

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

Annex III

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

B. Cyhexatin: rationale for the conclusion by the Committee that notification for Cyhexatin (CAS No. 13121-70-5) from Canada meets the criteria of Annex II of the Rotterdam Convention

1. In reviewing the notification of final regulatory action by Canada, together with the supporting documentary information provided by the Party, the Committee was able to confirm that the action had been taken in order to protect human health.

2. Cyhexatin was found to be teratogenic in rats and rabbits at low doses according to the information available to Canada at the time. It is used in orchards and greenhouses to control mites on apples, pears, peaches, nectarines, strawberries, hops, non-bearing raspberries and ornamental plants. Exposure occurs to workers in treated orchards or fields.

3. 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 upon estimated exposure of farm workers under different use scenarios.

4. A review of teratology studies in rats and rabbits at the time indicated cyhexatin to be teratogenic; margins of safety were considered to be low even in cases where rubber suits and gloves had been used.

5. The Committee concluded that the final regulatory action taken by Canada on the basis of the available supporting documentation at the time provided a sufficiently broad basis to merit including cyhexatin in Annex III of the Rotterdam Convention in the pesticide category. The Committee noted, however, the age of the decision and that subsequently new internationally peer-reviewed information had become available that called into question the basis for the regulatory action.

6. It noted that the action had led to a decrease in the quantities of the chemicals used in the notifying Party. All uses had been banned in Canada and therefore continued exposure did not occur in Canada. Accordingly, the risk for human health in the notifying Party had been significantly reduced.

7. There was no indication that there were any industrial uses of cyhexatin in Canada. The Committee also took into account that the considerations underlying the final regulatory action were not of limited applicability since all uses had been banned. On the basis of information provided to the members at the second session of the Chemical Review Committee and other available information, the Committee concluded also that there was evidence of ongoing international trade in cyhexatin.

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

9. At its second meeting, the Committee concluded that the notification of final regulatory action by Canada met the information requirements of Annex I and the criteria set out in Annex II to the Convention. Because new internationally peer-reviewed information had subsequently become available, showing that teratogenicity was not of concern for cyhexatin, the Committee considered that that fact should be taken into account before any recommendation for inclusion of the substance into Annex III of the Convention would be made in the future.