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Certain Hazardous Chemicals and  
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**Technical work: review of notifications of final  
regulatory action: atrazine****Draft rationale for the conclusion by the Chemical Review  
Committee that the notifications of final regulatory action submitted  
by the European Union, Cabo Verde, Chad, the Gambia,  
Mauritania, Niger, Senegal and Togo in respect of atrazine meet or  
do not meet the criteria of Annex II to the Rotterdam Convention****Note by the Secretariat**

The annex to the present note sets out a draft rationale for the conclusion by the Committee that the notifications of final regulatory action submitted by the European Union, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo in respect of atrazine meet or do not meet the criteria of Annex II to the Rotterdam Convention. It is presented as submitted by the contact group on atrazine established at the twelfth meeting of the Chemical Review Committee. The present note, including its annex, has not been formally edited.

## Annex

### **Draft rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by the European Union, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo in respect of atrazine meet or do not meet the criteria of Annex II to the Rotterdam Convention**

1. The notifications of final regulatory action by European Union, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo to ban atrazine as a pesticide, together with the supporting documentation provided by those parties were found to meet the information requirements of Annex I to the Rotterdam Convention.
2. The seven parties (Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo) from the Africa region are members of the Sahelian Pesticides Committee. As the members of the Committee work together to take decisions on the registration of pesticides on a regional basis, the notifications submitted by the seven African Parties refer to the same final regulatory action. Therefore, the Committee combined the notifications in its analysis.
3. The notifications and supporting documentation were made available to the Committee for its consideration in documents UNEP/FAO/RC/CRC.11/5 and UNEP/FAO/RC/CRC.11/INF/9 and UNEP/FAO/RC/CRC.11/INF/10. Information on ongoing international trade was provided by CropLife International in 2015 and made available in document UNEP/FAO/RC/CRC.11/INF/5.

#### **I. European Union**

##### **(a) Scope of the notified regulatory action**

4. The regulatory action notified by the European Union relates to the use of atrazine as a pesticide. The use of atrazine was severely restricted by the final regulatory action which prohibited placing on the market or use plant protection products containing atrazine. atrazine is not included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC. The authorisations for plant protection products containing atrazine had to be withdrawn by 10 September 2004. From 16 March 2004 no authorisations for plant protection products containing atrazine could be granted or renewed. For certain essential uses for specific Member States listed in the Annex to Commission Decision 2004/248/EC a prolonged period of withdrawal until 30 June 2007 was allowed (UNEP/FAO/RC/CRC.11/5, section 2, 2.2).
5. The regulation entered into force on 10 September 2004. However, authorisations for essential uses were allowed to be maintained until 30 June 2007 by four EU Member States, provided that they ensure that such plant protection products remaining on the market are relabelled in order to match the restricted use and conditions; impose all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment; and ensure that alternative products or methods for such uses are being seriously sought, in particular by means of action plans.
6. For all non-essential uses, for which existing authorizations had to be withdrawn by 10 September 2004, the EU Member States were allowed to grant a period of grace for disposal, storage, placing on the market and use of existing stocks that had to expire no later than 10 September 2005. For essential uses that could continue to be authorized until 30 June 2007, the grace period was 6 months (UNEP/FAO/RC/CRC.11/5, section 2, 2.5.2). As from 1 January 2008, the use of atrazine in plant protection products is no longer allowed in the EU.

7. The notification was found to comply with the information requirements of Annex I.

##### **(b) Annex II paragraph (a) criterion**

*(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;*

8. The Committee confirmed that the final regulatory action was taken in order to protect the environment.

9. In the EU, atrazine has been used as a pesticide. Atrazine is a triazine herbicide used as a selective pre- and post-emergence herbicide for annual control of grass and broad-leaved weeds in apples, pears, asparagus, maize and sorghum cultivation. Use within the European Union included the pre- and post-emergence control of grasses and broad-leaved weed species in salsify, apples, pears, maize, asparagus, sorghum and sweetcorn in commercial agriculture as a 500 g/L suspension concentrate or as the 900 g/L water dispersible granule at 1.5 kg active ingredient/ha. (UNEP/FAO/RC/CRC.11/5, section 1.7.2).

(c) **Annex II paragraph (b) criteria**

***(b) 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***

10. A risk assessment was carried out on the basis of Directive 91/414/EEC, which provides for the European Commission to issue a programme of work for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Article 8(7) of Regulation (EC) No 451/2000.

