Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Chemical Review Committee
Eighth meeting
Geneva, 19-23 March 2012

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

Annex II

Rationales and workplans for dicofol and trichlorfon

II. Trichlorfon

A. Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by Brazil and the European Community meet the criteria of Annex II to the Rotterdam Convention

In reviewing the notifications of final regulatory action by the European Community[1] and Brazil to ban trichlorfon as a pesticide together with the supporting documentation provided by those parties, the Committee was able to confirm that those actions had been taken to protect human health and, in the case of the European Community, the environment. The notifications from those parties were found to meet the information requirements of Annex I to the Rotterdam Convention.

The notifications and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.8/5, UNEP/FAO/RC/CRC.8/5/Add.1 and UNEP/FAO/RC/CRC.8/5/Add.2. Information on ongoing international trade was provided by the European Union and CropLife in the beginning of 2012 and made available in document UNEP/FAO/RC/CRC.8/INF/4/Rev.1.

1. European Community

(a) Scope of the notified regulatory action

The final regulatory action to ban the use of trichlorfon was taken for the category "pesticide" to protect human health and the environment. Complete entry into force of the final regulatory action (Commission Decision 2007/356/EC dated 21 May 2007) was 21 November 2008 since all uses of plant protection products containing trichlorfon were

1 The notification regarding a final regulatory action relating to trichlorfon was submitted by the European Community on 6 October 2009, thus before the entry into force of the Lisbon Treaty in December that same year. As indicated by the Depositary of the Convention in a notification dated 31 March 2010 (reference: C.N.182.2010.TREATIES-2), which was based on a communication from the Council of the European Union dated 8 March 2010, following the entry into force of the Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, with effect from 1 December 2009 the European Union replaced the European Community (Article 1, third paragraph, of the Treaty of Lisbon) and took over all rights and obligations of the European Community. The former European Community has accordingly been replaced by the European Union in respect of all conventions or agreements for which the Secretary-General of the United Nations is the depositary and to which the European Community is a signatory or a contracting party.

prohibited as from that date. Authorizations for plant protection products containing trichlorfon had to be withdrawn by 21 November 2007 by European Community member States. As of 25 May 2007, no authorizations for plant protection products containing trichlorfon were allowed to be granted or renewed by member States.

(b) Annex II paragraph (a) criterion

Confirm that the final regulatory action has been taken in order to protect human health or the environment.

The Committee confirmed that the final regulatory action had been taken to protect human health and the environment.

Regarding the risks for human health, the review of trichlorfon as an active substance in plant protection products resulted in the conclusion that the exposure estimates for operators, workers and bystanders were much higher than the provisional acceptable operator exposure level (AOEL). Regarding the environment, a high risk for aquatic invertebrates was identified.

(c) Annex II paragraph (b) criteria

Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(*ii*) *Data reviews have been performed and documented according to generally recognized scientific principles and procedures;*

Data on hazards and exposure used for the risk evaluation of trichlorfon were generated according to scientifically recognized methods as specified in annexes II and III to Directive 91/414/EEC. Scientific data on the technical active substance and at least one representative formulation had to be submitted by the applicant for registration. This data package consisted of a wide range of information concerning identity, physical, chemical and technical properties, methods of analysis, mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology. The data was reviewed by the rapporteur member State (RMS), and summarized in a draft assessment report (DAR).

The European Food Safety Authority (EFSA) initiated a peer review by the member States. Subsequently, the comments received on the DAR were examined by the RMS and the need for additional data was agreed upon in an evaluation meeting. Remaining issues as well as further data made available by the applicant were evaluated in a series of scientific meetings with experts from the member States.

A final discussion on the outcome of the DAR consultation took place with representatives from the member States. This discussion led to the EFSA conclusions, which are part of the Commission review report for trichlorfon. That report is the basis for the final regulatory action (Directive 2007/356/EC concerning the non-inclusion of trichlorfon in Annex I to Directive 91/414/EEC).

Thus, the Committee established that data were generated according to scientifically recognized methods and also that the data reviews were performed according to generally recognized scientific principles and procedures.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.

The risk evaluation took into account the proposed conditions of use within the European Union, including the intended uses, the recommended application rates and good agricultural practices. The conclusion of EFSA was reached on the basis of the evaluation of the representative use in the European Union.

