

Annex I

Rationales, recommendations and work-plans for chemicals for which two notifications met the criteria of Annex II

A. Alachlor

1. Rationale for the recommendation by the Chemical Review Committee that alachlor (CAS No 15972-60-8) should become subject to the prior informed consent procedure and for the decision by the Committee to establish an intersessional drafting group to prepare a draft decision guidance document

1. In reviewing the notification of final regulatory action by the European Community to ban alachlor as a pesticide and the supporting documentation, the Chemical Review Committee concluded at its fourth session that the regulatory action had been taken in order to protect human health and the environment. The notification and supporting documentation identified alachlor as an animal carcinogen and possible human carcinogen, and as very toxic for aquatic organisms* and able to cause long-term adverse effects in the aquatic environment.

2. Alachlor was used in the European Community as a herbicide for control of annual grasses and small weed broadleaf species in maize, sweet corns, soybean, sunflower, and cotton.

3. Exposure occurs to workers during application of pesticides containing alachlor, the environment is exposed during and after application. The review of the data submitted for alachlor concluded that exposure of operators, workers and bystanders had not been sufficiently addressed with the available information. Alachlor has been classified as carcinogenic category 3¹ (R40—limited evidence of carcinogenic effect). Though extremely unlikely, it cannot be concluded that nasal tumors discovered in animals are not relevant to humans. The calculations based on the UK and German operator exposure assessment models that are used during reviews in the European Community gave values higher than the agreed acceptable operator exposure level (AOEL) for all uses, even when adequate Personal Protective Equipment (PPE) is worn during mixing, loading and application. Therefore, these calculations indicate an unacceptable risk to the operator for all uses of alachlor for which data were submitted.

4. Some areas of concern have been identified for the environmental fate and behaviour of alachlor, in particular with the formation of a large variety of degradation products, some of which being of toxicological and/or ecotoxicological concern. Metabolites have been found in groundwater at concentrations higher than levels deemed acceptable in the European Community. The assessment of those soil metabolites showed no evidence of toxicity for some of them. However, the toxicity and genotoxicity of others could not be adequately tested, due to inadequate databases, meaning that uncertainty remains as to the danger of these metabolites. Alachlor has been proved to be very toxic for aquatic organisms, and may cause long-term adverse effects in the aquatic environment. Predicted Environmental Concentration (PEC) values for various exposure scenarios for crop use in Europe (different applications rates and buffer zones and run-off) were such that the Toxicity Exposure Ratios (TER) indicated a potential long-term risk to terrestrial vertebrates (large birds eating grass, mammals) and risks to fish, daphnia, algae and aquatic plants (acute or long-term).

5. The risk evaluations performed by the European Community included an assessment of the hazards (carcinogenicity, toxic for aquatic organisms) and the exposure (for human health, primarily occupational exposure, namely, exposure of applicators, for the environment, exposure of the aquatic and terrestrial compartments - including also monitoring data), and therefore meet the criteria for a risk evaluation.

6. 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

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

regulatory action had been based on a chemical-specific risk evaluation, involving prevailing conditions of exposure within the European Community.

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

8. There was no indication that there were any industrial uses of alachlor in the European Community. The Committee also noted that the considerations underlying the final regulatory action were not of limited applicability since similar concerns as identified in the European Community could occur in other countries, in particular also developing countries. On the basis of information provided to the Committee there was evidence of ongoing international trade in alachlor.

9. The Committee noted that the final regulatory action in the European Community was not based on concerns about intentional misuse of alachlor.

10. The Committee concluded 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.

11. Given that another notification of a final regulatory action from a Party (Canada) in another PIC Region (North America) had already been found to meet the criteria in Annex II at CRC.2 (as set out in the rationale in document UNEP/FAO/RC/CRC.4/8/Add.1), the Committee concluded also that the final regulatory actions taken by Canada and the European Community provided a sufficiently broad basis to merit including alachlor in Annex III of the Rotterdam Convention in the pesticide category.

2. Recommendation to the Conference of the Parties on the inclusion of Alachlor in Annex III of the Rotterdam Convention

The Chemical Review Committee,

Recalling Article 5 of the Rotterdam Convention,

Concluding that the notifications of final regulatory actions relating to alachlor by Canada and the European Community meet the criteria set forth in Annex II to the Convention,

Decides, in accordance with paragraph 6 of Article 5 of the Convention, to recommend to the Conference of the Parties that it should include alachlor (CAS No. 15972-60-8) in Annex III of the Convention as a pesticide.