

## **CRC-15/3: Nonylphenols and nonylphenol ethoxylates**

*The Chemical Review Committee,*

*Recalling* Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade,

1. *Concludes* that the notifications of final regulatory action for nonylphenols and nonylphenol ethoxylates submitted by the European Union and Switzerland<sup>1</sup> meet the criteria set out in Annex II to the Convention;
2. *Adopts* the rationale for the Committee's conclusion set out in the annex to the present decision;
3. *Notes* that, as notifications of final regulatory action from only one prior informed consent region in respect of nonylphenols and nonylphenol ethoxylates meet the criteria set out in Annex II to the Convention, it will take no further action on these chemicals at present.

### **Annex to decision CRC-15/3**

#### **Rationale for the conclusion by the Chemical Review Committee that the notifications of final regulatory action submitted by the European Union and Switzerland in respect of nonylphenols and nonylphenol ethoxylates in the industrial and pesticide categories meet the criteria of Annex II to the Rotterdam Convention**

1. The notifications on nonylphenols and nonylphenol ethoxylates from the European Union and Switzerland have been verified by the Secretariat as containing the information required by Annex I to the Rotterdam Convention. These notifications underwent a preliminary review by the Secretariat and the Bureau, which evaluated whether or not the notifications appeared to meet the requirements of the Convention.
2. The notifications, the supporting documentation and the results of the preliminary review were made available to the Chemical Review Committee for their consideration (documents UNEP/FAO/RC/CRC.15/6, UNEP/FAO/RC/CRC.15/INF/13/Rev.1, UNEP/FAO/RC/CRC.15/INF/14).

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

##### **(a) Scope of the regulatory action notified by European Union**

3. The notified regulatory action refers to nonylphenols (NPs) and nonylphenol ethoxylates (NPEs) industrial chemicals and as pesticides. The notification notes that there are various CAS numbers for NPs and NPEs included in the scope, including 25154-52-3 (phenol, nonyl-), 84852-15-3 (phenol, 4-nonyl-, branched), 11066-49-2 (isononylphenol) and 90481-04-2 (phenol, nonyl-, branched), 9016-45-9, 26027-38-3 (nonoxynols), 37205-87-1, 68412-54-4 (branched-nonylphenol, ethoxylate), and 127087-87-0 (poly(oxy-1,2-ethanediyl), alpha-(4-nonylphenyl)-omega-hydroxy-, branched).
4. According to the notification from 2 December 2005, NPs and NPEs were severely restricted and could only be placed on the market or used subject to the conditions specified in point 46 of Annex I to the directive 76/769/EEC. Point 46 states that NPs and NPEs may not be placed on the market or used as a substance or constituent in preparations in concentrations equal to or higher than 0.1 per cent by mass for certain purposes (UNEP/FAO/RC/CRC.15/6, European Union notification).

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<sup>1</sup> See UNEP/FAO/RC/CRC.15/6.

**(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;*

5. The Committee confirms that the regulatory action was taken to protect the environment.

6. The notification refers to an evaluation of scientific data, which concluded that NPs and NPEs posed an unacceptable risk to the environment and the final regulatory action was taken to protect aquatic and terrestrial ecosystems. The following areas of concern were identified: effects on local and regional aquatic environmental spheres including sediment, effects on terrestrial spheres and effects on secondary poisoning to fish and earthworm predators, as a consequence of exposure arising from the production, formulation and uses of NPs or NPEs.

7. The Committee therefore confirms that the criterion in paragraph (a) of Annex II 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;*

8. The government and agency reviews and scientific opinions (UNEP/FAO/RC/CRC.15/INF/13/Rev.1) provided are considered to be scientifically sound, generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

9. The Committee confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

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

10. The risk assessment report provided in the supporting documentation has been prepared according to methods laid down in Commission Regulation (EC) 1488/94, which is supported by a guidance document (Technical Guidance Document, Part I – V, ISBN 92-827-801). The risk assessment used information from the European Union on production, uses, trends in production volumes. The emissions for the environmental risk assessment have been calculated using the Technical Guidance Document (TGD) and implemented in the risk assessment model developed for the European Union region.

11. Assessment of the fate of NPs and NPEs in the environment was mainly based on modelling and studies using Organization for Economic Cooperation and Development (OECD) test methods but also field studies from Europe on degradation and bioaccumulation. Measured concentrations of NPs and NPEs in surface and ground waters, sediments, and sewage sludge were available and used from relevant countries.

12. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

13. The Committee confirms that the criteria of paragraph (b) of Annex II are 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;*

14. The notification states that the expected effect of the final regulatory action is reduction of risk to the environment. The final regulatory action severely restricts the use of NPs and NPEs in certain uses, in which the concentration may not be equal to or higher than 0.1 per cent.

