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INTERGOVERNMENTAL NEGOTIATING COMMITTEE FOR AN INTERNATIONAL LEGALLY BINDING INSTRUMENT FOR THE APPLICATION OF THE PRIOR INFORMED CONSENT PROCEDURE FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES IN INTERNATIONAL TRADE
Tenth session
Geneva, 17 – 21 November 2003
Item 4 (d) of the provisional agenda*

Implementation of the interim prior informed consent procedure: Inclusion of chemicals

INCLUSION OF THE CHEMICALS AMOSITE, ACTINOLITE, ANTHOPHYLLITE, TREMOLITE AND CHRYSOTILE ASBESTOS, AND ADOPTION OF THE DRAFT DECISION GUIDANCE DOCUMENT

Note by the secretariat

Introduction

1. In paragraph 8 of its resolution on interim arrangements,[1] the Conference of Plenipotentiaries decided that the Intergovernmental Negotiating Committee shall decide, between the date on which the Convention is opened for signature and the date of its entry into force, on the inclusion of any additional chemicals under the interim prior informed consent (PIC) procedure in accordance with the provisions of Articles 5, 6, 7 and 22 of the Convention.

2. Paragraph 5, subparagraph (a) of Article 22 states that amendments to Annex III shall be proposed and adopted according to the procedure laid down in Articles 5 to 9 and paragraph 2 of Article 21. Under paragraph 2 of Article 21, amendments to the Convention shall be adopted at a meeting of the Conference of the Parties and the text of any proposed amendment shall be communicated to the Parties by the Secretariat at least six months before the meeting at which it is proposed for adoption.

* UNEP/FAO/PIC/INC.10/1.

[1] *Final Act of the Conference of Plenipotentiaries on the Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Rotterdam, Netherlands, 10-11 September 1998* (UNEP/FAO/PIC/CONF/5), annex I, resolution 1.

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3. At its third session, the Interim Chemical Review Committee reviewed three notifications of final regulatory action from three PIC regions to ban or severely restrict the chemicals amosite, actinolite, anthophyllite and tremolite (amphibole forms of asbestos), and two notifications of final regulatory action from two PIC regions to ban or severely restrict the chemical chrysotile (serpentine form of asbestos) and, taking into account the criteria set forth in Annex II of the Convention, concluded that the requirements of that Annex had been met. Accordingly, the Interim Chemical Review Committee recommended to the Intergovernmental Negotiating Committee at its ninth session that asbestos (amosite, actinolite, anthophyllite, tremolite and chrysotile forms) should become subject to the interim PIC procedure,[2] noting that the Interim Chemical Review Committee would develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with Article 7 of the Convention. It was noted that crocidolite (an amphibole form of asbestos) was already included in the interim prior informed consent procedure.

4. At its fourth session, the Interim Chemical Review Committee finalized the draft decision guidance document and decided to forward it and the recommendation for inclusion of amosite, actinolite, anthophyllite, tremolite and chrysotile forms of asbestos in the interim Prior Informed Consent Procedure to the Intergovernmental Negotiating Committee. The text of that recommendation, a summary of the deliberations of the Committee including a rationale for the inclusion of amosite, actinolite, anthophyllite, tremolite and chrysotile forms of asbestos based on the criteria listed in Annex II of the Convention, and a tabular summary of comments received and how they had been addressed, are attached as annex I to the present note.[3] The draft decision guidance document is reproduced as annex II[4] to the present note. Following the fourth session of the Interim Chemical Review Committee, the Secretariat, mindful of the complexity of the draft decision guidance document, made some additional editorial and formatting changes to enhance the readability of the document.

5. In accordance with decision INC-7/6, which sets out the process for drafting decision guidance documents, and in line with the time frame specified in paragraph 2 of Article 21, the secretariat circulated the present document to all Parties and observers on 14 May 2003.

Suggested action by the Committee

6. The Committee may wish to decide to make the amosite, actinolite, anthophyllite, tremolite and chrysotile forms of asbestos subject to the interim prior informed consent procedure as defined in paragraph 2 of the resolution on interim arrangements, and to approve the draft decision guidance document.

[2] See UNEP/FAO/PIC/ICRC.3/19 (UNEP/FAO/PIC/INC.9/6, annex), para.70 and annex III.

[3] In part, annex I to the present note reproduces annex V of the report of the Interim Chemical Review Committee on its fourth session (UNEP/FAO/PIC/ICRC.4/18).

[4] Version of December 2002 circulated in annex to document UNEP/FAO/PIC/ICRC.4/11.

Annex I

Asbestos

The Interim Chemical Review Committee,

Noting that at its third session it had reviewed the notifications of final regulatory actions by Australia, the European Community and Chile on asbestos and, taking into account the requirements set forth in Annex II of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, and had come to the conclusion that the requirements of that Annex had been met,

Recalling that, in line with paragraph 6 of Article 5 of the Convention, at its third session it had accordingly decided to recommend to the Intergovernmental Negotiating Committee that five additional forms of asbestos (actinolite, anthophyllite, amosite, tremolite and chrysotile) should become subject to the interim prior informed consent procedure and noting (Annex III of its report of its third session UNEP/FAO/PIC/ICRC.3/19) that it was to develop a draft decision guidance document and forward it to the Intergovernmental Negotiating Committee in accordance with Article 7 of the Convention,

Recalling also that, in accordance with the operational procedures for the Interim Chemical Review Committee, set forth in decision INC-7/6 of the Intergovernmental Negotiating Committee on the process for drafting decision guidance documents, it had established a task group to draft a decision guidance document on asbestos and that that task group, upon fulfilling the requirements of the operational procedures and in accordance with paragraph 1 of Article 7 of the Convention, had developed a draft decision guidance document on asbestos (UNEP/FAO/PIC/ICRC.4/11) and had submitted it to the Committee at its fourth session for further action

Noting that the draft decision guidance document was based on the information specified in Annex I of the Convention, as required by paragraph 1 of Article 7 of the Convention,

Recalling that in accordance with step 7 of the process for drafting decision guidance documents, final documentation forwarded by the Secretariat to all Parties and observers in advance of Intergovernmental Negotiating Committee sessions must include a draft decision guidance document, a recommendation by the Interim Chemical Review Committee for inclusion in the prior informed consent procedure, a summary of the deliberations of the Interim Chemical Review Committee including a rationale for inclusion based on the criteria listed in Annex II to the Convention, and a tabular summary of comments received by the Secretariat and how they had been addressed,

Adopts the following recommendation to the Intergovernmental Negotiating Committee:

Recommendation ICRC-4/1: Inclusion of five forms of asbestos in the interim prior informed consent procedure

The Interim Chemical Review Committee

Recommends, in line with paragraph 6 of Article 5 of the Convention, that the Intergovernmental Negotiating Committee should make the following subject to the interim prior informed consent procedure:

Chemical	Relevant CAS Number(s)	Category
Actinolite	77536–66–4	Industrial
Anthophyllite	77536–67–5	Industrial
Amosite	12172–73–5	Industrial
Tremolite	77536–68–6	Industrial
Chrysotile	12001–29–5/132207-32-0	Industrial

Notes that the draft decision guidance document also covers crocidolite and will replace the existing decision guidance document for that chemical, when adopted by the Committee;

Forwards, in line with paragraph 2 of Article 7 of the Convention, this recommendation, together with the draft decision guidance document on asbestos, to the Intergovernmental Negotiating Committee for a decision on the inclusion of asbestos in the interim prior informed consent procedure and adoption of the draft decision guidance document.

Appendix I

Rationale for the recommendation that asbestos (amphibole forms and chrysotile) should become subject to the interim prior informed consent procedure

In reviewing the notifications of final regulatory actions from the European Community, Chile and Australia that cover amphibole forms of asbestos (crocidolite, amosite, actinolite, anthophyllite, tremolite), and the notifications from the European Community and Chile that also cover chrysotile, and considering the supporting documentation and supplementary information provided at the meeting by the notifying Parties, the Interim Chemical Review Committee was able to confirm that the regulatory actions had been taken in order to protect human health. The European Community action was based on a risk evaluation made by an independent scientific committee. Its conclusions were that all forms of asbestos were carcinogenic to humans and that there was no threshold of exposure below which asbestos did not pose carcinogenic risks. The Chilean regulatory action was taken on the basis of a review of the health effects of asbestos, the evaluation of occupational exposure and the fact that there were no thresholds for the carcinogenic effect of asbestos. The basis of the Australian regulatory actions was human health risk assessments, taken at national and state level that focused on the carcinogenicity of inhaled asbestos and conditions of exposure in that country.

The Committee established that the final regulatory actions had been taken on the basis of risk evaluations and that those evaluations had been based on a review of scientific data. The available documentation demonstrated that the data had been generated in accordance with scientifically recognized methods, that the data reviews had been performed and documented in accordance with generally recognized scientific principles and procedures, and that the final regulatory actions had been based on chemical-specific risk evaluations taking into account the conditions prevailing within the European Community, Chile and Australia respectively.

The Committee established that the final regulatory actions provided a sufficiently broad basis to merit including amphibole forms of asbestos and chrysotile in the interim PIC procedure, and that those actions had led to a significant decrease in the quantities and uses of asbestos and the risks for human health in each notifying Party. The Committee also took into account that the considerations underlying the final regulatory actions were not of limited applicability but of broader relevance and that on the basis of information from Chile and Australia, and other relevant information provided by members at the meeting, there was ongoing international trade in asbestos.

The Committee noted that intentional misuse was not relevant to this chemical and that one of the forms of asbestos, crocidolite, was already listed in Annex III to the Convention.

The Committee concluded that the notifications of final regulatory actions by the European Community, Chile and Australia in respect of amphibole forms of asbestos met the criteria set out in Annex II to the Convention and that the notifications of final regulatory action from the European Community and Chile in respect of chrysotile also met those criteria.

Appendix II

Task Group on asbestos

Second-round comments on the draft internal working document for asbestos

Country	Comment	Response
Canada	Overall comment on the DGD In general, the various chapters are a lot cleaner whereby they cover only the type of asbestos they are supposed to. However, there are still statements that are applicable to all forms of asbestos.	Where possible the chapters have been tailored to refer to the specific form of asbestos. However because much of the information provided in notifications and referenced documents does not clearly distinguish each variant, in some sections it has been considered more appropriate to quote the information as provided.
Canada	Overall comment on the DGD The document gives the few countries that have banned the substance a lot more voice than it does to countries that are following a controlled or safe use approach to the substance. For example the title page of the DGD should read (top part) Operation of the interim Prior Informed Consent procedure for (certain hazardous chemicals and pesticides in international trade) instead of (for banned or severely restricted chemicals in international trade). Chrysotile is not banned or severely restricted internationally.	This is the model established by the Secretariat. The general issue will be raised with the Secretariat, and if necessary, discussed at the next meeting of the ICRC for general application to all DGDs
Canada	Overall comment on the DGD Canada considers that some important information included in this document is outdated and/or incomplete. We understand that more information will be provided elsewhere, such as the website. However, the DGD may still remain the main reference consulted by Parties in deciding how to manage the substance. The DGD could potentially lead some countries to use alternatives that are also dangerous products (if not as dangerous as certain forms of asbestos) to human health.	The ICRC has agreed that DGDs will summarize the national actions, which are time- and information-specific. Appropriate linkages to new or alternative information have been identified as a requirement – see Table 7 on the PIC website http://www.pic.int/en/Table7.htm
Canada	Crocidolite: Protective measures that have been applied concerning the chemical: Alternatives (p.3) Canada is also of the opinion that, in light of the fibrous nature of substitutes, care should be taken to limit exposure of workers to these particles. This comment applies to same section in all chapters.	The following text has been added to the italicized preamble for Alternatives, in each of the 3 chapters: "The hazards of the substitute materials and the controls needed for safe use should also be evaluated."
Canada	Crocidolite: Hazards and risks to human health and/or the environment - Crocidolite (p.4) «NTP Asbestos is classified as "Known Human Carcinogen" (US. 2001)» This statement could easily be amended to make it specific to crocidolite: «NTP Crocidolite asbestos is classified as "Known Human Carcinogen" (US. 2001)»	Changed as requested after consultation with USA.

Country	Comment	Response
Canada	Crocidolite: Annex 1: 2. Toxicological properties : 2.5 Effects on humans: last paragraph (p.8) «Many cohort studies on different populations have suggested that cancer at sites other than the lung, pleura, and peritoneum has resulted from occupational exposure to asbestos. In contrast other studies have shown no excess of cancer at other sites (IPCS, 1986). Gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to asbestos.» The paragraph is confusing. Does IPCS report contradiction in the findings of studies, or does IPCS only report that some studies show no excess of cancer at other sites? If we understand the meaning correctly, we suggest rewording along those lines: «In a review of studies, IPCS (1986) has found that some studies suggest that cancer at sites other than the lung pleura, and peritoneum has resulted from occupational exposure to asbestos, while others have shown no excess of cancer at other sites. IARC (1987) reports that cancers occurred at an increased incidence in groups occupationally exposed to asbestos.» The comment applies to all chapters where this paragraph is found.	Text of first sentence covering IPCS 1986 review has been changed as requested. Second sentence has been rearranged and an extra phrase from the IARC document added to improve clarity. Second sentence now reads: "IARC (1987) reports that gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to asbestos, although not all studies are consistent in this respect." Similar changes have been made in the "other amphiboles" chapter.
Canada	Crocidolite: Annex 1: 3. Human exposure/Risk evaluation: 3.6 Public exposure (p.10) «In the general population, the risks of mesothelioma and lung cancer attributable to asbestos […]» This statement could easily be amended to make it specific to crocidolite: «In the general population, the risks of mesothelioma and lung cancer attributable to crocidolite asbestos […]»	This is a general conclusion of the 1986 IPCS report, and is written as "asbestos".
Canada	Crocidolite: Annex 2 : Country name: Chile: 4.1 Risk evaluation (p.12) «In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.» This statement could easily be amended to make it specific to crocidolite: «In Chile, this means in particular those workers who have been exposed to crocidolite fibres from the manufacture of construction materials.»	**Text from Chilean supporting documentation.**
Canada	Crocidolite: Annex 2: Country name: European Community: 2. Succinct details of the final regulatory action(s) (p.14) «The placing on the market and use of chrysotile may be allowed by Member States for diaphragms for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner. The derogation will be reviewed before January 1 2008.» This paragraph is irrelevant to crocidolite and should only be found in the chrysotile chapter. The comment applies to all chapters where this paragraph is found.	Amended as necessary.

