having regard to the judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74),

having regard to the judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (C-262/23 P, not published, EU:C:2024:862),

having regard to the written part of the procedure,

further to the hearing on 1 July 2025,

gives the following

Judgment

1 By their action under Article 263 TFEU, the applicants, UPL Europe Ltd and Indofil Industries (Netherlands) BV, seek annulment of Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 concerning the non-renewal of 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 contested Implementing Regulation').

Background to the dispute

2 The applicants are companies which market plant protection products containing the active substance 'mancozeb', including throughout the European Union. Mancozeb is a fungicide used to combat a number of fungal pathogens affecting potato, vine, pome fruit, tree fruit, carrot and onion crops.

3 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).

4 With the entry into force of 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 (OJ 2009 L 309, p. 1), the active substances included in Annex I to Directive 91/414, including mancozeb, were deemed to have been approved and were listed in the annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation No 1107/2009 as regards the list of approved active substances (OJ 2011 L 153, p. 1). Implementing Regulation No 540/2011 was amended, inter alia, by Commission Implementing Regulation (EU) 2019/2094 of 29 November 2019 (OJ 2019 L 317, p. 102). By that implementing regulation, the Commission extended the approval period of mancozeb until 31 January 2021 in order to allow the renewal procedure to be completed before the expiry of the approval period of that substance.

5 In June 2013 and November 2014, respectively, separate applications for renewal of the approval of mancozeb were submitted by the 'EU Mancozeb Task Force', a task force founded by the applicants specifically for the purposes of the procedure for renewal of the approval of mancozeb, and by another company.

6 The approval of mancozeb was subject to the standard regulatory procedure for the renewals of approval provided for in Article 14 et seq. of Regulation No 1107/2009 and to the various stages of that procedure provided for in 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).

7 In accordance with Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to the 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), the United Kingdom of Great Britain and Northern Ireland was designated as the rapporteur Member State for the evaluation of mancozeb in the context of the renewal procedure for its approval ('the initial RMS'), the co-rapporteur Member State being the Hellenic Republic.

8 In August 2017, in parallel with the procedure for renewal of the approval of mancozeb referred to in paragraph 6 above and pursuant to 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), the initial RMS sent the European Chemicals Agency (ECHA) a harmonised classification and labelling dossier ('the CLH dossier').

9 Although, at that time, mancozeb was formally classified as toxic for reproduction category 2, the initial RMS proposed no classification of mancozeb with regard to reprotoxicity. In December 2017, it submitted an updated CLH dossier to ECHA, which formed the basis of a public consultation which ran from February to April 2018.

10 At the forty-seventh meeting of the ECHA Risk Assessment Committee ('the RAC') in November 2018, it was concluded that mancozeb should be classified as a toxic substance for reproduction category 1B ('the RAC opinion'). On 7 March 2019, at its forty-eighth meeting, the RAC adopted a proposal to classify mancozeb as carcinogenic category 2.

11 Following those two meetings, there were a number of exchanges of correspondence between the applicants, on the one hand, and the RAC secretariat, ECHA and the Commission, on the other. More specifically, ECHA stated, inter alia, in a letter of 29 March 2019, that the issue of classification of mancozeb as a toxic substance for reproduction category 1B would be reopened only on the basis of 'new arguments' and 'new scientific evidence'.

12 In March 2019, as part of the procedure for renewal of the approval of mancozeb referred to in paragraph 6 above, the initial RMS submitted to the European Food Safety Authority (EFSA) an updated draft renewal assessment report. The applicants 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.

13 On 12 April 2019, the applicants 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 applicants 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 the metabolite ethylene thiourea (ETU) rather than to the substance itself.

14 On 12 June 2019, EFSA published its conclusions on the peer review of the pesticide risk assessment of mancozeb ('the EFSA conclusions'), 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.

15 On 20 June 2019, EFSA forwarded its conclusions to the Commission, which then invited the applicants to comment on those conclusions, which they did on 16 July 2019.

