Reports of Cases

Case T-742/20

(publication in extract form)

UPL Europe Ltd
and
Indofil Industries (Netherlands) BV
v
European Commission

Judgment of the General Court (Seventh Chamber), 15 February 2023

(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 – Designation of a new rapporteur Member State due to the withdrawal of the previous rapporteur Member State from the European Union – Rights of the defence – Principle of sound administration – Manifest error of assessment – Procedure for harmonised classification and labelling – Regulation (EC) No 1272/2008 – Legitimate expectations)

1. *Agriculture – Approximation of laws – Placing of plant protection products on the market – Regulation No 1107/2009 – Renewal of approval – Discretion of the Commission – Judicial review – Scope*
(European Parliament and Council Regulation No 1107/2009)

(see paragraphs 60-64)

2. *Agriculture – Approximation of laws – Placing of plant protection products on the market – Regulation No 1107/2009 – Approval of an active substance – Burden of proof on the applicant – Applicability in the context of a procedure for the renewal of the approval of an active substance*
(European Parliament and Council Regulation No 1107/2009, Art. 4(1) to (3))

(see paragraphs 65, 66)

3. *Judicial proceedings – Introduction of new pleas during the proceedings – Conditions – Amplification of an existing plea – No amplification – Inadmissibility*
(Rules of Procedure of the General Court, Art. 84(1))

(see paragraphs 87-89)

4. *Agriculture – Approximation of laws – Placing of plant protection products on the market – Regulation No 1107/2009 – Renewal of approval – Assessment of risks – Designation of a new rapporteur Member State during the procedure for renewal – Completion of the process of assessment by the initial rapporteur Member State – Assessment by the new rapporteur Member State having reached the same conclusion as that of the initial rapporteur Member State – Obligation for the Commission to submit the new rapporteur Member State's assessment to public consultation or ensure that the European Food Safety Authority (EFSA) produce its conclusions on that assessment – None*
(European Parliament and Council Regulation No 1107/2009, Art. 4; Commission Regulation No 844/2012, Arts 11 to 14)

(see paragraphs 97-99, 104-109)

5. *Agriculture – Approximation of laws – Placing of plant protection products on the market – Regulation No 1107/2009 – Renewal of approval – Assessment of risks – Obligation to submit the conclusions of the European Food Safety Authority (EFSA) to public consultation – None*
(Commission Regulation No 844/2012, Art. 12(3))

(see paragraphs 112, 113)

6. *Agriculture – Approximation of laws – Placing of plant protection products on the market – Regulation No 1107/2009 – Renewal of approval – Assessment of risks – Designation of a new rapporteur Member State during the procedure for renewal – Proposal for renewal by the Commission before the new rapporteur Member State's assessment finalised – Final decision taken after that assessment – Infringement of the requirement of impartiality – None*
(European Parliament and Council Regulation No 1107/2009; Commission Regulation 2020/2087)

(see paragraphs 124-126)

7. *Agriculture – Approximation of laws – Placing of plant protection products on the market – Regulation No 1107/2009 – Renewal of approval – Assessment of risks – Concerns relating to the substance at issue – Account taken by the Commission of the opinion issued by the Risk Assessment Committee in the procedure for harmonised classification and labelling under Regulation No 1272/2008 – Manifest error of assessment – None*
(European Parliament and Council Regulations No 1272/2008 and No 1107/2009)

(see paragraphs 136-143, 145, 149-152)

Résumé

Mancozeb, an active substance used as a fungicide to combat pathogens affecting potato, vine, pome fruit, tree fruit, carrot and onion crops, was first approved in the European Union in 2005.[1] Applications for renewal of that approval were submitted in 2013 and 2014.

[1] That substance was included in 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) 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).

By an implementing regulation of 14 December 2020,[2] the European Commission refused to renew the approval of mancozeb. In that regard, the recitals of the contested implementing regulation refer, inter alia, to the conclusions of the European Food Safety Authority (EFSA), in which EFSA noted, inter alia, that mancozeb had been classified as toxic for reproduction category 1B and that the new criteria for identifying endocrine disrupting properties were met for humans and most likely for non-target organisms.

The applicants UPL Europe Ltd and Indofil Industries (Netherlands) BV, companies which market plant protection products containing mancozeb, brought an action for annulment of the contested implementing regulation. The General Court dismisses that action.

This case raises two novel issues in the case-law of the General Court, concerning, first, the designation, during the procedure for the renewal of a substance, of a new rapporteur Member State ('RMS') for the assessment of an active substance and, second, the impact of the procedure for harmonised classification and labelling on the procedure for the renewal of an active substance.