Country	Comment	Response
Canada	Crocidolite; Annex 2; Country name: European Community; 4.2. Criteria used Relevance to other States and Region (p.14) «General health problem in all states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban would protect health of workers and of the general public» There seems to be something missing in the first sentence. Further we question the relevance of this statement in this section. We understand the purpose of this section to be a description of how the regulatory action in the notifying country affects other countries. The comment applies to all chapters where this paragraph is found.	The first sentence amended in all 3 chapters to read: "There are general health problems…." in order to improve clarity. We note that this section of the notification form has been interpreted in different ways. However the statement is consistent with the guidance in the PIC document "Instructions for Submission of Notification of Final Regulatory Action to Ban or Severely Restrict a Chemical".
Canada	Crocidolite; Annex 2; Country name: European Community; 5. Alternatives (p.14) « The risk assessment undertaken by the CSTEE on chrysotile asbestos and candidate substitutes concludes that, both for the induction […]» This paragraph relates to chrysotile, therefore it is not relevant to the crocidolite chapter. The comment applies to all chapters where this paragraph is found.	Linking text has been added in the "crocidolite" and "other amphibole" chapter, indicating that the comparison is relevant for these variants of asbestos also**.**
Canada	Other amphibole forms; Hazards and risks to human health and/or the environment - Other amphibole forms (p.21) «NTP Asbestos is classified as "Known Human Carcinogen" (US. 2001)» This statement could easily be amended to make it specific to amphibole asbestos: «NTP Amphibole asbestos is classified as "Known Human Carcinogen" (US. 2001)»	Changed as requested after consultation with USA.
Canada	Other amphibole forms; Annex 1; 2.5 Effects on humans; 2nd paragraph (p.25) «Asbestosis was the first asbestos-related lung disease to be anthophyllite.» Something is missing in the sentence.	Amended, sentence now reads: "Asbestosis was the first asbestos-related lung disease to be recognized."
Canada	Other amphibole forms; Annex 1; 3.6. Public exposure (p.25) «In the general population, the risk of mesothelioma and lung cancer attributable to asbestos cannot be quantified reliably and are probably undetectably low.» This statement could easily be amended to make it specific to amphibole asbestos: «In the general population, the risk of mesothelioma and lung cancer attributable to amphibole asbestos cannot be quantified reliably and are probably undetectably low.»	This is a general conclusion of the 1986 IPCS report and is written as "asbestos".
Canada	Other amphibole forms; Annex 2; Country name: Australia; 3. Reasons for action (p.28) «Carcinogenic when inhaled. Should minimize exposure of people to risk of inhalation of asbestos.» This statement could easily be amended to make it specific to amphibole asbestos: «Carcinogenic when inhaled. Should minimize exposure of people to risk of inhalation of amphibole asbestos.»	This and previous section amended, in both "crocidolite" and "other amphibole" chapters. Although original text is taken directly from Australian notification, it would be more accurate to use the term "amphibole asbestos" as this is the scope of Australia's notification. .

Country	Comment	Response
Canada	Other amphibole forms Annex 2 Country name: Chile 4.1. Risk evaluation (p.29) «In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.» This statement could easily be amended to make it specific to amphibole asbestos: «In Chile, this means in particular those workers who have been exposed to amphibole fibres from the manufacture of construction materials.»	**Text from Chilean supporting documentation**
Canada	Chrysotile Hazards and risks to human health and/or the environment - Chrysotile (p.38) «NTP Asbestos is classified as "Known Human Carcinogen" (US. 2001)» This statement could easily be amended to make it specific to chrysotile: «NTP chrysotile is classified as "Known Human Carcinogen" (US. 2001)»	Changed as requested, after consultation with USA.
Canada	Chrysotile 2. Toxicological properties 2.1 General (p.40) Compared to the previous version of the DGD, text has been deleted from this section. We believe that an important statement has been lost, whereby chrysotile may cause cancer with a dose-response relationship.	Similar text reinstated
Canada	Chrysotile 2. Toxicological properties 2.2 Deposition and clearance (p.40) Chrysotile fibres are cleared from the lungs quickly.	Text added from IPCS, 1998 to cover this topic.
Canada	Chrysotile 2. Toxicological properties 2.5 Effects on humans 2.5.1 Asbestosis 1st paragraph (p.42) «Studies of workers exposed to chrysotile in different sectors have broadly demonstrated exposure-response or exposure-effect relationships for chrysotile-induced asbestosis, in so far as increasing levels of exposure have produced increases in the incidence and severity of the disease (IPCS, 1998).» The exact same statement is found in the next paragraph.	Duplication removed.
Canada	Chrysotile 2. Toxicological properties 2.5 Effects on humans 2.5.2 Lung cancer (p.42) Most of these case reports are mixed exposures: chrysotile and amphibole. Should report studies with chrysotile exposure only.	Text added from summary section of IPCS 1998 p8
Canada	Chrysotile 2. Toxicological properties 2.5 Effects on humans 2.5.3 Mesothelioma (p.42) There is only circumstantial evidence. Should only report factual evidence. Canada would be pleased to submit studies with factual information on chrysotile. These studies demonstrate that there is only little incidence of mesothelioma associated with chrysotile.	Replaced second paragraph of 2.5.3 in chrysotile chapter with "Available information suggests that the capacity to cause mesothelioma is substantially less for chrysotile than for amphiboles (especially crocidolite) (IPCS, 1986).

Country	Comment	Response
Canada	Chrysotile Annex 1 3.4. Occupational exposure (p.44) «The IPCS 1998 evaluation of chrysotile concludes that: […]» One of the conclusions is missing: «Control measures, including engineering controls and work practices, should be used in circumstances where occupational exposure to chrysotile can occur. Data from industries where control technologies have been applied have demonstrated the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient.» Further we do agree that materials should be used instead of minerals.	Two extra paragraphs now included. Introductory text changed to indicate that the section now covers conclusions and recommendations of IPCS 1998 evaluation, rather than conclusions alone as in previous version. Alternate text material/minerals placed in square brackets pending checking with IPCS.
Canada	Chrysotile Annex 1 3.5. Para-occupational exposure (p.44) High-speed tools are not the recommended tools to use.	Noted
Secretariat	It is not obvious that the document comprises, what are essentially three separate DGDs, suggest that a table of contents be inserted in the front end so that readers might more easily find the chemicals of interest	Table of contents included
Secretariat	For each of the three chapters - the range of the uses subject to the regulatory actions is not immediately clear, this could cause confusion for the reader, so if possible suggest that a sentence or two be added to more clearly define the scope of the uses that are no longer allowed for each of the different types of asbestos	FOR DISCUSSION AT ICRC
Secretariat	HS Codes: to consider the inclusion of HS code numbers for the various products made of or containing asbestos that are covered by the DGD. While all forms of asbestos have the same HS code (2524.00), there are a number of codes for products made of or containing asbestos, all in Chapter 68, - but also here there is no distinction between the various types of asbestos.	FOR DISCUSSION AT ICRC Possible text to be cleared by WCO. “Material and articles containing asbestos may also be found in Ch 68. Subsection 6812 covers certain items that contain asbestos; subsections 6811 and 6813 cover certain items that may or may not contain asbestos.”
Additional changes agreed at ICRC 4		
Switzerland	The heading ‘chapter’ is used on page one, but the sections are not referred to as chapters within the document.	Delete ‘chapter’ column from page one.

Country	Comment	Response
Australia	ICRC3 agreed to include a reference in the DGD to International Labour (ILO) Convention 162 for the information of States that chose not to ban asbestos and asbestos products totally	The following text is included in each of the three chapters (Crocidolite, Other amphibole forms and Chrysotile), under Protective measures that have been applied concerning the chemical / Other measures to reduce exposure: Further guidance is provided in the International Labour Organisation (ILO) Convention No. 162 "Safety in the Use of Asbestos" (http://www.ilo.org/ilolex/cgi-lex/convde.pl?C162) which applies to all activities involving exposure of workers to asbestos in the course of work The ILO recommendation 172 (http://www.ilo.org/ilolex/cgi-lex/convde.pl?R172), contains recommendations on safety in the use of asbestos, including details on protective and preventative measures, surveillance of the working environment and workers' health, information and education measures. ILO will also be added to the list of abbreviations.
Canada	The International Standards Organisation has produced a document on safe working practices for the use of asbestos	A reference to the ISO document, "Asbestos reinforced cement products – Guidelines for on-site work practices" is included, under Protective measures that have been applied concerning the chemical / Other measures to reduce exposure
Canada	Wording of disclaimer on alternatives is not the same in each section	Harmonized. The sentence "*The hazards of the substitute materials and the controls needed for safe use should also be evaluated"* was inserted for the other amphibole forms and chrysotile sections.
Canada	General reference to alternatives found in IPCS EHC 151 "Selected Synthetic Organic Fibres	Added to the end of the 'alternatives' section for each form of asbestos.
Canada	The section on socio-economic effects for the European Community included in each section is only relevant to the chrysotile section.	Deleted from crocidolite and other amphibole forms sections.
Canada	Information needed on IMDG codes for other amphibole forms and chrysotile	Information added.

Country	Comment	Response
Canada	Information on Emergency Procedure Guide number only available for chrysotile and may not be an internationally recognised code.	Deleted from each section.
Canada	In Annex I, section 3.4, second paragraph, line 6 'dispersed' should be deleted	Deleted
Canada	In Annex 2 for Chile, under alternatives, there was a suggestion to replace 'product of similar quality' with 'product of similar properties'.	No change was made, as the original text reflected the text of the notification.
Canada	In Annex 2 for the European Community, section 4.2 may be interpreted as a strong recommendation for a ban.	The paragraph was replaced by the text: Health problems similar to the ones experienced in the E.C. may occur in states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban protects the health of workers and of the general public.
Canada	In chrysotile asbestos, Annex I section 2.4, Effects on experimental animals, the text was considered to be equivocal. The issue of risks associated with ingestion needed to be addressed further.	The following text was inserted at the end of paragraph one of section 2.4 Since the publication of Environmental Health Criteria 53 (IPCS, 1986), there have been only a few studies in which possible harmful effects of the ingestion of chrysotile asbestos have been examined in experimental animals. All these studies gave negative findings
Canada	In chrysotile asbestos, Annex I section 2.5.4 'other malignant diseases' additional information on effects on workers was required.	The following text was inserted at the end of section 2.5.4 In predominantly "chrysotile"-exposed cohorts of workers, there is no consistent evidence of excess mortality from stomach or colorectal cancer.

Operation of the interim Prior Informed Consent procedure
for banned or severely restricted chemicals

Decision Guidance Document

Asbestos

(All forms of asbestos as listed below)
crocidolite
amosite
actinolite
anthophyllite
tremolite
chrysotile

This document incorporates information in previous Decision Guidance Document for *Crocidolit*e

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

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Introduction

The Rotterdam Convention is a multilateral environmental agreement of which the interim Secretariat is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization (FAO) of the United Nations. The objective of the Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.

Candidate chemicals for the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties in two different regions. Inclusion of a chemical in the Convention is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control/reduce such risks. However, inclusion does not imply that all Parties to the Convention have banned or severely restricted this chemical. For each chemical included in the Rotterdam Convention, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

In the period before the Convention enters into force the interim PIC procedure is in operation which follows the obligations of the Convention. During this period chemicals are approved for inclusion in the interim PIC procedure by the Intergovernmental Negotiating Committee (INC).

At its XXXX session, held in XXXX on XXXX the Intergovernmental Negotiating Committee adopted the decision guidance document for asbestos with the effect that this chemical became subject to the interim PIC procedure.

The present decision guidance document was communicated to the Designated National Authorities on [xxxx] in accordance with Article 10 paragraph 2 of the Rotterdam Convention.

Purpose of the Decision Guidance Document

For each chemical included in the interim PIC procedure a decision guidance document has been approved by the Intergovernmental Negotiating Committee. Decision guidance documents are sent to all Parties with a request that they provide a decision regarding future import of the chemical.

The decision guidance document is prepared by the Interim Chemical Review Committee (ICRC). The ICRC is a group of government designated experts established in line with Article 18 of the Convention, that evaluates candidate chemicals for possible inclusion in the Convention. The decision guidance document reflects the information provided by two or more Parties in support of the national regulatory actions to ban or severely restrict the chemical. It is not intended as the only source of information on a chemical nor is it updated or revised following its adoption by the Intergovernmental Negotiating Committee.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical as well as others that have not banned or severely restricted it. Such risk evaluations or information on alternative risk mitigation measures submitted by Parties may be found on the Rotterdam Convention web-site.

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or

through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in this document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries

Background

This decision guidance document includes six forms of asbestos, five amphibole forms **amosite**, a**nthophyllite, actinolite, crocidolite** and **tremolite** and one serpentine form, **chrysotile**.

Crocidolite asbestos was included in Annex III with the adoption of the text of the Rotterdam Convention in September 1998 by the Conference of Plenipotentiaries. A decision guidance document (dated 1992) has been circulated to all participating countries. Crocidolite was included here in the interest of completeness. This decision guidance document replaces the one for crocidolite circulated previously.

This six forms of asbestos included in this decision guidance document are divided among three chapters. First in the light of the fact that it was already included in Annex III crocidolite forms the first chapter. The four remaining amphibole forms of asbestos (actinolite, amosite, anthophyllite and tremolite) are grouped into a second chapter. The third chapter concerns the serpentine form of asbestos chrysotile. While there is some redundancy among the chapters the information has been presented in this way to try to improve the usability of the document.

Separate import decisions must be submitted for each of the six individual forms of asbestos. Where import responses have been provided for crocidolite, they need not be resubmitted.