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

17 On 1 February 2020, following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, the Hellenic Republic officially became the RMS for the evaluation of mancozeb ('the new RMS').

18 On 2 September 2020, the new RMS submitted a further updated draft renewal assessment report ('the draft RAR of September 2020') to the Commission. It maintained the proposal of the initial RMS in its draft renewal assessment report 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 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 draft RAR of September 2020 was also made available to EFSA, the other Member States and the applicants.

19 By letter of 21 September 2020, the applicants asked the Commission to allow them to submit comments on the draft RAR of September 2020 and to mandate EFSA to organise expert meetings and to adjust its conclusions accordingly. They considered that the new RMS's conclusions as to the existence of a safe use for human health meant that they could apply for application of the derogation provided for in Article 4(7) of Regulation No 1107/2009.

20 On the same day, the Commission sent the applicants an updated draft renewal report, in which it proposed not to renew the approval of mancozeb. The applicants submitted comments on the draft renewal report on 2 October 2020.

21 In September and October 2020, the applicants and the Commission were in contact on a number of occasions concerning the applicants' request to mandate EFSA to organise a peer review of the draft RAR of September 2020.

22 At a Standing Committee on Plants, Animals, Food and Feed 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 approval for mancozeb.

23 On 14 December 2020 the Commission adopted the contested Implementing Regulation.

24 Recitals 12 and 15 of the contested Implementing Regulation set out the reasons for the non-renewal of approval 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 … No 1107/2009. Given the concerns identified the derogation provided for in Article 4(7) to Regulation … No 1107/2009 cannot apply.

…

(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 … No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance mancozeb.'

Events subsequent to the bringing of the action

25 On 11 March 2021, the Commission classified mancozeb as a toxic substance for reproduction category 1B (Delegated Regulation (EU) 2021/849 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation No 1272/2008 (OJ 2021 L 188, p. 27)).

Forms of order sought

26 The applicants claim, in the final form of their pleadings, that the Court should:

– annul the contested Implementing Regulation;

– order the costs of the present proceedings and the proceedings in Cases T-742/20 and C-262/23 P to be shared between the parties.

27 The Commission contends, in the final form of its pleadings, that the Court should:

– dismiss the action;

– order the applicants to pay the costs of the present proceedings and the proceedings in Case C-262/23 P.

Law

The subject matter of the action

28 By the judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74), the General Court dismissed the applicants' action.

29 However, by the judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (C-262/23 P, not published, EU:C:2024:862), the Court of Justice set aside in part the judgment referred to in paragraph 28 above and referred Case T-742/20 back to the General Court for it to rule on the fourth plea raised before it.

30 More specifically, the Court of Justice stated that the General Court had to examine the entirety of the fourth plea put forward by the applicants in support of their action, in particular its substance, alleging, specifically, 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 (judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraph 194).

31 In the present proceedings, the General Court will therefore examine only the fourth plea.

Fourth plea in law: manifest error of assessment

32 The applicants submit that the Commission made a manifest error of assessment in the mancozeb renewal procedure, for three reasons. First of all, in the contested Implementing Regulation, the Commission relied on the RAC opinion, which accorded undue influence to the metabolite ETU, and not on the properties of the substance itself. Next, the Commission failed to take account of significant factors supporting the classification of mancozeb as toxic for reproduction category 2 in the context of the CLH dossier and demonstrating that there were scientific flaws in the classification of mancozeb as a toxic substance for reproduction category 1B. Lastly, the RAC opinion proposing that mancozeb should be classified as a toxic substance for reproduction category 1B is not legally binding, as only delegated acts deciding the substance classification and published in the *Official Journal of the European Union* are legally binding.

