

Comments on Draft Risk Assessments and Draft Risk Management Scope for Batch 2 Challenge Substances

General Comments

The risk assessment and management scope for the challenge substances is aimed to determine the potential harm or danger a chemical substance can cause to human health and/or the environment, and the ways in which humans or the environment can be exposed to the substance. Assessment takes into consideration the way that the chemical is used in products and potential exposure paths to humans and the environment.

While the risk assessment includes product disposal, a concern that does not appear to be explicitly addressed in any of the risk assessments or draft risk managements is the ultimate fate of constituent chemicals in products that are recycled. A specific concern is the many paper products that use chemicals included in batch 2 and others. Undetermined amounts of the paper products will end up in recycling plants where various processes are used for de-inking and decontaminating the fiber so it can be used in recycled paper products. One of the main repositories for chemicals removed from the recycled paper is in recycling plant pulp sludge.

Related to this are the many chemicals that are used in a very wide range of products that find disposal in the sewage system. Since there is no separation between industrial and residential sewage system in most cases, the thousands of chemicals that can be found in sewage sludge can span the range of challenge substances.

In Canada, pulp mill sludge and sewage sludge can be used in land applications as soil amendment, creating an exposure path to both the environment and humans. The ways and quantities of this exposure do not appear to be anticipated in the risk management scopes for the substances discussed below.

It is vital that the entire life cycle of the *chemical*, rather than the *products* it is used in, be considered.

Although some of the substances below report low amounts of production or import in Canada, there does not appear to be any comprehensive manner to assess the presence of chemicals in imported products. Imported paper products to Canada for use in food containers, packaging or one of the many other uses identified below, for instance, are likely to contain some of these chemicals. They would not be included in surveys since the chemicals would not be identified on and in the imported paper products. There is no way to know the real volume of the chemicals that could be landspread in Canada. For that reason, the volume criteria that are used in the risk assessments should be considered to have a high margin of error.

Significant exposure to human population does not appear to include occupational exposure. Workers in industrial facilities, trades people and other concentrated exposure in manufacturing and wholesale operations should be considered as significant populations as well as the general population exposed through ambient air and consumer products.

Interactive and iterative effects of chemicals, conditions and specific population characteristics all have tremendous impact on the effects of chemicals both on human and on non-human populations. Consideration of isolated chemicals is inadequate to address the real risks of exposure that are faced. The scope of risk management must consider the context of exposure to chemicals by humans and the environment including:

- vulnerable populations (infants, juveniles, breeding wildlife);
- other chemical exposures or chemical reactions before exposure; and
- duration and longevity of exposure (workers vs. ambient levels).

Risk management scope in all cases should consider the existence of alternatives to the chemical or the products it is used in.

RECOMMENDATIONS

- Include recycled products and by-products, particularly pulp sludge, in the scope of risk management.
- Include the ultimate fate of constituent chemicals of products that contain residual amounts of the substances, and the potential for increased concentration in recycled pulp sludge and sewage sludge in the scope of risk management.
- Include occupational exposure in the scope of risk management activities.
- Include consideration for compound and interactive effects of chemicals in the risk assessment, rather than isolated chemical effects.
- Include consideration for specific vulnerable populations that may be exposed to chemicals and experience significantly more acute toxicity (children, infants, nursing mothers).
- The use of genotoxins and carcinogens in food packaging is completely inappropriate and should be disallowed.

The following Batch 2 substances are found on the NPRI at a reporting threshold of 10 tonnes manufactured, processed or otherwise used. As noted from the table, no releases of these substances were reported by the Pulp and Paper Industry for any of the years 2002-2006.

Year	Releases in Tonnes			
		2006		2002-5
Substance	CAS No.	Pulp and Paper	Other Industries	Pulp and Paper
Thiourea	62-56-6	0	0	0
1,3-Butadiene, 2-methyl - (Isoprene)	78-79-5	0	15 (air)	0
Oxirane, - (chloromethyl) - (Epichlorohydrin)	106-89-8	0	0	0
Acetic acid ethenyl ester (Vinyl Acetate)	108-05-4	0	110 (air) 101 (disposal)	0

RECOMMENDATION

- The threshold for reporting of the substances discussed below to the NPRI may not be appropriate to capture the releases to air and disposal. Considering the inherent toxicity of the substances, the threshold should be re-evaluated. Further, the other batch 2 substances should be added to the NPRI at an appropriate threshold.

