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October 15, 2012

The Honourable Leona Aglukkaq
Minster of Health

Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario
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Dear Minister Aglukkaq,

Re: Request for Special Review of 30 Substances under *Pest Control Products Act*

Ecojustice, on behalf of the David Suzuki Foundation (DSF) and Équiterre, requests the Minister undertake special reviews under section 17 of the *Pest Control Products Act* ('PCPA') of the registration of pest control products containing one or more of the 30 active ingredients listed in Appendix 1 attached to this letter.

Ecojustice is Canada's leading charity of lawyers and scientists using the law to protect and restore the environment. Ecojustice provides legal and scientific services free-of-charge to charities and citizens on the front lines of the environmental movement helping ensure equitable access to environmental justice nationwide.

DSF's mission is to protect the diversity of nature and our quality of life, now and for the future. DSF works with government, business and individuals to conserve our environment by providing science-based research, education and policy work, and acting as a catalyst for the change that today's situation demands.

Founded in 1993, Équiterre's mission is to help build a social movement by encouraging individuals, organizations and governments to make ecological and equitable choices, in a spirit of solidarity. Supported by more than 8,000 members and donors, Équiterre offers concrete solutions aimed at making Quebec a society where sustainable development and the social economy take centre stage.

Section 17 of the *PCPA* imposes a statutory duty on the Minister of Health to initiate a special review of the registration of pest control products containing active ingredients banned by a member nation of the Organization for Economic Co-operation and Development (OECD) because of health or environmental concerns.

Initiation of special review by Minister

17. (1) The Minister shall initiate a special review of the registration of a pest control product if the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable.

Special review where OECD ban

(2) Without limiting the generality of subsection (1), when a member country of the Organisation for Economic Co-operation and Development prohibits all uses of an active ingredient for health or environmental reasons, the Minister shall initiate a special review of registered pest control products containing that active ingredient.

Pursuant to subsection 17(4) of the *PCPA,* any person may request a special review of the registration of a pest control product by making a direct request to the Minister.

Request for special review

Any person may request a special review of the registration of a pest control product by making a request to the Minister in the form and manner directed by the Minister.

The 30 active ingredients listed in Appendix 1 are used in registered pest control products in Canada but banned in at least one other OECD member country for reasons pertaining to health and/or the environment.

The primary purpose of the *PCPA* is to ensure that the use of pest control products will not result in harm to human health, future generations or the environment. As subsection 2(2) of the *PCPA* states:

Acceptable risks

For the purposes of this Act, the health or environmental risks of a pest control product are acceptable if there is reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration.

The primary objective is to provide a stronger level of protection for the health of Canadians and the environment from the harmful effects of pesticides. As subsection 4 (1) of the *PCPA* states:

Primary objective

4. (1) In the administration of this Act, the Minister's primary objective is to prevent unacceptable risks to people and the environment from the use of pest control products.

In addition, section 4.1 of the new *PCPA* provides for protection to future generations.

Protection of future generations

For greater certainty, protection and consideration afforded to children in this Act shall also extend to future generations.

As a result of a special review, the Minister may cancel or amend the registration of a pest control product when taking into account the precautionary principle which is defined under subsection 20(2) of the *PCPA*.

Precautionary principle

Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent adverse health impact or environmental degradation.

Appendix 1 provides a list of 30 active ingredients registered in Canada for use in pest control products but prohibited in at least one other OECD nation.[1] For each of the 30 active ingredients in Appendix 1, we have provided the common name, the Chemical Abstracts Service registry number (CAS No.), a summary of its approved use in Canada and information on the ban(s) in other OECD nations for environmental and/or health reasons.

Below are some examples of the 30 active ingredients included in this request that are still used in registered pest control products in Canada but banned in another OECD nation.

[1] Although the European Union (EU) is not a member of the OECD and could not be because it is not a country, several of its Member States are members of the OECD (Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy Luxembourg, Netherlands, Poland, Portugal, Slovak Republic, Slovenia, Spain, Sweden and United Kingdom). Where the EU adopts a Regulation, the Regulation is legally binding on all of its Member States, with no further implementation required by the national governments themselves. It also takes precedence over national law where there is a conflict.

Atrazine was banned by the European Union in 2004 due to concerns regarding groundwater contamination, yet it is still approved in Canada for use on corn. Environment Canada reports detecting Atrazine in waters across Canada with the highest frequency of detection in Ontario and Quebec followed by British Columbia.[2]

Carbaryl is an herbicide that was banned in Europe in May of 2007 due to concerns regarding potential carcinogenicity and high toxicity to animals but it is still used in 44 pesticide products approved by Health Canada for use on a wide range of crops from grains to fruits and vegetables.

Diazinon is an insecticide banned in Europe since June 2007 due to concerns regarding toxicity to operators and bystanders during use, and ecotoxicological impacts from impurities in the pesticide. Diazinon is still used in 15 registered pesticide products in Canada, many of which are applied to fruit and vegetable crops. A recent Environment Canada study detected Diazinon in 75 of 93 surface water samples taken in agricultural areas of British Columbia.[3]

Banned in Norway in 2007, Linuron is a herbicide found in eight agricultural use pesticide products approved for use in Canada and is the fifth highest use active ingredient in Atlantic Canada by sales. Linuron is used to control weeds in fields where grains, vegetables or fruit are grown. Linuron has been found to induce malformations in male reproductive organs and was found to be carcinogenic in animal studies. It is also very persistent and as result has been detected in surface water in Atlantic Canada, Ontario and British Columbia.[4]

Triluralin is an herbicide used in 17 pest control products used on grains and beans and is one of the top selling herbicides in the Prairie Provinces. It was banned in Europe in 2010 due to its toxicity to fish and other aquatic organisms, and also due to its ability to travel by air. It has been detected in

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[2] Water Science and Technology Directorate, Environment Canada, Presence and Levels of Priority Pesticides in Selected Canadian Aquatic Systems. March, 2011 available at < http://www.ec.gc.ca/Publications/FAFE8474-C360-46CC-81AB-30565982E897%5CPresenceAndLevelsOfPriorityPesticidesInSelectedCanadianAquaticEcosystems.pdf>

[3] Ibid

[4] Ibid

surface water in Ontario, the Prairies and British Columbia as well as in the air and precipitation of Ontario. [5]

Ecojustice, on behalf of our clients, the DSF and Équiterre, request that you initiate special reviews of all the pest control products registered for use in Canada containing the 30 active ingredients listed in Appendix 1, attached to this letter.