11. The Committee concluded that the data on which the Commission decision of 10 March 2004, the Review report for the active substance atrazine (SANCO/10496/2003 – final), and the Opinion of the Scientific Committee on Plants on specific questions from the commission concerning the evaluation of atrazine in the context of Council Directive 91/414/EEC – adopted on 30/01/2003 - rely upon have been generated according to scientifically recognized methods and that data reviews have been performed and documented according to generally recognized scientific principles and procedures.

12. Therefore, the Committee concluded that sub-criteria (b) (i) and b (ii) are met.

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

13. [Taking into account the following:

(a) The regulatory action of the EU was clearly not based on a risk evaluation, but solely on the groundwater limit of 0.1 µg/L (generally applicable threshold value for all pesticides and relevant metabolites in ground water). The drinking water limit in Canada is 5 µg/L, whereas the USEPA describes a limit of 3 µg/L. The WHO guideline for drinking water is 2 µg/L.

(b) The EU criteria might have taken into account water (surface water and groundwater), air, soil and sediment put together. The environmental risk has not been linked with groundwater contamination.

(c) A risk evaluation needs to involve substance specific hazard data, and substance specific exposure data, and the relation between them. The application of generally applicable threshold level in groundwater does not satisfy this criterion.

(d) Reference is made to the bromacil case which has been discussed and concluded upon during ICRC-1 in 2000.

(e) Because no adverse risk has been identified by the EU, they have allowed continuation of essential uses which included application in the key crop maize.

The Committee concluded that sub-criteria (b) (iii) is not met.]

14. [Taking into account the following:

(a) The regulatory action of the EU was based not only on the groundwater limit but was based on a dossier, including data on physico-chemical properties, fate and behavior in the environment, ecotoxicology, mammalian toxicology, residues and analytical methods (UNEP/FAO/RC/CRC.11/INF/9). As a result of that risk assessment, risks have also been identified for aquatic organisms (UNEP/FAO/RC/CRC.11/INF/9, page 19).

(b) Drinking water limits in other countries are not relevant to the situation in the European Union.

(c) Referring to section 2.3 of the notification, there is a clear substance specific relation between hazard and exposure. There were data on mammalian toxicity, ecotoxicity, even groundwater included. Data were based on generally approved methods and procedures relating to risk evaluation. No data were lacking.

(d) The handbook of working procedures and policy guidance for the Chemical Review Committee (October 2014)<sup>1</sup> does not require a link between hazard and exposure to be established. However, in this case, there is a link between hazard and exposure.

(e) Modelling data are sufficient to show that there was risk to groundwater. Groundwater was protected for its intrinsic value. Contamination of groundwater constitutes a hazard. The modelling data established a relationship between hazard and exposure. One of the problems with atrazine is its suspected endocrine disrupting properties, and therefore, no threshold level can be determined. The level of 0.1 µg/L is in line with this approach.

(f) Reference to the bromacil case during ICRC-1 is not relevant to the current discussion. The information received from Germany at the time was limited to high persistence combined with high leaching potential. The draft decision guidance document for bromacil did not contain information on the underlying dossier or risk evaluation. Furthermore, since ICRC-1 the working procedures of the Committee have evolved.

(g) The preambular text to the final regulatory action of the EU states that in the absence of alternatives, use was still allowed for certain limited type of uses for a limited period under strict conditions to minimize risks. Even those essential uses had to be withdrawn by 30 June 2007.

(h) The EU dossier did identify an adverse effect to groundwater.

The Committee concluded that sub-criteria (b) (iii) is met.]

**(d) Annex II paragraph (c) criteria**

**(c) 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;**

15. Taking into account the following:

(a) Use of atrazine is severely restricted by the final regulatory action which prohibited placing on the market or use of plant protection products containing atrazine. Therefore, it is expected that the final regulatory action will lead to a significant reduction of the quantity of the chemical used.

The Committee concluded that sub-criteria (c) (i) is met.

**(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;**

16. Taking into account the following:

(a) The risks are expected to significantly decrease after the EU ban of atrazine.

The Committee concluded that sub-criteria (c) (ii) is met.

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

17. The notification states that similar concerns to those identified could arise in other countries where the substance is used, particularly developing countries. The Committee therefore concludes that similar environmental problems are likely to be encountered in other countries.