Substances identified as persistent, bioaccumulative, and inherently toxic to non-human organisms and believed to be in commercial use in Canada

Spiro[isobenzofuran-1(3H),9'-[9H]xanthen]-3-one, 2',4',5',7'-tetrabromo-3',6'-dihydroxy- (D & C Red No. 21)
CAS No. 15086-94-9

D & C Red No. 21 is a synthetic organic dye not currently manufactured in or imported into Canada. It is used internationally, however, in cosmetics, as a solvent dye for paper and inks, as a textile dye and in dyeing difficult tissues. Production within the EU has been estimated to be in the order of 10 tonnes per year. In 2002, D&C Red No. 21 met the reporting threshold of 4.5 tonnes, with a reported use of 4.5 to 225 tonnes. Releases to the Canadian environment are presumed to be very low, however, D&C Red No. 21 has been found to be an ingredient in numerous cosmetics that are available for purchase in Canada and it is unclear to what degree paper products have been tested.

No experimental degradation data, experimental bioaccumulation data, or toxicity to aquatic life data are available for D&C Red No. 21 and instead, the data of a close chemical analogue was used. Based on the proxy data it is suggested that D&C Red No. 21 would not meet the criteria for persistence, bioaccumulation and would exhibit low toxicity.

It has been proposed that D&C Red No. 21 is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health and it is therefore proposed that D&C Red No. 21 does not meet the definition of "toxic" as set out in section 64 of CEPA 1999.

The conclusions, based on the weight of evidence, that D&C Red No. 21 does not meet the criteria for persistence, bioaccumulation or toxicity, are all based on proxy data of a close chemical analogue. Several uncertainties are noted with regard to this. Further, for the exposure assessment, the Predicted Environmental Concentration (PEC) represents concentrations in water only, so exposure through soils is not considered since that exposure pathway was not considered to be significant.

RECOMMENDATION

- Further analysis should be done on the presence of this chemical in printed and coated paper products that are imported into Canada, the disposal route for those paper products and the potential for this chemical to be entering the environment in significant volume through the land application of recycled pulp sludge.

Substances identified as a high hazard to humans and a high likelihood of exposure to individuals in Canada

Thiourea
CAS No. 62-56-6

Thiourea is an organic chemical compound that exists both naturally and as a manufactured chemical. Thiourea is a chemical intermediate used for chemical processing and synthesis in several industrial and commercial sectors. The main uses of this substance are to extract silver and gold from ore, and its use in various types of copy paper. It is also used in the manufacturing of paper and paperboard food packaging, and as an auxiliary agent in diazo paper (blueprint papers) as well as other types of paper.

Thiourea was identified as a high priority as it was considered to pose greatest potential for exposure (GPE) to individuals in Canada and had been classified by other international and national agencies on the basis of carcinogenicity and reproductive/developmental toxicity. It was imported into Canada in 2006 in a quantity ranging between 10 000 kg and 100 000 kg, however it is unclear to what degree the chemical would be present on paper products and packaging of products that are imported into Canada.

The risk assessment concludes that exposure to thiourea via the general environment is considered to be negligible, and that therefore, the predominant source of general population exposure is expected to be through consumer products.

Given its significant presence in many types of paper products and packaging, there is a high likelihood that it would be present in recycled pulp mill sludge. However no assessment of this has been done. The sludge that is subsequently landspread on agricultural land and forests would represent a significant exposure route to humans and the environment.

There is a complete absence of data on the concentrations of thiourea in environmental media or in food, either in Canada or elsewhere and there is low confidence in the estimate of exposure from consumer products. There is also a lack of data on concentrations of thiourea in these products, as well as the frequency and quantities of their use in Canada, or their disposal and recycling routes.

It is stated that: If the final screening assessment report concludes that thiourea meets the criteria under section 64 of CEPA 1999, options for risk management would focus on ensuring that any potential changes in the use-pattern for thiourea do not substantially increase the potential for exposure of the general Canadian population.