Respectfully,

Tim Leadem Q.C.
Staff Lawyer

Elaine MacDonald, P.Eng., Ph.D.
Senior Scientist

cc Pest Management information Service, PMRA, Health Canada

[5] ibid

Appendix 1

Summary of Decisions Regarding Pesticide Active Ingredients Registered in Canada but Prohibited in another OECD Nation

1. 2,4 D (2,4-Dichlorophenoxyacetic Acid)

CAS No. 94-75-7

Uses in Canada: There are several different formulations of the herbicide 2,4 D approved for use in Canada: 2,4 D (present as Acid); 2,4 D (present as Amine Salts: Dimethylamine Salt, Diethanolamine Salt or other Amine Salt); 2,4-D (present as Low Volatile Esters); 2,4 D present as Choline Salt in total these represent 149 registered products and 19 current applications.

The herbicide 2,4 D has been banned in Norway since January, 2000 due to reasons pertaining to human health and the environment. The following is an excerpt from the Rotterdam Convention PIC Circular XIII describing the reasons for the Norwegian ban.

> *The reasons for the final regulatory action were relevant to: Human health and the environment.*
> *Summary of known hazards and risks to human health: 2.4-D is moderate acute toxic and irritating to eyes, but these characteristics is comparable to the alternative preparations or active substances.*
>
> *In addition there are some **studies indicating a risk of cancer in soft tissue and lymph**, but the evidence isn't strong enough to label the product for risk of cancer.*
>
> *Expected effect of the final regulatory action relevant to human health: Reduced risk of cancer in people normally using pesticides with the agricultural needs covered by Weedar 64.*
>
> *Summary of known hazards and risks to the environment: **High mobility.***
>
> *Expected effect of the final regulatory action relevant to the environment: Reduction of risk to the environment.*[6] *[emphasis added]*

[6] PIC CIRCULAR XIII – June 2001. Available at: <http://www.pic.int/Portals/5/en/Circular/CIRC13EN.pdf> p. 12

2. *Acephate*

CAS No. 30560-19-1

Uses in Canada: Insecticide used in 5 registered end products

Acephate has been banned in Europe since 2003 due to reasons pertaining to both human health and the environment. More specifically, the European Commission's decision to not approve Acephate under European pesticide law was based on concerns regarding consumer safety and possible impacts on non target organisms:

> *(6) The assessment report prepared by Italy has been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. It appeared that the information submitted was not sufficient to determine whether or not, under the proposed conditions of use, plant protection products containing the active substance concerned would satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. Therefore, Commission Decision 2001/134/EC of 14 February 2001 concerning the decision on the possible inclusion of certain active substances into Annex I to Council Directive 91/414/EEC(7) allowed the notifier to complete its dossier by 31 March 2001 at the latest for a limited range of representatives uses. Upon receipt of the additional information, the review was finalised on 28 June 2002 in the format of the Commission review report for acephate, in accordance with Article 7(6) of Regulation (EEC) No 3600/92.*
>
> *(7) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing acephate satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC,* ***in particular with regard to the safety of consumers potentially exposed to acephate and with regard to its possible impact on non-target organisms****.*
>
> *(8) Acephate should therefore not be included in Annex I to Directive 91/414/EEC.*[7] *[emphasis added]*

3. *Aminopyralid*

CAS No. 150114-71-9

Uses in Canada: Herbicide used in 10 registered products, 3 current applications.

[7] *Official Journal L 082 , 29/03/2003 P. 0040 – 0041.* Commission Decision of 25 March 2003 concerning the non-inclusion of Acephate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32003D0219:EN:HTML >

The PMRA granted temporary registration in January 2007.

The status of Aminopyralid is pending in EU[8], but all uses of Aminopyralid were prohibited in Norway by a regulation passed in 2004 that took effect in February of 2011. The reasons for the ban are concerns regarding environmental impacts. The following is an excerpt from the Rotterdam Convention PIC Circular XXXIII of June 2011 describing the reasons for the Norwegian ban.

> *The conclusion of the assessment was that aminopyralid is **highly mobile in soil and the substance is very likely to reach ground water** at concentrations above the threshold of 0.1 g/L. According to water sediment studies, aminopyralid is persistent.*
>
> *Expected effect of the final regulatory action in relation to the environment: Reducing the risk of groundwater contamination of aminopyralid.* [9] *[emphasis added]*

4. Amitraz

CAS No. 33089-61-1

Uses in Canada: Insecticide used in3 registered products, 2 current applications.

Amitraz has been banned in Europe since 2004 due to concerns regarding possible neurological effects. The following in an excerpt from, "2004/141/EC: Commission Decision of 12 February 2004 concerning the non-inclusion of amitraz in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance."

