Notice of Objection to Listing *Pest Control Products Act* and *Regulations* on Schedule 2 of the *Canadian Environmental Protection Act 1999*: Issues Beyond the Legal Criteria for Listing

Issue

Notice of Objection filed by the Canadian Environmental Law Association and the World Wildlife Fund Canada to the proposed listing of the *Pest Control Products Act* (PCPA) and *Regulations* (PCPR) on Schedule 2 of *the Canadian Environmental Protection Act 1999* (CEPA)

Background

The Notice of Objection has been analysed with respect to the two criteria specified in CEPA for listing an Act on Schedule 2, ie. notice prior to manufacture, import or sale, and an assessment of "toxic". That analysis reconfirmed the rationale whereby PCPA and PCPR meet the listing requirements, and is documented elsewhere.

A number of additional issues were raised in the Notice of Objection. While these issues go beyond the legal criteria in CEPA for listing an Act on Schedule 2, it is important to note how these issues are being addressed as part of the regulatory regime for pesticides under the PCPA.

Additional Issues in the Notice of Objection

Renewal of PCPA

The proposed Order assesses whether the current PCPA meets the CEPA requirements for listing and not what may appear in a revised Act. Nevertheless, the government is strongly committed to amend the PCPA. The government has re-iterated its commitment to legislative renewal in the *Government Response to the Report of the House of Commons Standing Committee on the Environment and Sustainable Development, Pesticides: Making the Right Choice for the Protection of Health and the Environment* (October 2000), and is working to introduce legislation in the near future.

Transparency

Regulatory proposals and consultation documents are issued in order to provide Canadians with the opportunity to provide input into the requirements, processes and policies for assessing pesticide risks and value. In addition, the Pest Management Regulatory Agency (PMRA) issues detailed summaries of the assessments of the new pesticide, which outline such matters as the characteristics of the candidate pesticides, the results of the PMRA's health risk, environmental

risk and value assessments, proposed uses, application rates, label information and the Agency's rationale for its decisions. These documents are publicly available on the PMRA website.

Virtual elimination of persistent, bioaccumulative and toxic substances

The PMRA published its strategy for implementing the Toxic Substances Management Policy (TSMP) in March, 1999. The strategy addresses active ingredients, formulants and micro-contaminants in both currently registered products and new products. Restricting use of existing pesticides, or denying registration of new active ingredients according to the TSMP implementation strategy, contributes to achieving the ultimate reduction of quantity or concentration of the substances in releases to the environment to below the level of quantification. The federal TSMP Interdepartmental Forum, including Environment Canada, supported PMRA's implementation strategy as being consistent with the federal TSMP, and the concepts expressed in the TSMP have been used for many years in regulating pesticides.

Data requirements

A comprehensive set of health and environmental data are required for all new pesticides. The data required under CEPA in the New Substances Notification Regulations (NSNR), highlighted in the Notice of Objection, are also required for assessment of pesticides under the PCPA. Because the assessment of pesticides relates to specific defined uses, some information related to exposure assessment is gathered in a different way than for New Substances. Additional data is required for pesticides, including data on long-term effects such as carcinogenicity, reproductive effects, and developmental effects, and tests on a wide range of indicator species.

Although the data requirements are not detailed in the PCPR as they are in the NSNR, the regulations under the PCPA do prescribe the type of information that is required to be provided by an applicant to register a pesticide. Detailed data requirements are set out in Directives and Guidelines. The regulations also authorize the Minister to impose additional information requirements and this authority is exercised as needed during assessment of a product. These requirements are enforceable because the Minister is required to refuse to register the control product when the information is insufficient to enable the product to be assessed or evaluated. An applicant who does not comply with the information requirements imposed by the regulations and the Minister will not obtain a registration

Precautionary principle

The PCPA pre-dates the precise notion and definition of the precautionary principle, therefore the term is not used in the Act. However, the concept of exercising precaution underlies regulatory decision-making. The Act and Regulations specify that scientific data on health and environmental risks are needed as a basis for regulatory decisions. A detailed rigorous assessment of those data is necessary before a pesticide can be used in Canada. A product will be registered only if there is sufficient scientific evidence to show that health or environmental

risks posed by a product are acceptable and that it serves a useful purpose. Conditions of registration are specified for every product, including detailed use instructions, and a product can only be used according to label directions. If the proposed use could pose an unacceptable risk, additional conditions or restrictions can be imposed so that the remaining risk becomes acceptable. If the risks remain unacceptable, a registration is denied and the product cannot be used.

Therefore, fundamentally, the whole approach to pesticide regulation is precautionary.

Ecosystem approach

The ecosystem approach under CEPA is manifested in the new substance notification requirements by including testing for the toxicity of indicator species, and physical-chemical data to estimate the movement of the substance from an area of application, persistence and other factors which could have impact on ecosystems. The assessment of pesticides matches that of CEPA, and considers the same types of data. In addition, because of the nature of pesticides, a number of additional indicator species are tested, including earthworms, pollinating insects, and birds (including chronic studies). The assessment of pesticides also includes, but is not limited to, information on adverse effects to non-target species, ability to migrate between environmental compartments, potential for bioaccumulation, and whether they are ozone depleting substances. The data are used to define conditions of use and restrictions. Where the data indicate that there may be impact on organisms and ecosystems of areas surrounding the location of application, additional restrictions can be imposed.

Preventive and remedial action

The pre-market assessment and registration process for pesticides is preventive in nature. No pesticide can be registered until it has been assessed. The Minister must be satisfied that he has sufficient information to assess health and environmental risks, and that the product will not pose unacceptable risk of harm to human health or the environment. Furthermore, use of the product in a manner other than that specified as part of the registration conditions is prohibited. Therefore, any use that has not been determined to be acceptable is not allowed.

Remedial action may be taken on a registered product via the re-evaluation programs and special reviews. Re-evaluation and special reviews of pesticides allow the product to be reviewed in light of new scientific knowledge of toxicological end points of concern, often combined with new investigative methods; results from epidemiological studies, and environmental monitoring and surveys. Actions that can be taken include changing the conditions of use, or removing the product from the market.

Safety, merit and value

Under the PCPA, the applicant must fulfil the requirement to demonstrate the safety, merit and value of a pest control product. The assessment of merit and value determines the product's contribution to pest management. However, the Minister cannot register a product if the health and environmental risks are unacceptable, regardless of the value of the product (PCPR 18(d)). Similarly, a product that is found to be of no, or insufficient, value will not be registered even though the health and environmental risks have been found to be acceptable ((PCPR 18(c)). In other words, all of the bases for approval (health and environment, merit and value) must be satisfied before registration can be granted.

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