33 The Commission disputes the applicants' arguments. In particular, the Commission argues that the fourth plea has become ineffective. In the fourth plea, the applicants disputed only in part the assessments set out in recital 12 of the contested Implementing Regulation. According to the Commission, the applicants' arguments, put forward in support of the other pleas and seeking to call into question the assessments not disputed by them in the fourth plea, have already been rejected in the judgments of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (C-262/23 P, not published, EU:C:2024:862), and of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74). For the sake of completeness, the Commission submits that the fourth plea is unfounded.

Preliminary observations on the reasons for non-renewal of approval of mancozeb

34 As noted by UPL Europe in its letter of 16 July 2019, EFSA identified six specific concerns regarding mancozeb in Section 9.2 of its conclusions ('Critical areas of concern').

35 In recital 12 of the contested Implementing Regulation, the Commission justified the non-renewal of approval of mancozeb by adopting the EFSA conclusions (see paragraph 24 above).

36 However, in that recital, the Commission expressly referred only to three of the six specific concerns identified by EFSA in order to refuse to renew the approval of mancozeb, namely the fact that mancozeb was, in its view, classified as toxic for reproduction category 1B ('the first specific concern'), the fact that the new criteria to identify endocrine disrupting properties are met for humans and most likely for non-target organisms ('the second specific concern') and the fact that the non-dietary exposure estimates exceed the reference values for the representative uses in tomatoes, potatoes, cereals and grapevines ('the third specific concern').

37 In that connection, it is necessary to ascertain whether the applicants have demonstrated that the Commission made a manifest error of assessment in relying on each of those three specific concerns in order to refuse to renew the approval of mancozeb.

The first specific concern

38 As regards the first of those specific concerns, EFSA and, subsequently, the Commission relied on the RAC opinion, which proposed the classification of mancozeb as a toxic substance for reproduction category 1B. That opinion was not legally binding and had been given in the context of a regulatory procedure other than the procedure for renewal of the approval of mancozeb, namely the procedure established by Regulation No 1272/2008 on classification, labelling and packaging of substances and mixtures (see paragraphs 8 to 10 above).

39 However, on the date of adoption of the contested Implementing Regulation, mancozeb was still formally classified as a toxic substance for reproduction category 2 for developmental toxicity (see, to that effect, judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraphs 164 and 169).

40 Although the RAC opinion was therefore not legally binding; had been given in the context of another regulatory procedure, and proposed a classification of mancozeb in category 1B and, thus, in a category formally separate from that which was then applicable, namely that of toxic substances for reproduction category 2 (see paragraphs 9, 10, 38 and 39 above), the Court of Justice nevertheless did not exclude the possibility of that opinion being used as scientific evidence in the procedure for renewal of the approval of mancozeb, to the extent that it is established that that opinion represents the most recent scientific knowledge (see, to that effect, judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraphs 176, 177 and 179).

41 The Court of Justice nonetheless stated that, since a formal classification existed (see paragraph 39 above), that RAC opinion alone could not, because of its non-binding nature, justify the non-renewal of approval of mancozeb. In the absence of any duly reasoned justification on the part of the Commission, that RAC opinion alone was not sufficient for rejecting that formal classification of mancozeb or for showing that that active substance could not be approved on the ground that it had to be classified as toxic for reproduction category 1B (see, to that effect, judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraphs 170 and 171).

42 The General Court also recalls that, pursuant to the second paragraph of Article 61 of the Statute of the Court of Justice of the European Union, where a case is referred back to the General Court, it is bound by the decision of the Court of Justice on points of law.

43 Accordingly, the General Court will determine, as a first step, whether EFSA and/or the Commission relied on other relevant evidence to support the RAC's opinion that mancozeb should be classified as a toxic substance for reproduction category 1B. If that is the case, the Court will examine, as a second step, the applicants' arguments seeking to contest the RAC opinion and, consequently, the taking into account of the first specific concern.

44 In that regard, in Section 2 (page 9, last paragraph) and point 5 of Section 9.2 of its conclusions, EFSA refers only to the RAC opinion, in stating that mancozeb is 'classified' as a toxic substance for reproduction category 1B.