> *8) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing amitraz satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. In particular, Article 5(2)(b) provides that an acceptable daily intake (ADI) for man must be taken into account in deciding on the inclusion of an active substance in*

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[8] *Official Journal L 201, 04/08/2011 P. 0016 – 0018.* Commission Implementing Decision of 2 August 2011 allowing Member States to extend provisional authorisations granted for the new active substances acequinocyl, Adoxophyes orana granulovirus, aminopyralid, flubendiamide, mandipropamid, metaflumizone, phosphane, pyroxsulam and thiencarbazone. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:201:0016:01:EN:HTML>

[9] PIC Circular XXXIII – June 2011. Secretariat for the Rotterdam Convention on prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. Available at <http://www.pic.int/Portals/5/en/Circular/Circ33-EN.pdf>p. 17

> *Annex I. In setting the ADI the* ***possible neurological effects of amitraz had to be considered.*** *These effects were also considered for setting the Acute Reference Dose, i.e. the estimate of the amount of the substance that can be ingested over a short period of time without appreciable health risk to the consumer****. It has not been demonstrated for the proposed uses that consumers might not be exposed to amitraz exceeding the Acute Reference Dose****. A probabilistic risk assessment was prepared by the notifier. It must however be taken into consideration that agreed criteria for the interpretation of such a probabilistic risk assessment are not yet established and it would not be appropriate, in view of the possible risks, to delay decision-making further until such criteria are agreed.* [10] [emphasis added]

Amitraz is also banned in the non-OECD countries of Iran and Syria, the latter ban was for reasons pertaining to human health.[11]

5. Atrazine

CAS No. 1912-24-9

Uses in Canada: Herbicide used in 10 registered end products, 8 current applications. Atrazine was banned in Europe in 2004 due to concerns regarding groundwater contamination.

The following is an excerpt from the," Commission Decision of 10 March 2004 concerning the non-inclusion of atrazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance."

> *Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing atrazine satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.* ***In particular available monitoring data were insufficient to demonstrate that in large areas concentrations of the active substance and its breakdown products will not exceed 0,1 µg/l in groundwater. Moreover it cannot be assured that continued use in other areas will permit a satisfactory recovery of groundwater quality where concentrations already exceed 0,1 µg/l in***

[10] *Official Journal L 046 , 17/02/2004 P. 0035 – 0037.*Commission Decision of 12 February 2004 concerning the non-inclusion of amitraz in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (notified under document number C(2004) 332). Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0141:EN:HTML>

[11] Database of Notifications of Final Regulatory Action. Rotterdam Convention. Available at < http://www.pic.int/Procedures/FinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx >

groundwater. *These levels of the active substance exceed the limits in Annex VI to Directive 91/414/EEC and would have an unacceptable effect on groundwater.* [12][emphasis added]

6. Bifenthrin

CAS No. 82657-04-3

Uses in Canada: Insecticide used in 1 registered end product, 4 current applications.

Bifenthrin was banned in Europe in 2009 due to concerns regarding ecotoxicology and insufficient information regarding the risk of groundwater contamination and the risk to the consumer.

An excerpt is copied below from the, "2009/887/EC: Commission Decision of 30 November 2009 concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5)During the evaluation of this active substance, a number of concerns have been identified. In particular, based on the data lodged by the notifier within the legal deadlines, it was not possible to assess the p****otential contamination of groundwater by a major soil degradation product (TFP acid)****. Furthermore, concerns have been raised as regards a possible underestimation of the risk to consumers, due to the limited number of residue data made available and the lack of investigation on the metabolism pattern of the two isomers constituting bifenthrin. As regards ecotoxicology, the* ***risk to aquatic vertebrates has not shown to generate acceptable uses, while there is a remaining uncertainty as regards the effects of the experienced bioaccumulation in fish of the active substance.*** *Furthermore,* ***high risks have been identified for mammals (long-term risk and secondary poisoning), earthworms (long-term risk) and non-target arthropods (in-field), while the risk to non-target plants and non-target soil macro-organisms has not been sufficiently addressed.*** *Consequently, it was not possible to conclude, on the basis of the information made available within the legal deadlines, that bifenthrin met the criteria for inclusion in Annex I to Directive 91/414/EEC.*

[12] *Official Journal L 078 , 16/03/2004 P. 0053 – 0055.* Commission Decision of 10 March 2004 concerning the non-inclusion of atrazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance (notified under document number C(2004) 731). Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0248:EN:HTML >.

> *(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing bifenthrin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.[emphasis added]*
>
> *(7) Bifenthrin should therefore not be included in Annex I to Directive 91/414/EEC.* [13][emphasis added]

Bifenthrin was banned in Netherlands in 2001 for reason pertaining to human health and the environment.[14] The Netherlands is now part of the European community.

7. Bromoxynil

CAS No. 1689-99-2

Uses in Canada: Herbicide 48 registered products and 11 current applications.

Bromoxynil Octanoate was banned in Norway in 2000 for reasons pertaining to the environment and human health. The following is a summary from the Rotterdam Convention database describing the reasons for the Norwegian ban.

> *Bromoxynil is labeled with many risk phrases, including **may cause cancer, and possible risk of harm to the unborn child**. The risks to the applicator are judged to be too high to be found acceptable. In addition, an important reason to not accept bromoxynil is that there are already alternatives on the market that pose a lower risk to human health.[15][emphasis added]*

8. Carbaryl

CAS No. 63-25-2

Uses in Canada: Pesticide used in 44 registered end products, 3 current applications,

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[13] *Official Journal L 318 , 04/12/2009 P. 0041 – 0042.* Commission Decision of 30 November 2009 concerning the non-inclusion of bifenthrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document C(2009) 9196). Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0887:EN:HTML>

[14] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Default.aspx?tabid=1368>

[15] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Default.aspx?tabid=1368>

Carbaryl was banned in Europe in May 2007 due to concerns regarding toxicity to humans and animals. An excerpt is copied below from the, "Commission Decision of 21 May 2007 concerning the non-inclusion of carbaryl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5) During the evaluation of this active substance, a number of concerns were identified. In particular based on the available data it has not been demonstrated that the consumer exposure is acceptable. The information available indicates concerns for* ***metabolites which are at the same level of toxicity as the active substance, and their presence at levels which might be of toxicological concerns cannot be excluded. Moreover there are concerns on potential carcinogenic properties of the active substance. There is also a high long-term risk for insectivorous birds and a high acute risk to herbivorous mammals, a high acute and long-term risk to aquatic organisms and a high risk for beneficial arthropods****.*
>
> *(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments advanced, the above concerns remained unsolved, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing carbaryl satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*
>
> *(7) Carbaryl should therefore not be included in Annex I to Directive 91/414/EEC.* [16]*[emphasis added]*

Carbaryl is also banned in the non-OECD countries of Jordan and Syria.

