

## **Report of the Chemical Review Committee on the work of its first meeting**

### **Annex V**

#### **Rationales for conclusions by the Committee that notifications had met the criteria of the Annex II of the Rotterdam Convention**

##### **C. Notification for benzidine (CAS No 92-87-5) and benzidine dihydrochloride (CAS No. 531 85-1) from Canada**

15. In reviewing the notification of final regulatory action by Canada to severely restrict benzidine and benzidine dihydrochloride, 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. Canada had concluded that benzidine was a non-threshold carcinogen in humans. Benzidine dihydrochloride was also addressed because it dissociates in water into benzidine.

16. Generally speaking, benzidine is used as an intermediate in the manufacture of dyes and pigments, in very limited specialty laboratory applications, and for research and development purposes. Because benzidine is a non-threshold toxicant, it is understood that there is some probability of adverse effect at any level of exposure.

17. Data used in the Canadian risk evaluation had been identified through the evaluation of existing review documents (United States Agency for Toxic Substances and Disease Registry, United States Environmental Protection Agency and the International Agency for Research on Cancer), as well as information from published reference texts and literature identified through on-line searches of various databases (Hazardous Substances Data Bank, Registry of Toxic Effects of Chemical Substances, Integrated Risk Information System, etc.). All original studies used in the risk evaluation had been critically evaluated by Canada. Although levels at the time of the regulatory action did not pose a threat to human health, the regulatory action was put in place as a precautionary measure to protect the health of Canadians. This approach is consistent with the objective that exposure to non-threshold carcinogens should be reduced wherever possible, and obviates the need to establish an arbitrary de minimis level of risk.

18. Based on this, the Committee established that the final regulatory action had been taken on the basis of 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 chemical-specific risk evaluations taking into account the conditions of exposure within Canada.

19. The Committee concluded that the final regulatory action provided a sufficiently broad basis to merit including benzidine and benzidine dihydrochloride in

Annex III of the Rotterdam Convention in the industrial category. Given that preventive action precludes future exposure, the Committee noted that the action would lead to a decrease in the quantities of the chemicals potentially used in the notifying Party. Hence, potential use and the risk for human health in the notifying Party had been significantly reduced.

20. Use of benzidine and benzidine dihydrochloride is severely restricted in Canada, and allowed only in very limited specialty laboratory applications, and for research and development purposes. There was no indication of any pesticide uses for benzidine. The Committee also took into account that the considerations underlying the final regulatory action were not of limited applicability since benzidine is a non-threshold carcinogen and conditions of exposure can apply to most countries. On the basis of information provided to the members at the first session of the Chemical Review Committee and other available information, the Committee concluded also that there was evidence of ongoing international trade in benzidine.

21. The Committee noted that the final regulatory action was not based on concerns about intentional misuse of benzidine.

22. At its first session, 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.