45 The EFSA conclusions are therefore based exclusively on the RAC opinion as regards the 'classification' of mancozeb as a toxic substance for reproduction category 1B. Moreover, and in any event, the Court notes that, contrary to what EFSA states in its conclusions and the Commission states in recital 12 of the contested Implementing Regulation, the RAC did not itself make that classification but merely proposed it (see paragraph 10 above).

46 Next, in paragraph 59 of its defence, the Commission reproduced an extract from an opinion of the Polish Risk Assessment Body ('the E.V.A.'), which concluded that the approval of that substance should not be renewed, in particular because of its 'accepted classification [in] category 1B'.

47 However, as stated on pages 2 and 3 of that opinion, the E.V.A. essentially confined itself to summarising the RAC opinion and to stating that it agreed with its conclusions concerning the classification of that substance in category 1B. Accordingly, the E.V.A. opinion cannot be considered to be additional evidence supporting the RAC opinion, since the E.V.A.'s assessment of mancozeb is based, decisively, on that RAC opinion.

48 Moreover, the Commission claims that, on the date of adoption of the contested Implementing Regulation, it was finalising the adoption of Delegated Regulation 2021/849 (see paragraph 25 above), which, in its view, confirms that mancozeb was certain to be regarded as a toxic substance for reproduction category 1B. That delegated regulation was, furthermore, adopted less than three months after the adoption of the contested Implementing Regulation.

49 However, the fact that the process of adopting Delegated Regulation 2021/849 was ongoing on the date of adoption of the contested Implementing Regulation is irrelevant in the present case. At that date, the delegated regulation did not exist. According to settled case-law, the legality of an EU measure must be assessed on the basis of the facts and the law as they stood at the time when that measure was adopted, so that measures postdating the adoption of a decision cannot affect that decision's validity (see judgment of 28 January 2021, *Qualcomm and Qualcomm Europe* v *Commission*, C-466/19 P, EU:C:2021:76, paragraph 82 and the case-law cited).

50 In addition, as the Commission itself acknowledges and as is stated in recitals 2 and 4 of Delegated Regulation 2021/849, that delegated regulation is based, as regards the classification of mancozeb, solely on the RAC opinion. Accordingly, even if the Court were entitled to take it into account, the adoption of that delegated regulation cannot be regarded as additional evidence supporting the RAC opinion, since that delegated regulation is based specifically on that opinion.

51 Finally, even in its observations of 27 November 2024, which were subsequent to the judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (C-262/23 P, not published, EU:C:2024:862), the Commission does not refer to any other relevant evidence which supports the RAC opinion.

52 In the light of the foregoing considerations, and in the absence of any duly reasoned justification on the part of the Commission, the Court finds that the Commission made a manifest error of assessment in considering that the RAC opinion, although not supported by any other evidence, was capable of establishing that mancozeb should be classified as a toxic substance for reproduction category 1B and that, consequently, its approval could not be renewed under Article 4 of Regulation No 1107/2009 (see, to that effect, judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraph 171).

53 Since it has been established that the Commission made a manifest error of assessment in basing the contested Implementing Regulation on the first specific concern, the Court does not consider it necessary to rule on the merits of the applicants' other arguments relating to the first specific concern or on the admissibility of the letter of 30 June 2025 which they submitted during the hearing on 1 July 2025.

The second specific concern

54 In point 6 of Section 9.2 of its conclusions, EFSA stated that mancozeb was an endocrine disruptor. That ground was then reproduced in recital 12 of the contested Implementing Regulation.

55 In that regard, the applicants argued, both in their pleadings and at the hearing on 1 July 2025, that the evaluation of mancozeb's endocrine disruption properties carried out by the initial RMS was incomplete and that the new RMS had applied incorrect criteria in establishing that mancozeb was an endocrine disruptor. Accordingly, in the applicants' view, the alleged endocrine disruption properties of mancozeb cannot be regarded as a determining factor for the non-renewal of its approval, since that substance is not an endocrine disruptor. In particular, it is claimed that the evaluations carried out by the two RMSs accorded undue influence to the metabolite ETU rather than to mancozeb itself.

