

DRAFT

MEMORANDUM

April 26, 1985.

Memo To: Grace Patterson, Steve Shryubman, Eva Ligeti, Murray
Klippenstein, Bonnie Gibson, Sarah Miller, Doug
Macdonald, Marcia Valiante, Paul Muldoon and Doug
Edward

From: Frank Giorno

Re: Recommended amendments to Environmental Contaminants Act New
Chemicals Section

I have provided the following information:

I Deficiencies in existing new chemicals section S.4(6)

II Federal Government Proposals

III Proposed CELA response

Your comments are welcomed on this section. Marcia Valiante is
preparing a similar brief or proposal for upgrading the ECA.

That section will deal with a) powers of inspectors b) collection of information c) compliance d) regulation making.

Deadline for CELA's written comments to the feds is May 24, 1985 so I'd appreciate your response as soon as possible.

I Proposals for Amending S.4(6) New Chemicals Notification

1. Deficiencies to existing S.4(6) Definition

Definition of chemicals is vague and is causing problems with interpretation.

2. Definition of new chemicals

- Difficult to define what new chemicals are. At present manufacturers are required to notify if they import a chemical for the first time, regardless if that chemical is in use by other manufacturers

3. Inadequate Data Requirements

Existing S.4(6) requires only information available. If information is not available. If information is not available the company is not required to provide the information.

4. Problems with Notification, Scheduling and Timing of Notification

At present only post-marketing notification is required.

5. Insufficient Legal Control to prevent entry of New Chemicals into the Canadian Environment

Under ECA action can only commence once a chemical is in Canada and on the Canadian markets.

6. Current ECA is not aligned with OECD or legislation of other trading partners.

Existing ECA doesn't permit the exchange of information on chemicals.

II Amendments Proposed by Environment Canada and Health and Welfare Canada

A. Definition

The existing ECA uses the term chemical compound but does not define it.

For practical purposes it is proposed that the TSCA (U.S.) definition of chemical substance be adopted to define chemical:

A chemical is any organic or inorganic substance of a particular molecular identity including (i) any combination occurring as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical.

Included in this definition are:

- i) new chemicals that form part of a mixture

Excluded and therefore not reportable:

- i) mixtures or formulations are not considered unique chemicals therefore changes in proportions are not reportable.

ii) Finished articles are not considered chemicals and are outside of the notification scheme.

iii) Classes of chemicals will be excluded because of their use or because they are subject to other regulatory systems.

a) Nuclear material and explosives under the AECS Act and the Explosives Act

b) food, drugs, cosmetics under the Food and Drug Act.

c) Pesticides which are covered under the Pest Control Products Act.

A chemical used for pesticide is excluded. However the same chemical used as an additive in rubber will be included.

B. Definition of New Chemical/Canadian Inventory

Canada proposes to include in the amended Act the powers to develop a list or lists of existing chemicals unique to Canadian Commerce. A new chemical may be defined as one not on the list. Pesticides, food additives, drugs, etc. would not be included on the inventory.

1. Existing Chemicals Inventory

The information on the inventory would include:

- i) the name of the chemical
- ii) molecular formula
- iii) structure
- iv) synonyms
- v) quantities
- vi) uses

Nomination to the list will require certification as proof that the chemical was actually imported or manufactured and could be subject to certification.

The Inventory will be dynamic. New chemicals will be listed every two years. The list will be updated every two years.

Once a new chemical is added to the inventory, the name of the chemical may not be considered confidential.

C. Notification

1. PreMarket or Premanufacture Notification

It is proposed that premanufacture notification, be adopted in order to provide better protection of human health and the environment.

Premarket notification while probably acceptable from an environmental point of view may not be adequate to protect plant workers.

2. Exemptions for Notification

Based on experience with the existing Environmental Contaminants Act, the use of a quantity to trigger notification or to define an exemption appears to be the most appropriate way of proceeding.