18. Therefore the Committee concludes that this sub-criterion (c) (iii) is met.

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

19. The notification from the European Union gives no information on the estimated quantity of atrazine produced, imported, exported and used.

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<sup>1</sup> [www.pic.int/crcguidance](http://www.pic.int/crcguidance).

20. However, the information gathered by the Secretariat (UNEP/FAO/RC/CRC.11/INF/5) indicates that atrazine was exported from the EU in the period 2012-2105 (2015 until July) to 16 countries. In the same document, CropLife International confirms the ongoing international trade of atrazine.

21. The Committee concludes that, based on the information in the gathered by the secretariat, ongoing international ongoing trade of atrazine may be expected.

22. Therefore, the Committee concludes that this sub-criterion (c) (iv) is met.

**(e) Annex II paragraph (d) criterion**

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

23. There is no indication in the notification that concerns for intentional misuse of atrazine prompted the regulatory action.

24. Based on the above point the Committee confirms that criterion (d) is met.

**(f) Conclusion**

25. [The Committee concluded that the notification of final regulatory action by the European Union met all the criteria set out in Annex II to the Convention.]

26. [The Committee concluded that the notification of final regulatory action by the European Union did not meet the sub-criteria (b) (iii), set out in Annex II to the Convention.]

## **II. Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo**

**(a) Scope of the notified regulatory action**

27. The regulatory action notified by Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo (hereafter referred to as the CILSS countries) relates to the use of atrazine as a pesticide. Use of atrazine pesticides were prohibited effective 8 April 2015. The final regulatory action states that all products containing atrazine are banned due to its highly toxic potential to human health and mainly the environment (UNEP/FAO/RC/CRC.11/5 section 2.1, 2.2.1 and 2.2.3).

28. The notification was found to comply with the information requirements of Annex I.

**(b) Annex II paragraph (a) criterion**

*(a) Confirm that the final regulatory action has been taken in order to protect human health or the environment;*

29. The Committee confirms that the regulatory action was taken to protect human health and the environment (UNEP/FAO/RC/CRC.11/5 section 2.4.2).

30. Atrazine is used in pre and post-emergence treatment of weeds and many annual and perennial crops (UNEP/FAO/RC/CRC.11/5 section 2.3.1).

31. In April 2015, on recommendation of the Sahelian Pesticides Committee, atrazine was banned by decision of the CILSS Coordinating Minister (Minister of Agriculture and Environment) due to its highly toxic potential to human health and mainly the environment. (UNEP/FAO/RC/CRC.11/5 section 2.1, 2.2.1 and 2.2.3)

32. The Committee confirms that this criterion is met.

**(c) Annex II paragraph (b) criteria**

*(b) 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;*

33. Taking into account the following:

(a) The CILSS countries have provided data from international sources which were generated according to scientifically recognised methods. For example: Atrazine Footprint PPDB, 2014; L'atrazine (Institut national de Sante publique du Quebec, 1993); Fiche complète pour Atrazine CSST; Fiche PMSD pour Atrazine CSST and EXTOTOXNET, Pesticide Information Profiles – Atrazine; INERIS – Atrazine (UNEP/RC/CRC.11/INF/10). They have compared the data from international sources to other available information, which has limitations and is qualitative in nature. The international data reviews provided by the CILSS countries have been performed and documented according to generally recognised scientific principles and procedures

(b) The Committee concluded that sub-criteria (b) (i) and (ii) are met.

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

34. [Taking into account the following:

(a) As the final regulatory action has not been taken as a result of a risk evaluation, this criterion is not met.

(b) According to the conclusions of the Sahelian region report, the potential presence of atrazine in water sources underpinned by the EU decision on atrazine was the real basis of the decision by the Sahelian Pesticide Committee. The EU's decision was not made as a consequence of a risk evaluation. Accordingly, the Sahelian concerns on the presence of atrazine in water do not satisfy this criterion even if bridging information would have been made available.

(c) No details on the specific conditions of use within the CILSS were presented. Regulatory action in other jurisdictions was a basis for the decision, however there is no bridging information (Handbook of working procedures and policy guidance for the Chemical Review Committee (October 2014)<sup>2</sup>) to establish the relevance of other jurisdictions' decisions to the CILSS. Hazard endpoints are a basis for the decision; however, the documentation does not present any national policies relating to the use of hazard endpoints in regulation as is referenced in the Handbook concerning criteria (b) requirements.

