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Pest Management Regulatory Agency
Publications Section
Health Canada
2720 Riverside Drive
Ottawa, Ontario K1A 0K9

*** **BY EMAIL @ PMRA.PUBLICATIONS@HC-SC.GC.CA AND MAIL** ***

Dear Sirs/Mesdames:

Re: Re-Evaluation Note on the Re-Evaluation Program (REV2010-18)

Thank you for the opportunity to comment on the PMRA's Re-Evaluation Note (REV2010-18, the "Note"), dated December 1, 2010, on the Re-Evaluation Program (the "Program").

Complaint about the process

My first and most general comment is that I would have hoped for broader public consultations, rather than just an opportunity to comment on a Note posted to your website, and better advertising of the consultations. I have been in touch with your office frequently in past years, including by email November 15th, 2010 related to questions around the conduct of a past re-evaluation, but did not learn of the opportunity to engage in this consultation until January 14th, 2011 from an individual not affiliated with your office. I received a response to my November 15th email on January 19th (after I followed up) which did notify me of the consultation.

There are many health, environmental and community groups which should have been explicitly invited to participate in a consultation of this importance. This is not equivalent to the re-evaluation of a pesticide, but rather relates to the entire system of evaluation. Opportunities for meetings, webinars or other formats that allow for interaction and questions would have been an obvious addition, as would greater efforts to encourage public engagement.

Need to justify the abandonment of the Old Approach

The second paragraph of the Note demonstrates the rather stunning accomplishments of the four-program approach to re-evaluation. Given West Coast Environmental Law's rather cautious approach when it comes to what is an "acceptable" risk, we're inclined to believe that the re-evaluation should have gone even further than banning more than 20% of the pre-1995 pesticides evaluated and changing conditions of use for "the vast majority" of the others. But nonetheless, it's clear that the four-program approach was by in large a success in terms of allowing the PMRA to assess the risks of these pesticides.

Which is why it is surprising to hear that a new approach is required. And the Note doesn't really explain why. At p. 3 it states that despite the old program's success "there have been challenges and lessons learned." However, only 3 specific challenges are identified.

The first two relate directly to the age of the studies and scientific standards used in the pre-1995 approvals. As the Note discusses "these demands are expected to lesson in subsequent re-evaluations …"

The third challenge arises from the complaints of both agency personnel and unspecified "stakeholders" related to "the clarity of the scope and timelines of the re-evaluation process." I have little doubt that there were challenges related to the timelines – since in the case of the re-evaluation of Endosulphan it took about 5 years from when **interim** mitigation measures were first proposed to implement even the **interim** measures. Although it remains unclear to me that this delay had anything to do with the scope or the re-evaluation process itself. To the extent that such delays were a result of the process itself (as opposed to say, inadequate funding), this should have been discussed in the Note.

The point is that a vague desire of stakeholders and agency personnel to clarify scope and time-lines is not a sufficient justification for abandoning an approval process which your agency agrees has been largely successful. If there are additional reasons for abandoning the old approach, these should have been spelled out in the Note.

One possible reason implicit in the proposed new approach might relate to the resources required to conduct a re-evaluation. But even this requires a bit of justification, since the old Approach itself aimed for administrative efficiency by relying heavily on re-evaluations being done by US agencies, and only involved Canada-only reviews in a limited range of circumstances – primarily as required to protect human health and the environment.

Scoping under the proposed new approach

The central feature of the Proposed New Approach seems to be the initial scoping and development of a workplan for pesticides which are due for re-evaluation. The intent is ostensibly to focus available resources, but the proposal raises a number of very real concerns for us.

Self-evaluation: First, PMRA scientists are reviewing work done by PMRA scientists to determine its quality. This is hardly arms-length, independent or transparent. There may be circumstances (if the requirement of a review every 15 years is realised or where a special review is required) in which PMRA scientists are involved in assessing research that they were involved in, or which their superiors were involved in.

Adequacy of information assessment: We are not scientists, but we wonder whether the quality of data can be truly determined from a cursory review of the type contemplated. Further, it seems to us that there should be a point in which original data is re-checked even if the original studies seem sound on their surface.

We also have significant questions from the Note as to exactly what type of information is contemplated by the scoping review. Will studies related to the impacts of inactive ingredients or particular formulations be enough to result in a broader review? What about studies showing developmental, reproductive or endocrine related health problems – problems which are not generally tested for by the PMRA and which are difficult to test for in a controlled manner?

Moreover, the assessment of risk should involve not only the original scientific data, and its quality, but also empirical and sociological information (which the PMRA can and should be tracking) about actual instances of pesticide poisoning, contamination or environmental-impacts, patters of pesticide use, cultural attitudes of users, levels of compliance with the labels, etc.

There is also a question arising from the Old Approach, which relied upon re-evaluations done by the US authorities to assist in Canadian evaluations. As we understand it the re-evaluation process could limit itself to only a very cursory examination of new US re-evaluation data (or other quality new data) that is readily available.

Changes in evaluation of "acceptability": While the PMRA makes its assessments based on scientific data, the public and governmental sense of how the *Pest Control Products Act* is to be interpreted and the determination of what risks are deemed acceptable may change over time. We have noted that the PMRA often appears to take a very loose interpretation of "reasonable certainty" in determining what risks are acceptable,[1] and there may well be circumstances in which the scientific data is high quality, but the application of the PCPA was not, and the original registration and its conditions deserve a second look.