Canada proposes the following:

- a) New chemicals in the scope of the scheme that are intended for importation or manufacture in quantities of 1000 kg or greater per year will be subject to a full premanufacture notification.
- b) Total exemption from premanufacture and inventory reporting will apply to:
 - impurities
 - non-isolated intermediates
 - byproducts
 - coincidentally produced chemicals

- c) New chemicals intended for manufacture or import in quantities between 100 kg and 1000 kg per year will be considered low volume chemicals, and will be subject to reporting of basic information. When the 1000 kg per year limit is reached, they will cease to be considered low volume and a full report will be required. As low volume chemicals, they will not be included on the inventory.
- d) Special notification provisions will apply for new short chain polymers and those with high monomer content, in order to limit the cases in which polymers are required to be notified to those of greater concern. In some cases the content of the dossier will be simplified.
- The situation with polymers is complex. EEC exempts polymers, but keeps track of new monomers. The U.S.A., at the present time, recognizes polymers under their scheme, but a proposed partial exemption for polymers is being considered. Australia has published a working paper that proposes a detailed strategy for notification of polymers.
- e) Exemptions for site-limited chemicals, research and development chemicals and test marketing chemicals will be considered in order to achieve compatibility with legislation in other countries that does provide some form of exemptions for these categories.

Timing Notification

It is proposed that the Act be amended to ensure that a manufacturer or importer who intends to introduce a new chemical will be responsible for modifying that intention at least 90 days prior to the intended date of manufacture or import. This applies to both low volume chemicals and those in quantities greater than 1000 kg per year. The time limit will not run if the dossier is incomplete. The initial 90-day limit will include the time required to review the report for completeness but will exclude the length of time it takes for industry to submit required data. Furthermore, the review period may be extended an additional 90-days if there is concern about the chemical.

D. Information Requirements

Canada proposes the following:

- 1) New chemicals manufactured or imported in quantities than 1000 kg per year will be subject to notification to allow an initial assessment of hazard to health and the environment.
 - a) The OECD concept of minimum premarketing set of data would be applied.
 - b) A provision for omission and/or substitution of test data, where there is justification for doing so, will be included.

c) The initial notification will include the complete minimum premarketing data package including

- i) chemical identity
- ii) uses
- iii) physical-chemical properties
- iv) acute toxicity
- v) ecotoxicity data
- vi) environmental impact data

- 2) The low volume new chemicals (100 kg to 1000 kg per year) will be subject to a report of basic information such as identity, use quantities, and any available information on dangers to human health or environment.
- 3) OECD Testing Guidelines or equivalent acceptable test methods and OECD Principles of Good Laboratory Practice, or acceptable equivalent where appropriate.
- 4) Power to demand testing and additional data will be available if the government suspects on reasonable grounds that a danger may exist. The data will be for information beyond that of the MPD.

For low-volume chemicals more data to include MPD will be allowed.

Since Canada imports the bulk of chemicals a unique problem arises. Chemicals in use in other countries which are not subject to new chemical reporting may enter Canada. Since no information exists the Canadian importer would have to be responsible for developing data. The Interdepartmental Working Group found this to be unfair to the importer. They recommend leniency and flexibility in applying the information requirements during the first few years.

5. Notification Follow-up

The original notifier be required to report again if: -

1. Significant change in the use of a new chemical
2. Significant increase in quantity imported or manufactured
3. New knowledge about hazardous properties surface.
4. A change in methods of manufacture

E. Control Action

There is no authority to control new chemicals in the existing ECA.

It is proposed that in addition to the powers to enforce the features associated with the notification scheme, such as the power to suspend or extend the initial review period, to demand

testing, require follow-up reporting, the amended legislation will have power to:

1. issue general orders to prohibit a new chemical from being imported or to restrict the uses of the new chemicals in Canada.
2. issue specific orders addressing packaging, disposal, record keeping.