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(N.B. Chemical elements and pesticides are not included in this list)

<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
µm	Micrometre
a.i.	active ingredient
ACGIH	American Conference of Governmental Industrial Hygienists
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CA	Chemicals Association
CAF	Compressed asbestos fibre
cc	Cubic centimetre
CCPR	Codex Committee on Pesticide Residues
CHO	Chinese hamster ovary
cm	centimetre
CSTEE	E.C. Scientific Committee on Toxicity, Ecotoxicity and the Environment
D	Dust
DNA	Deoxyribose Nucleic Acid
E.C.	European Community
EC_{50}	Effect concentration, 50%
ED_{50}	Effect dose, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
ERL	Extraneous residue limit
FAO	Food and Agriculture Organization of the United Nations
g	Gram
GL	Guideline level
GR	Granules
h	Hour
ha	Hectare
i.m.	Intramuscular
i.p.	Intraperitoneal
IARC	International Agency for Research on Cancer
IC_{50}	Inhibition concentration, 50%;
ILO	International Labour Organisation
IPCS	International Programme on Chemical Safety
IRPTC	International Register of Potentially Toxic Chemicals
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
k	Kilo- (x 1000)
kg	Kilogram
Koc	Organic carbon-water partition coefficient
l	Litre

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(N.B. Chemical elements and pesticides are not included in this list)

LC_{50}	Lethal concentration, 50%
LD_{50}	Lethal dose, 50%
LOAEL	Lowest observed adverse effect level
LD_{LO}	Lowest lethal dose
LOEL	lowest observed effect level
m	Metre
m.p.	melting point
mg	Milligram
ml	Millilitre
mPa	MilliPascal
MRL	maximum residue limit
MTD	maximum tolerated dose
NCI	National Cancer Institute (United States)
ng	Nanogram
NIOSH	National Institute of Occupational Safety and Health (United States)
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NOHSC	National Occupational Health and Safety Commission (Australia)
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
OP	organophosphorus pesticide
PCM	Phase contrast microscopy
PHI	pre-harvest interval
PIC	Prior Informed Consent
Pow	octanol-water partition coefficient
POP	persistent organic pollutant
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure (comparable to ADI)
SBC	secretariat for the Basel Convention
SC	Soluble concentrate
SG	water soluble granules
SL	soluble concentrate
SMR	standardized mortality ratio
STEL	short term exposure limit
TADI	temporary acceptable daily intake
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRL	temporary maximum residue limit
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
WP	wettable powder
wt	Weight

Crocidolite
(amphibole form of asbestos)

ASBESTOS: AMPHIBOLE – CROCIDOLITE

1. Identification and uses (see Annex 1) - Crocidolite

Common name	Crocidolite
Chemical name	Crocidolite, asbestos, Blue asbestos
Other names/ synonyms	
CAS-No.(s)	Crocidolite CAS number 12001–28–4
Other CAS numbers that may be used	General CAS number for asbestos: 1332–21–4
Harmonized System Customs Code	2524.00 (asbestos)
Other numbers:	European Community Customs number: CUS-No: 23648 (crocidolite)
Category	Industrial
Regulated Category	Industrial
Use(s) in regulated category	Asbestos cement, insulation material, protective textile products, beverage filters.
Trade names	Amorphous crocidolite asbestos, asbestos, blue asbestos, fibrous crocidolite asbestos, krokydolith, NCI C09007, riebeckite asbestos.
Formulation types	Natural mineral fibre
Uses in other categories	No reported uses as a pesticide chemical.
Basic manufacturers	Naturally occurring, mined

2. Reasons for inclusion in the PIC procedure – Crocidolite

Crocidolite is included in the PIC procedure as an industrial chemical. It is listed on the basis of the final regulatory actions to ban all uses of crocidolite notified by the European Community, Chile, Australia and Sri Lanka.

2.1. Final regulatory action: (see Annex 2 for details)

Australia

Severe restriction on use of all forms of amphibole asbestos (crocidolite, amosite, anthophyllite, actinolite and tremolite) is implemented through State and Territory legislation.

Reason: Human Health

Chile

Asbestos is severely restricted:
Production, importation, distribution, sale and use of crocidolite and any material or product containing it is prohibited.

Reason: Human Health

European Community

Banned - The placing on the market and use of all forms of asbestos (crocidolite, amosite, anthophyllite, actinolite, tremolite and chrysotile), and products containing these fibres added intentionally, is prohibited, with one limited exception in the case of chrysotile.

Reason: Human Health

Previous notifications

Crocidolite is included in Annex III on the basis of notifications from Sri Lanka, European Community countries and Sweden (not a member of the E.C. at that time).

Reason: Human Health

2.2 Risk evaluation

Australia

Decisions (by States and Territories of Australia) to take final regulatory action were taken on the basis of established risk/hazard to human health. Risk evaluations were undertaken to the standards then current.

Chile

A hazard evaluation was carried out based on a compilation of bibliographic sources and verification of adverse chronic effects in exposed workers in the asbestos cement industry. It was concluded that those at greatest risk are

workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.

European Community

An independent risk assessment was undertaken. This confirmed that all forms of asbestos can cause lung cancer, mesothelioma, and asbestosis; that no threshold level of exposure could be identified below which asbestos does not pose carcinogenic risks.

3. Protective measures that have been applied concerning the chemical – Crocidolite

3.1 Regulatory measures to reduce exposure

Australia	Protective measures were taken by prohibiting all uses of all amphibole forms of asbestos except sampling and analysis, maintenance, removal, disposal, encapsulation or enclosure, and uses associated with reducing the risk of human exposure to it.
Chile	Protective measures were taken by prohibiting all uses of crocidolite for use as an input to the manufacture of construction materials. All types of asbestos prohibited for use for any item, component or product that does not constitute a construction material unless excepted.
European Community	Protective measures were taken by prohibiting the placing on the market and use of crocidolite, amosite, anthophyllite, actinolite, tremolite and chrysotile and of products containing these fibres added intentionally, with one specific exception for chrysotile in respect of diaphragms for existing electrolysis installations (see Annex 2 for further details).

3.2 Other measures to reduce exposure

Australia

Guidance provided in documents available from NOHSC website at http://www.nohsc.gov.au/OHSLegalObligations/NationalStandards/asbest.htm are:
Code of Practice for the Safe Removal of Asbestos [NOHSC: 2002 (1988)]
Guidance Note on the Membrane Filter Method for Estimating Airborne Asbestos Dust [NOHSC: 3003(1988)]
Guide to the Control of Asbestos Hazards in Buildings and Structures [NOHSC: 3002 (1998)]

European Community

Directive on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom (Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48))
Directive on disposal of construction materials (Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20))

General

Dust control by wetting material, use of respirators, use of full protective clothing with attention when further treating any contaminated clothing.
Further guidance is provided in the ILO Convention No. 162 “Safety in the Use of Asbestos” (http://www.ilo.org/ilolex/cgi-lex/convde.pl?C162) which applies to all activities involving exposure of workers to asbestos in the course of work.
The ILO recommendation 172 (***http://www.ilo.org/ilolex/cgi-lex/convde.pl?R172***), contains recommendations on safety in the use of asbestos, including details on protective and preventative measures, surveillance of the working environment and workers’ health, information and education measures.
More specific information on measures to reduce exposures on construction sites is provided in the International Standard Organisation (ISO) 7337 “Asbestos-reinforced cement products – Guidelines for on-site work practices.”

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Chile

It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibro-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In the case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use, until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.

European Community

Identified alternatives include cellulose fibres, polyvinyl alcohol (PVA) fibres and P-aramid fibres.

General

Guidance on substituting alternatives to asbestos fibres is provided in IPCS Environmental Health Criteria 151 "Selected Synthetic Organic Fibres" (www.inchem.org).

3.4 Socio-economic effects

Australia

A regulatory impact statement for 1991 regulations in Victoria, a State of Australia, concluded that a process of substituting alternative materials had eliminated the use of asbestos in the majority of its former applications.

Chile

No assessment of socio-economic effects was undertaken.

4. Hazards and risks to human health and/or the environment – Crocidolite

4.1 Hazard Classification

IARC	Carcinogenic to humans (*Group 1*) IARC (1987)
European Community	Carc. Cat. 1 R45 May cause cancer T:R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation (E.C., 2001)
NTP	Crocidolite is classified as "Known Human Carcinogen" (US, 2001)

4.2 Exposure limits

No internationally agreed exposure limits available.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	UN number: 2212 Class 9 - Miscellaneous dangerous goods and articles Proper shipping name: BLUE ASBESTOS Packaging Group: II Hazchem Code: 2X Special Provision number: 168 Packaging requirements: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. Crocidolite (blue asbestos) should be regarded as the most hazardous type of asbestos. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping, will prevent the atmosphere from becoming dust laden.
International Maritime Dangerous Goods (IMDG) Code	UN No: 2212: Class or division: 9
Transport Emergency Card	TEC (R) – 912

4.4 First aid

NOTE: The following advice was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Not acutely toxic. In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children. There is no antidote. Seek medical advice.

4.5 Waste management

Asbestos may be recovered from waste slurries. Otherwise friable waste should be wetted and containerised (sealed, double bagging) to avoid dust formation during transport and disposal. Landfilling is recommended in a supervised landfill and waste should initially be covered with at least 15 cm of soil. For final closure of an area containing asbestos, a cover of at least 1 m of compacted soil should be applied.

Annexes

Annex 1 **Further information on the substance**

Annex 2 **Details on Final regulatory action**

Annex 3 **Address of designated national authorities**

Annex 4 **References**

Introduction to Annex I

The information presented in this Annex reflects the conclusions of the notifying parties: Australia, Chile and the European Community. In a general way, information provided by these parties on these hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in these countries, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning asbestos, including international reviews. The notification from Australia was first reported in the PIC Circular XI of June 2000, the notification from Chile was first reported in the PIC Circular XV of June 2002 and the notification from the European Community in PIC Circular XIII of June 2001.

Crocidolite was included as one of the subjects of an IPCS Environmental Health Criteria document (Asbestos and other Natural Mineral Fibres, EHC 53) published in 1986.

Annex 1 – Further information on Crocidolite

1. Physico-Chemical properties

1.1	**Identity**	Crocidolite
1.2	**Formula**	$Na_2FeII_3FeIII_2(Si_8O_{22})\ (OH)_2$
1.3	**Colour and Texture**	Blue, Flexible to brittle and tough
1.4	**Decomposition temperature**	400–600^oC
1.6	**Density (g/cm^3)**	3.3–3.4
1.7	**Resistance to acids**	Good
1.8	**Resistance to alkalis**	Good
1.9	**Tensile strength (10^3 kg/cm^2)**	35

2 Toxicological properties

2.1	**General**	Crocidolite is an amphibole form of asbestos (as are amosite, actinolite, anthophyllite and tremolite). There is general consensus amongst the scientific community that all types of asbestos fibres are carcinogenic (IPCS, 1986, 1998; Royal Society of Canada, 1996 cited by E.C., 1997) and can cause asbestosis, lung cancer and mesothelioma when inhaled.
2.2	**Deposition and Clearance**	Depending largely on size and shape, deposition of inhaled asbestos fibres may occur in lung tissue. Some fibres may be removed by mucociliary clearance or macrophages while others may be retained in the lungs for extended periods. Inhalation exposure is, therefore, generally regarded as cumulative, and exposures have been expressed in terms of concentration of fibres over time or phase contrast microscopy (PCM) fibre-years/ml.
2.3	**Mode of Action**	The ability of fibres to induce fibrogenic and carcinogenic effects seems to be dependent on their individual characteristics, including fibre dimension and durability (i.e. biopersistence in target tissues), which are determined in part by the physico-chemical properties (IPCS, 1998). It is well documented from experimental studies that fibres shorter than 5μm are less biologically active than fibres longer than 5μm. However, it is still uncertain whether short fibres have any significant biological activity. Furthermore it is still uncertain as to how long a fibre needs to remain in the lung in order to induce preneoplastic effects (IPCS, 1998). The mechanisms by which these fibres cause fibrogenic and carcinogenic effects are not completely understood. Possible mechanisms of fibrogenic effects of fibres include chronic inflammation processes mediated by production of growth factors (e.g., TNF-alpha) and reactive oxygen species. With regard to fibre-induced carcinogenicity, several hypotheses have been proposed. These include: DNA damage by reactive oxygen species induced by fibres; direct DNA damage by physical interactions between fibres and target cells; enhancement of cell proliferation by fibres; fibre-provoked chronic inflammatory reactions leading to prolonged release of lysozymal enzymes, reactive oxygen species, cytokines and growth factors; and action by fibres as co-carcinogens or carriers of chemical carcinogens to the target tissues (IPCS, 1998).
2.4	**Effects on animals**	Lowest published lethal dose for rat: 300 mg/kg bw. Results from animal studies reflect the known human health effects of asbestos. IARC (1977) reports that there was sufficient evidence for carcinogenicity to animals. All types of commercial asbestos fibre that have been tested are carcinogenic to mice, rats, hamsters and rabbits, producing mesotheliomas and lung

carcinomas after inhalation exposure and after administration intrapleurally, intratracheally, or intraperitoneally (IPCS, 1986) .

Crocidolite produced mesothelioma and lung carcinomas in rats after inhalation and mesothelioma following intrapleural administration. Crocidolite induced mesothelioma in hamsters following intrapleural administration. Intraperitoneal administration of crocidolite induced peritoneal tumours, including mesothelioma, in mice and rats. Given by the same route, crocidolite produced abdominal tumours in hamsters.

There is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986).

2.5 Effects on humans

Inhalation of asbestos dust including crocidolite can cause fibrosis of the lung (asbestosis), changes in one or both surfaces of the pleura, bronchial carcinoma (lung cancer), mesothelioma of the pleura and peritoneum, and possibly cancers of other sites (IPCS, 1986).

2.5.1 Asbestosis

Asbestosis was the first asbestos-related lung disease to be recognised. It is defined as diffuse interstitial fibrosis of the lungs resulting from exposure to asbestos dust. Scarring of the lungs reduces their elasticity and function resulting in breathlessness. It can appear and progress many years after the termination of exposure.

Under recent exposure conditions, asbestosis will rarely be detectable, even in its early stages, in less than 20 years from first exposure (IPCS, 1986). There is no substantial evidence that asbestos fibre type influences the frequency or severity of pulmonary fibrosis. However the risk may be higher in the textile industry than in mining or milling, or in the manufacture of friction products (McDonald, 1984 cited by IPCS, 1986).

2.5.2 Lung cancer

The first reports (Gloyne, 1935; Lynch & Smith, 1935, both cited by IPCS, 1986), suggesting that asbestos might be related to lung cancer occurrence were followed by approximately 60 case reports over the next 20 years. The first epidemiological confirmation of this association was published by Doll (1955, cited by IPCS 1986). Since then, over 30 cohort studies (on various forms of asbestos) have been carried out in industrial populations in several countries. The majority, but not all, have shown an excess lung cancer risk (IPCS 1986*)*.

Crocidolite is in IARC Group I: sufficient evidence for carcinogenicity to humans. Inhalation can cause fibrosis of the lung (asbestosis), bronchial carcinoma, mesothelioma of the pleura and peritoneum, and possibly cancers at other sites. Extra risk for mesothelioma: 10^{-4} at life-time exposure to 500 fibres/m^3 (0.0005 fibres/ml).

Type of industrial process may affect the incidence of lung cancer. The variations may be related to the state and physical treatment of the asbestos in different situations, the dust clouds thus containing asbestos fibres of different physical dimensions (IPCS, 1986). Combined exposure to asbestos and cigarette smoke synergistically increases the risk of lung cancer.

2.5.3 Mesothelioma

Pulmonary mesothelioma is a primary malignant tumour of the mesothelial surfaces, generally affecting the pleura and less commonly the peritoneum. Mesothelioma has been associated with occupational exposure to various types and mixtures of asbestos (including talc containing asbestos), although occupational exposures have not been identified in all cases. The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications. An increasing proportion of cases have been seen with increasing duration of exposure (IARC, 1987). It has been suggested that increased risk of mesothelioma may be related to the duration and intensity of asbestos exposure, and perhaps also the time from first exposure (IPCS, 1986).

The majority of known cases of mesothelioma arise as a result of occupational or para-occupational exposure to asbestos (IPCS, 1986). No association with smoking has been observed (McDonald, 1984 cited by IPCS 1986).

There is a general consensus that amphiboles, and crocidolite in particular, pose a risk of induction of mesothelioma in exposed workers. (Meldrum, 1996 cited by E.C., 1997). Mesothelioma has appeared frequently in subjects with exposure to amphiboles. Current information does not suggest an important differential of mesothelioma risk according to the industrial process (IPCS, 1986).