56 It is true that in paragraph 10 of their reply the applicants stated, referring explicitly to paragraphs 138 and 139 of the application, that the evaluation by the two RMSs had focused on the endocrine disruption properties of the metabolite ETU and not on mancozeb.

57 However, the Court notes that, in paragraph 138 of the application, the applicants contested solely the fact that 'the RAC opinion' had accorded undue influence to the metabolite ETU rather than to mancozeb itself. By contrast, in paragraphs 138 and 139 of the application, the applicants raise no similar complaint against the evaluations carried out by the two RMSs.

58 Accordingly, the applicants' line of argument, as described in paragraph 55 above, does not constitute an amplification of the fourth plea, as set out in the application. Consequently, that line of argument must be regarded as new, with the result that it must be rejected as inadmissible (see, to that effect, judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraphs 87 to 89 (not published) and the case-law cited).

59 In any event, even if that line of argument were admissible, it would have to be rejected as unfounded.

60 In so far as the applicants call into question compliance by the two RMSs with the procedure, it suffices to recall that those arguments have already been rejected by the General Court in the examination of the first and second pleas (judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraphs 72 to 82 and 86 to 92 (not published)), and that the Court of Justice confirmed that reasoning in its judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (C-262/23 P, not published, EU:C:2024:862, paragraphs 64 to 70, 83 to 91 and 94).

61 Moreover, in paragraph 138 of the application, the applicants state that it follows from point 32 of Article 3 of Regulation No 1107/2009 that metabolites are not a determining factor in the procedure for the renewal of an active substance.

62 However, in certain cases, metabolites may be a determining factor. Point 32 of Article 3 of Regulation No 1107/2009 states that a 'metabolite is deemed relevant if there is a reason to assume that it has intrinsic properties comparable to the parent substance in terms of its biological target activity, or that it poses a higher or comparable risk to organisms than the parent substance or that it has certain toxicological properties that are considered unacceptable. Such a metabolite is relevant for the overall approval decision or for the definition of risk mitigation measures'.

63 Furthermore, the applicants have not disputed the Commission's contention that, if a substance is metabolised and the resulting metabolites produce critical effects, that is relevant for the classification of an active substance, since it is exposure to the substance that leads to the critical toxic effect (directly or through metabolic activity in humans).

64 In those circumstances, and although the burden of proof lay with them (see, to that effect, judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraph 62 (not published) and the case-law cited), the applicants have not demonstrated that the Commission made a manifest error of assessment in relying on the second specific concern in order to refuse to renew the approval of mancozeb under Article 4 of Regulation No 1107/2009.

The third specific concern

65 In point 7 of Section 9.2 of its conclusions, EFSA stated that the estimates of non-dietary exposure to mancozeb exceed the reference values for the representative uses in tomatoes, potatoes, cereals and grapevines. That ground was then reproduced in recital 12 of the contested Implementing Regulation.

66 In that regard, the applicants recalled, both in their pleadings and at the hearing on 1 July 2025, that the new RMS had found that, by altering the good agricultural practices 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 (see paragraph 18 above). In the light of those factors, the Commission should have renewed the approval of that substance.

67 However, the Court notes that neither the heading of the fourth plea, as set out in the application, nor paragraphs 136 to 143 thereof make any reference to the third specific concern.

68 Accordingly, the applicants' line of argument, as described in paragraph 66 above, does not constitute an amplification of the fourth plea, as set out in the application. Consequently, that line of argument must be regarded as new, with the result that it must be rejected as inadmissible (see, to that effect, judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraphs 87 to 89 (not published) and the case-law cited).