In the absence of any data that implies that the chemical is entering the environment in safe quantities, and considering the potential for carcinogenic and reproductive impacts, options for risk management should also include assessing opportunities for employing alternatives and for ensuring that the potential for exposure of the general Canadian population is reduced. Further investigation is required to determine the levels entering and present in the environment

RECOMMENDATION

- ❑ Based on the factors above, it is premature to conclude that: thiourea is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends Further investigation is required on its presence in pulp sludge subsequently released to the environment through landspreading.
- ❑ The risk management should include assessment of safer alternatives.
- ❑ As it is a carcinogen and genotoxin, its use in food packaging is inappropriate and should be disallowed. This should be included in risk management scope.

Oxirane, (chloromethyl)-(Epichlorohydrin)
CAS No. 106-89-8

Epichlorohydrin is a synthetic chemical that is manufactured for use in making other chemicals. No epichlorohydrin is manufactured in Canada, but it is imported into Canada. The most important use of epichlorohydrin (75%) is in the production of epoxy resins which are used in paints and other coatings, in structural composites, adhesives, and other products. About 10% of epichlorohydrin is used to make glycerine, which is an ingredient or processing aid in personal care products, drugs, food, and beverages. Epichlorohydrin is also used to make wet strength agents used in paper and cellulose products, which are then used in food and beverage preparations.

Polymers made with epichlorohydrin are used as additives in papermaking to preserve the strength of the paper in the presence of water. They are used in paper products such as tissues, toweling, beverage filters and other cellulose products. Epichlorohydrin is used in the manufacture of wet-strength resins, which are used in Canada in the production of papers used in food contact applications

Epichlorohydrin is a known carcinogen and genotoxin.

Given the low quantity of reported industrial releases, it is suggested that epichlorohydrin is unlikely to be causing ecological harm in Canada.

However, responses also indicate that the presence of the chemical would be in resins that are likely imported into Canada rather than manufactured in Canada, and that it is present in food packaging and protective coatings for packages. Since epichlorohydrin is present only as a residual substance, exposure is considered to be low. Further investigation is required to draw this conclusion as the levels of presence in imported products and the potential exposure route of the chemical through migration to other environmental media during disposal and recycling is unknown. No measured concentrations of epichlorohydrin in environmental media, food or water in Canada are available.

It cannot be established without further investigation that:

epichlorohydrin is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

RECOMMENDATION

- Further investigation is required to determine the levels entering and present in the environment, particularly through the application of recycled pulp mill sludge.
- As it is a carcinogen and genotoxin, its use in food packaging is inappropriate and should be disallowed. This should be included in risk management scope.

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Acetic acid ethenyl ester (Vinyl acetate)
CAS No. 108-05-4

Vinyl acetate is a colourless liquid that has a wide variety of industrial and commercial applications. It is manufactured in Canada and it is used a wide variety of industrial and commercial applications including; paints and coatings, plastics and synthetic resins, direct and indirect food additives and pulp and paper. It is used in flexible food packaging, paperboard and film adhesives. Adhesives containing vinyl acetate are applied to food packaging to cover seams and surfaces. Vinyl acetate was imported above 10,000 tonnes in 2006.

Commercial or industrial products (including food contact plastics, food packaging and adhesives) manufactured from vinyl acetate may contain residual levels of un-reacted monomer that may migrate and result in exposures.

Vinyl acetate is a carcinogen and genotoxin with no known safe threshold.

Its use in food packaging, paperboard and adhesives applied to packaging is of particular concern with regard to the migration of the chemical to environmental media through the land application of recycled paper sludge. In food packaging, it rarely comes into contact with food and it is, therefore, concluded that there is a low risk of exposure through this route. There has been no known assessment of the potential risk for environmental release or human exposure through this route and further investigation is required. Vinyl acetate has been found to remain in the environmental media to which it is released. Assessment suggests a high mobility in soil.

Indoor air inhalation has been identified as the main route of exposure and pathways including flexible food packaging, are not being considered for additional investigation or risk management.

RECOMMENDATION

- ❑ Risk management should include the mitigation or elimination of environmental release through the route of pulp sludge land application.
- ❑ As it is a carcinogen and genotoxin, its use in food packaging is inappropriate and should be disallowed. This should be included in risk management scope.

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