9. Chloropicrin

CAS No. 76-06-2

Uses in Canada: Fungicide and other pesticide uses in 6 registered end products.

[16] *Official Journal L 133, 25/05/2007 P. 0040 – 0041.* Commission Decision of 21 May 2007 concerning the non-inclusion of carbaryl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document number C(2007) 2093). Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0355:EN:NOT >

Chloropicrin has been banned in Europe since December 2011 due to reasons pertaining to the risks posed to pesticide operators and aquatic organisms, birds and bees, in addition to other concerns.

The following is an excerpt from the, "Commission Implementing Regulation (EU) No 1381/2011of 22 December 2011 concerning the non-approval of the active substance chloropicrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Decision 2008/934/EC."

> *(7) During the evaluation of this active substance, concerns were identified. Those concerns were, in particular, the following. There is an unacceptable risk to operators. It was* ***not possible to perform a reliable groundwater exposure assessment as data were missing concerning the metabolite dichloronitromethane and impurities of the active substance*** *as manufactured.* ***Insufficient data were available to conclude on the risks to sediment dwellers, bees, earthworms and non-target plants. A high risk to aquatic organisms, birds and mammals was identified****. It was not possible to perform a reliable surface water and sediment exposure assessment as data were missing for chloropicrin and the metabolite dichloronitromethane. No reliable assessment of exposure concentrations in air of phosgene could be performed.* ***A high potential for long-range atmospheric transport was identified****.*
>
> *(8) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with Article 21(1) to Regulation (EC) No 33/2008, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.*
>
> *(9) However, despite the arguments put forward by the applicant, the concerns referred to in recital 7 could not be eliminated. Consequently, it has not been demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing chloropicrin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*[17] *[emphasis added]*

[17] *Official Journal L 343, 23/12/2011 P. 0026 – 0027.* Commission Implementing Regulation (EU) No 1381/2011 of 22 December 2011 concerning the non-approval of the active substance chloropicrin, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Decision 2008/934/EC Text with EEA relevance. Available at< http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:343:0026:01:EN:HTML>

Chloropicrin is also banned in the non-OECD country of Saudi Arabia.[18]

10. Chlorthal-dimethyl

CAS No. 1861-32-1

Uses in Canada: Herbicide used in 3 registered end products.

Chlorthal-dimethyl has been banned in Europe since September 2009 due to concerns regarding impacts on groundwater.

The following is an excerpt from, "Commission Decision of 23 September 2009 concerning the non-inclusion of chlorthal-dimethyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5) During the evaluation of this **active substance it was found that its metabolite MPA leaches to groundwater.** On the basis of the information available, it cannot be concluded that it may be expected that the plant protection products containing that active substance fulfil the conditions provided for in Article 5(1) of Directive 91/414/EEC, in particular as regards toxicological significance of that metabolite.*
>
> *(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing chlorthal-dimethyl satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*
>
> *(7) Chlorthal-dimethyl should therefore not be included in Annex I to Directive 91/414/EEC. [19][emphasis added]*

11. Diazinon

CAS No. 333-41-5

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[18] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Default.aspx?tabid=1368>

[19] *Official Journal L 251 , 24/09/2009 P. 0031 – 0032.* Commission Decision of 23 September 2009 concerning the non-inclusion of chlorthal-dimethyl in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document C(2009) 6431). Also available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:251:0031:01:EN:HTML>

Uses in Canada: Insecticide used in 15 registered end products.

Diazinon has been banned in Europe since June 2007 for reasons pertaining to its very toxic impurities that have toxicological and ecotoxicological concerns.

The following is an excerpt from the, "Commision Decision of 6 June 2007 concerning the non-inclusion of diazinon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5) During the evaluation of this active substance, a number of concerns were identified. In particular based on the available data* ***it has not been demonstrated that the operator, worker and bystander exposure is acceptable. Moreover there is insufficient information on some very toxic impurities and their presence at levels which might be of toxicological or ecotoxicological concern cannot be excluded.***
>
> *(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments advanced, the above concerns remained unsolved, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing diazinon satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*
>
> *(7) Diazinon should therefore not be included in Annex I to Directive 91/414/EEC.* [20]*[emphasis added]*

12. Dichlobenil

CAS No: 1194-65-6
Uses in Canada: Herbicide used in 12 registered end products.

Dichlobenil was banned in Europe in April 2011 due to concerns regarding groundwater contamination, long range transport and risks to birds and high risks to earthworm eating birds and mammals.

[20]*Official Journal L 148, 09/06/2007 P. 0009 – 0010.* Commission Decision of 6 June 2007 concerning the non-inclusion of diazinon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document number C(2007) 2339). Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:148:0009:01:EN:HTML>

The following is an excerpt from, "Commission Implementing Decision of 11 April 2011 concerning the non-inclusion of dichlobenil in Annex I to Council Directive 91/414/EEC."

> *(9) During the evaluation of this active substance, a number of concerns have been identified. Several unacceptable effects on the environment were identified. In particular,* ***the potential groundwater contamination by the very persistent metabolite 2,6-dichlorobenzamide (BAM) is expected to be very high, with concentrations well above 10 µg/l for all modelled scenarios****. There is a* ***potential for long-range transport of the metabolite BAM*** *through the atmosphere.* ***A high acute risk to birds and a high long-term risk to earthworm-eating birds and mammals were identified.*** *The available data were insufficient to address the nature of residues of the metabolite BAM in processed commodities.*
>
> *(10) The Commission invited the applicant to submit its comments on the conclusion by the Authority. Furthermore, in accordance with Article 21(1) to Regulation (EC) No 33/2008, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.*
>
> *(11) However, despite the arguments put forward by the applicant, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the expert meetings of the Authority have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing dichlobenil satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*
>
> *(12) Dichlobenil should therefore not be included in Annex I to Directive 91/414/EEC.*[21][emphasis added]

Dichlobenil was completely banned in Norway as of the year 2000 for reasons pertaining to human health and the environment.[22]

13. Dichlorvos

CAS No: 62-73-7

Uses in Canada: Insecticide used in 11 registered end products and one current application.