69 In any event, even if it were admissible, that line of argument could not succeed, since it has already been rejected by the General Court in its examination of the first and second pleas (judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraphs 103 to 106). In paragraphs 103 to 106 of that judgment, the General Court found that the new RMS's assessment had led to the same conclusion as that of the initial RMS, namely that mancozeb did not satisfy the conditions for approval laid down in Article 4 of Regulation No 1107/2009. Moreover, the Court of Justice rejected as ineffective the applicants' complaints challenging the General Court's assessment in paragraphs 101 to 109 of the judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74) and concerning the comparative analysis of the conclusions reached by the initial RMS and those reached by the new RMS (judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraph 116).

70 In those circumstances, and although the burden of proof lay with them (see, to that effect, judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraph 62 (not published) and the case-law cited), the applicants have not demonstrated that the Commission made a manifest error of assessment in relying on the third specific concern in order to refuse to renew the approval of mancozeb under Article 4 of Regulation No 1107/2009.

71 Consequently, since the applicants have not demonstrated that the Commission made manifest errors of assessment in relying on the second and third specific concerns in order to adopt the contested Implementing Regulation, the fourth plea must be rejected.

72 That conclusion cannot be invalidated by the other arguments put forward by the applicants in their observations of 3 December 2024, which are based on procedural irregularities committed by EFSA and the Commission. Those arguments, which do not appear in the fourth plea, as set out in the application, do not seek to establish any manifest error of assessment on the part of the Commission and are therefore unrelated to the actual subject matter of the fourth plea. Moreover, in rejecting the applicants' first three pleas, the General Court has already confirmed the lawfulness of the procedure which led to the adoption of the contested Implementing Regulation (see, to that effect, judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, T-742/20, EU:T:2023:74, paragraphs 72 to 94 (not published), 95 to 118 and 124 to 129 (not published)), and the Court of Justice confirmed that reasoning (judgment of 4 October 2024, *UPL Europe and Indofil Industries (Netherlands)* v *Commission*, C-262/23 P, not published, EU:C:2024:862, paragraphs 64 to 70, 73 to 76, 83 to 91, 94 and 95, 101 to 117, 121 to 129, 132 to 143 and 146 to 150).

73 In the light of the foregoing considerations, the action must be dismissed in its entirety.

Costs

74 Pursuant to Article 195 of the Rules of Procedure of the General Court, in decisions of the General Court given after its decision has been set aside and the case referred back to it, it is to decide on the costs relating to the proceedings instituted before it and to the proceedings on the appeal before the Court of Justice.

75 However, since the Court of Justice did not set aside the judgment of 15 February 2023, *UPL Europe and Indofil Industries (Netherlands)* v *Commission* (T-742/20, EU:T:2023:74), in respect of the decision as to costs, the present proceedings no longer concern the costs relating to the proceedings in Cases T-742/20 R and T-742/20.

76 Moreover, under Article 134(1) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings. In addition, under Article 134(2) of the Rules of Procedure, where there is more than one unsuccessful party the Court is to decide how the costs are to be shared.

77 In the present case, both the applicants and the Commission have been unsuccessful in part in the appeal, and therefore each of them must bear their own costs incurred in the proceedings in Case C-262/23 P. However, the applicants must bear their own costs and pay the costs incurred by the Commission in Case T-742/20 RENV, in accordance with the form of order sought by the Commission.

On those grounds,

THE GENERAL COURT (Fifth Chamber)

hereby:

1. **Dismisses the action;**

2. **Orders each party to bear its own costs in Case C-262/23 P;**

3. **Orders UPL Europe Ltd and Indofil Industries (Netherlands) BV to bear their own costs and to pay those incurred by the European Commission in Case T-742/20 RENV.**

Svenningsen Mac Eochaidh Laitenberger

Delivered in open court in Luxembourg on 29 October 2025.

V. Di Bucci M. van der Woude

Registrar President

* Language of the case: English.