Studies suggest that amphibole asbestos may result in the development of mesothelioma at lower levels of cumulative exposure than that required for lung cancer, although no reliable exposure-response curve can be produced for asbestos-induced mesothelioma in animals or humans (Meldrum, 1996 cited by E.C., 1997). Bignon (1997 cited by E.C., 1997) states that mesothelioma can develop at doses of maybe 10 to 1,000 times lower than those required for broncho-pulmonary cancer.

Case-control epidemiological studies, in employees at plants manufacturing asbestos cement products, showed a relationship between duration of employment and risk of mesothelioma especially from crocidolite. A strong correlation between mesothelioma and exposure to asbestos (mostly crocidolite) was found in mine workers (Western Australia) and in gas masks makers. In an asbestos factory (East London 1933-1980) mesotheliomas and lung cancer rates showed a dose response relationship and were related to duration of employment.

In a review of studies, IPCS (1986) has found that some studies suggest that cancer at sites other than the lung, pleura and peritoneum has resulted from occupational exposure to asbestos, while others have shown no excess of cancer at other sites. IARC (1987) reports that gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to asbestos, although not all studies are consistent in this respect.

2.6 Summary of mammalian toxicity and overall evaluation

Fibrosis in many animal species, and bronchial and pleural carcinomas in the rat, have been observed following inhalation of amphibole asbestos. In these studies there were no consistent increases in tumour incidence at other sites, and there is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986). Epidemiological studies, mainly on occupational groups, have established that all types of asbestos fibres are associated with diffuse pulmonary fibrosis (asbestosis), bronchial carcinoma (lung cancer), and primary malignant tumours of the pleura and peritoneum (mesothelioma). That asbestos causes cancers at other sites is less well established. Cigarette smoking increases the asbestosis mortality and the risk of lung cancer in persons exposed to asbestos but not the risk of mesothelioma (IPCS, 1986).

3 Human exposure/Risk evaluation

3.1 Food

In tallow-treated rice concentrations up to 3.7×10^{12} fibres/kg may be found. Crocidolite may occur in beverages up to 12×10^{6} fibres per litre (National Drinking Water regulations 1991). Up to 12×10^{6} fibres/litre have been found in soft drinks (IPCS, 1986).

3.2 Air

At remote rural locations, fibre levels (> 5μm) are generally < 1 fibre/litre (< 0.001 fibre/ml) and in urban air they range from < 1 to 10 fibres/litre (0.001 to 0.01 fibres/ml) or occasionally higher. Airborne levels in residential areas in the vicinity of industrial sources have been found to be within the range of those in urban areas or occasionally slightly higher. Non-occupational indoor levels are generally within the range found in ambient air (IPCS, 1986; 1998).

Concentrations in air: near mills, mines and industrial sites up to 600,000 fibres/m^3 (0.6 fibres/ml), at urban locations 10,000 fibres/m^3 (0.01 fibres/ml).

3.3 Water

Reported concentrations of asbestos in drinking-water range up to 200×10^{6} fibres/litre (all fibre lengths) (IPCS. 1986).

Maximum residue limits: In drinking water: 7×10^{6} fibres/l (National drinking water, 1991)

3.4 Occupational exposure

Main exposure sources are handling, processing and disposal of dry asbestos or asbestos containing products, where fibres are released into the air. The highest concentrations measured during mining and industrial handling were 800×10^{6} fibres/m^3 (800 fibres/ml), but were without any means of dust suppression. During home construction and renovation up to 10×10^{6} fibres/m^3 (10 fibres/ml) have been recorded. Exposure limits: USA, 200,000 fibres/m^3 (0.2 fibres/ml) (TLV, 8-hr TWA); EEC 300,000 fibres/m^3 (0.3 fibres/ml) for fibre length >5μm.

Among occupational groups, exposure to asbestos poses a health hazard that may result in asbestosis, lung cancer and mesothelioma. The incidence of these diseases is related to fibre type, fibre size, fibre dose and industrial processing (IPCS, 1986).

The European Community notification noted that exposure of workers and other users of asbestos-containing products is in general technically extremely difficult to control in practice and may greatly exceed current limit values on an intermittent basis. It was recognized that a controlled and safe occupational use of asbestos could not be established for several working situations like e.g. building sites, repairs, or waste removal. As asbestos was widely used and no safe concentration threshold could be established it was decided to severely restrict the use of asbestos.

The Chile notification noted that in general the highest exposures to asbestos are amongst the working population whether during manufacture of materials containing asbestos or during installation or demolition. In Chile this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. In the case of brake linings or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. Health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.

3.5 Para-occupational exposure

Members of the families of asbestos workers handling contaminated work clothes and, in some cases, members of the general population may be exposed to elevated concentrations of airborne asbestos fibres. Asbestos has been used widely in building materials for domestic application (e.g. asbestos-cement products and floor tiles) and elevated airborne levels have been measured during the manipulation of these materials (e.g. home construction and renovation by the homeowner) (IPCS, 1986).

In para-occupational groups, which include persons with household contact and neighbourhood exposure, the risk of mesotheliomas and lung cancer is generally much lower than for occupational groups. Risk estimation is not possible because of the lack of exposure data required for dose-response characterization. The risk of asbestosis is very low (IPCS, 1986).

The Chile notification notes that asbestos fibres are not easily released from asbestos in a cement matrix, in sheeting used in construction. However, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from the asbestos-fibre dust given off.

3.6 Public exposure

In the general population, the risks of mesothelioma and lung cancer attributable to asbestos cannot be quantified reliably and are probably undetectably low. The risk of asbestosis is virtually zero. (IPCS, 1986).

4 Environmental fate and effects

4.1 Fate

Crocidolite fibres are relatively stable and are transported via air and water over great distances.

4.2 Effects

Not enough data available to draw a conclusion.

5 Environmental Exposure/Risk Evaluation

Environmental effects are not relevant to the risk evaluation used to support the regulatory decisions.

Annex 2 – Details on final regulatory actions reported – Crocidolite

Country Name: Australia

1	**Effective date(s) of entry into force of actions**	Most jurisdictions placed severe restrictions on asbestos use during the late 1970's and early 1980s (some of the legislation under which the current restrictions are in force was enacted during the 1990s and incorporated/superseded existing restrictions).
	Reference to the regulatory document	Commonwealth – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*. New South Wales – *Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996* under *Occupational Health and Safety Act 1983.* Northern Territory – *Work Health (Occupational Health and Safety) Regulations 1996* under *Work Health Act 1996.* Queensland – *Workplace Health and Safety Regulation 1997* under *Work Health and Safety Act 1995.* South Australia – *Occupational Health, Safety and Welfare Regulations 1995* under *Occupational Health, Safety and Welfare Act 1986.* Tasmania – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*. Victoria – *Occupational Health and Safety (Asbestos) Regulations 1992* under *Occupational Health and Safety Act 1985*. Western Australia – *Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992* under *Health Act 1911*.
2	**Succinct details of the final regulatory action(s)**	Amphibole forms of asbestos are severely restricted. Legislation is primarily through States and Territories.
3	**Reasons for action**	Carcinogenic when inhaled. Should minimise exposure of people to risk of inhalation of amphibole asbestos.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	The basis of the Australian regulatory actions was human health risk assessments, taken at national and state level that focussed on the carcinogenicity of inhaled asbestos and conditions of exposure in that country.
4.2	**Criteria used**	Unacceptable risk to human health. Regulatory actions for asbestos were taken incrementally, reflecting the building knowledge on its risks. The major health effects identified as a result of inhalation of amphibole asbestos are asbestosis and carcinogenicity (NHMRC 1982).
	Relevance to other States and Region	Crocidolite is already included in the Rotterdam Convention.
5	**Alternatives**	No information
6	**Waste management**	No information
7	**Other**	Crocidolite is listed in the Australian National Occupational Health and Safety Commission (NOHSC) *Draft* List of Designated Hazardous Substances, with the classification: Carcinogen. Cat.1 • R45 – May cause cancer Toxic (T) R48/23 – Toxic: danger of serious damage to health by prolonged exposure through inhalation No exposure standards available. Previously TWA 0.1 fibre per ml of air. Currently being reviewed by Chemicals Framework Team under the NOHSC.

Country Name: Chile

1	**Effective date(s) of entry into force of actions**	Supreme Decree No. 656 entered into force 180 days after its publication in the Official Journal, on 12 July 2001.
	Reference to the regulatory document	Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001
2	**Succinct details of the final regulatory action(s)**	Production, importation, distribution, sale and use of crocidolite and any material or product containing it are prohibited. Production, importation, distribution, sale and use of construction materials containing any type of asbestos are prohibited. Production, importation, distribution, sale and use of chrysotile, actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material are prohibited, with certain specific exceptions.
3	**Reasons for action**	Human Health To reduce exposure to asbestos amongst the working population during manufacture of material containing asbestos or during installation or demolition.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	The foreign literature and analysis of domestic cases of asbestosis and mesothelioma indicate that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. No epidemiological precedents are known that show that there is a risk to the population from asbestos, which is already included within a cement matrix in sheeting used in construction, given that the asbestos fibres are not easily released from the matrix. Nor is there any significant known risk from consuming water piped through asbestos cement piping. Nevertheless, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from asbestos-fibre containing dust given off. In the case of brake lining or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. It should be noted that health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.
4.2	**Criteria used**	Unacceptable risk to workers. All types of asbestos are hazardous to health to varying degrees depending on the form of exposure (it has been shown that the risk is from inhalation), the class of asbestos (blue asbestos is the most toxic), the size of the fibres, fibre concentration and interaction with other factors (tobacco smoking potentiates the effects). Generally speaking, the highest exposures are amongst the working population whether during manufacture of the materials containing asbestos or during installation or demolition.
	Relevance to other States and Region	The regulatory action prohibits imports of asbestos in general, whatever the country of origin. Therefore no country may export asbestos to Chile except in specific cases, which exclude material and inputs for construction material and must be expressively authorized by Health Authority.
5	**Alternatives**	It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibre-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use until the existing in-use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.

6	**Waste management**	No information
7	**Other**	Crocidolite is listed in the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), with the classification: A.1 Proved Human Carcinogen In accordance with the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), crocidolite fibres exposure limit value for workers is 0.16 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5μm length and a ratio length to diameter equal to or greater than 3:1.

Country Name: European Community

1	**Effective date(s) of entry into force of actions**	Regulatory action was first taken in 1983, in relation to crocidolite. Subsequently, such action has progressively been extended to all forms of asbestos. The latest regulatory action entered in force on 26.8.1999 (OJ L 207 of 6.8 1999, p. 18). Member States of the E.C. were obliged to implement the necessary national legislation at the latest by 1st January 2005.
	Reference to the regulatory document	Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.91983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)
2	**Succinct details of the final regulatory action(s)**	The placing on the market and use of crocidolite fibres and products containing these fibres added intentionally are prohibited. The use of products containing asbestos fibres that were already installed and/or in service before the implementation date of Directive 1999/77/ E.C. by the Member State concerned could continue to be authorised until they are disposed of, or reach the end of their service life. However, Member States could, for reasons of protection of health, prohibit within their territory the use of such products before they are disposed of or reach the end of their service life.
3	**Reasons for action**	Prevent health effects (asbestosis, lung cancer, mesothelioma) for workers and general public.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	A comparison of asbestos with possible substitutes by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) concluded that all forms of asbestos are carcinogenic to humans and are likely to present a greater risk than substitutes (CSTEE 1998).
4.2	**Criteria used**	Standard E.C. criteria used for evaluation of exposure.
	Relevance to other States and Region	Health problems similar to the ones experienced in the E.C. may occur in states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban protects health of workers and of the general public.
5	**Alternatives**	The risk assessment under taken by the CSTEE on chrysotile asbestos and candidate substitutes would be relevant for other variants of asbestos also. It concludes that, both for the induction of lung and pleural cancer and lung fibrosis and for other effects, it is unlikely that the alternatives cellulose fibres, PVA fibres or P-aramid fibres pose an equal or greater risk than chrysotile asbestos. With regard to carcinogenesis and induction of lung fibrosis the risk is regarded to be lower. (CSTEE, 1998)
6	**Waste management**	In accordance with Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48) on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom or materials containing asbestos involving the release of asbestos fibres or dust must not cause significant environmental pollution. Construction materials have been classified as hazardous waste and will thus, as from 1 January 2002, have to be disposed of in line with the obligations laid down in Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20). In addition, the Commission is considering measures to promote the practice of selective demolition in order to segregate the hazardous waste present in construction materials and ensure their safe disposal.
7	**Other**	In accordance with Council Directive 83/477/EEC (OJ L 263, 24.9.1983, p.25), as amended by Council Directive 91/382/EEC (OJ L 206, 29.7.1991, p.16) the European Community exposure limit values for workers are currently 0.3 fibres/ml for forms of asbestos other than chrysotile. Exposure limit values for workers: Proposal still under

consideration before the Council and the European Parliament: in 2001 the European Commission proposed (OJ C 304 E 30/10/2001, p.175) that these limits be replaced by a reduced, single limit value of 0.1 fibres/ml for all forms of asbestos.

Previous notifications

Crocidolite is already listed on Annex III of the Rotterdam Convention on the basis of: regulatory actions in Sri Lanka in 1986, European Community in1988 and Sweden in1988. In Sri Lanka, import and sale were banned. In E.C. countries, crocidolite asbestos fibre or products containing it were prohibited for use. In Sweden, the substance was severely restricted and could not be used without the permission of the Labour Inspectorate.

Reason for the control action: The link between exposure to crocidolite and asbestos-type diseases such as mesothelioma (lung cancer) is well documented from occupational data and scientific evidence. The substance is carcinogenic in both humans and test animals, and is considered to be a more potent carcinogen than white or brown asbestos (DGD for crocidolite, 1992).

Annex 3 – Addresses of designated national authorities

AUSTRALIA

P

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C

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EUROPEAN COMMUNITY

CP

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C Industrial chemicals
CP Pesticides, industrial chemicals
P Pesticides

Annex 4 – References – Crocidolite

Regulatory actions

Australia

Commonwealth of Australia – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*.

New South Wales – *Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996* under *Occupational Health and Safety Act 1983.*

Northern Territory – *Work Health (Occupational Health and Safety) Regulations 1996* under *Work Health Act 1996.*

Queensland – *Workplace Health and Safety Regulation 1997* under *Work Health and Safety Act 1995.*

South Australia – *Occupational Health, Safety and Welfare Regulations 1995* under *Occupational Health, Safety and Welfare Act 1986.*

Tasmania – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979* .

Victoria – *Occupational Health and Safety (Asbestos) Regulations 1992* under *Occupational Health and Safety Act 1985*.

Western Australia – *Occupational Health Safety and Welfare Regulation 1988 ; Health (Asbestos) Regulations 1992* under *Health Act 1911*.