Final conclusions regarding a number of aspects of the evaluation process were not possible due to a lack of reliable data. However, assessments made by the RMS and during EFSA expert meetings on the basis of the available information demonstrated that the concerns for human health and the environment described in the following paragraphs were likely to occur under the proposed conditions of use in the European Union.

Trichlorfon is harmful during oral exposure and is a skin sensitizer. The proposed classification was Xn; R22 “Harmful if swallowed” and Xi; R43 “May cause sensitization by skin contact”. The most sensitive effect observed during short-term exposure was reduction in acetylcholinesterase activity.

Taking into account the physical and chemical properties of trichlorfon, experts considered the default dermal absorption value of 100% to be appropriate for the risk evaluation. Based on the provisional AOEL provided by the RMS in the DAR, together with the dermal absorption value of 100%, exposure models led to the conclusion that the operator, worker and bystander exposure estimates exceeded the AOEL to a large extent. The models took into account in their input parameters the conditions prevailing in the European Union (e.g., maximum applied dose, mode of application).

Furthermore, trichlorfon is metabolized into dichlorvos, which is also an impurity of toxicological concern in trichlorfon. Dichlorvos was identified as a carcinogen category 2 by IARC in 2004. The potential evaporation of dichlorvos from plants to which it is applied was shown to be more than 30% of the applied trichlorfon. This could be relevant for worker exposure by inhalation.

As a result of the evaluation on fate and behaviour of trichlorfon, surface water contamination from glasshouse use could not be excluded. For this reason, an evaluation of the risks to aquatic organisms was considered necessary. It was agreed at the EFSA expert meetings that Daphnia magna was the most sensitive species by more than one order of magnitude. Based on the existing study with Daphnia magna, a high risk for aquatic invertebrates was identified.

Based on the risks to human health and the environment that were identified during the review based on the available data, the Committee established that a risk evaluation involving prevailing conditions in the European Union had been the basis for the final regulatory action.

(d) Annex II paragraph (c) criteria

Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

By prohibiting all placing on the market and use of trichlorfon in plant protection products, the regulatory action will lead to a significant decrease in the use of trichlorfon as a pesticide in the European Union.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

Since the final regulatory action is expected to lead to a significant decrease in the quantity of trichlorfon used, the risks for human health and the environment associated with its use would be expected to decrease significantly.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

Similar health and environmental problems are likely to be encountered in other countries where trichlorfon is used, particularly in developing countries where its use is not limited to tomatoes in greenhouses.

(iv) Whether there is evidence of ongoing international trade in the chemical.

According to the information available to the Committee, there is evidence of ongoing international trade.

(e) Annex II paragraph (d) criterion

Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

There is no indication in the notification or supporting documentation that concerns for intentional misuse prompted the final regulatory action.

2. Brazil

(a) Scope of the notified regulatory action

The final regulatory action relates to trichlorfon and its use as an agricultural pesticide, which was registered for use in aerial parts of a large number of vegetable and field crops.

The final regulatory action (Resolution-RDC No. 37 of 16 August 2010: technical regulation on the active ingredient trichlorfon as a result of a toxicological re-evaluation) was based on the results of a toxicological re-evaluation and resulted in a ban of all uses of trichlorfon-based products for plant protection. The decision was based on the Technical Note of Toxicological Reassessment on Trichlorfon commissioned by the National Health Surveillance Agency (ANVISA). The decision entered into force on 18 August 2010 and prevents future registrations of this pesticide.

(b) Annex II paragraph (a) criterion

Confirm that the final regulatory action has been taken in order to protect human health or the environment.

The final regulatory action was taken to protect human health.

In 2008, a re-evaluation of trichlorfon was initiated because there were concerns about possible risks for human health and the environment.

The environmental part of the re-evaluation could not be completed by the Brazilian Institute of Environmental and Renewable Natural Resources (IBAMA) because no data had been provided to allow a conclusion on environmental risks. The Ministry of Agriculture, Livestock and Food Supply (MAPA) thus announced by an administrative act in February 2010 that the registrations of the three trichlorfon-based pesticides were cancelled, because without a valid environmental evaluation as a necessary element of the registration, the registrations could not be maintained. However, only upon completion of the toxicological assessment could the re-evaluation (which identified concerns for human health) be concluded. As a consequence, ANVISA finally cancelled the trichlorfon monograph and banned the import of trichlorfon by Resolution RDC 37/2010 of 16 August 2010. Only this final regulatory action established the definitive prohibition of the registration of pesticides containing trichlorfon.

