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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
First meeting
Geneva, 11–18 February 2005
Item 7 (m) of the provisional agenda*

Inclusion of chemicals in Annex III of the Rotterdam Convention: Review of notifications of final regulatory actions to ban or severely restrict a chemical: Chrysotile asbestos

Chrysotile asbestos

Note by the secretariat

1. In line with article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, when the secretariat has received at least one notification from each of two prior informed consent (PIC) regions that contain the information required in Annex I of the Convention, it shall forward the notifications and accompanying documentation to the members of the Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III and a decision guidance document drafted.

2. In addition to the four notifications from three PIC regions that meet the information requirements of Annex I relating to chrysotile asbestos (South-West Pacific – Australia; Latin America and the Caribbean – Chile; Europe – European Community and Latvia) presented in UNEP/FAO/RC/CRC/26, the secretariat has received an additional notification from Switzerland. A summary of this notification will be included in PIC Circular XXI, for June 2005. Annexed to this note is the notification as it was received from Switzerland.

3. The supporting documentation provided by Switzerland, where available, will be found in document UNEP/FAO/RC/CRC.1/26/Add.6.

* UNEP/FAO/RC/CRC.1/1.

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Annex

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: SWITZERLAND

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Chrysotile asbestos
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	Naturally occurring fibrous hydrated magnesium silicate belonging to the serpentine group of minerals
1.3	**Trade names and names of preparations**	Chrysotile, Asbestos, Serpentine asbestos, white asbestos
1.4	**Code numbers**	
1.4.1	**CAS number**	12001–29–5 1332–21–4 (general CAS number for asbestos) 132207-32-0 (additional CAS number for chrysotile)
1.4.2	**Harmonized System customs code**	2524.00 (asbestos)
1.4.3	**Other numbers (specify the numbering system)**	650–013–00–6 (EC), GC2625000 (RTECS)

1.5	**Indication regarding previous notification on this chemical, if any**	
1.5.1	✓ This is a first time notification of final regulatory action on this chemical.	

PLEASE RETURN THE COMPLETED FORM TO:

Interim Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Interim Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ θ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
IARC	Carcinogenic to humans (*Group 1*)
Hazard Class and Packing Group	UN number: 2590 Class 9 - Miscellaneous dangerous goods and articles Proper shipping name: WHITE ASBESTOS Packaging Group: III Special Provision number: 168 Packaging requirements: 3.8.9
International Maritime Dangerous Goods (IMDG) Code	UN No: 2590 Class or division: 9
Other classification systems	**Hazard class**
EU	Carc. Cat. 1 R45 May cause cancer T toxic R48/23 danger of serious damage to health by prolonged exposure through inhalation
NTP (2001)	Known Human Carcinogen
Switzerland	Poison Class 1* (prohibited for general use)

1.7 Use or uses of the chemical	
1.7.1	**Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
1.7.2	✓ **Industrial**
	Describe the industrial uses of the chemical in your country:
	Asbestos has been banned in Switzerland since 1986. Apart from certain very specific uses where exemptions may be granted, all uses are prohibited.

1.8 Properties	
1.8.1	**Description of physico-chemical properties of the chemical**

Formula: $Mg_3(Si_2O_5)(OH)$; Colour and Texture: Usually white to pale green yellow, pink. Usually flexible, silky and tough; Decomposition temperature: 450–700°C; Density (g/cm^3): 2.55; Resistance to acids: undergoes fairly rapid attack; Resistance to alkalis: very good; Tensile strength (10^3 kg/cm^2): 31

UNEP/ILO/WHO (1986) International Programme on Chemical Safety, Environmental Health Criteria No. 203: Chrysotile Asbestos (http://www.inchem.org/documents/ehc/ehc/ehc203.htm)