Chile

Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001

European Community

Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.91983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)

Other Documents

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CSTEE (1998) Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) – Opinion on Chrysotile asbestos and candidate substitutes expressed at the 5th CSTEE plenary meeting, Brussels, 15 September 1998 http://europa.eu.int/comm/food/fs/sc/sct/out17_en.html

Directive 1999/77/ E.C. 0f 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex I to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p. 24).

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IPCS (1986) Environmental Health Criteria 53: Asbestos and other Natural Mineral Fibres. World Health Organisation, Geneva.

IPCS (1998) Environmental Health Criteria 203: Chrysotile asbestos. World Health Organisation, Geneva.

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McDonald J C (1984) Mineral fibres and cancer. Ann. Acad Med Singapore 13:345-352

Meldrum M (1996) Review of fibre toxicology. Health and Safety Executive, UK.

National primary drinking water regulations—synthetic organic chemicals and inorganic chemicals, final rule, 56 Federal Register 3526 (January 30, 1991)

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Amosite, Anthophyllite, Actinolite, Tremolite (amphibole forms of asbestos)

ASBESTOS: AMPHIBOLE – OTHER FORMS

1. Identification and uses (see Annex 1) - Other amphibole forms

Common names	**AMOSITE**	**ANTHOPHYLLITE**	**ACTINOLITE**	**TREMOLITE**
Chemical name	Varieties of asbestiform hydrated silicates, with complex crystal structures			
Other names/ synonyms	Brown asbestos Mysorite	Anthophyllite asbestos Azbolen asbestos	Actinolite asbestos	Tremolite asbestos
CAS-No.(s)	12172–73–5	77536–67–5	77536–66–4	77536–68–6
Other CAS numbers that may be used	1332–21–4 (general CAS number for asbestos)			

E.C. number	E.C.-No: 310–127–6 Naturally occurring substances (Asbestos fibres fall under this E.C.-number)
Harmonized System Customs Code	2524.00: amphibole asbestos concentrates, amphibole asbestos crude ore, asbestos, asbestos flakes, asbestos powder, asbestos, crude, asbestos, raw, chrysotile asbestos concentrates, chrysotile asbestos crude ore, waste and scrap of asbestos)
Other numbers:	E.C. Customs numbers: CUS-No: 23743 (amosite), 23672 (anthophyllite), 23696 (actinolite), 23706 (tremolite),
Category	Industrial
Regulated Category	Industrial
Use(s) in regulated category	**Australia –** (Information on amphibole forms) Fireproof fabrics, yarn and thread; gaskets and compressed asbestos fibre jointing; reinforcing agent in rubber, plastics, cement, sheets and panels; paper, millboard and felt; tubes and pipes; chemical filters and diaphragms. **Chile** – (Information on all forms) Manufacture of construction materials, in particular asbestos-cement panelling, asbestos pipes, roof tiles, and preformed products such as tanks. Manufacture of brake lining and clutches. **European Community** – (Information on all forms) Used mainly in seals, gaskets, joints, diaphragms, and armaments. Former usage (before restriction/ban in E.C.) in heat-resistant insulators, cements, furnace and hot pipe coverings, inert filler medium (laboratory & commercial), fireproof gloves, clothing, brake lining. NaOH treated asbestos, AscariteBaker, has been used to absorb CO_2 in combustion analysis.
Trade names	-
Formulation types	Asbestos has been used in the manufacture of a wide range of articles and products.
Uses in other categories	No reported uses as a pesticide chemical.
Basic manufacturers	Naturally occurring, mined

2. Reasons for inclusion in the PIC procedure – Other amphibole forms

Amosite, anthophyllite, actinolite and tremolite (amphibole forms of asbestos) are included in the PIC procedure as industrial chemicals. They are listed on the basis of the final regulatory actions to ban or severely restrict their uses as notified by Australia, Chile and the European Community.

2.1 Final regulatory action: (see Annex 2 for details)

Australia

Severe restriction on use of all forms of amphibole asbestos (crocidolite, amosite, anthophyllite, actinolite and tremolite) is implemented through State and Territory legislation.

Reason: Human Health

Chile

Severely restricted:

Production, importation, distribution, sale and use of construction materials containing any type of asbestos is prohibited.

Production, importation, distribution, sale and use of actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material is prohibited, with certain specific exceptions.

Reason: Human Health

European Community

Banned – The placing on the market and use of, amosite, anthophyllite, actinolite and tremolite, and products containing these fibres added intentionally, is prohibited.

Reason: Human Health

2.2 Risk evaluation

Australia

Decisions (by States and Territories of Australia) to take final regulatory action were taken on the basis of established risk/hazard to human health. Risk evaluations were undertaken to the standards then current.

Chile

A hazard evaluation was carried out based on a compilation of bibliographic sources and verification of adverse chronic effects in exposed workers in the asbestos cement industry. It was concluded that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.

European Community

An independent risk assessment was undertaken. This confirmed that all forms of asbestos can cause lung cancer, mesothelioma, and asbestosis; that no threshold level of exposure could be identified below which asbestos does not pose carcinogenic risks.

3. Protective measures that have been applied concerning the chemical – Other amphibole forms

3.1 Regulatory measures to reduce exposure

Australia	Protective measures were taken by prohibiting all uses of all amphibole forms of asbestos except sampling and analysis, maintenance, removal, disposal, encapsulation or enclosure, and uses associated with reducing the risk of human exposure to it.
Chile	Protective measures were taken by prohibiting all uses of all types of asbestos for use as an input to the manufacture of construction materials.
	All types of asbestos prohibited for use for any item, component or product that does not constitute a construction material unless excepted.
	Any type of asbestos (except crocidolite): the use of asbestos may be authorized in the manufacture of products or components that are not construction materials so long as the interested parties can prove that there is no technically or economically feasible substitute for it.
European Community	Protective measures were taken by prohibiting the placing on the market and use of, amosite, anthophyllite, actinolite, tremolite and of products containing these fibres added intentionally, (see Annex 2 for further details).

3.2 Other measures to reduce exposure

Australia

Guidance documents available from NOHSC website at http://www.nohsc.gov.au/OHSLegalObligations/NationalStandards/asbest.htm are:
Code of Practice for the Safe Removal of Asbestos [NOHSC:2002 (1988)]
Guidance Note on the Membrane Filter Method for Estimating Airborne Asbestos Dust [NOHSC:3003(1988)]
Guide to the Control of Asbestos Hazards in Buildings and Structures [NOHSC:3002 (1998)]

European Community

Directive on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom (Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48))
Directive on disposal of construction materials (Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20))

General

Dust control by wetting material, use of respirators, use of full protective clothing with attention when further treating any contaminated clothing.
Further guidance is provided in the ILO Convention No. 162 "Safety in the Use of Asbestos" (http://www.ilo.org/ilolex/cgi-lex/convde.pl?C162) which applies to all activities involving exposure of workers to asbestos in the course of work.
The ILO recommendation 172 (***http://www.ilo.org/ilolex/cgi-lex/convde.pl?R172***), contains recommendations on safety in the use of asbestos, including details on protective and preventative measures, surveillance of the working environment and workers' health, information and education measures.
More specific information on measures to reduce exposures on construction sites is provided in the International Standard Organisation (ISO) 7337 "Asbestos-reinforced cement products – Guidelines for on-site work practices."

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Chile

It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibro-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In the case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use, until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.

European Community

Identified alternatives include cellulose fibres, polyvinyl alcohol (PVA) fibres and P-aramid fibres.

General

Guidance on substituting alternatives to asbestos fibres is provided in IPCS Environmental Health Criteria 151 "Selected Synthetic Organic Fibres".

3.4 Socio-economic effects

Australia

A regulatory impact statement for 1991 regulations in Victoria, a State of Australia, concluded that a process of substituting alternative materials had eliminated the use of asbestos in the majority of its former applications.

Chile

No assessment of socio-economic effects was undertaken.

4 Hazards and risks to human health and/or the environment – Other amphibole forms

4.1 Hazard Classification	
IARC	*Carcinogenic to humans (*Group 1*)* IARC (1987)
European Community	Carc. Cat. 1 R45 May cause cancer T:R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation (E.C., 2001)
NTP	Amphibole asbestos is classified as "Known Human Carcinogen" (US, 2001)

4.2 Exposure limits

No internationally agreed exposure limits available.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing group for amosite:	UN number: 2212 Class 9 – Miscellaneous dangerous goods and articles Proper shipping name: BROWN ASBESTOS Packing Group: II Hazchem Code: 2X Special Provision number: 168 Packaging requirements: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. Crocidolite (blue asbestos) should be regarded as the most hazardous type of asbestos. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping, will prevent the atmosphere from becoming dust laden.
Hazard Class and Packing group for actinolite, anthophyllite and tremolite	UN number: 2590 Class 9 – Miscellaneous dangerous goods and articles Proper shipping name: WHITE ASBESTOS Packing Group: III Hazchem Code: 2X Emergency Procedure Guide: *This item of information not yet available* Special Provision number: 168 Packaging requirements: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping will prevent the atmosphere from becoming dust laden. This entry may also include talc containing tremolite and/or actinolite.
International Maritime Dangerous Goods (IMDG) Code	Amosite: UN No: 2212: Class or division: 9 Actinolite, anthophyllite and tremolite: UN No:2590 Class or division: 9
Transport Emergency Card	Information not available on these forms. (Note: numbers have been assigned for crocidolite and chrysotile.)

4.4 First aid

NOTE: The following advice was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Not acutely toxic. In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children. There is no antidote. Seek medical advice.

4.5 Waste management

Asbestos may be recovered from waste slurries. Otherwise friable waste should be wetted and containerised (sealed, double bagging) to avoid dust formation during transport and disposal. Landfilling is recommended in a supervised landfill and, waste should initially be covered with at least 15 cm of soil. For final closure of an area containing asbestos a cover of at least 1 m of compacted soil should be applied.

Annexes

Annex 1 **Further information on the substance**
Annex 2 **Details on Final regulatory action**
Annex 3 **Address of designated national authorities**
Annex 4 **References**

Introduction to Annex I

The information presented in this Annex reflects the conclusions of the notifying parties: Australia, Chile, and European Community. In a general way, information provided by these parties on these hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in these countries, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning asbestos, including international reviews. The notification from Australia was first reported in the PIC Circular XI of June 2000, the notification from Chile was first reported in the PIC Circular XV of June 2002 and the notification from the European Community in PIC Circular XIII of June 2001.

The amphibole forms of asbestos were included as subjects of an IPCS Environmental Health Criteria document (Asbestos and other Natural Mineral Fibres, EHC 53) published in 1986.

Annex 1 – Further information – Other amphibole forms

1. Physico-Chemical properties

		AMOSITE	ANTHOPHYLLITE	TREMOLITE	ACTINOLITE
1.1	**Identity**				
1.2	**Formula**	$(Fe,Mg)_7(Si_8O_{22})(OH)_2$	$(Mg,Fe)_7Si_8O_{22}(OH)_2$	$Ca_2Mg_5(Si_8O_{22})(OH)_2$	$Ca_2(Mg,Fe)_5(Si_8O_{22})(OH)_2$
1.3	**Colour and Texture**	Light grey to pale brown Usually brittle	White to grey pale brown Usually brittle	White to grey Usually Brittle	Pale to dark green
1.4	**Decomposition Temperature (°C)**	600–800	600–850	950–1040	620-960
1.5	**Fusion temperature of Residual material (°C)**	1400	1450	1315	1400
1.6	**Density (g/cm^3)**	3.4 – 3.5	2.85 – 3.1	2.9 – 3.1	3.0 – 3.2
1.7	**Resistance to acids**	Attacked slowly	Very good	Very good	Attacked slowly
1.8	**Resistance to alkalis**	Good	Very good	Good	Good
1.9	**Tensile strength (10^3 kg/cm^2)**	17	(<7)	5	5

2 Toxicological properties

2.1	**General**	Amosite, actinolite, anthophyllite and tremolite are amphibole forms of asbestos (as is crocidolite). There is general consensus amongst the scientific community that all types of asbestos fibres are carcinogenic (IPCS, 1986, 1998; Royal Society of Canada, 1996 cited by E.C., 1997) and can cause asbestosis, lung cancer and mesothelioma when inhaled. Mesothelioma has appeared more frequently in subjects with exposure to amphiboles than in those exposed to chrysotile. As commercial chrysotile may contain low levels of tremolite, it has been suggested that tremolite may be the cause of mesothelioma in populations exposed primarily to chrysotile because the association of chrysotile with mesothelioma did not seem clear (IPCS, 1986).
2.2	**Deposition and Clearance**	Depending largely on size and shape, deposition of inhaled asbestos fibres may occur in lung tissue. Some fibres may be removed by mucociliary clearance or macrophages while others may be retained in the lungs for extended periods. Inhalation exposure is, therefore, generally regarded as cumulative, and exposures have been expressed in terms of concentration of fibres over time or PCM fibre-years/ml.
2.3	**Mode of action**	The ability of fibres to induce fibrogenic and carcinogenic effects seems to be dependent on their individual characteristics, including fibre dimension and durability (i.e. biopersistence in target tissues), which are determined in part by the physico-chemical properties (IPCS, 1998). It is well documented from experimental studies that fibres shorter than 5µm are less biologically active than fibres longer than 5µm. However, it is still uncertain whether short fibres have any significant biological activity. Furthermore it is still uncertain as to how long a fibre needs to remain in the lung in order to induce preneoplastic effects (IPCS, 1998). The mechanisms by which asbestos fibres cause fibrogenic and carcinogenic effects are not completely understood. Possible mechanisms of fibrogenic effects of fibres include chronic inflammation process mediated by production of growth factors (e.g., TNF-alpha) and reactive oxygen species. With regard to fibre-induced carcinogenicity, several hypotheses have been proposed. These include: DNA damage by reactive oxygen species

induced by fibres; direct DNA damage by physical interactions between fibres and target cells; enhancement of cell proliferation by fibres; fibre-provoked chronic inflammatory reactions leading to prolonged release of lysozymal enzymes, reactive oxygen species, cytokines and growth factors; and action by fibres as co-carcinogens or carriers of chemical carcinogens to the target tissues (IPCS, 1998).

2.4 Effects on animals

Results from animal studies reflect the known human health effects of asbestos. IARC (1987) reports that asbestos has been tested for carcinogenicity by inhalation in rats, by intrapleural administration in rats and hamsters, by intraperitoneal injection in mice, rats and hamsters and by oral administration in rats and hamsters. Amosite, anthophyllite and tremolite produced mesothelioma and lung carcinomas in rats after inhalation and mesothelioma following intrapleural administration. Amosite and anthophyllite induced mesothelioma in hamsters following intrapleural administration. Intraperitoneal administration of amosite induced peritoneal tumours, including mesothelioma, in mice and rats. Given by the same route, tremolite and actinolite produced abdominal tumours in rats. .

There is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986).