15. The risk assessment provided in the supporting documentation indicates that the concentration of NPEs in, for example, cleaning products for the metal industry was approximately 5 per cent w/w, in final formulations used in laundries, for floor and surface cleaning in buildings, as vehicle cleaners, anti-static cleaners and metal cleaning <5 per cent w/w. Typical paints contained 0.6–3 per cent of NPEs. In the pesticide formulations, the final product NPE level was reported between 0.1–2 per cent and in industrial water treatment chemicals and paper industry process aids up to 20 per cent.

16. Quantitative information on decrease in use due to the regulatory action is not available. According to the available information, 73,500 tonnes of NPs was produced in the European Union in 1997, of which 60 per cent was used for the production of NPEs. Cleaning and washing agent applications, many of which were restricted, represented 44.7 per cent of the use. A total of 18 per cent of NPEs was used in textile and leather applications, which was also restricted (UNEP/FAO/RC/CRC.15/INF/13/Rev.1).

17. Considering the levels of use of NPs and NPEs in the products placed on the market before the severe restriction, it can be considered that banning uses and restricting the levels to below 0.1 per cent for the remaining uses, the quantity of the chemical used would be expected to decrease significantly.

18. The Committee therefore confirms that the criterion in paragraph (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;*

19. The risk assessment contained in the supporting documentation concluded that there was a need to limit the risk from several production processes, formulations and uses related to NPs and NPEs.

20. In addition, there were some concerns raised in the risk assessment with respect to the workers of the industry sectors involving the manufacture of NPs and its use as an intermediate. The margin between the actual exposure and the no observed adverse effect levels (NOAELs)/lowest observed adverse effect levels (LOAELs) for repeated dose toxicity and reproductive effects were low. Thus, reduction of risks to workers is anticipated.

21. As the regulatory action set low concentration limit values for sources that were identified posing risk for the environment in the risk assessment, it led to a significant reduction of risk to the environment.

22. The Committee confirms that the criterion in paragraph (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;*

23. The notification notes that similar concerns to those identified in the European Union are likely to be encountered in other countries where the substances are used, particularly in developing countries.

24. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

25. Several export notifications of NPEs from the European Union to third countries can be found on the European Chemicals Agency website (<https://echa.europa.eu>). Canada provided recent information on use of NPEs as a pesticide adjuvant (UNEP/FAO/RC/CRC.15/INF/4). NPEs are also present as formulants in over 400 pesticide products in Canada. CropLife International confirmed international trade of NPs and NPEs (UNEP/FAO/RC/CRC.15/INF/4).

26. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

27. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.*

28. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

29. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

**(f) Conclusion**

30. The Committee concludes that the notification of final regulatory action by the European Union meets the criteria set out in Annex II to the Convention.

## **II. Switzerland**

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

31. The notified regulatory action refers to nonylphenols (NPs) and nonylphenol ethoxylates (NPEs) as an industrial chemical and as a pesticide. The notification covers the following chemical names: 4-Nonyl phenol (branched), Nonylphenol, 4-Nonyl phenol; Polyethylene glycol nonylphenyl ether, PEG-X nonyl phenyl ether, Nonoxynol-X ( $X \geq 1$ ); Poly(oxy-1,2-ethanediyl),  $\alpha$ -(4-nonylphenyl)- $\omega$ -hydroxy-, branched. Trade names and names of preparation included are Marlophen NP9, Imbentin-N/020, Sympatens NP090, Berol 09, Berol 268, Igepal CO 630, Lutensol AP10, Arkopal N090, and Dowfax 9N20. The CAS numbers subject to the regulatory action are: 84852-15-3, 25154-52-3, 90481-04-2, 104-40-5, 37205-87-1, 9016-45-9, 68412-54-4, 127087-87-0, 26027-38-3, and 11066-49-2. Harmonized System codes are 2907 13 and 3402 13.

32. The regulatory action prohibits placing the following product types on the market if their content of octylphenol (molecular formula  $C_{14}H_{22}O$ ), nonylphenol (molecular formula  $C_{15}H_{24}O$ ) or ethoxylates of these is equal to or greater than 0.1 per cent by mass for certain purposes (UNEP/FAO/RC/CRC.15/6, Switzerland notification).

**(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;*

33. The Committee confirms that the regulatory action was taken to reduce the risk from NPs and NPEs to human health and the environment.

34. The notification concluded that direct exposure of consumers to NPs may have occurred by using products containing them although estimated exposure level was low. Local exposure scenarios like vicinity to textile industry gave high exposure levels. It was estimated that the main indirect exposure of humans to NPs occurs via food intake (mainly fish and root crops). Contamination of crops with nonylphenols can occur via application of pesticides containing nonylphenol ethoxylates as co-formulant (up to 5 per cent). However, there were no data on residue

levels in the harvested crops. Concerns for human health for workers in certain processes have been identified (e.g., spray application of specialty paint) in the European Union risk assessment.