1.8.2 Description of toxicological properties of the chemical

Chrysotile is the serpentine form of asbestos.
There is general consensus amongst the scientific community that all types of asbestos fibres are carcinogenic and can cause asbestosis, lung cancer and mesothelioma when inhaled.
Chrysotile is classified as a known human carcinogen. Exposure poses increased risks for asbestosis, lung cancer and mesothelioma in a dose-dependent manner. 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.
The deposition of inhaled chrysotile asbestos is dependent upon the aerodynamic diameter, the length and the morphology of the fibre. Most airborne chrysotile fibres are considered respirable because their fibre diameters are less than 3 μm, equal to an aerodynamic diameter of about 10 μm. In laboratory rats, chrysotile fibres are deposited primarily at alveolar duct bifurcations. In the nasopharyngeal and tracheobronchial regions, chrysotile fibres are cleared via mucocilliary clearance. At the alveolar duct bifurcations the fibres are taken up by epithelial cells. Fibre length is an important determinant of alveolar clearance of chrysotile fibres. There is extensive evidence from animal studies that short fibres (less than 5 μm long) are cleared more rapidly than long fibres (longer than 5 μm). The mechanisms of the relatively more rapid clearance of chrysotile fibres compared to those of amphiboles are not completely known. It has been hypothesized that short chrysotile fibres are cleared through phagocytosis by alveolar macrophages, while long chrysotile fibres are cleared mainly by breakage and/or dissolution. To what extent chrysotile fibres are translocated to the interstitium, pleural tissue and other extrathoracic tissues is not fully understood. 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.
Epidemiological studies, mainly on occupational groups, have established that all types of asbestos fibres are associated with diffuse pulmonary fibrosis (asbestosis), bronchial carcinoma, and primary malignant tumours of the pleura and peritoneum (mesothelioma). Commercial grades of chrysotile have been associated with anincreased risk of pneumoconiosis, lung cancer and mesothelioma innumerous epidemiological studies of exposed workers. That asbestos causes cancers at other sites is less well established. Cancers other than of the lung or mesothelioma have been considered in many studies. Some indicated an approximately two-fold risk with regard to gastrointestinal cancer in connection with shipyard work, and some increased risk was also seen in association with exposure to both chrysotile and crocidolite, to crocidolite or to chrysotile. Cancer of the colon and rectum was associated with asbestos exposure during chrysotile production, with an approximately two-fold risk; a similar excess was found for unspecified asbestos exposure.
Generally, cases of malignant mesothelioma are rapidly fatal. The observed incidence of these tumours, which was low until about 30 years ago, has been increasing rapidly in males in industrial countries. The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications. An increasing proportion of cases has been seen with increasing duration of exposure. As asbestos-related mesothelioma became more widely accepted and known to pathologists in western countries, reports of mesothelioma increased. The incidence of mesothelioma prior to, e.g., 1960, is not known. Mesotheliomas have seldom followed exposure to chrysotile asbestos only. Most, but not all, cases of mesothelioma have a history of occupational exposure to amphibole asbestos, principally crocidolite, either alone or in amphibole-chrysotile mixtures. Mesotheliomas related to shipyard work and other exposures, including household contact with asbestos workers, have also been subject to epidemiological studies, resulting in risk ratios of about 3-15 in comparison with background rates not clearly referable to asbestos exposure. Exposure to crocidolite has been studied with regard to risk of lung cancer, and risk ratios of about 2-3 have been reported. Three lung cancers and two mesotheliomas occurred in 20 individuals after one year of high exposure to crocidolite; at least 17 of the cases had asbestos-induced lung changes on X-ray films. It should be recognized that although the epidemiological studies of chrysotile-exposed workers have been primarily limited to the mining and milling, and manufacturing sector, there is evidence, based on the historical pattern of disease

associated with exposure to mixed fibre types in western countries, that risks are likely to be greater among workers in construction and possibly other user industries.

