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INTERIM CHEMICAL REVIEW COMMITTEE
Fourth session
Rome, 3 – 7 March 2003
Item 5 (b) (i) of the provisional agenda*

Inclusion of chemicals in the Interim
Prior Informed Consent Procedure

CONSIDERATION OF DRAFT DECISION GUIDANCE DOCUMENTS: ASBESTOS

Note by the secretariat

1. At its third session, the Interim Chemical Review Committee determined that the notifications of final regulatory actions by Australia, Chile and the European Community met the criteria of Annex II for the amphibole forms of asbestos. It also determined that the notifications by Chile and the European Community met the criteria of Annex II for the chrysotile form of asbestos. The existence of ongoing international trade in asbestos was reconfirmed by information provided to the Committee.

2. The Committee agreed that all criteria for listing all the notified forms of asbestos had been met and it decided to recommend to the Intergovernmental Negotiating Committee that it should make the actinolite, anthophyllite, amosite, tremolite and chrysotile forms of asbestos subject to the interim PIC procedure.

3. The Committee noted that the crocidolite form of asbestos was already listed under Annex III and, in keeping with the recommendation of the Task Group, it was agreed that the crocidolite decision guidance document should be updated where appropriate and incorporated into a single draft decision guidance document covering all forms of asbestos and showing all CAS numbers for the various forms of asbestos. Parties would not be required to resubmit an already provided import response for crocidolite but would need to submit it for the first time or to update it as appropriate.

4. The Committee agreed that International Labour Organization Convention 162 of 1986, which had been based on World Health Organization guidelines on occupational hygiene in the handling of

* UNEP/FAO/PIC/ICRC.4/1

asbestos, should be referred to in the draft guidance document for the information of States which chose not to ban asbestos and asbestos products totally.

5. Accordingly, the Committee agreed to establish an intersessional drafting group with the following members: Mr. Arndt (Coordinator), Ms. Barnes, Mr. El Zarka, Mr. Goede, Ms. Hacon, Mr. Khan, Mr. Kurlyandskiy, Mr. Malifu Negewo, Mr. Mayne and Mr. Monreal.

6. The drafting group developed a detailed work plan for the development of the decision guidance document in line with the process adopted by the Intergovernmental Negotiating Committee at its seventh session (decision INC-7/6). The work plan was annexed to the report of third session of the Interim Chemical Review Committee (ICRC-3) and posted on the Rotterdam Convention website. The goal was to have a draft decision guidance document available for consideration by the Committee at its fourth session in March 2003.

7. On 22 April 2002 the secretariat circulated detailed guidance to the drafting group including a summary of the results of ICRC-3, a copy of the working paper on the preparation of internal proposals and decision guidance documents for banned or severely restricted chemicals and a list of the relevant supporting documentation.

8. The chair of the drafting group prepared an internal proposal, based on the submitted notifications and supporting documentation and in consultation with the secretariat. The internal proposal and the draft working paper were circulated to members of the drafting group for comment on 18 July 2002. The documents were amended in the light of the comments received.

9. The draft decision guidance document on asbestos and the working paper were circulated to all members of the Interim Chemical Review Committee and observers[1] to the third session of the Committee, on 24 September 2002. Reponses were received from members of the Committee, Brazil and Canada as well as one intergovernmental organization. The drafting group revised the draft decision guidance document and the working paper in light of the comments received.

10. A status report on the work of the drafting group, including a compilation of the comments and the revised draft decision guidance document were circulated to drafting group members on 20 November 2002. As a result of this last round of comment several minor editorial changes were incorporated in the draft decision guidance document. A tabular summary of all of the comments received and how they were addressed will be made available to the Committee as document UNEP/FAO/PIC/ICRC.4/INF/4.

11. Annexed to this note is a copy of the draft decision guidance document on asbestos as submitted to the secretariat by the drafting group on 23 December 2002.

Issues to consider in reviewing the draft decision guidance document on Asbestos

A. Availability of additional relevant information

12. Relevant information and/or additional risk evaluations on asbestos that have been provided to the drafting group will be made available on the website of the Convention. The Committee may wish to identify those specific documents to be posted.