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[21] *Official Journal L 098, 13/04/2011 P. 0014 – 0015.* Commission Implementing Decision of 11 April 2011 concerning the non-inclusion of dichlobenil in Annex I to Council Directive 91/414/EEC. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:098:0014:01:EN:HTML>

[22] PIC CIRCULAR XII – December 2000. Available at < http://www.pic.int/Portals/5/en/Circular/circ12en.pdf.> p. 30

Dichlorvos was banned in Europe in June 2007 as an active ingredient in plant protection products for reasons pertaining to concerns regarding human genotoxicity and carcinogenicity.

The following is an excerpt from the, **"**Commission Decision of 6 June 2007 concerning the non-inclusion of dichlorvos in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5) During the evaluation of this active substance, a number of concerns were identified. In particular,* ***based on the available toxicological data and taking into account the uncertainties of the genotoxic and carcinogenic properties of the substance also considering the overall poor quality of the dossier, it has not been demonstrated that the estimated operator, worker and bystander exposure, is acceptable****.*
>
> *(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments advanced, the above concerns remained unsolved, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing dichlorvos satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*
>
> *(7) Dichlorvos should therefore not be included in Annex I to Directive 91/414/EEC.*[23] *[emphasis added]*

14. Difenoconazole

CAS No: 119446-68-3

Uses in Canada: Fungicide used in 13 registered end products, 12 current applications.

Difenoconazole has been banned in Norway since 1998 due to environmental reasons pertaining to persistence, bioaccumulation in fish, and toxic effects on aquatic organisms. The following is an excerpt from the Rotterdam Convention PIC Circular XXXII describing the reasons for the Norwegian ban.

> *Difenoconazole's half-life in laboratory experiments vary somewhat but exceeds 1 year in many cases. In field experiments, dissipation is moderate but this is*

[23] *Official Journal L 145, 07/06/2007 P. 0016 – 0017.* Commission Decision of 6 June 2007 concerning the non-inclusion of dichlorvos in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document number C(2007) 2338). Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:145:0016:01:EN:HTML>

under climatic conditions that are not comparable with Norwegian conditions. ***The substance has a high bioaccumulation in fish. Difenoconazole has significant acute and chronic toxic effects on aquatic organisms****.*[24][*emphasis added]*

15. Diphenylamine

CAS No. 122-39-4

Uses in Canada: Plant growth regulator used in 5 registered end products, 2 current applications.

Diphenylamine was banned in Europe in 2009 due to concerns regarding human toxicity.

The following is an excerpt from the**, "**Commission Decision of 30 November 2009 concerning the non-inclusion of diphenylamine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5) During the evaluation of this active substance, a number of concerns have been identified. In particular****, it was not possible to perform a reliable consumer exposure assessment, as data are missing on the presence and toxicity of unidentified metabolites of the substance,*** *as well as on the possible formation of nitrosamines during storage of the active substance and during processing of treated apples. Moreover, no data was available on the* ***potential breakdown or reaction product of diphenylamine residues in processed commodities****. Consequently, it was not possible to conclude on the basis of the information available that diphenylamine met the criteria for inclusion in Annex I to Directive 91/414/EEC.*
>
> *(6) The Commission invited the notifier to submit its comments on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing diphenylamine satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*

[24] PIC CIRCULAR XXXII – December 2010. Available at <http://www.pic.int/Portals/5/en/Circular/Circ32-EN.pdf > p. 28

(7) Diphenylamine should therefore not be included in Annex I to Directive 91/414/EEC.[25] *[emphasis added]*

16. Ethylene oxide

CAS No: 75-21-8

Uses in Canada: Fumigant used in 1 registered end product

Ethylene oxide has been banned in Europe since 1986 for reasons pertaining to human and animal health.

The following is an excerpt from, 'Council Directive 86/355/EEC of 21 July 1986 amending Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances',

> *Whereas it has now been established that the use of ethylene oxide as a plant protection product, in particular for the fumigation of plants or plant products in storage,* ***leaves residues in foodstuffs which may give rise to harmful effects on human or animal health****;*
>
> *Whereas alternative treatments are available for plant protection except for certain minor commodities;*
>
> *Whereas the marketing and use of ethylene oxide as a plant protection product should therefore be prohibited;*
>
> *Whereas, however, temporary national exceptions from this prohibition may be permitted for certain minor commodities, where special need exists, until other methods of treatment become available,*
>
> *HAS ADOPTED THIS DIRECTIVE:*
>
> *Article 1*
>
> *The following entry is hereby added to the Annex to Directive 79/117/EEC:*
>
> *1.2 // // // 'C. Ethylene oxide // (a) pathogen reduction of the following dried vegetables, intended for incorporation in food preparations which do not undergo full cooking treatment prior to consumption // // - asparagus // // - onions // // - leeks // // - mushrooms // // (b) pathogen reduction of dried herbs and spices (1) // // (c) pathogen reduction of dried herbs intended exclusively for marketing without further processing as medicinal products // // (d) pathogen reduction of cocoa powder and cake // // (e)*

[25] *Official Journal L 098, 13/04/2011 P. 0014 - 0015*. Commission Decision of 30 November 2009 concerning the non-inclusion of diphenylamine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:314:0079:01:EN:HTML>

> *fumigation of tobacco leaf // // These derogations shall expire on 31 December 1989 at the latest // //…*[26] *[emphasis added]*

Ethylene oxide was also banned in the OECD country of Switzerland in August 2005 due to human health concerns. [27]

In addition, ethylene oxide is banned in the following non-OECD countries: Brazil in 2002 due to reasons pertaining to human health and animal toxicity, Bulgaria in 2004, Panama in 2001 for reasons pertaining to human health and the environment, Romania in 2003 for reasons pertaining to the environment and human health and Thailand in 2001 for reasons pertaining to human health. [28]

17. Fluazifop-P-Butyl

CAS No: 79241-46-6

Uses in Canada: Herbicide used in 3 registered end products.