F. Confidentiality of Data and Public Disclosure

The Act will continue to recognize the importance of protecting trade secrets and other confidential information. However confidentiality must be compatible with the Access to Information Act and the OECD principles for the exchange of confidential business information.

The government realizes a need to keep the public informed.

Therefore it is proposed that a company be required to include a non-confidential report to be made available to the public.

III CELA's Position

A. Definition of Chemical

The TSCA definition is a good starting point. However it has limitations.

Japan's definition of chemicals includes mixtures and formulations.

CELA should recommend that the definition be wide enough in scope to include all substances which when released into the environment may become environmental contaminants. That would include micro-organisms, chemical mixtures and finished products.

Exclusions may be provided for explosives, however, CELA should recommend that nuclear material and pesticides be brought under the Environmental Contaminants Act for existing substance and for new chemicals notification.

B. Definition of New Chemicals as Chemicals not on an existing chemicals list

CELA should support the development of an existing chemicals list for Canada, with the recommendation that only existing chemicals with reliable scientific data be included on the

list. Existing chemicals that have never been properly tested should be tested prior to being included.

Being placed on the existing chemicals list may be misinterpreted as meaning that they are safe for human health and the environment. Many existing chemicals are suspected of being detrimental to health and environment. Health effects and environmental impacts information should be provided for all chemicals on an existing chemicals list.

It is also important to stress that placing a new chemical on the list of existing chemicals (after two years) does not mean a chemical is necessarily safe. Evaluations should be required from time to time if health or environmental impacts are suspected.

C. PreManufacture or PreMarket Notification

CELA should support the concept of premanufacture notification.

The one concern I have is with when the premanufacture notice comes into effect? I think chemicals for use in research should be included in the scheme for premanufacture notification.

D. Exemptions from Notifications

Exemptions should not be based exclusively on quantity. For example 100 kg of a substance may be more hazardous than 1000 kg.

Total exemptions should not be allowed for impurities; non-isolated intermediates; byproducts; coincidentally produced chemicals.

Reporting should be required on testing of new chemicals for production of impurities, by-products, etc.

Knowledge on the impurities, by-products, coincidentally produced, chemicals and synergistic effects should be obtained at the research phase prior to the commercial manufacturing.

A standardized protocol for research into new chemicals should be included in the Act.

New chemicals that are imported into Canada from nations that do not have stringent testing requirements should be tested by the Canadian importing company. At a minimum the chemicals should be monitored closely for possible production of impurities, byproducts coincidentally produced chemicals etc.

In addition manufacturers, users and importers should be required to be informed of procedures for safe a) use b) transport and disposal of the material.

E. Information Requirements

CELA recommends that all new chemicals entering or manufactured in Canada regardless of quantity should provide the maximum amount of information about a chemical.

- i) chemical identity
- ii) uses
- iii) procedure for safe use
- iv) by-products, synergistic effects
- v) physical - chemical properties
- vi) acute toxicity
- vii) ecotoxicity data
- viii) recommendation for safe handling, transportation and disposal
- ix) dangers to human health (long term and short term)

CELA urges the development of standardized protocol for testing and evaluating new chemicals.

CELA agrees that federal government be given powers to request more information and to gather follow-up information.

F. Control Action

CELA should support basic recommendation to include power to
a) issue general orders prohibiting a new chemical from being
imported or restrict its use b) issue specific orders
addressing packaging, disposal record keeping

In addition CELA recommends that:

a) citizens be given the statutory right to prosecute
the manufacturer, or user of a new chemical which after
given clearance causing damage.

b) a victim compensation fund should be established.

G. Confidentiality

CELA generally should support recommendatioins guaranteeing
trade secrets, except in situations where that knowledge will
aid in determining environmental and health impacts.

Reports submitted in the premanufacture data should be made
available to the public.

H. Sharing Information with OECD and other trading partners

CELA endorses recommendation to exchange info on new chemicals with countries which import into Canada and also exports from Canada to other countries.