(d) Two incidents are reported in the background information which may not be sufficient to establish a prevailing pattern of risk. One of these incidents involved a co-formulation with another pesticide which raises issues of causality.

The Committee concluded that sub-criteria (b) (iii) is not met.]

35. [Taking into account the following:

(a) Risk evaluation was made as a basis for the final regulatory action, which took into account scientific information on hazard as well as information on exposure from the region of the notifying party.

(b) Proposal has very clearly set out what risks have been considered and how the decision to impose regulatory action was taken to address these risks. So the regulatory action was based on a risk evaluation.

(c) The notifying party also took into account information on hazard and risk from other sources such as pesticide properties databases with information on evaluation made by Canada. Bridging information is not required because the country undertook independent risk evaluation using information on agricultural exposure generated within the notifying party.

(d) The Sahelian area countries are characterized by torrential rains on soils that often pour in organic matter content therefore the chances of leaching is high. In the absence of the good environmental management system, e.g. a buffer between the treated field and streams, surface water which is used as human drinking water is at risk of atrazine contamination.

(e) It should be taken into consideration that the incident is just a one part of the information of exposure in the notifying party.

The Committee concluded that sub-criteria (b) (iii) is met.]

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<sup>2</sup> [www.pic.int/crcguidance](http://www.pic.int/crcguidance).

**(d) Annex II paragraph (c) criteria**

**(c) 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;**

36. The use of atrazine is banned by the final regulatory action which entered into force on 08 April 2015. The final regulatory action states that all products containing atrazine are banned due to its highly toxic potential to human health and mainly the environment (UNEP/FAO/RC/CRC.11/5 section 2.1, 2.2.1 and 2.2.3).

37. The final regulatory action is therefore expected to lead to a significant decrease in the quantity of the chemical used, resulting in significant reduction of risk to human health and the environment.

38. Therefore, the Committee concludes that this sub-criterion (c) (i) is met.

**(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;**

39. It is expected that since the regulatory action to ban the use of atrazine significantly reduces the quantity of the chemical used, the risks to human health and the environment will also be significantly reduced.

40. Therefore, the Committee concludes that this sub-criterion (c) (ii) is met.

**(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;**

41. The notifications states that this measure (the final regulatory action) will be of great interest to other Sahel countries using the product under the same conditions (UNEP/FAO/RC/CRC.11/5 section 2.5.2). In the notifications it is also indicated that the high risk of water resource pollution has justified its ban in many countries of the world among which all the European Union countries (UNEP/FAO/RC/CRC.11/5 section 2.4.2.2).

42. In the supporting documentation (Annex to the decision to ban atrazine (French and English) in UNEP/FAO/RC/CRC.11/INF/10, p 13), reference is made to regulatory actions on atrazine in the European Union, Australia, the United States of America and the Province of Quebec. The Committee concluded that the considerations that led to the final regulatory action been taken are applicable to a wide geographical area and circumstances.

43. Therefore the Committee concludes that this sub-criterion (c) (iii) is met.

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

44. The notifications from Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo give no information on the estimated quantity of atrazine produced, imported, exported and used.

45. However, the information gathered by the Secretariat (UNEP/FAO/RC/CRC.11/INF/5) indicates that atrazine was exported from the EU in the period 2012-2105 (2015 until July) to 16 countries. In the same document, CropLife International confirms the ongoing international trade of atrazine.

46. The Committee concludes that, based on the information in the gathered by the secretariat, ongoing international ongoing trade of atrazine may be expected.

47. Therefore the Committee concludes that this sub-criterion (c) (iv) is met.

**(e) Annex II paragraph (d) criterion**

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

48. There is no indication in the notification that concerns for intentional misuse of atrazine prompted the regulatory action.

49. The Committee concludes that criterion (d) is met.

**(f) Conclusion**

50. [The Committee concluded that the notifications of final regulatory action by Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo met the criteria set out in Annex II to the Convention.]

51. [The Committee concluded that the notifications of final regulatory action by Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo did not meet sub-criteria, (b) (iii) set out in Annex II to the Convention.]

**III. Conclusion**

52. The Committee concluded that the notifications of final regulatory action by the European Union, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo [met] [not 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, Cabo Verde, Chad, the Gambia, Mauritania, Niger, Senegal and Togo provided a sufficient basis to merit including atrazine 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.]

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