Fluazifop-P-Butyl has been banned in Norway since January 1999 due to reasons pertaining to human health, specifically effects on reproduction and because it is teratogenic. The following is an excerpt from the Rotterdam Convention PIC Circular XIII describing the reasons for the Norwegian ban.

> *Fluazifop-P-butyl has shown in animal studies, rat and rabbit, that it causes* ***effects on reproduction*** *and that it is a teratogen. This means that it also has the potential to cause these effects in humans. The risk of this happening is higher for the workers than for the consumers, although it is also possible that* ***residues can be high and thus also be a risk to the consumer*** *too.*[29] *[emphasis added]*

18. Fluazinam

CAS No: 79622-59-6

Uses in Canada: Fungicide used in 2 registered end products, 1 current application.

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[26] *Official Journal L 212, 02/08/1986 P. 0033 – 0034.* COUNCIL DIRECTIVE of 21 July 1986 amending Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0355:EN:HTML>

[27] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Default.aspx?tabid=1368>

[28] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Default.aspx?tabid=1368>

[29] PIC CIRCULAR XIII – June 2001. Available at <http://www.pic.int/Portals/5/en/Circular/CIRC13EN.pdf>.p. 15

Fluazinam was banned in Norway in June 2010 for reasons pertaining to the environment, specifically because of its persistence and toxicity to fish and earthworms. The following is an excerpt from the Rotterdam Convention PIC Circular XXXII describing the reasons for the Norwegian ban.

> *The application for re-registration of the product Shirlan and the active substance fluazinam was denied. The underlying reasons were strong indications of **fluazinam's persistency**, a potential for soil accumulation after repeated use; indications that fluazinam has a high potential to be found in the atmosphere as well as a potential to bioaccumulate; and that fluazinam is **extremely reproductively toxic to earthworms** and the risk of effects on earthworms is very high. **Fluazinam is furthermore classified with possible risk of harm to the unborn child**.*[30] *[emphasis added]*

19. Hexazinone

CAS No. 51235-04-2

Uses in Canada: Herbicide used in 8 registered products, 2 current applications.

Hexazinone was banned in Norway in 1998 due to concerns regarding impacts on the environment. The following is an excerpt from the summary of the Norwegian decision from the Rotterdam Convention database.

> *Persistent under Norwegian climatic conditions, **high mobility in soil, extremely toxic to algae**.*[31] *[emphasis added]*

20. Imazapyr

CAS No. 81334-34-1

Uses in Canada: Herbicide used in 5 registered end products and 6 current applications.

Imazapyr was banned in Norway as of December 31, 2001 for reasons pertaining to groundwater contamination and persistence and mobility in soils. The following is an excerpt from the Rotterdam Convention PIC Circular XIV describing the reasons for the Norwegian ban.

> *Arsenal 250 was denied re-registration due to **unacceptable risk for ground water contamination, caused by high mobility and persistence in soil**.* [32] *[emphasis added]*

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[30] PIC CIRCULAR XXXII – December 2010. Available at < http://www.pic.int/Portals/5/en/Circular/Circ32-EN.pdf>p. 28 and 29

[31] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Default.aspx?tabid=1368>

21. Linuron

CAS No. 330-55-2

Uses in Canada: Herbicide used in 8 registered end products, 3 current applications.

Linuron has not been approved for use in Norway as a active ingredient in pesticides since January 2007 due to concerns regarding impacts on human health and the environment, specifically concerns regarding it ability to cause malformations and cancer, it persistence in the environment, toxicity to aquatic organisms and risk to aquatic wildlife. The following are excerpts from the Rotterdam Convention PIC Circular XXVI describing the reasons for the Norwegian ban.

> ***Linuron was found to induce malformations, typical for anti-androgens, in male reproductive organs and was carcinogenic in animal studies.*** *It was also shown to induce haemolytic anaemia at low doses.*
>
> *During the assessment of this pesticide, a number of areas of concern were identified. Linuron can under certain circumstances be persistent in both soil and water/sediment systems.*
>
> *The risk of chronic negative effects on terrestric wildlife is regarded as low but as* ***linuron is very toxic to algae and other aquatic organisms*** *the risk to aquatic wildlife can be considered as considerable. In addition, linuron has anti androgenic properties that may cause unwanted effects in the environment.* [33] *[emphasis added]*

22. Paraquat (dichloride)

CAS No. 910-42-5

Uses in Canada: Herbicide used in 3 registered end products, 1 current application.

The approval of Paraquat in Europe was overturned by a court challenge by Sweden, supported by Denmark, Austria and Finland.[34] Those countries within the EU had already banned paraquat and did not want the EU approval to overturn their bans. The

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[32] PIC CIRCULAR XIV – December 2001.<http://www.pic.int/Portals/5/en/Circular/CIRC14EN.pdf>. p. 12

[33] PIC CIRCULAR XXVI – December 2007. Available at <http://www.pic.int/Portals/5/en/Circular/CIRC-26-EN.pdf> p. 22-23

[34] *International Chemical Secretariat. July 11, 2007. Paraquat banned in the EU.* <http://www.chemsec.org/news/news-2007/178-paraquat-banned->

court cited protection of human health and the environment in their reasons for their decision.[35]

23. Pentachlorophenol

CAS No. 87-86-5

Uses in Canada: Preservative used in 5 registered end products and 1 current application.

Pentachlorophenol has been banned in Switzerland since August 2005 due to reasons pertaining to the environment. The following are excerpts from the Rotterdam Convention PIC Circular XXII describing the reasons for the Swiss ban.