2.5 Effects on humans

Inhalation of asbestos dust can cause fibrosis of the lung (asbestosis), changes in one or both surfaces of the pleura, bronchial carcinoma (lung cancer), mesothelioma of the pleura and peritoneum, and possibly cancers of other sites (IPCS, 1986). .

2.5.1 Asbestosis

Asbestosis was the first asbestos-related lung disease to be recognised. It is defined as diffuse interstitial fibrosis of the lungs resulting from exposure to asbestos dust. Scarring of the lungs reduces their elasticity and function resulting in breathlessness. It can appear and progress many years after the termination of exposure.

Under recent exposure conditions, asbestosis will rarely be detectable, even in its early stages, in less than 20 years from first exposure (IPCS, 1986). There is no substantial evidence that asbestos fibre type influences the frequency or severity of pulmonary fibrosis. However the risk may be higher in the textile industry than in mining or milling, or in the manufacture of friction products (McDonald, 1984 cited by IPCS, 1986).

2.5.2 Lung cancer

The first reports (Gloyne, 1935; Lynch & Smith, 1935, both cited by IPCS, 1986), suggesting that asbestos might be related to lung cancer occurrence were followed by approximately 60 case reports over the next 20 years. The first epidemiological confirmation of this association was published by Doll (1955, cited by IPCS 1986). Since then, over 30 cohort studies (on various forms of asbestos) have been carried out in industrial populations in several countries. The majority, but not all, have shown an excess lung cancer risk (IPCS 1986).

Type of industrial process may affect the incidence of lung cancer. The variations may be related to the state and physical treatment of the asbestos in different situations, the dust clouds thus containing asbestos fibres of different physical dimensions (IPCS, 1986). Combined exposure to asbestos and cigarette smoke synergistically increases the risk of lung cancer (IPCS, 1986).

2.5.3 Mesothelioma

Pulmonary mesothelioma is a primary malignant tumour of the mesothelial surfaces, generally affecting the pleura and less commonly the peritoneum. Mesothelioma has been associated with occupational exposure to various types and mixtures of asbestos (including talc containing asbestos), although occupational exposures have not been identified in all cases. The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications. An increasing proportion of cases have been seen with increasing duration of exposure (IARC, 1987). It has been suggested that increased risk of mesothelioma may be related to the duration and intensity of asbestos exposure, and perhaps also the time from first exposure (IPCS, 1986). Current information does not suggest an important differential of mesothelioma risk according to the industrial process (IPCS, 1986).

The majority of known cases of mesothelioma arise as a result of occupational or para-occupational exposure to asbestos (IPCS, 1986). No association with smoking has been observed (McDonald, 1984 cited by IPCS 1986).

Studies suggest that amphibole asbestos may result in the development of mesothelioma at lower levels of cumulative exposure than that required for lung cancer, although no reliable exposure-response curve can be produced for asbestos-induced mesothelioma in animals or humans (Meldrum, 1996 cited by E.C., 1997). Bignon (1997 cited by E.C., 1997) states that mesothelioma can develop at doses of maybe 10 to 1,000 times lower than those required for broncho-pulmonary cancer.

2.5.4 Other malignant effects

In a review of studies, IPCS (1986) has found that some studies suggest that cancer at sites other than the lung, pleura and peritoneum has resulted from occupational exposure to asbestos, while others have shown no excess of cancer at other sites. IARC (1987) reports that gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to asbestos, although not all studies are consistent in this respect.

2.6 Summary of mammalian toxicity and overall evaluation

Fibrosis in many animal species, and bronchial and pleural carcinomas in the rat, have been observed following inhalation of amphibole asbestos. In these studies there were no consistent increases in tumour incidence at other sites, and there is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986). Epidemiological studies, mainly on occupational groups, have established that all types of asbestos fibres are associated with diffuse pulmonary fibrosis (asbestosis), bronchial carcinoma (lung cancer), and primary malignant tumours of the pleura and peritoneum (mesothelioma). That asbestos causes cancers at other sites is less well established. Cigarette smoking increases the asbestosis mortality and the risk of lung cancer in persons exposed to asbestos but not the risk of mesothelioma (IPCS, 1986).

3 Human exposure/Risk evaluation

3.1 Food

The extent of asbestos contamination of solid foodstuffs has not been well studied. Asbestos fibres have been detected in beverages. Up to 12 x 10^6 fibres/litre have been found in soft drinks (IPCS, 1986).

3.2 Air

At remote rural locations, fibre levels (> 5μm) are generally < 1 fibre/litre (< 0.001 fibre/ml) and in urban air they range from < 1 to 10 fibres/litre (0.001 to 0.01 fibres/ml) or occasionally higher. Airborne levels in residential areas in the vicinity of industrial sources have been found to be within the range of those in urban areas or occasionally slightly higher. Non-occupational indoor levels are generally within the range found in ambient air (IPCS, 1986; 1998).

3.3 Water

Reported concentrations of asbestos in drinking-water range up to 200 x 10^6 fibres/litre (all fibre lengths) (IPCS, 1986).

3.4 Occupational exposure

Occupational exposure levels vary depending on the effectiveness of dust-control measures; they may be up to several hundred fibres/ml in industry or mines without or with poor dust control, but are generally well below 2 fibres/ml in modern industry (IPCS, 1986).

Among occupational groups, exposure to asbestos poses a health hazard that may result in asbestosis, lung cancer and mesothelioma. The incidence of these diseases is related to fibre type, fibre size, fibre dose and industrial processing (IPCS, 1986).

The European Community notification noted that exposure of workers and other users of asbestos containing products is in general technically extremely difficult to control in practice, and may greatly exceed current limit values on an intermittent basis. It was recognized that a controlled and safe occupational use of asbestos could not be established for several working situations like e.g. building sites, repairs, or waste removal. As asbestos was widely used and no safe concentration threshold could be established it was decided to severely restrict the use of asbestos.

The Chile notification noted that in general the highest exposures to asbestos are amongst the working population whether during manufacture of materials containing asbestos or during installation or demolition. In Chile this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. In the case of brake linings or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair

workshop mechanics who blow off the dust produced by wear. Health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.

3.5 Para-occupational exposure

Members of the families of asbestos workers handling contaminated work clothes and, in some cases, members of the general population may be exposed to elevated concentrations of airborne asbestos fibres. Asbestos has been used widely in building materials for domestic application (e.g. asbestos-cement products and floor tiles) and elevated airborne levels have been measured during the manipulation of these materials (e.g. home construction and renovation by the homeowner) (IPCS, 1986).

In para-occupational groups, which include persons with household contact and neighbourhood exposure, the risk of mesotheliomas and lung cancer is generally much lower than for occupational groups. Risk estimation is not possible because of the lack of exposure data required for dose-response characterization. The risk of asbestosis is very low (IPCS, 1986).

The Chile notification notes that asbestos fibres are not easily released from asbestos in a cement matrix, in sheeting used in construction. However, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from the asbestos-fibre dust given off.

3.6 Public exposure

In the general population, the risks of mesothelioma and lung cancer attributable to asbestos cannot be quantified reliably and are probably undetectably low. The risk of asbestosis is virtually zero. (IPCS, 1986). See also sections on occupational and para-occupational exposure above.

4 Environmental fate and effects

5 Environmental Exposure/Risk Evaluation

Environmental effects are not relevant to the risk evaluation used to support the regulatory decisions.

Annex 2 – Details on final regulatory actions reported – Other amphibole forms

Country Name: Australia

1	**Effective date(s) of entry into force of actions**	Most jurisdictions placed severe restrictions on asbestos use during the late 1970's and early 1980s (some of the legislation under which the current restrictions are in force was enacted during the 1990s and incorporated/superseded existing restrictions).
	Reference to the regulatory document	Commonwealth – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*. New South Wales – *Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996* under *Occupational Health and Safety Act 1983.* Northern Territory – *Work Health (Occupational Health and Safety) Regulations 1996* under *Work Health Act 1996.* Queensland – *Workplace Health and Safety Regulation 1997* under *Work Health and Safety Act 1995.* South Australia – *Occupational Health, Safety and Welfare Regulations 1995* under *Occupational Health, Safety and Welfare Act 1986.* Tasmania – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*. Victoria – *Occupational Health and Safety (Asbestos) Regulations 1992* under *Occupational Health and Safety Act 1985*. Western Australia – *Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992* under *Health Act 1911*.
2	**Succinct details of the final regulatory action(s)**	Amphibole forms of asbestos severely restricted. Legislation is primarily through States and Territories.
3	**Reasons for action**	Carcinogenic when inhaled. Should minimise exposure of people to risk of inhalation of amphibole asbestos.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	The basis of the Australian regulatory actions was human health risk assessments, taken at national and state level that focussed on the carcinogenicity of inhaled asbestos and conditions of exposure in that country.
4.2	**Criteria used**	Unacceptable risk to human health. Regulatory actions for asbestos were taken incrementally, reflecting the building knowledge on its risks. The major health effects identified as a result of inhalation of amphibole asbestos are asbestosis and carcinogenicity (NHMRC, 1982).
	Relevance to other States and Region	
5	**Alternatives**	No information available
6	**Waste management**	No information available
7	**Other**	Actinolite, amosite, anthophyllite, tremolite are listed in the Australian National Occupational Health and Safety Commission (NOHSC) *Draft* List of Designated Hazardous Substances, with the classification: Carcinogen. Cat.1 • R45 – May cause cancer Toxic (T) R48/23 – Toxic: danger of serious damage to health by prolonged exposure through inhalation No exposure standards available Previously TWA was 0.1 fibre/ml. *NOHSC: 10005(1999)*. Currently being reviewed by Chemicals Framework Team under the National Occupational Health & Safety Commission.

Country Name: Chile

1	**Effective date(s) of entry into force of actions**	Supreme Decree No. 656 entered into force 180 days after its publication in the Official Journal, on 12 July 2001.
	Reference to the regulatory document	Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001
2	**Succinct details of the final regulatory action(s)**	Production, importation, distribution, sale and use of crocidolite and any material or product containing it are prohibited. Production, importation, distribution, sale and use of construction materials containing any type of asbestos are prohibited. Production, importation, distribution, sale and use of chrysotile, actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material are prohibited, with certain specific exceptions.
3	**Reasons for action**	Human Health To reduce exposure to asbestos amongst the working population during manufacture of material containing asbestos or during installation or demolition.
4	**Basis for inclusion into Annex III**	-
4.1	**Risk evaluation**	The foreign literature and analysis of domestic cases of asbestosis and mesothelioma indicate that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. No epidemiological precedents are known that show that there is a risk to the population from asbestos which is already included within a cement matrix in sheeting used in construction, given that the asbestos fibres are not easily released from the matrix. Nor is there any significant known risk from consuming water piped through asbestos cement piping. Nevertheless, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from asbestos-fibre containing dust given off. In the case of brake lining or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. It should be noted that health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.
4.2	**Criteria used**	Unacceptable risk to workers. All types of asbestos are hazardous to health to varying degrees depending on the form of exposure (it has been shown that the risk is from inhalation), the class of asbestos, the size of the fibres, fibre concentration and interaction with other factors (tobacco smoking potentiates the effects). Generally speaking, the highest exposures are amongst the working population whether during manufacture of the materials containing asbestos or during installation or demolition.
	Relevance to other States and Region	The regulatory action prohibits imports of asbestos in general, whatever the country of origin. Therefore no country may export asbestos to Chile except in specific cases, which exclude material and inputs for construction material and must be expressively authorized by Health Authority.
5	**Alternatives**	It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibre-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings

		in Chile has replaced asbestos with other fibres such as cellulose. In case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.
6	**Waste management**	No information available.
7	**Other**	Amosite and others forms of asbestos are listed in the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), with the classification: A.1 Proved Human Carcinogen. In accordance with the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), Amosite fibres exposure limit value for workers is 0.4 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5µm length and a ratio length to diameter equal to or greater than 3:1. For other types of asbestos, except crocidolite and amosite, fibres exposure limit value for workers is 1.6 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5µm length and a ratio length to diameter equal to or greater than 3:1.

Country Name: European Community

1	**Effective date(s) of entry into force of actions**	Regulatory action was first taken in 1983, in relation to crocidolite. Subsequently, such action has progressively been extended to all forms of asbestos. The latest regulatory action entered in force on 26.8.1999 (OJ L 207 of 6.8 1999, p. 18). Member States of the E.C. were obliged to implement the necessary national legislation at the latest by 1st January 2005.
	Reference to the regulatory document	Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.91983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)
2	**Succinct details of the final regulatory action(s)**	The placing on the market and use of amosite, anthophyllite, actinolite or tremolite fibres and products containing these fibres added intentionally are prohibited. The use of products containing asbestos fibres that were already installed and/or in service before the implementation date of Directive 1999/77/ E.C. by the Member State concerned could continue to be authorised until they are disposed of, or reach the end of their service life. However, Member States could, for reasons of protection of health, prohibit within their territory the use of such products before they are disposed of or reach the end of their service life.
3	**Reasons for action**	Prevent health effects (asbestosis, lung cancer, mesothelioma) for workers and general public.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	A comparison of asbestos with possible substitutes by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) concluded that all forms of asbestos are carcinogenic to humans and are likely to present a greater risk than substitutes (CSTEE, 1998).
4.2	**Criteria used**	Standard E.C. criteria used for evaluation of exposure.
	Relevance to other States and Region	Health problems similar to the ones experienced in the E.C. may occur in states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban protects health of workers and of the general public.
5	**Alternatives**	The risk assessment under taken by the CSTEE on chrysotile asbestos and candidate substitutes would be relevant for other variants of asbestos also. It concludes that, both for the induction of lung and pleural cancer and lung fibrosis and for other effects, it is unlikely that the alternatives cellulose fibres, PVA fibres or P-aramid fibres pose an equal or greater risk than chrysotile asbestos. With regard to carcinogenesis and induction of lung fibrosis the risk is regarded to be lower (CSTEE, 1998).
6	**Waste management**	In accordance with Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48) on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom or materials containing asbestos involving the release of asbestos fibres or dust must not cause significant environmental pollution. Construction materials have been classified as hazardous waste and will thus, as from 1 January 2002, have to be disposed of in line with the obligations laid down in Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20). In addition, the Commission is considering measures to promote the practice of selective demolition in order to segregate the hazardous waste present in construction materials and ensure their safe disposal.
7	**Other**	In accordance with Council Directive 83/477/EEC (OJ L 263, 24.9.1983, p.25), as amended by Council Directive 91/382/EEC (OJ L 206, 29.7.1991, p.16) the European Community exposure limit values for workers are currently 0.3 fibres/ml for forms of asbestos other than chrysotile. Exposure limit values for workers: Proposal still under consideration before the Council and the European Parliament: in 2001 the European Commission proposed (OJ C 304 E 30/10/2001, p.175) that these limits be replaced by a reduced, single limit value of 0.1 fibres/ml for all forms of asbestos.