Evidence for carcinogenicity to animals (*sufficient*): 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. Chrysotile, crocidolite, amosite, anthophyllite and tremolite produced mesotheliomas and lung carcinomas in rats after inhalation exposure and mesotheliomas following intrapleural administration. Chrysotile, crocidolite, amosite and anthophyllite induced mesotheliomas in hamsters following intrapleural administration. Intraperitoneal administration of chrysotile, crocidolite and amosite induced peritoneal tumours, including mesotheliomas, in mice and rats. A statistically significant increase in the incidence of malignant tumours was observed in rats given filter material containing chrysotile orally. In more recent studies, tumour incidence was not increased by oral administration of amosite or tremolite in rats, of amosite in hamsters or of chrysotile in hamsters. In two studies in rats, oral administration of chrysotile produced a low incidence of benign adenomatous polyps of the large intestine in males (9/250 *versus* 3/524 pooled controls) and of mesenteric haemangiomas (4/22 *versus* 0/47 controls. Synergistic effects were observed following intratracheal administration of chrysotile and benzo[*a*]pyrene to rats and hamsters and of intratracheal administration of chrysotile and subcutaneous or oral administration of *N*-nitrosodiethylamine to hamsters. 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 of the lung and pleura. 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 (mainly in rats) using other modes of administration (e.g., intratracheal instillation and intrapleural or intraperitoneal injection). Exposure/dose-response relationships for chrysotile-induced pulmonary fibrosis, lung cancer and mesothelioma have not been adequately investigated in long-term animal inhalation studies. Inhalation studies conducted to date, mainly using a single exposure concentration, show fibrogenic and carcinogenic responses at airborne fibre concentrations ranging from 100 to a few thousand fibres/ml. When data from various studies are combined, there appears to be a relationship between airborne fibre concentrations and lung cancer incidence. This type of analysis, however, may not be scientifically sound as different experimental conditions were used in available studies. In non-inhalation experiments (intrapleural and intraperitoneal injection studies), dose-response relationships for mesothelioma have been demonstrated for chrysotile fibres. Data from these types of studies, however, may not be suitable for the evaluations of human risk from inhalation exposure to fibres. Other relevant data: Insulation workers exposed to asbestos 'displayed a marginal increase' in the incidence of sister chromatid exchanges in lymphocytes in one study. Chrysotile did not induce micronuclei in bone-marrow cells of mice or chromosomal aberrations in bone-marrow cells of rhesus monkeys treated *in vivo*. In cultured human cells, conflicting results were reported for the induction of chromosomal aberrations and negative results for the induction of sister chromatid exchanges by chrysotile and crocidolite; amosite and crocidolite did not induce DNA strand breaks, and crocidolite was not mutagenic. Amosite, anthophyllite, chrysotile and crocidolite induced transformation of Syrian hamster embryo cells, chrysotile and crocidolite transformed BALB/c3T3 mouse cells, and chrysotile transformed rat mesothelial cells. Neither amosite nor crocidolite transformed CH3 10T1/2 cells. In cultured rodent cells, amosite, anthophyllite, chrysotile and crocidolite induced chromosomal aberrations, and amosite, chrysotile and crocidolite induced sister chromatid exchanges; chrysotile and crocidolite induced aneuploidy and micronuclei. Chrysotile did not induce unscheduled DNA synthesis in rat hepatocytes. Amosite, chrysotile and crocidolite were inactive or weakly active in inducing mutation in rodent cells *in vitro*; none were mutagenic to bacteria.

UNEP/ILO/WHO (1986) International Programme on Chemical Safety, Environmental Health Criteria No. 203: Chrysotile Asbestos (http://www.inchem.org/documents/ehc/ehc/ehc203.htm)
UNEP/ILO/WHO (1987) International Agency for Research on Cancer, Summaries & Evaluations: Asbestos (Actinolite, amosite, anthophyllite, chrysotile, crocidolite, tremolite) (Group 1) Supplement 7: (1987) (p. 106) (http://www.inchem.org/documents/iarc/suppl7/asbestos.html)