The final regulatory action was based on the results of the toxicological review of trichlorfon, which describes this pesticide as causing acute neurotoxic, genotoxic, immunotoxic, carcinogenic and teratogenic effects. In addition, trichlorfon affects reproduction and the endocrine system. Studies on poisoning incidents in Brazil were reviewed. Pesticides in general and especially organophosphorous pesticides (the group to which trichlorfon belongs) had been involved in the poisoning incidents. Information on the

use of pesticides (including trichlorfon) by farmers in the Amazon region of Brazil not following recommended practices was also taken into account.

The Committee thus confirmed that the final regulatory action had been taken to protect human health.

(c) Annex II paragraph (b) criteria

Establish that the final regulatory action has been taken as a consequence of a risk evaluation. This evaluation shall be based on a review of scientific data in the context of the conditions prevailing in the Party in question. For this purpose, the documentation provided shall demonstrate that:

(i) Data have been generated according to scientifically recognized methods;

(ii) Data reviews have been performed and documented according to generally recognized scientific principles and procedures;

As a basis for the toxicological re-evaluation around 300 references were reviewed, most of them from international, peer-reviewed sources. The Committee established that the data had been generated according to scientifically recognized methods.

The Committee also established that the review of the data had been documented in the "Technical Note of the Toxicological Reassessment on Trichlorfon" according to generally recognized scientific principles and procedures.

(iii) The final regulatory action was based on a risk evaluation involving prevailing conditions within the Party taking the action.

The Technical Note cites several studies that have shown that pesticide poisonings, especially with organophosphorous pesticides, occurred in different regions of Brazil. In addition, it indicates that many poisoning incidents were not reported in Brazil. According to a study from the Amazon area of Brazil, agricultural workers were not prepared to use pesticides (including trichlorfon) correctly. They were not sufficiently aware of the risks of pesticides to human health and the environment. The study further concludes that farmers did not use protective clothing or equipment because it was expensive and not suitable for a tropical climate. Owing to a lack of training and poor knowledge of pesticide hazards, pesticides were handled carelessly during preparation and application and disposal of empty packages. Exposure of farmers, their families, consumers (via residues in food) and the environment was thus high.

Although no poisoning incidents with trichlorfon itself have been reported from Brazil, the decision to ban trichlorfon was taken on the basis of the evaluation of its hazardous properties as well as on expected exposure of agricultural workers to pesticides in general, including trichlorfon, under conditions of use in Brazil.

The Committee established that the final regulatory action was based on a risk evaluation, which was based on a review of scientific data, taking into account the conditions of use prevailing in Brazil.

(d) Annex II paragraph (c) criteria

Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III, by taking into account:

(i) Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses;

The final regulatory action prohibits all uses of trichlorfon as a pesticide, including its production, trade and import. It also definitely prevents future registration of all technical products and pesticide formulations based on trichlorfon as an active ingredient. This will therefore lead to a significant decrease in the use of trichlorfon.

(ii) Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification;

Since the final regulatory action is expected to lead to a significant decrease in the quantity of trichlorfon used, the risks for human health associated with its use would be expected to decrease significantly.

(iii) Whether the considerations that led to the final regulatory action being taken are applicable only in a limited geographical area or in other limited circumstances;

Similar health problems are likely to be encountered in other countries where trichlorfon is used, particularly in developing countries.

(iv) Whether there is evidence of ongoing international trade in the chemical.

According to the information available to the Committee, there is evidence of ongoing international trade.

(e) Annex II paragraph (d) criterion

Take into account that intentional misuse is not in itself an adequate reason to list a chemical in Annex III.

There is no indication in the notification or supporting documentation that concerns for intentional misuse prompted the final regulatory action.

3. Conclusion

The Committee concluded that the notifications of final regulatory action by the European Union and Brazil met the criteria set out in Annex II to the Convention. The Committee also concluded that the final regulatory actions taken by the European Union and Brazil provided a sufficient basis to merit including trichlorfon in Annex III to the Convention in the pesticide category and that a decision guidance document should be drafted on the basis of the notifications.