Annex 3 – Addresses of designated national authorities

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P

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CP

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C Industrial chemicals
CP Pesticides, industrial chemicals
P Pesticides

Annex 4 – References – Other amphibole forms

Regulatory action

Australia

Commonwealth of Australia– *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*.

New South Wales – *Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996* under *Occupational Health and Safety Act 1983.*

Northern Territory – *Work Health (Occupational Health and Safety) Regulations 1996* under *Work Health Act 1996.*

Queensland – *Workplace Health and Safety Regulation 1997* under *Work Health and Safety Act 1995.*

South Australia – *Occupational Health, Safety and Welfare Regulations 1995* under *Occupational Health, Safety and Welfare Act 1986.*

Tasmania – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979* .

Victoria – *Occupational Health and Safety (Asbestos) Regulations 1992* under *Occupational Health and Safety Act 1985*.

Western Australia – *Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992* under *Health Act 1911*

Chile

Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001

European Community

Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.91983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)

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Chrysotile
(serpentine form of asbestos)

ASBESTOS: SERPENTINE – CHRYSOTILE

1. Identification and uses (see Annex 1) – Chrysotile

Common name	Chrysotile
Chemical name	Naturally occurring fibrous hydrated magnesium silicate belonging to the serpentine group of minerals
Other names/synonyms	Asbestos, Serpentine asbestos, white asbestos
CAS-No.(s)	12001–29–5
Other CAS numbers that may be used	General CAS number for asbestos: 1332–21–4 Additional CAS number for chrysotile 132207-32-0
Harmonized System Customs Code	2524.00 (asbestos)
Other numbers:	E.C. Number – 650–013–00–6 RTECS number – GC2625000
Category	Industrial
Regulated Category	Industrial
Use(s) in regulated category	Chrysotile is by far the predominant asbestos fibre consumed today (94% of the world's production) and is processed into products such as friction materials, asbestos-cement, cement pipe and sheet, gaskets and seals, paper and textiles (IPCS, 1998). European Community: chrysotile diaphragms (see below), chrysotile-containing spare parts for maintenance.
Trade names	
Formulation types	Asbestos has been used in the manufacture of a wide range of articles. Available in solid formulations for the manufacture of friction materials and gasket production.
Uses in other categories	No reported uses as a pesticide chemical.
Basic manufacturers	Naturally occurring, mined

2. Reasons for inclusion in the PIC procedure – Chrysotile

2.1 Final regulatory action: (see Annex 2 for details)

Chile

Severely restricted:

Production, importation, distribution, sale and use of construction materials containing any type of asbestos is prohibited.

Production, importation, distribution, sale and use of chrysotile and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material is prohibited, with certain specific exceptions. (No exceptions apply to crocidolite.)

Reason: Human Health

European Community

Banned – The placing on the market and use of all forms of asbestos, and products containing these fibres added intentionally, is prohibited, with one limited exception in the case of chrysotile.

Reason: Human Health

2.2 Risk evaluation

Chile

A hazard evaluation was carried out based on a compilation of bibliographic sources and verification of adverse chronic effects in exposed workers in the asbestos cement industry. It was concluded that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.

European Community

An independent risk assessment was undertaken. This confirmed that all forms of asbestos can cause lung cancer, mesothelioma, and asbestosis; that no threshold level of exposure could be identified below which asbestos does not pose carcinogenic risks.

3. Protective measures that have been applied concerning the chemical – Chrysotile

3.1 Regulatory measures to reduce exposure

Chile	Protective measures were taken by prohibiting all uses of all types of asbestos for use as an input to the manufacture of construction materials. All types of asbestos prohibited for use for any item, component or product that does not constitute a construction material unless excepted. Any type of asbestos (except crocidolite): the use of asbestos may be authorized in the manufacture of products or components that are not construction materials so long as the interested parties can prove that there is no technically or economically feasible substitute for it.
European Community	Protective measures were taken by prohibiting the placing on the market and use of chrysotile and of products containing these fibres added intentionally, with one specific exception for chrysotile in respect of diaphragms for existing electrolysis installations (see Annex 2 for further details).

3.2 Other measures to reduce exposure

European Community

Directive on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom (Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48))

Directive on disposal of construction materials (Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20))

General Dust control by wetting material, use of respirators, use of full protective clothing with attention when further treating any contaminated clothing (information from crocidolite DGD).

Further guidance is provided in the ILO Convention No. 162 "Safety in the Use of Asbestos" (http://www.ilo.org/ilolex/cgi-lex/convde.pl?C162) which applies to all activities involving exposure of workers to asbestos in the course of work.

The ILO recommendation 172 (***http://www.ilo.org/ilolex/cgi-lex/convde.pl?R172***), contains recommendations on safety in the use of asbestos, including details on protective and preventative measures, surveillance of the working environment and workers' health, information and education measures.

More specific information on measures to reduce exposures on construction sites is provided in the International Standard Organisation (ISO) 7337 "Asbestos-reinforced cement products – Guidelines for on-site work practices."

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Chile

It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibro-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In the case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use, until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.

European Community

Identified alternatives include cellulose fibres, polyvinyl alcohol (PVA) fibres and P-aramid fibres.

General

Guidance on substituting alternatives to asbestos fibres is provided in IPCS Environmental Health Criteria 151 "Selected Synthetic Organic Fibres".

3.4 Socio-economic effects

Chile

No assessment of socio-economic effects was undertaken.

European Community
The prohibition in respect of chrysotile had to be implemented at the latest by 1st January 2005, but Member States were able to implement it as from 26.8.1999. A study into the economic implications of replacing asbestos cement products and the availability of alternatives to chrysotile concluded that about 1500 jobs would be lost in some Member States of the European Community and that there could be subsequently rather severe effects on local economics in the regions concerned. However, the impact would be softened, if a 5-year transitional period was foreseen, and through the creation of new jobs in other sectors.

4. Hazards and risks to human health and/or the environment – Chrysotile

4.1 Hazard Classification	
IARC	Carcinogenic to humans (*Group 1*) IARC (1987)
European Community	Carc. Cat. 1 R45 May cause cancer T:R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation (E.C., 2001)
NTP	Chrysotile is classified as "Known Human Carcinogen" (US, 2001)

4.2 Exposure limits

No internationally agreed exposure limits available

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group	UN number 2590 Class 9 – Miscellaneous dangerous goods and articles Proper shipping name: WHITE ASBESTOS Packaging group: III Emergency Procedure Guide: 9B7 Special Provision number: 168 Packaging method: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping will prevent the atmosphere from becoming dust laden. This entry may also include talc containing tremolite and/or actinolite.
International Maritime Dangerous Goods (IMDG) Code	UN No: 2590: Class or division 9
Transport Emergency Card	TEC (R) –913

4.4 First aid

NOTE: The following advice was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Not acutely toxic. In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children. There is no antidote. Seek medical advice.

4.5 Waste management

Asbestos may be recovered from waste slurries. Otherwise friable waste should be wetted and containerised (sealed, double bagging) to avoid dust formation during transport and disposal. Landfilling is recommended in a supervised landfill and, waste should initially be covered with at least 15 cm of soil. For final closure of an area containing asbestos a cover of at least 1 m of compacted soil should be applied.

Annexes

Annex 1	**Further information on the substance**
Annex 2	**Details on Final regulatory action**
Annex 3	**Address of designated national authorities**
Annex 4	**References**

Introduction to Annex I

The information presented in this Annex reflects the conclusions of the notifying parties: Chile and European Community. In a general way, information provided by these parties on these hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in these countries, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning asbestos, including international reviews. The notification from Chile was first reported in the PIC Circular XV of June 2002 and the notification from the European Community in PIC Circular XIII of June 2001.

Chrysotile asbestos was included as a subject of an IPCS Environmental Health Criteria document (Asbestos and other Natural Mineral Fibres, EHC 53) published in 1986. It was also reviewed the an IPCS Environmental Health Criteria Document (Chrysotile Asbestos, EHC 203) published in 1998.

Annex 1 – Further information – Chrysotile

1. Physico-Chemical properties

1.1	**Identity**	Chrysotile
1.2	**Formula**	$Mg_3(Si_2O_5)(OH)$
1.3	**Colour and Texture**	Usually white to pale green yellow, pink. Usually flexible, silky and tough
1.4	**Decomposition temperature**	450–700°C
1.5	**Fusion temperature of Residual material**	1500°C
1.6	**Density**	2.55 g/cm^3
1.7	**Resistance to acids**	Undergoes fairly rapid attack
1.8	**Resistance to alkalis**	Very good
1.9	**Tensile strength**	31 (10^3 kg/cm^2)

2 Toxicological properties

2.1	**General**	Chrysotile is the serpentine form of asbestos. Other variants of asbestos (crocidolite, amosite, actinolite, anthophyllite and tremolite) are amphibole forms. There is general consensus amongst the scientific community that all types of asbestos fibres are carcinogenic (Royal Society of Canada, 1996 cited by E.C., 1997) and can cause asbestosis, lung cancer and mesothelioma when inhaled. Chrysotile is classified as a known human carcinogen (IARC, 1987). Exposure poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner (IPCS, 1998). It has been shown that smoking and asbestos act in a synergistic manner, increasing the overall risk of lung cancer. In 1998, the EC Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) concluded that chrysotile is a proven carcinogen and there is not sufficient evidence that it acts through a non-genotoxic mechanism (CSTEE 1998).
2.2	**Deposition and clearance**	Depending largely on size and shape, deposition of inhaled asbestos fibres may occur in lung tissue. Some fibres may be removed by mucociliary clearance or macrophages while others may be retained in the lungs for extended periods. Inhalation exposure is, therefore, generally regarded as cumulative, and exposures have been expressed in terms of concentration of fibres over time or PCM fibre-years/ml. Analyses of human lungs of workers exposed to chrysotile asbestos indicate much greater retention of tremolite, an amphibole asbestos commonly associated with commercial chrysotile in small proportions, than of chrysotile. The more rapid removal of chrysotile fibres from the human lung is further supported by findings from animal studies showing that chrysotile is more rapidly cleared from the lung than are amphiboles including crocidolite and amosite (IPCS, 1998).
2.3	**Mode of action**	The ability of fibres to induce fibrogenic and carcinogenic effects appears to be dependent on their individual characteristics, including dimension and durability (i.e. biopersistence in target tissues, which are determined in part by the physico-chemical properties. It is well documented from experimental studies that fibres shorter than 5 μm are less biologically active than fibres longer than 5μm. However, it is still uncertain whether short fibres have any significant biological activity. Furthermore it is still uncertain as to how long a fibre needs to remain in the lung in order to induce preneoplastic effects (IPCS, 1998).

IPCS (1998) concluded that the significance of physical and chemical properties (e.g. fibre dimension, surface properties) of fibres and their biopersistence in the lung in relation to their biological and pathogenic effects needs further elucidation.

2.4 Effects on experimental animals

Results from animal studies reflect the known human health effects of asbestos. IARC (1987) reports that chrysotile produced mesothelioma and lung carcinomas in rats after inhalation and mesothelioma following intrapleural administration. Chrysotile induced mesothelioma in hamsters following intrapleural administration, and peritoneal mesothelioma in mice and rats following intraperitoneal administration. Results of experiments in which chrysotile was given orally to rats or hamsters have been equivocal. For most of these experiments, it is not known whether and to which extent the chrysotile was contaminated with amphiboles (IARC, 1987 cited by CSTEE, 1998). Since the publication of Environmental Health Criteria 53 (IPCS, 1986), there have been only a few studies in which possible harmful effects of the ingestion of chrysotile asbestos have been examined in experimental animals. All these studies gave negative findings.

Various experimental samples of chrysotile fibres have been shown in numerous long-term inhalation studies to cause fibrogenic and carcinogenic effects in laboratory rats. These effects include interstitial fibrosis and cancer in the lung and pleura (Wagner et al, 1984; Le Bouffant et al, 1987; Davis et al, 1986; Davis et al, 1988, Bunn et al, 1993, all cited IPCS, 1998). In most cases, there appears to be an association between fibrosis and tumours in the rat lung. Fibrogenic and carcinogenic effects have also been found in long-term animal studies using other modes of administration (e.g. intratracheal instillation and intrapleural or intraperitoneal injection) (Lemaire, 1985, 1991; Lemaire et al, 1985, 1989; Bissonnette et al 1989; Begin et al, 1987 and Sebastien et al, 1990, all cited IPCS, 1998).

Exposure/dose-response relationships for chrysotile-induced pulmonary fibrosis, lung cancer and mesothelioma have not been adequately investigated in long-term animal inhalation studies (IPCS, 1998).

In non-inhalation experiments (intrapleural and intraperitoneal injection studies), dose-response relationships for mesothelioma have been demonstrated for chrysotile fibres. However data from these studies may not be suitable for the evaluations of human risk inhalation exposure to fibres (Coffin et al, 1992; Fasske, 1988; Davis et al, 1986, all cited IPCS, 1998).

Overall, the available toxicological data provide clear evidence that chrysotile fibres can cause fibrogenic and carcinogenic hazard to humans even though the mechanisms by which chrysotile and other fibres cause fibrogenic and carcinogenic effects are not completely understood. The data however, are not adequate for providing quantitative estimates of the risk to humans. This is due to inadequate exposure-response data from inhalation studies, and there are uncertainties concerning the sensitivities of the animal studies predicting human risk (IPCS, 1998).

Carcinogenic effects have not been reported in several oral carcinogenicity studies (IPCS, 1998).

2.5 Effects on humans

Chrysotile can cause asbestosis, lung cancer and mesothelioma in a dose-dependent manner (IPCS, 1998).

2.5.1 Asbestosis

Asbestosis was the first asbestos-related lung disease to be recognised. It is defined as diffuse interstitial fibrosis of the lungs resulting from exposure to asbestos dust. It is this scarring of the lungs which reduces their elasticity and function resulting in breathlessness. It can appear and progress many years after the termination of exposure.

Studies of workers exposed to chrysotile in different sectors have broadly demonstrated exposure-response or exposure-effect relationships for chrysotile-induced asbestosis, in so far as increasing levels of exposure have produced increases in the incidence and severity of disease. However, there are difficulties in defining

this relationship, due to factors such as uncertainties in diagnosis and the possibility of disease progression on cessation of exposure (IPCS, 1998).

In addition, some variation in risk estimates is evident among the available studies. The reasons for the variations are not entirely clear, but may relate to uncertainties in exposure estimates, airborne fibre size distributions in the various industry sectors and statistical models. Asbestotic changes are common following prolonged exposures to 5 to 20 fibres/ml (IPCS, 1998).

2.5.2 Lung cancer

The first reports (Gloyne, 1935; Lynch & Smith, 1935, both cited by IPCS, 1986), suggesting that asbestos might be related to lung cancer occurrence were followed by approximately 60 case reports over the next 20 years. The first epidemiological confirmation of this association was published by Doll (1955, cited by IPCS 1986). Since then, over 30 cohort studies (on various forms of asbestos) have been carried out in industrial populations in several countries. The majority, but not all, have shown an excess lung cancer risk (IPCS 1986).