> *PCP is extremely toxic to aquatic organisms*
>
> *PCP is rather persistent, quite mobile, and found in all environmental compartments. At the higher concentrations found in the surface water near point sources or discharges (mg/litre), aquatic life is adversely affected. Ambient concentrations of PCP commonly found in surface waters (0.1 - 1 ug/litre)* ***may adversely affect very sensitive organisms*** *and may lead to alterations in the ecosystem.*
>
> *The use of technical PCP and its improper disposal (landfill and low-temperature combustion) can contribute significantlz to the contamination of the environment with PCP, PCDDs (polychlorodibenzodioxins) and PCDFs (polychlorodibenzofurans).* [36] *[emphasis added]*

Pentaclorophenol is also banned in the OECD country of Japan for human health reasons[37] and the non-OECD countries of Armenia, Côte d'Ivoire, Gambia, Guyana, Japan, Kyrgystan, Nigeria and Panama.[38]

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[35] Press Release No° 45/07. 11 July 2007. Judgment of the Court of First Instance in Case T-229/04.*Kingdom of Sweden v Commission of the European Communities* .THE COURT OF FIRST INSTANCE ANNULS THE DIRECTIVE AUTHORISING PARAQUAT AS AN ACTIVE PLANT PROTECTION SUBSTANCE. http://curia.europa.eu/en/actu/communiques/cp07/aff/cp070045en.pdf

[36] PIC CIRCULAR XXII – June 2006. Rotterdam. Secretariat for the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. Available at <http://www.pic.int/Portals/5/en/Circular/CIRC-23-EN.pdf>. Appendix 1

[37] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at < http://www.pic.int/Procedures/NotificationsofFinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx>

[38] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at:<http://www.pic.int/Procedures/NotificationsofFinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx>.

24. Permethrin

CAS no. 52645-53-1

Uses in Canada: Insecticide used in 296 registered end products, 21 applications

Permethrin is not approved for use in Europe. The application seeking approval of Permethrin was withdrawn in January 2000.[39] The application was found to not contain sufficient information to demonstrate that Permethrin met the health and environmental requirements of the European Directive regarding pest control products, particular with regard to the environmental fate and ecotoxicology of the substance in an aquatic ecosystem. [40]

Permethrin is also banned in the non-OECD country of Syria.[41]

25. Petroleum Hydrocarbon Blend

Uses in Canada: Adjuvant, Surfactant used in 8 registered end products

Some petroleum oils have not been approved as pesticides in Europe since June 2007 because their approval was not sought. One petroleum oil (CAS No. 92062-35-6) was not approved due to reasons pertaining to human health impacts.

The following is an excerpt from, "Commission Decision of 17 August 2009 concerning the non-inclusion of petroleum oil CAS 92062-35-6 in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

> *(5) During the examination of petroleum oil CAS 92062-35-6 by the Committee, it was concluded, taking into account comments received from Member States, that it has to be considered that there are clear indications that it may be expected that that* ***active substance has harmful effects on human health and in particular on consumers and operators****, because the existing evidence is not sufficient to allow the establishment of an ADI, ARfD and an AOEL.*

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[39] *Official Journal L 332, 28/12/2000 P. 0114 - 0115* . Commission Decision of 27 December 2000 concerning the non-inclusion of permethrin in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000D0817:EN:HTML>.

[40]European Commission Directorate General for Agriculture. Review report for the active substance permethrin. 13 July 2000. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000D0817:EN:NOT>

[41] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Procedures/NotificationsofFinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx

(6) The Commission invited the notifier to submit its comments on the results of the examination of Petroleum oil CAS 92062-35-6 and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments put forwards by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing Petroleum oil CAS 92062-35-6 satisfies in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(7) Petroleum oil CAS 92062-35-6 should therefore not be included in Annex I to Directive 91/414/EEC.[42] *[emphasis added]*

26. Quintozene

CAS No. 82-68-8

Use in Canada: Fungicide used in 5 registered end products in Canada

Quintozene is not approved for use in Europe since December 2000 due to concerns regarding human health and the environmental effects.

The following is an excerpt from, "Commission Decision of 27 December 2000 concerning the non-inclusion of quintozene in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing this active substance."

(7) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant-protection products containing quintozene satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the safety of operators and consumers potentially exposed to quintozene and with regard to the ***persistence of the substance in the environment and its possible impact on non-target organisms****.*

(8) The main notifier informed the Commission and the rapporteur Member State that it no longer wished to participate in the programme of work for this active substance, and therefore further information will not be submitted.

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[42] *Official Journal L 213, 18/08/2009 P. 0026 – 0027.* Commission Decision of 17 August 2009 concerning the non-inclusion of petroleum oil CAS 92062-35-6 in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009D0616:EN:NOT>

(9) Therefore it is not possible to include this active substance in Annex I to Directive 91/414/EEC.[43] *[emphasis added]*

Quintozene has also been banned in the OECD country of Switzerland since October 1998 due to reasons pertaining to the environment, in particular impacts on earthworms and fish.[44]

27. Simazine

CAS No: 122-24-9

Use in Canada: Herbicide used in 7 registered end products, 1 current application.

Simazine is not approved for use in Europe due to concerns regarding environmental contamination of groundwater.

The following is an excerpt from, "Commission Decision of 10 March 2004 concerning the non-inclusion of simazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance."