13. Specific information on alternatives to the identified uses of asbestos submitted to the secretariat will be made available on the website of the Convention. Also here, the Committee may wish to identify the information to be posted.

[1] 16 countries, two non-governmental organizations and two intergovernmental organizations

B. Response of the ninth session of the Intergovernmental Negotiating Committee to issues identified at the third session of the Interim Chemical Review Committee.

14. At its third session the Committee agreed that, in making the various forms of asbestos subject to the interim PIC procedure, it was their intent that the forms should be listed in such a way that countries could take import decisions for each individual form. The Committee agreed also that the exact approach for listing might best be left to the Intergovernmental Negotiating Committee.

15. In reviewing this issue at the ninth session of the Intergovernmental Negotiating Committee a number of countries indicated that they might wish to make individual decisions on imports of the separate forms of asbestos. The INC agreed that the individual forms of the asbestos and the relevant CAS number should be explicitly identified, if those forms were included in the interim PIC procedure.

C. Points identified by the drafting group

16. In preparing the draft decision guidance document a question arose regarding how the document and the resultant import decisions might be applied to products containing asbestos. It would seem that there are a range of views as to what constitutes a product. As a first approach it will be important to ensure that the decision guidance document reflects the scope of the underlying regulatory actions. In preparing a final recommendation to the INC the ICRC may also need to consider seeking guidance from the INC on this question.

17. The Committee may wish to consider including Harmonized System code numbers for asbestos and for materials and articles made of or containing asbestos.

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

DRAFT
Internal Proposal for DGD

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

UNEP

Mandate

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted at the Conference of Plenipotentiaries held in Rotterdam on 10 and 11 of September 1998. The same Conference also adopted a Resolution on interim arrangements in order to operate an interim PIC procedure between the time of the adoption of the Convention and its entry into force, and to prepare for its effective operation once it enters into force.

At its [xxxxxxx] session, held in [xxxxxxxxxxx] on [xxxxxxxx] the Intergovernmental Negotiating Committee (INC) adopted the decision guidance document for asbestos [Decision xxxxxxx] with the effect that this chemical became subject to the interim PIC procedure.

The present decision guidance document for asbestos was communicated to the Designated National Authorities on [xxxxxxxxxx] with the request that they submit a response concerning future imports of the chemical to the Secretariat, in accordance with Article 10, paragraph 2 of the Rotterdam Convention.

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

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
ARfD	acute reference dose
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
EC	Emulsifiable concentration
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
GAP	Good agricultural practice
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%;
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

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

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

Koc	Organic carbon-water partition coefficient
l	Litre
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

PIC – Decision guidance document for a banned or severely restricted chemical

Asbestos

Published: ***Draft – Dec 2002***

This DGD is divided into 3 sections, referring to:

Asbestos: amphibole – crocidolite
Asbestos: amphibole – other forms
Asbestos: serpentine – chrysotile

The commercial term asbestos refers to a group of fibrous serpentine and amphibole minerals that have extraordinary tensile strength, conduct heat poorly, and are relatively resistant to chemical attack. The principal varieties of asbestos used in commerce are **chrysotile**, a serpentine mineral, and **crocidolite** and **amosite**, both of which are amphiboles. **Anthophyllite, tremolite**, and **actinolite** asbestos are also amphiboles, but they are more rarely occurring and used (IPCS, 1986).

Crocidolite is already listed in Annex III, and a 1992 Decision Guidance Document was circulated under the previous voluntary PIC procedure. Information in that document is subsumed in this Decision Guidance Document.

Contents of Asbestos Decision Guidance Document

ASBESTOS: AMPHIBOLE – CROCIDOLITE

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

Reasons for inclusion in the PIC procedure – Crocidolite

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 and was added to the voluntary PIC procedure 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

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.

Protective measures that have been applied concerning the chemical – Crocidolite

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).

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.

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.

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.

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.