1.8.3	Description of ecotoxicological properties of the chemical
	n/a

PART II: FINAL REGULATORY ACTION

2.	FINAL REGULATORY ACTION			
2.1	The chemical is:	✓ banned	OR	θ severely restricted

2.2	Information specific to the final regulatory action
2.2.1	**Summary of the final regulatory action**

Asbestos shall no longer be used, except to manufacture products or articles which may be supplied or imported as commercial goods in accordance with Annex 3.3 of the Ordinance relating to Environmentally Hazardous Substances (SR 814.013).
The specified conditions are:
If the intended use is subject to the provisions and exemptions of Annex 3.3 of the Ordinance relating to Environmentally Hazardous Substances.
Exemptions:
1. On reasoned request, the Federal Agency for the Environment, Forests and Landscape may permit a manufacturer or trader to continue to supply certain products or articles or to import them as commercial goods after the dates laid down in Annex 3.3, Number 31 if:
   a. according to the state of the art, there is no replacement substance for the asbestos and provided that no more than the minimum amount of asbestos necessary for the desired purpose is employed, or
   b. due to particular design conditions, only spare parts containing asbestos can be used

Labeling:
Manufacturers may only supply packing drums and packaging for asbestos, products or articles containing asbestos and unpackaged products or articles containing asbestos if they carry a label giving the information laid out in Annex 3.3, Number 33 of the Ordinance relating to Environmentally Hazardous Substances.
All other provisions stated in Annex 3.3 apply equally.

2.2.2	Reference to the regulatory document
	Ordinance relating to Environmentally Hazardous Substances (Ordinance on Substances, Osubst) of 9 June 1986, update 3 June 2003, Annex 3.3

2.2.3	Date of entry into force of the final regulatory action
	9 June 1986

2.3	Was the final regulatory action based on a risk or hazard evaluation?	✓ Yes	θ No

	If yes, give information on such evaluation
	Asbestos was considered to be a hazard and grave risk to workers and consumers. It was therefore banned in 1986.

	Reference to the relevant documentation
	The ban was written directly into the Ordinance relating to Environmentally Hazardous Substances. No documents describing a hazard or risk evaluation exist.

2.4	Reasons for the final regulatory action		
2.4.1	Is the reason for the final regulatory action relevant to the human health?	✓ Yes	θ No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers		
	see section 1.8.2		
	Reference to the relevant documentation		
	Expected effect of the final regulatory action		
	A reduction of exposure to asbestos for workers.		

2.4.2	Is the reason for the final regulatory action relevant to the environment?	θ Yes	✓ No
	If yes, give summary of the known hazards and risks to the environment		
	Reference to the relevant documentation		
	Expected effect of the final regulatory action		

2.5	Category or categories where the final regulatory action has been taken	
2.5.1	Final regulatory action has been taken for the chemical category	✓ Industrial
	Use or uses prohibited by the final regulatory action	
	All uses are prohibited (but see Section 2.2.1)	
	Use or uses that remain allowed	

2.5.2	Final regulatory action has been taken for the chemical category	θ Pesticide
	Formulation(s) and use or uses prohibited by the final regulatory action	
	Formulation(s) and use or uses that remain allowed	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.		
	Quantity per year (MT)	Year
Produced		
Imported		

Exported		
Used		

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

2.7	Other relevant information that may cover:
2.7.1	Assessment of socio-economic effects of the final regulatory action

2.7.2	Information on alternatives and their relative risks
2.7.3	Relevant additional information

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Federal Department of Environment, Transport, Energy and Communications
Address	Parliament Building North 3000 Berne, Switzerland
Telephone	+41 31 3225512 (General Secretary)
Telefax	+41 31 3242692 (General Secretary)
E-mail address	
Designated National Authority	
Institution	Swiss Agency for the Environment, Forests and Landscape Hazardous Substances, Soil and Biotechnology Division
Address	3003 Berne Switzerland
Name of person in charge	Prof. Dr. Georg Karlaganis
Position of person in charge	Head
Telephone	+41 31 3226955
Telefax	+41 31 3247879
E-mail address	Georg.Karlaganis@buwal.admin.ch

Date, signature of DNA and official seal: _09 September 2004

Swiss Agency for the
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and Landscape
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Biotechnology Division
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