Findings of the Court

In the first place, the Court rejects the complaint alleging failure to comply with the renewal procedure laid down in Implementing Regulation No 844/2012.[3]

As a preliminary matter, the Court finds, first, 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, the designation of a new RMS cannot be regarded as requiring the assessment procedure to be recommenced.[4]

Second, in accordance with the second subparagraph of Article 13(1) of that regulation, it is compulsory for that assessment to be submitted to EFSA and the applicant and for it to be the subject of public consultation, followed by the adoption of EFSA's conclusions, unless the Commission decides to inform EFSA that such conclusions are not necessary.

In the present case, the designation of the new RMS for the assessment of mancozeb and its assessment of that substance were made after the completion of the mancozeb risk assessment process by the initial RMS and EFSA. Accordingly, the applicants had already had the opportunity to submit comments.

It is true that, in updating its draft renewal assessment report ('the draft RAR') of September 2020, the new RMS found that it was, under certain conditions, possible to identify a use that was safe for human health in relation to non-dietary exposure to mancozeb. However, the new RMS's assessment led to the same conclusion as that of the initial RMS, namely that mancozeb did not

[2] 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 contested implementing regulation').

[3] 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 (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ 2012 L 252, p. 26).

[4] The procedure laid down in Articles 12 and 13 of Implementing Regulation No 844/2012.

satisfy the conditions for approval laid down in Article 4 of Regulation No 1107/2009.[5] Furthermore, the new RMS's conclusions are not substantively different from EFSA's conclusions as regards the concerns identified. It follows that the concerns identified by the new RMS had already been assessed by the initial RMS and EFSA.

In addition, the Court rejects the applicants' argument that, given the new RMS's conclusions as to the existence of a safe use for human health, they could apply for application of the derogation provided for in Article 4(7) of Regulation No 1107/2009. It observes that that derogation is not applied at the scientific assessment stage, but at the risk management stage. In that regard, the Court notes, as is apparent from recital 12 of Regulation No 1107/2009, that it is the Commission which assumes the risk management role and takes the final decision concerning an active substance.

Therefore, in the circumstances of the present case, and having regard to the broad discretion conferred on the Commission by Regulation No 1107/2009 to adopt appropriate protection measures at the stage of managing risks initially identified during the scientific evaluation, 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 particular aspect.

In addition, the Court notes that Article 12(3) of Implementing Regulation No 844/2012 does not require EFSA's conclusions to be the subject of public consultation.

Lastly, given that the Commission sent the applicants and the Standing Committee on Plants, Animals, Food and Feed the updated version of its draft renewal report following the submission by the new RMS of the updated version of the draft RAR, it cannot be maintained that the Commission adopted its renewal report before the new RMS completed its own risk assessment.

In the second place, the Court considers that the Commission made no manifest error of assessment in the mancozeb renewal procedure.

First, the Commission was entitled to take into consideration, for the purposes of the procedure for the renewal of mancozeb, the opinion of the Risk Assessment Committee ('RAC') of the European Chemicals Agency ('ECHA'), which is based on EFSA's finding on that substance being classified as toxic for reproduction category 1B, despite the fact that it is not legally binding for the purposes of the procedure for harmonising classification and labelling provided for in Regulation No 1272/2008.[6] The fact that that opinion, adopted in the context of the harmonised classification and labelling procedure for mancozeb, is not legally binding does not diminish its scientific value. Furthermore, the existence of a formal classification of an active substance is not decisive for the purposes of its approval under Regulation No 1107/2009.

Second, unless otherwise specified, the decisions which the Commission takes in the context of Regulation No 1107/2009 must always take account of the latest scientific and technical knowledge.

[5] 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).

[6] 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 Court finds that the Commission could regard the RAC's opinion as a document showing the most recent scientific knowledge concerning the classification of mancozeb as a toxic substance. That opinion had been adopted on a proposal from the initial RMS and before EFSA's conclusions were adopted in the procedure for the renewal of that substance, namely when the scientific assessment of mancozeb was under way in that procedure.

As regards the complaint alleging that the RAC's opinion is based on an old study, the Court finds that the applicants may not rely on an alleged material infringement occurring in the context of the procedure for the harmonisation of the classification and labelling of substances in accordance with Regulation No 1272/2008 in order to call into question the lawfulness of the contested implementing regulation. It was under Regulation No 1272/2008, and not under Regulation No 1107/2009, that the RAC adopted its opinion on the classification of mancozeb as a toxic substance for reproduction category 1B.

As regards the Republic of Malta's notification of its intention to submit a new classification dossier for that substance to ECHA in the procedure for the harmonisation of the classification and labelling of substances in accordance with Regulation No 1272/2008, confirming the classification of mancozeb as a toxic substance for reproduction category 2, the Court notes that, on the date of adoption of the contested implementing regulation, that proposal by the Republic of Malta had not yet been assessed from a scientific point of view.

Third, in the absence of any well-founded arguments formulated by the applicants, the Court rejects the complaint alleging that the RAC's opinion accorded undue influence to the metabolite ETU rather than to the substance itself.