REGULATION No 1107/2009

DECISION TO WITHDRAW APPROVAL OF THE ACTIVE SUBSTANCE MANCOZEB IN GB

DRAFT

Issue

This report sets out the decision to withdraw approval of the active substance mancozeb in Great Britain (GB). It explains the process for reviewing the approval and the reasons for the decision. It summarises the information relevant to the decision and the grace periods that apply.

Background

Mancozeb is a fungicidal active substance used in plant protection products, which are regulated under retained Regulation (EC) No 1107/2009 ("the Regulation"). The Regulation requires that active substances must be approved for such use. Approval is given if, in the light of current scientific and technical knowledge, authorisation of a plant protection product is expected to be possible for at least one representative use.

Regulatory process

On 14 December 2020 the European Commission decided not to renew the approval of mancozeb in the European Union (EU) and Northern Ireland. Although this decision had no legal effect in GB, the approval criteria in GB are the same as in the EU. In the light of new scientific and technical knowledge, HSE considered that this decision indicated that mancozeb may no longer satisfy the criteria for approval in the Regulation. Therefore, on 23 July 2021 HSE proposed a review of the GB approval of mancozeb under Article 21(1) of the Regulation. The proposed review would examine the endocrine disrupting potential of mancozeb and the non-dietary risks to human health (ie Annex II, paragraph 3.6.5 and Art. 4(3)(b) of the Regulation). In accordance with the agency agreements which delegate work under the Regulation to HSE, the GB competent authorities gave their consent to this review in July 2021.

At the time of the initiation of the review, four companies held authorisations for mancozeb-containing products in the UK and were considered producers. These were UPL Europe Ltd, Indofil Industries (Netherlands) BV (together, UPL and Indofil form the EU Mancozeb Task Force (EU MTF)), Agria SA, and Corteva Agriscience UK Limited. On 2 September 2021, HSE informed these producers of the initiation of the review and the reasons for it. They were given one month to submit comments for consideration as part of the review. A summary of the comments/responses received are included in Annex I of this document. Note that

BASF was a major producer, but chose to withdraw production, and consequently the GB products, shortly after the EU non-renewal decision.

Following the submission of comments, HSE undertook an independent, objective, assessment of mancozeb in light of current scientific and technical knowledge. This included a review of the scientific evidence that supported the EU non-renewal decision and the comments received from the producers. HSE concluded that mancozeb failed to meet the approval criteria and so approval should be withdrawn in GB. A summary of HSE's scientific review is at Annex II.

HSE concluded that the failure to meet approval criteria as regards endocrine disrupting potential and non-dietary risks to human health was sufficiently clear cut that it was unnecessary to obtain independent scientific advice. Moreover, a detailed assessment of any further criteria was unnecessary given the concerns identified.

In accordance with the agency agreements, HSE notified the GB competent authorities of its decision that approval of mancozeb should be withdrawn, the reasons for that decision, and the details of the grace period it proposed to set. GB Administrations gave their consent to HSE carrying out the decision-making function in this case and HSE notified the producers of the decision, the reasons for it and the grace period set on [dd mm yyyy].

Decision

HSE has decided that approval of mancozeb for use in plant protection products should be withdrawn in GB.

The decision reflects the overall conclusion from the assessment and consideration of the scope to manage the risks arising from use of plant protection products containing this active substance.

Consequently, plant protection products containing mancozeb can no longer be authorised in in GB and existing authorisations must be withdrawn in accordance with the requirements of the Regulation.

Statement of reasons

The reasons for the decision to withdraw mancozeb in GB are that:

- it meets the criteria to be classified as having endocrine disrupting properties for humans and non-target organisms according to the T (thyroid) modality;
- non-dietary exposure exceeds the reference Acceptable Operator Exposure Level / Acute Acceptable Operator Exposure Level (AOEL/AAOEL).

Grace period

In accordance with Art. 21(7) of the Regulation, authorisations of existing products should be phased out so that:

- advertisement, sale and supply of each product are allowed until dd mm yyyy;
- storage, disposal and use are allowed until dd mm yyyy.

Further information

The GB Approvals register will be updated to reflect this decision.

[date]

Annex I – List of information submitted in response to GB Article 21 review, with brief HSE action

Commenting company	Date	Comments received
EU Mancozeb Task Force (UPL Europe Ltd and Indofil Industries (Netherlands) BV):	29 September 2021	Reference made to the supplementary dossier submitted to GB in support of the renewal of mancozeb with particular attention drawn to the sections on ED and non-dietary human health. This information has been taken into account in the GB assessment.
Fieldfisher on behalf of Agria SA	30 September 2021	Reference made to the additional information provided by Agria in their submission that was considered by Greece as part of a consideration for an updated Renewal Assessment Report (RAR). Particular attention was drawn to the ED aspects, Toxicological Reference Values and non-dietary exposure, the risk to birds and mammals, and the risk to non-target arthropods and soil macro-organisms. As detailed in Annex II, Greece would not share this assessment with GB and neither Fieldfisher or Agria responded to requests for further detail relating to this information. Where possible the detail provided by Fieldfisher in their original comment was taken into account as part of the GB assessment.
Corteva Agriscience UK Limited	20 September 2021	Review was acknowledged but no technical comments supplied

Annex II – Summary Assessment by HSE Supporting the Recommendation

The HSE review took account of the information that supported the EU decision to non-renew approval of mancozeb. As requested in the comments from the EU MTF, HSE also considered the information that was provided in support of the application for the renewal in GB of mancozeb under Article 14 of the Regulation. As requested in the comments from FieldFisher on behalf of Agria SA, HSE contacted the Greek authority to request a copy of their assessment. After consulting with the EU Commission, the Greek authority advised that they would not provide HSE with the document. In response, HSE sent a number of requests to FieldFisher and Agria SA asking that they provide the assessment direct to HSE, otherwise it would not be considered in the review. HSE did not receive a response. The further comments from FieldFisher on behalf of Agria SA were taken into account.