Combined exposure to asbestos and cigarette smoke synergistically increases the risk of lung cancer (IPCS, 1986). Type of industrial process may affect the incidence of lung cancer, with some studies suggesting the effect is greater for textile workers. The variations may be related to the state and physical treatment of the asbestos in different situations, the dust clouds thus containing asbestos fibres of different physical dimensions (IPCS, 1986).

For chrysotile the overall relative risks for lung cancer are generally not elevated in the studies of workers in asbestos-cement production and in some of the cohorts of asbestos-cement production workers. The exposure-response relationship between chrysotile and lung cancer risk appears to be 10-30 times higher in studies of textile workers than in studies of workers in mining and milling industries. The relative risks of lung cancer in the textile manufacturing sector in relation to estimated cumulative exposure are, therefore, some 10-30 times greater than those observed in chrysotile mining. The reasons for this variation in risk are not clear, so several hypotheses, including variations in fibre size distribution, have been proposed (IPCS, 1998).

2.5.3 Mesothelioma

Pulmonary mesothelioma is a primary malignant tumour of the mesothelial surfaces, generally affecting the pleura and less commonly the peritoneum. Mesothelioma has been associated with occupational exposure to various types and mixtures of asbestos (including talc containing asbestos), although occupational exposures have not been identified in all cases. The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications. An increasing proportion of cases have been seen with increasing duration of exposure (IARC, 1987).

Available information suggests that the capacity to cause mesothelioma is substantially less for chrysotile than for amphiboles (especially crocidolite) (IPCS, 1986).

There is evidence that fibrous tremolite causes mesothelioma in humans. Since commercial chrysotile may contain fibrous tremolite, it has been hypothesized that the latter may contribute to the induction of mesothelioma in some populations exposed primarily to chrysotile. The extent to which the observed excesses of mesothelioma might be attributed to the fibrous tremolite content has not been resolved (IPCS, 1998).

2.5.4 Other malignant diseases

The epidemiological evidence that chrysotile exposure is associated with an increased risk for cancer sites other than the lung or pleura is inconclusive. There is limited information on this issue for chrysotile per se, although there is some inconsistent evidence for an associated between asbestos exposure (all forms) and laryngeal, kidney and gastrointestinal tract cancers. A significant excess of stomach cancer has been observed in a study of Quebec chrysotile miners and millers, but possible confounding by diet, infections or other risk factors has not been addressed (IPCS, 1998). In predominantly “chrysotile”-exposed cohorts of workers, there is no consistent evidence of excess mortality from stomach or colorectal cancer.

2.6	**Summary of mammalian toxicity and overall evaluation**	Fibrosis in many animal species, and bronchial and pleural carcinomas in the rat, have been observed following inhalation of chrysotile. In these studies there were no consistent increases in tumour incidence at other sites, and there is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986). Epidemiological studies, mainly on occupational groups, have established that all types of asbestos fibres are associated with diffuse pulmonary fibrosis (asbestosis), bronchial carcinoma (lung cancer), and primary malignant tumours of the pleura and peritoneum (mesothelioma). That asbestos causes cancers at other sites is less well established. Cigarette smoking increases the asbestosis mortality and the risk of lung cancer in persons exposed to asbestos but not the risk of mesothelioma (IPCS, 1986).

3 Human exposure/Risk evaluation

3.1	**Food**	The extent of asbestos contamination of solid foodstuffs has not been well studied. Asbestos fibres have been detected in beverages. Up to 12 x 10^6 fibres/litre have been found in soft drinks (IPCS, 1986).
3.2	**Air**	At remote rural locations, fibre levels (> 5μm) are generally < 1 fibre/litre (< 0.001 fibre/ml) and in urban air they range from < 1 to 10 fibres/litre (0.001 to 0.01 fibres/ml) or occasionally higher. Airborne levels in residential areas in the vicinity of industrial sources have been found to be within the range of those in urban areas or occasionally slightly higher. Non-occupational indoor levels are generally within the range found in ambient air. The major fibre type observed in the general environment is chrysotile (IPCS, 1986; 1998).
3.3	**Water**	Available data on effects of exposure to chrysotile asbestos (specifically) in general environment are restricted to those in populations exposed to relatively high concentrations of chrysotile asbestos in drinking-water, particularly from serpentine deposits or asbestos-cement pipe. These include ecological studies of populations in Connecticut, Florida, California, Utah and Quebec, and a case-control study in Puget Sound, Washington, USA (IPCS, 1998). On the basis of these studies, it was concluded that there was little convincing evidence of an association between asbestos in public water supplies and cancer induction. More recent identified studies do not contribute additionally to our understanding of health risks associated with exposure to chrysotile in drinking water (IPCS, 1998).
3.4	**Occupational exposure**	The current main activities resulting in potential chrysotile exposure are: (a) mining and milling; (b) processing into products (friction materials, cement pipes and sheet gaskets and seals, paper and textiles' (c) construction, repair and demolition; (d) transportation and disposal. The asbestos-cement industry is by far the largest user of chrysotile fibres, accounting for about 85% for all use. Fibres are released during processing, installation and disposal of asbestos-containing products, as well as through normal wear of products in some instances. Manipulation of friable products may be an important source of chrysotile emission. The conclusions and recommendations of the IPCS 1998 evaluation of chrysotile are that: a) Exposure to chrysotile asbestos poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. No threshold has been identified for carcinogenic risks. b) Where safer substitute materials for chrysotile are available, they should be considered for use. c) Some asbestos-containing products pose particular concern and chrysotile use in these circumstances is not recommended. These uses include friable products with high exposure potential. Construction materials are of particular concern for several reasons. The construction industry workforce is large and measures to control asbestos are difficult to institute. In-place building materials may also pose risk to those carrying out alterations, maintenance and demolition. [Minerals] [materials] in place have the potential to deteriorate and create exposures.

d) Control measures, including engineering controls and work practices, should be used in circumstances where occupational exposure to chrysotile can occur. Data from industries where control technologies have been applied demonstrate the feasibility of controlling exposure to levels generally below 0.5 fibres/ml. Personal protective equipment can further reduce individual exposure where engineering controls and work practices prove insufficient.
e) Asbestos exposure and cigarette smoking have been shown to interact to increase greatly the risk of lung cancer. Those who have been exposed to asbestos can substantially reduce their lung cancer risk by avoiding smoking.

The European Community notification noted that exposure of workers and other users of asbestos containing products is in general technically extremely difficult to control in practice, and may greatly exceed current limit values on an intermittent basis. It was recognized that a controlled and safe occupational use of asbestos could not be established for several working situations like e.g. building sites, repairs, or waste removal. For instance, working under conditions of 0.25 fibres/ml (at the level of the exposure limit value) was still associated with a 35 yr working-life chrysotile-associated cancer risk of 0.77% (0.63% of lung cancers and 0.14% of mesothelioma chrysotile-induced, respectively) when relating to the studies of Doll and Peto (1985). As asbestos was widely used and no safe concentration threshold could be established it was decided to severely restrict the use of asbestos.

The Chile notification noted that in general the highest exposures to asbestos are amongst the working population whether during manufacture of materials containing asbestos or during installation or demolition. In Chile this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. In the case of brake linings or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. Health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.

3.5 Para-occupational exposure

Members of the families of asbestos workers handling contaminated work clothes, and, in some cases, members of the general population may be exposed to elevated concentrations of building materials for domestic application (e.g. asbestos-cement products and floor tiles), and elevated airborne levels have been measured during the manipulation of these materials (e.g. home construction and renovation by the home owner) (IPCS, 1986).

The Chile notification notes that asbestos fibres are not easily released from asbestos in a cement matrix, in sheeting used in construction. However, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from the asbestos-fibre dust given off.

3.6 Public exposure

Fibres are released during processing, installation and disposal of asbestos-containing materials.

In studies reviewed, increases in lung cancer were not observed in four limited ecological epidemiological studies of populations in the vicinity of natural or anthropogenic sources of chrysotile (including the chrysotile mines and mills in Quebec) (IPCS, 1986.).

In general, as exposures experienced by the public will normally be considerably lower and less frequent than those experienced in the industrial environment, the expected lung cancer incidence in the public due to exposure to chrysotile will be lower than those estimated for workers.

The Internal Programme on Chemical Safety (IPCS) in assessing the risk to the public from asbestos exposure concluded that 'the risks of mesothelioma and lung cancer cannot be quantified and are probably undetectably low' and that 'the risk of asbestosis is virtually zero' (IPCS, 1986).

See also information in "occupational" and "para-occupational" sections above.

4 Environmental fate and effects

Serpentine outcroppings occur world-wide. Mineral components, including chrysotile, are eroded through crustal processes and are transported to become a component of the water cycle, sediment population and soil profile. Chrysotile presence and concentrations have been measured in water, air and other units of the crust.

Chrysotile and its associated serpentine minerals chemically degrade at the surface. This produces profound changes in soil pH and introduces a variety of trace metals into the environment. This has in turn produced measurable effects on plant growth, soil biota (including microbes and insects), fish and invertebrates. Some data indicate that grazing animals (sheep and cattle) undergo changes in blood chemistry following ingestion of grasses grown on serpentine outcrops.

5 Environmental Exposure/Risk Evaluation

Environmental effects are not relevant to the risk evaluation used to support the regulatory decisions.

Annex 2 – Details on final regulatory actions reported – Chrysotile

Country Name: Chile

1	**Effective date(s) of entry into force of actions**	Supreme Decree No. 656 entered into force 180 days after its publication in the Official Journal, on 12 July 2001.
	Reference to the regulatory document	Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001
2	**Succinct details of the final regulatory action(s)**	Production, importation, distribution, sale and use of crocidolite and any material or product containing it are prohibited. Production, importation, distribution, sale and use of construction materials containing any type of asbestos are prohibited. Production, importation, distribution, sale and use of chrysotile, actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material are prohibited, with certain specific exceptions.
3	**Reasons for action**	Human Health To reduce exposure to asbestos amongst the working population during manufacture of material containing asbestos or during installation or demolition.
4	**Basis for inclusion into Annex III**	-
4.1	**Risk evaluation**	The foreign literature and analysis of domestic cases of asbestosis and mesothelioma indicate that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. No epidemiological precedents are known that show that there is a risk to the population from asbestos which is already included within a cement matrix in sheeting used in construction, given that the asbestos fibres are not easily released from the matrix. Nor is there any significant known risk from consuming water piped through asbestos cement piping. Nevertheless, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from asbestos-fibre containing dust given off. In the case of brake lining or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. It should be noted that health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.
4.2	**Criteria used**	Unacceptable risk to workers. All types of asbestos are hazardous to health to varying degrees depending on the form of exposure (it has been shown that the risk is from inhalation), the class of asbestos (blue asbestos is the most toxic), the size of the fibres, fibre concentration and interaction with other factors (tobacco smoking potentiates the effects). Generally speaking, the highest exposures are amongst the working population whether during manufacture of the materials containing asbestos or during installation or demolition.
	Relevance to other States and Region	The regulatory action prohibits imports of asbestos in general, whatever the country of origin. Therefore no country may export asbestos to Chile except in specific cases, which exclude material and inputs for construction material and must be expressively authorized by Health Authority.
5	**Alternatives**	It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibre-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose.

		In case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.
6	**Waste management**	
7	**Other**	Chrysotile is listed in the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), with the classification: A.1 Proved Human Carcinogen. In accordance with the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), chrysotile fibres exposure limit value for workers is 1.6 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5 μm length and a ratio length to diameter equal to or greater than 3:1.

Country Name: European Community

1	**Effective date(s) of entry into force of actions**	Regulatory action was first taken in 1983, in relation to crocidolite. Subsequently, such action has progressively been extended to all forms of asbestos. The latest regulatory action entered in force on 26.8.1999 (OJ L 207 of 6.8 1999, p. 18). Member States of the E.C. were obliged to implement the necessary national legislation at the latest by 1st January 2005.
	Reference to the regulatory document	Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.91983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)
2	**Succinct details of the final regulatory action(s)**	The placing on the market and use of chrysotile fibres and products containing these fibres added intentionally are prohibited. The placing on the market and use of chrysotile may be allowed by Member States for diaphragms for existing electrolysis installations until they reach the end of their service life, or until suitable asbestos-free substitutes become available, whichever is the sooner. The derogation will be reviewed before 1 January 2008. The use of products containing asbestos fibres that were already installed and/or in service before the implementation date of Directive 1999/77/ E.C. by the Member State concerned could continue to be authorised until they are disposed of, or reach the end of their service life. However, Member States could, for reasons of protection of health, prohibit within their territory the use of such products before they are disposed of or reach the end of their service life.
3	**Reasons for action**	Prevent health effects (asbestosis, lung cancer, mesothelioma) for workers and general public.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	A comparison of asbestos with possible substitutes by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) concluded that all forms of asbestos are carcinogenic to humans and are likely to present a greater risk than substitutes (CSTEE, 1998).
4.2	**Criteria used**	Standard E.C. criteria used for evaluation of exposure.
	Relevance to other States and Region	Health problems similar to the ones experienced in the E.C. may occur in states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban protects health of workers and of the general public.
5	**Alternatives**	The risk assessment under taken by the CSTEE on chrysotile asbestos and candidate substitutes concludes that, both for the induction of lung and pleural cancer and lung fibrosis and for other effects, it is unlikely that the alternatives cellulose fibres, PVA fibres or P-aramid fibres pose an equal or greater risk than chrysotile asbestos. With regard to carcinogenesis and induction of lung fibrosis the risk is regarded to be lower (CSTEE, 1998).
6	**Waste management**	In accordance with Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48) on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom or materials containing asbestos involving the release of asbestos fibres or dust must not cause significant environmental pollution. Construction materials have been classified as hazardous waste and will thus, as from 1 January 2002, have to be disposed of in line with the obligations laid down in Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20). In addition, the Commission is considering measures to promote the practice of selective demolition in order to segregate the hazardous waste present in construction materials and ensure their safe disposal.

7	**Other**	In accordance with Council Directive 83/477/EEC (OJ L 263, 24.9.1983, p.25), as amended by Council Directive 91/382/EEC (OJ L 206, 29.7.1991, p.16) the European Community exposure limit values for workers are currently 0.6 fibres/ml for chrysotile. Exposure limit values for workers: Proposal still under consideration before the Council and the European Parliament: in 2001 the European Commission proposed (OJ C 304 E 30/10/2001, p.175) that these limits be replaced by a reduced, single limit value of 0.1 fibres/ml for all forms of asbestos

Annex 3 – Addresses of designated national authorities

CHILE

Head, Department of Environmental Programmes
Ministry of Health
Health Subsecretariat
Environmental Health Division
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C Industrial chemicals
CP Pesticides, industrial chemicals
P Pesticides

Annex 4 – References - Chrysotile

Regulatory action

Chile

Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001

European Community

Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.91983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)

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