

Report of the Chemical Review Committee on the work of its fourth meeting

Annex II

Rationales for those chemicals for which only one notification met the criteria of Annex II

Carbaryl

Rationale for the conclusion by the Committee that the notification for carbaryl (CAS No. 63-25-2) submitted by the European Community meets the criteria of Annex II of the Convention

1. In reviewing the notification of final regulatory action by the European Community to ban carbaryl as a pesticide, and the supporting documentation, the Committee at its fourth meeting confirmed that the action had been taken in order to protect human health and the environment. The notification and supporting documentation identified carbaryl as a carcinogen Category 3¹ (R40–limited evidence of carcinogenic effect) and as harmful by inhalation and if swallowed. Additionally, it is very toxic to the aquatic environment, mammals and birds.
2. Carbaryl was authorized for use as an agricultural pesticide in some Member States of the European Community for many years. Carbaryl belongs to a class of carbamate insecticides and acaricides. It is a red blood cell cholinesterase inhibitor. Carbaryl has also been used as a plant growth regulator in orchards (e.g. apple trees) for the purpose of fruit thinning.
3. The review of the data submitted for carbaryl by the European Community resulted in the following main conclusions:
 - (a) Carbaryl is a carcinogen Category 3[†] (R40–limited evidence of a carcinogenic effect) and it is harmful by inhalation as well as if swallowed;
 - (b) A robust risk assessment for the safety of consumers was not possible due to the lack of information on the actual levels of two metabolites of carbaryl (4- and 5-hydroxy carbaryl) in apples. Considering that the exposure to the parent compound alone is close to 50% of the Acute Reference Dose (ARfD) for some specific population sub-groups, it cannot be excluded that the contribution of the metabolites leads to a global exceedance of the ARfD for those sub-groups;
 - (c) Concerns were identified with regard to:
 - (i) A high long-term risk to insectivorous birds and a high acute risk to herbivorous mammals;
 - (ii) A high risk to non-target arthropods (particularly insects) which requires considerable risk mitigation measures, e.g. no-spray buffer zones of more than 250 m would be required to protect non-target arthropods in the off-field area;

¹ Classification in the European Community in accordance with Council Directive 67/548/EEC.

- (iii) A high acute and chronic risk to aquatic invertebrates which requires considerable risk mitigation measures (with a 50 m buffer zone, the risk is still not acceptable).

4. The risk evaluations performed by the European Community included an assessment of the hazards (carcinogenicity, harmful by inhalation as well as if swallowed, very toxic for the aquatic environment) and the exposure (for humans, primarily exposure of consumers, and for the environment, in particular exposure of the terrestrial and aquatic compartments), and therefore meet the criteria for a risk evaluation.

5. The Committee established that the final regulatory action had been taken on the basis of a risk evaluation and that the evaluation had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods and that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures. It also showed that the final regulatory action had been based on a chemical-specific risk evaluation involving prevailing conditions of exposure within the European Community.

6. The Committee noted that as the regulatory action in the European Community was a ban of all uses, the risks to human health and the environment from carbaryl in the notifying Party had been eliminated.

7. There was no indication that there were industrial uses of carbaryl in the European Community. The Committee also noted that the considerations underlying the final regulatory action were not of limited applicability because it could be expected that the identified risks arising from the use of carbaryl were also relevant for other countries, particularly developing countries. On the basis of information provided to the members at the fourth meeting of the Chemical Review Committee there was evidence of ongoing international trade in carbaryl.

8. The Committee noted that the final regulatory action had not been based on concerns about intentional misuse of carbaryl.

9. The Committee concluded at its fourth meeting that the notification of final regulatory action by the European Community met the information requirements of Annex I and the criteria set out in Annex II to the Convention.