Public Consultation: The Note seems to suggest at times that the scoping decision will not be open to public consultation. While noting the legal requirement to consult the public, the Note suggests that only some "stages in the re-evaluation" will be "open to consultations" and suggests that only "the PMRA's conclusions [related to 'those areas of risk assessment that require an update'] … will be published for consultation…" By contrast the result of the scoping phases (an "outline [of] the anticipated focus of the re-evaluation") is to be shared with "stakeholders."

This further emphasizes the self-referential nature of the scoping decision and the potential for errors and abuse. The Note should be a lot clearer about how Public consultation is to be done in this case. It is our view that the *Pest Control Products Act*, s. 28, does not contemplate a public consultation process that excludes the scoping stage. Indeed, it is essential that this stage be as open and transparent as possible due to the potential for abuse.

Actual impact of the New Approach: Finally, given that the PMRA has almost a decade of experience with the Old Approach it would be useful to know how the outcomes of the New Approach might compare. The PMRA could, for example, complete the re-evaluation of the roughly 40 pre-1995 pesticides remaining under both the New and Old Approaches (conducted independently) and then compare the results.

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[1] "Acceptable risk" for the purposes of the Act means "reasonable certainty that no harm to human health, future generations or the environment will result from exposure to or use of the product, taking into account its conditions or proposed conditions of registration." (s. 2(2)) Given that thousands of pesticide poisoning occur each year in Canada from registered pesticides (D. Boyd. Northern Exposure: Acute Pesticide Poisonings in Canada. (David Suzuki Foundation, 2007)) it is clearly not the case that it is reasonably certain that the pesticides causing the poisoning will cause "no harm" to harm human health. Even recognizing that in many cases the poisoning occurred due to a failure to follow pesticide labels, the Act, while allowing the PMRA to "take into account" the conditions contained on those labels, does not mandate the PMRA to ignore the fact that children can't read labels or that labels are not always followed for a number of reasons.

In conclusion, the scoping phases (steps 1 and 2) greatly decreases the transparency and accountability of the re-evaluation process. The Note seems not even to recognize these potential problems. While we understand the value of efficiencies, at this stage and as proposed we cannot support what seems like a secretive and not obviously necessary scoping stage.

Special Review

We have been concerned about the fact that the PMRA has not to date accepted a request for a special review under s. 17(4) of the Act (since the Act came into force in 2006). We believe that your Re-evaluation process is holding such requests to an overly onerous standard and that this should be re-evaluated.

A special review must be initiated when the Minister has "the Minister has reasonable grounds to believe that the health or environmental risks of the product are, or its value is, unacceptable" (not necessarily limited to scientific evidence, as your Note suggests). However, the PMRA appears to have interpreted this as placing the onus for proving such grounds on a balance of probability basis on the person requesting a special review. We do not agree with that approach.

We have been supporting Ms. Josette Wier in her efforts to have you review Glyphosate-based pesticides containing POEA. As we understand the situation, Ms. Wier's request for a Special Review cited several studies related to the toxicity of such pesticides. The PMRA's response was essentially to point out that those studies, while relevant, did not in and of themselves prove an unacceptable health or environmental risk.

However, as we understand it, the last evaluation of Glyphosate by the PMRA occurred prior to most of the evidence concerning the toxicity of POEA. Since inactive ingredients such as POEA are not generally tested for by the PMRA, we believe that the PMRA has never actually done an evaluation which examines the toxicity of that ingredient in the context of a Glyphosate-based pesticide.

The Pest Control Products Act contemplates a precautionary approach, and we do not believe that the onus should be on a member of the public to prove that an ingredient that the PMRA has never evaluated for safety poses an unacceptable risk. Rather, in the absence of such an evaluation, the onus is on the registrant to prove that the pesticide as a whole, including the inactive ingredients, is safe.

We are concerned, also, about the idea of merely incorporating special reviews into previously scheduled Re-evaluations. In Josette Wier's case the PMRA proposed doing so, and in fact argued that her legal challenge to the failure to conduct the review was moot as a result, despite the fact that the agency also conceded that a focussed review of POEA could be conducted more quickly than a full re-evaluation. While some level of integration only makes sense, the existence of a full re-evaluation should not slow a special review, possibly resulting in an interim order in the context of the full re-evaluation.

Concerns about Evaluation generally

Some of our most significant concerns about re-evaluation relate to evaluation of pesticides more generally. While going beyond the scope of the Note, we did want to reiterate our ongoing concern that:

- Reasonable certainty is not interpreted particularly strictly in evaluation and a more precautionary approach should be taken;
- Compliance with labels is assumed despite little available evidence;
- Substitution of safer products for more harmful products is desireable; and
- Conditions can and should emphasize pollution prevention, pesticide reduction and integrated pest management.

Conclusion

Thank you again for the (somewhat belated) opportunity to comment on your Note and the proposed Program. The PMRA's mandate to protect the public and the environment from the possible impacts of pesticides is a critical one. We fear that the Proposed Program will weaken this mandate. The scoping stages contemplated by the Note may result in reduced protections and the Note does not make out a compelling case for these changes.

Sincerely,

Andrew Gage,
Acting Executive Director