Toxicology (Human Health)

Two critical areas of concern were identified in the EFSA Conclusion for mancozeb:

- Classification as toxic for reproduction category 1B (Repr.1B) under Regulation 1272/2008 (RAC Opinion, 2019);
- Meeting the criteria to be classified as having endocrine disrupting properties for humans according to the T (thyroid) modality.

These are two hazard-based cut-off criteria for approval. Negligible exposure could not be demonstrated as the non-dietary exposure exceeded the reference values. In addition, due to the other safety concerns identified, a derogation under Art 4(7) of 1107/2009 was not applicable.

With regard to classification as Repr 1B, HSE Toxicology has considered the RAC Opinion and developed its own GB-specific position which is documented in a Technical Report published on HSE website. In this report, HSE disagrees with RAC and concludes that Repr.2 is the most appropriate classification for mancozeb based on the available evidence. Classification as Repr.2 is not an exclusion criterion for approval/renewal.

With regard to mancozeb meeting the criteria for being a thyroid endocrine disruptor (ED) for humans, HSE's toxicology assessment reaches the same conclusion as in the EU assessment (whose own conclusion was originally proposed by the UK when acting as rapporteur Member State for the renewal of mancozeb in the EU). Mancozeb is a potent ED, with effects occurring in experimental animals from approx. 6 mg/kg bw/d.

Overall, having carefully considered the information that was considered as part of the EU evaluation of the toxicology of mancozeb and taking account of the comments received under this review, HSE has concluded that the ED exclusion criterion of the Regulation has been met and that regulatory action is warranted.

Non-dietary Exposure

The EU Renewal was supported by three representative products:

- Penncozeb 80 WP (also supported in the application submitted for GB renewal of approval)
- Dithane M-45 (also supported in the application submitted for GB renewal of approval)
- Mancozeb 800 WP

All three products are wettable powders (WP) containing 805 g/kg, 800 g/kg and 805 g/kg mancozeb, respectively. The representative uses evaluated for Penncozeb 80 WP and Dithane M-45 were as a fungicide applied as a foliar spray on wheat, potato and grapes, with the same application rates and timings for both products. The representative uses for 'Mancozeb 800 WP' was as a fungicide applied to protected tomatoes grown in greenhouses. HSE has considered the information supporting the EU decision as well as looking at the information provided in support of the GB renewal application as part of this review.

The HSE assessment reaches the same conclusion as the EU evaluation in which the acceptable operator exposure level (AOEL) for mancozeb was as set at 0.011 mg/kg bw/day, with an acute acceptable operator exposure level (AAOEL) of 0.075 mg/kg bw/day. Exposure was also assessed for ethylene thiourea (ETU), a major metabolite of mancozeb which is formed when a formulation of mancozeb is dissolved in solution (i.e. ETU is present in the in-use concentration of the spray solution). The AOEL of ETU was set at 0.002 mg/kg bw/day and the AAOEL at 0.01 mg/kg bw/day. Dermal absorption values for the 3 representative formulations were 0.7% for the concentrate products and 1% for the spray dilutions.

For application of Penncozeb 80 WP/Dithane M-45 to wheat, unacceptable exposure above the AOEL/AAOEL for mancozeb was estimated for operators with the use of PPE, and also for residents. Combined exposure for mancozeb and ETU was estimated to be above acceptable levels for operators and residents.

For application of Penncozeb 80 WP/Dithane M-45 to potatoes, unacceptable exposure above the AOEL/AAOEL for mancozeb was estimated for operators with the use of PPE, and also for residents. Combined exposure for mancozeb and ETU was estimated to be above acceptable levels for operators, residents and workers.

For application of Penncozeb 80 WP/Dithane M-45 to grapes, unacceptable exposure above the AOEL/AAOEL for mancozeb was estimated for operators with the use of PPE and a closed cabin tractor, and also for residents. Combined exposure for mancozeb and ETU was estimated to be above acceptable levels for operators and residents.

For application of Mancozeb 800 WP to protected tomatoes, unacceptable exposure above the AOEL for mancozeb was estimated for workers with the use of gloves. No data were provided to determine the level of ETU in the spray solution for Mancozeb 800 WP; therefore, it was not possible to conduct a non-dietary exposure

assessment for ETU or a combined exposure assessment of mancozeb and ETU for the proposed use of Mancozeb 800 WP on protected tomatoes. This was reported as a data gap in the EFSA Conclusion and the issue not finalised.

HSE's assessment reaches the same conclusion as the EU exposure assessment conducted for the three representative products. Exposure estimates for mancozeb and combined exposure for mancozeb and ETU have not been demonstrated at acceptable levels below the reference values for all exposed groups (operators, residents, bystanders and workers).

In addition, two hazard-based cut-off criteria for approval were identified as critical areas of concern. Negligible exposure could not be demonstrated as non-dietary exposure exceeds the reference values for the representative uses. Therefore, based on the representative products and uses, HSE concludes that the requirements for this area of the risk assessment are not met and regulatory action is warranted.