> *(8) The dossier and the information from the review were also submitted to the Scientific Committee for Plants. The Committee was asked to comment on the aspects of possible contamination of groundwater by simazine. In its opinion(7), the Scientific Committee on Plants did not accept the reported calculations of the environmental concentrations in groundwater. The Committee is also of the opinion that available monitoring data does not demonstrate that concentrations of simazine or its breakdown products will not exceed 0,1 µg/l in groundwater.*
>
> *(9) Assessments made on the basis of the information submitted have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing simazine satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.* ***In particular available monitoring data were insufficient to demonstrate that in large areas concentrations of the active substance and its breakdown products will not exceed 0,1 µg/l in groundwater. Moreover it cannot be assured that continued use in other areas will permit a satisfactory recovery of groundwater quality where concentrations***

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[43] *Official Journal L 332, 28/12/2000 P. 0112 – 0113.* Commission Decision of 27 December 2000 concerning the non-inclusion of quintozene in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant-protection products containing this active substance. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32000D0816:EN:NOT>

[44] PIC CIRCULAR XX – December 2004. Rotterdam. Secretariat for the Rotterdam Convention on Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. http://www.pic.int/Portals/5/en/Circular/CIRC20EN.pdf p. 140

> ***already exceed 0,1 µg/l in groundwater.*** *These levels of the active substance exceed the limits in Annex VI to Directive 91/414/EEC and would have an unacceptable effect on groundwater.*
>
> *(10) Simazine should therefore not be included in Annex I to Directive 91/414/EEC.*[45] *[emphasis added]*

Simazine has also been banned in Norway since 1998 for reasons pertaining to the environment. More specifically, concerns regard its high mobility, persistence in soil and water, extremely toxic to algae.[46]

28. Thiabendazole

CAS No. 148-79-8

Use in Canada: Material preservative and fungicide used in 12 products and 3 current applications.

Norway banned Thiabendazole in 1999 due to concerns regarding toxicity to animals and other environmental effects. The following is an excerpt from the Rotterdam Convention database regarding the reasons for the Norwegian ban.

> Thiabendazol is very toxic to daphnids, mysids and fish and toxic to earthworms, and it is also very persistent. [47]

29. Triclorfon

CAS No: 66758-31-4

Use in Canada: Insecticide used in 3 registered end products

Triclorfon was banned in Europe in 2007 due to reasons pertaining to human health and the environment.

The following in an excerpt from, "Commission Decision of 21 May 2007 concerning the non-inclusion of trichlorfon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance."

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[45] Commission Decision of 10 March 2004 concerning the non-inclusion of simazine in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing this active substance. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004D0247:EN:NOT>

[46] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Procedures/NotificationsofFinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx>

[47] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at <http://www.pic.int/Procedures/NotificationsofFinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx>

> *(5) Due to significant lack of supporting studies, it has not been possible to demonstrate a safe use of the substance. Based on the* ***available information it was not possible to perform the risk assessment of consumers, operators, workers and bystanders exposure****. Moreover, the* ***evaluation of fate and behaviour of the substance in the environment was limited and its eco-toxicological properties were not completely assessed****.*
>
> *(6) The Commission invited the notifier to submit its comments within four weeks on the results of the peer review and on its intention or not to further support the substance. The notifier submitted its comments which have been carefully examined. However, despite the arguments advanced, the above concerns remained unsolved, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing trichlorfon satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.*
>
> *(7) Trichlorfon should therefore not be included in Annex I to Directive 91/414/EEC.*[48] *[emphasis added]*

Also banned by the non-OECD country of Brazil for human health reasons.[49]

30. Trifluralin

CAS No: 1582-09-8

Uses in Canada: Herbicide used in 17 registered end products

Trifluralin was banned in Europe in 2010 due to reasons pertaining to its high toxic risk to aquatic organisms and benthic organisms.

The following is an excerpt from the, "Commission Decision of 25 June 2010 concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC".

> *(6) The new assessment by the rapporteur Member State and the new conclusion by the EFSA concentrated on the* ***concerns that lead to the non-inclusion, which were due to the high risk for aquatic organisms, especially fish, the toxicity of metabolites to sediment dwelling***

[48] *Official Journal L 133, 25/05/2007 P. 0042 – 0043.* Commission Decision of 21 May 2007 concerning the non-inclusion of trichlorfon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. Available at < http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32007D0356:EN:NOT>

[49] Rotterdam Convention. Database of Notifications of Final Regulatory Action. Available at < http://www.pic.int/Procedures/NotificationsofFinalRegulatoryActions/Database/tabid/1368/language/en-US/Default.aspx>

organisms, the consumer exposure for non-cereal applications, the high persistence in soil, the high potential for bioaccumulation, and the potential for long range transport via air.

(7) New data and information were submitted by the notifier in the updated dossier, in particular as regards the aquatic risk assessment, especially fish, the toxicity of metabolites to sediment dwelling organisms, the high persistence in soil and the high potential for bioaccumulation. In order to reduce the risk to consumers, the notifier, in the context of the resubmission, only supported applications on oil seed rape. As regards the potential for long range transport via air, the submitted data simply reproduced a monitoring report which already figured in the original dossier. A new assessment was performed, as included in the additional report and in the EFSA Scientific Report for trifluralin.

(8) However, the additional data and information provided by the notifier did not permit to eliminate all the specific concerns that led to the non-inclusion.

*(9**) In particular, the concern on potential high risk for aquatic organisms, especially fish, could not be solved due to shortcomings in the newly submitted studies. As a consequence, the surface water risk assessment could not be finalised. Furthermore, the potential for long range transport via air has not been adequately elucidated by the produced information which was of an obsolete nature.***

(10) The Commission invited the notifier to submit its comments on the results of the peer review. Furthermore, in accordance with Article 21(1) to Regulation (EC) No 33/2008, the Commission invited the notifier to submit comments on the draft review report and in particular on the remaining concerns for the aquatic risk and the potential for long range transport. The notifier submitted its comments, which have been carefully examined.

(11) However, despite the arguments put forward by the notifier, the concerns identified could not be eliminated, and assessments made on the basis of the information submitted and evaluated during the EFSA expert meetings have not demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing trifluralin satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC.

(12) Trifluralin should therefore not be included in Annex I to Directive 91/414/EEC.[50] *[emphasis added]*

[50] *Official Journal L 160, 26/06/2010 P. 0030 – 0031.* Commission Decision of 25 June 2010 concerning the non-inclusion of trifluralin in Annex I to Council Directive 91/414/EEC. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010D0355:EN:NOT>