35. With regards to risks to human health the notification further states that contamination of different fish tissues with metabolites of nonylphenol ethoxylates metabolites in Swiss rivers was documented in 1984/85. Furthermore, the notification summarizes several toxicity studies on rodents showing adverse effects.

36. Regarding the risk to the environment, the notification notes that NPEs in laundry detergents were banned in Switzerland already in 1987, decreasing the metabolite concentrations in waste waters significantly. Nevertheless, in certain cases concentrations of NPs that exceeded what is considered to have no effect on aquatic organisms were found, especially in the effluents of water treatment plants.

37. The Committee therefore confirms that the criterion in paragraph (a) of Annex II 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;*

38. The Committee considers that the three government evaluations in the supporting documentation (UNEP/FAO/RC/CRC.15/INF/14) are scientifically sound, generated according to scientifically recognized methods and reported according to generally recognized scientific principles and procedures.

39. The Committee confirms that the criteria in paragraph (b) (i) and (ii) of Annex II are met.

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

40. The notification states that Switzerland takes over most of the European Union chemicals regulations and in certain cases adapts them to Swiss circumstances. In the summary of hazard evaluation, the notification refers to Swiss data on NPEs concentrations in fish, testicular cancer statistics as well as NP concentrations in Swiss rivers and waste water treatment plant effluents.

41. The European Union risk assessment report included in the supporting documentation has been prepared using information from the European Union on production, uses, and trends in production volumes. The default emissions for the environmental risk assessment have been calculated using the Technical Guidance Document (TGD) and implemented in the risk assessment model developed for the European Union region, the western part of which – as was stated in the notification – is socially and economically similar to Switzerland. Assessment of the fate of NPs and NPEs in the environment was mainly based on modelling and studies using OECD test methods but also field studies from Europe on degradation and bioaccumulation. Some measured concentrations of NPs and NPEs in surface and ground waters or sediments used in the European Union risk assessment were also from Switzerland.

42. The Committee therefore confirms that the criterion in paragraph (b) (iii) of Annex II is met.

43. The Committee confirms that the criteria of paragraph (b) of Annex II are 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;*

44. Information on production, import, and export quantities was provided for only one year.

45. The risk assessment provided in the supporting documentation indicates that the concentration of NPEs in, for example, cleaning products for the metal industry was approximately 5 per cent w/w, in final formulations used in laundries, for floor and surface cleaning in buildings, as vehicle cleaners, anti-static cleaners and metal cleaning <5 per cent w/w. Typical paints contained 0.6–3 per cent NPEs. In the pesticide formulations, the final product NPEs level was reported between 0.1–2 per cent and in industrial water treatment chemicals and paper industry process aids up to 20 per cent.

46. Considering the levels of use of NPs and NPEs in the products placed on the market before the severe restriction, it can be considered that banning uses and restricting the levels to below 0.1 per cent for the remaining uses, the quantity of the chemical used would be expected to decrease significantly.

47. The Committee therefore confirms that the criterion in paragraph (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;*

48. The risk assessment contained in the supporting documentation concluded that there was a need to limit the risk from NPs and NPEs (UNEP/FAO/RC/CRC.15/INF/14).

49. As the regulatory action set low concentration limit values for many sources that were identified as posing risks for the environment in the risk assessment provided to support the notification, it is considered to lead to a significant reduction of risk to the environment.

50. The Committee confirms that the criterion in paragraph (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;*

51. The notification notes that many of the uses of NPEs (e.g., co-formulant in pesticides) that had been banned in Switzerland were still permitted in many countries. Concerns mentioned in the risk evaluation, such as water pollution, might be relevant for other countries as well.

52. The Committee therefore confirms that the criterion in paragraph (c) (iii) is met.

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

53. Several export notifications of NPEs from the European Union to third countries can be found on the European Chemicals Agency website (<https://echa.europa.eu>). Canada provided recent information on use of NPEs as a pesticide adjuvant (UNEP/FAO/RC/CRC.15/INF/4). NPEs are also present as formulants in over 400 pesticide products in Canada. CropLife International confirmed international trade of NPs and NPEs (UNEP/FAO/RC/CRC.15/INF/4).

54. The Committee therefore confirms that the criterion in paragraph (c) (iv) is met.

55. The Committee confirms that the criteria of paragraph (c) of Annex II are 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.*

56. There is no indication in the notification that concerns about intentional misuse prompted the regulatory action.

57. On the basis of the above point, the Committee confirms that the criterion in paragraph (d) of Annex II is met.

**(f) Conclusion**

58. The Committee concludes that the notification of final regulatory action by Switzerland meets the criteria set out in Annex II to the Convention.

**III. Conclusion**

59. The Committee concludes that the notifications of final regulatory action submitted by the European Union and Switzerland meet all the criteria set out in Annex II to the Convention.