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

Exposure limits

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
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. 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: Blue Asbestos (crocidolite): Class or division: 9

Transport Emergency Card

TEC (R) – 912

First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and 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. There is no antidote. Seek medical advice.

In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children.

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

Introductory text to Annex I

The information presented in this Annex reflects the conclusions of the notifying parties: Australia, Chile, 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.

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°C
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 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**	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).

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).

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.

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 x 10^{12} fibres/kg may be found. Crocidolite may occur in beverages up to 12 x 10^6 fibres per litre (National Drinking Water regulations 1991). 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).

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 x 10^6 fibres/litre (all fibre lengths) (IPCS. 1986).

Maximum residue limits: In drinking water: 7 x 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 x 10^6 fibres/m^3 (800 fibres/ml), but were without any means of dust suppression. During home construction and renovation up to 10 x 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 E.C. 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 dispersed 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 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 PIC listed under the Rotterdam Convention.
5	**Alternatives**	
6	**Waste management**	
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

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	There are general health problems 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.
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 on the basis of: notifications made by Sri Lanka in 1986, E.C. 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.

Annex 3 – Addresses of designated national authorities

AUSTRALIA

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EUROPEAN COMMUNITY

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C Industrial and consumer product chemicals
CP Pesticides, industrial and consumer product 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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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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Lynch K M and Smith W A (1935) Pulmonary asbestosis. III. Carcinoma of lung in asbestos-silicosis. American Journal of Cancer 24:56

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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)

NHMRC (1982) National Health and Medical Research Council (NHMRC) Report on the Health Hazards of Asbestos *(Adopted by the NHMRC in June 1981 and published in 1982)*

Royal Society of Canada: (1996). A review of the INSERM Report on the health effects of exposure to asbestos: Report of the Expert Panel on Asbestos Risk.

US (2001) U.S National Toxicology Program '9th Report on Carcinogens', revised Jan 2001

ASBESTOS: AMPHIBOLE – OTHER FORMS

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

Reasons for inclusion in the PIC procedure – Other amphibole forms

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. (No exceptions apply to crocidolite)

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

Previous notifications

Crocidolite is included in Annex III and was added to the voluntary PIC procedure on the basis of notifications from Sri Lanka, E.C. countries and Sweden (not a member of the E.C. at that time).

Reason: Human Health

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.

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

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).

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.

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.

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.

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.

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.

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

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)

Exposure limits

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
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. 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	UN No: 2212: Brown Asbestos (amosite, mysorite): Class or division: 9
Transport Emergency Card	Information not available on these forms. (Note: numbers have been assigned for crocidolite and chrysotile.)

First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and 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. There is no antidote. Seek medical advice.

In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children.

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**

Annex 1 Further information on the substance

Introductory text 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.

Annex 1 – Further information – Other amphibole forms

1. Physico-Chemical properties

1.1	**Identity**	**AMOSITE**	**ANTHOPHYLLITE**	**TREMOLITE**	**ACTINOLITE**
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). .

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).

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).

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.

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 E.C. 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 dispersed 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**	
6	**Waste management**	
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

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	There are general health problems 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.
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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Industrial and consumer product chemicals
CP Pesticides, industrial and consumer product 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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ASBESTOS: SERPENTINE – CHRYSOTILE

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). E.C.: 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 productions.
Uses in other categories	No reported uses as a pesticide chemical.
Basic manufacturers	Naturally occurring, mined

Reasons for inclusion in the PIC procedure – Chrysotile

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

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.

Protective measures that have been applied concerning the chemical – Chrysotile

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).

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).

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.

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.

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.

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

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)

Exposure limits

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

Information required on this code

Transport Emergency Card

TEC (R) -913

First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and 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. There is no antidote. Seek medical advice.

In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children.

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**

Annex 1 Further information on the substance

Introductory text 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.

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 (IARC1987 cited by CSTEE, 1998).

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).

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 E.C. 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 dispersed 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	There are general health problems 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.
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

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C Industrial and consumer product chemicals
CP Pesticides, industrial and consumer product 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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