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PMRA Publications
Pest Management Regulatory Agency
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Via email: <u>pmra.infoserv@hc-sc.gc.ca</u>

RE: PMRA New Approach to Re-evaluation – response to consultation

Response to Re-evaluation Note, REV2010-18: Re-evaluation Program, outlining the Pest Management Regulatory Agency's (PMRA) new approach to re-evaluation.

About CELA

The Canadian Environmental Law Association (CELA) is a non-profit, public interest organization and environmental law clinic – within Legal Aid Ontario - dedicated to providing legal services to low income people and disadvantaged communities, and advancing the cause of strong environmental protection through advocacy, education and law reform.

CELA's law reform and public educational mandates include advocacy on ensuring access to environmental justice and protecting public environmental rights. Within this public interest mandate, CELA has worked on pesticide issues, on behalf of clients and for the sake of improved pesticide legislation, for over twenty-five years.

We offer the following comments on the PMRA's proposed new approach to pesticide reevaluation.

1. The progress achieved thus far on pesticide re-evaluation is laudable; extensive registration changes underscore the need for the program

First, we commend the PMRA for having completed the re-evaluation of over 90% of the 401 pesticide active ingredients slated for re-evaluation in 1995. As noted in the consultation document introduction, this work has resulted in substantial changes in pesticide use in Canada with over 20% of active ingredients identified for discontinuation or phase-out and very few active ingredients accepted for continued use without any label changes.

These results are an indication of change across the full suite of pesticides used in Canada. The fact that so many pesticide registrations were altered as a result of this work underscores the need for pesticide re-evaluation, a program long called for by expert and Parliamentary reviews,

independent scientists, public interest organizations and concerned members of the public in Canada.

2. International scientific collaboration makes sense but needs to assign priority to address statutory obligations to evaluating information about the cumulative assessment of groups of similar pesticides.

We support in principle an approach to re-evaluation that continues to take advantage of international efforts and collaboration among scientific and regulatory agencies so long as it does not result in decision-making delays in Canada. In particular, we are supportive of such efforts where they can serve to more efficiently address Canada's obligations under Section 19(2)(b)(i) of the *Pest Control Products Act* to consider available information on the "cumulative effects of the pest control product and other pest control products that have a common mechanism of toxicity."

We have been told repeatedly by PMRA officials that cumulative effects assessment is complex and progress will occur in conjunction with activities occurring within the US Environmental Protection Agency. Given the direct relevance of this work on cumulative effects assessment to continued efforts on pesticide re-evaluation, including pesticides of considerable public health and environmental concern, a new approach to re-evaluation should specify the manner in which those efforts will be incorporated into pesticide re-evaluation going forward.

Given that very limited progress has occurred during the re-evaluation program thus far to address cumulative effects of groups of pesticides it is discouraging to find that the proposed new approach to re-evaluation does not mention how this shortcoming will be addressed other than in a vague reference under the heading of "scheduling."

3. The initial two-step review to determine adequacy of existing information should be publicly accessible and not an "internal file review."

In introducing the proposed new approach, the statement is made that "this regulatory proposal describes a focussed re-evaluation approach where the breadth and depth of the review would be commensurate with the complexity of issues associated with *a given* pesticide (emphasis added)." To address cumulative effects, while this statement might be interpreted as providing recognition of the complex breadth and depth involved, the rest of the document appears to focus on narrowing the scope of future reviews.

The document presents a very brief rationale for various means of scoping future re-evaluations, re-using existing information, targeted gathering of new information, etc.

We can appreciate the efficiencies that flow from a process of using existing information where it is adequate for subsequent re-evaluations. Such efficiencies can make sense so long as the assessment of the currency of information does not compromise statutory requirements for the scientific integrity of the exercise. Hence, we are not opposed to the scoping exercise per se but

cannot see how public confidence will be assured when this exercise is not open to public scrutiny and therefore object that this exercise should be an "internal file review."

These concerns are especially pertinent to the need to expand the range of health endpoints considered during the assessment of pesticides and indeed other toxic substances. Across all chemicals regulation in Canada, including pesticides, greater consideration during assessments is necessary to address exposure circumstances and health endpoints related to endocrine disruption and developmental neurotoxicity. Therein, data requirements need to be refined to address novel circumstances with respect to both exposure and health endpoints. For exposure, evaluation of endocrine disruption potential needs to address the challenges of non-monotonic dose-response curves and the related issue of evidence of effects at extremely low doses. For developmental neurotoxicity, greater consideration is needed in the assessment of functional endpoints (behaviour, learning) as a result of early life exposure, particularly *in utero*.

As the PMRA well knows, there is a high degree of public concern about the human health effects of pesticides. This concern arises in part from the perception that pesticides are not comprehensively assessed by the PMRA for all relevant health endpoints, including endocrine disruption and effects on the developing brain. It is therefore likely that an internal review to determine the sufficiency of existing data will create further mistrust of the PMRA and as such should be avoided. The review envisioned in Steps 1 and 2 should be subject to public scrutiny.

4. The scheduling plan should recognize statutory requirements beyond Section 28(1) of the PCPA and specify the details and timetable for meeting obligations to consider information about cumulative effects of groups of similar pesticides. Greater clarity is also needed when related efforts occur for the same chemicals under the Chemicals Management Plan.

The discussion of scheduling refers to setting priorities for re-evaluation to meet statutory obligations. It further notes "prioritization may be changed to cluster active ingredients where it makes sense to complete the re-evaluations as a group instead of strictly according to the statutory time requirements." In response, we note that this approach does not just "make sense" but flows from outstanding statutory obligations to consider information about the cumulative effects of similar pesticides.

We also suggest that the design of a new approach to pesticide re-evaluation and specifically consideration of scheduling issues, should address the need for improved coordination and timing between screening assessments conducted under the Chemicals Management Plan of substances that have both industrial and pesticide applications. It has been our experience that in situations where a pesticide application has been identified in a screening assessment of a chemical being evaluated under the *Canadian Environmental Protection Act*, significant uncertainty arises about when the pesticide re-evaluation will occur and whether and how the CMP assessment results are considered in the pesticide re-evaluation.

Considerable progress has been made getting through the large back-log in pesticide reevaluation. During this time scientific evidence about cumulative effects of pesticides, and
indeed other combinations of chemical exposures, and particularly the science of endocrine
disruption, has continued to expand. Likewise, the Chemicals Management Plan has continued to
move forward. It is important that the PMRA specify in a new approach to re-evaluation how
statutory requirements will be met for considering information about cumulative effects of
groups of pesticides, and how ongoing work will be coordinated with the Chemicals
Management Plan. If more detail about how this work will occur were explicitly integrated into
the re-evaluation priority setting exercise going forward, the document would be more
transparent and open to public scrutiny and accountability.

All of which is respectfully submitted.

Yours truly,

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