

DEBATE ON:

PROTOCOL 6 - ELIGIBILITY FOR APPLICATIONS FOR REVIEW BY APPROVED PROFESSIONALS (RISK ASSESSMENT FOCUS)

“Any application listed in Table 1 for a contaminated sites legal instrument for a non-high risk site must be preapproved by a Director before submission to the ministry with the recommendation by an Approved Professional.”

5	Where the application is based on a risk assessment that includes any of the following: <ul style="list-style-type: none">• probabilistic analysis;• toxicity testing of materials (soil, water, sediment), or organisms obtained at or from the parcel;• modification of toxicity reference values;• food chain modelling;• weight-of-evidence arguments;• assessments of the aquatic receiving environment
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Summary and Recommendations:

1. There was a desire among RA practitioners and Approved Professionals (AP) to find ways of allowing some limited use of the RA tools (listed in Table1, part 5); and discussed further below.
2. An incremental approach was proposed, whereby some level of use of the RA tools would not require preapproval. It was suggested that a “box” be defined for what would be acceptable. The size of the box could expand over time. The use RA tools falling outside the “box” would still require preapproval. The “box” could be defined based on a subset of tools provided in the DERA guidance.
3. There was interest in assisting MOE with developing this guidance. Options discussed included:
 - a. CSAP sponsored task group
 - b. The Risk Forum (MOE and SAB sponsored)
 - c. The Risk Symposium
4. It was also suggested that the incremental use of RA tools (within the defined box) could be best carried out as a team; with two risk assessment APs co-signing the SoSC. This approach would provide a certain degree of peer review with “checks and balances” in the application of the RA tools, and therefore add a level of confidence to MOE, the Industry and the Public.

Preapproval Submission Q & A

1. What does an application for pre-approval look like?
 - a. Now available on the MOE website
<http://www.env.gov.bc.ca/epd/remediation/forms/index.htm>
2. Who is responsible for preparing a submission for preapproval (practitioner or approved professional)?
 - a. The practitioner (on behalf of the responsible person - client) prepares the submission not the AP.
3. When a submission for preapproval is made to the Director, who does it (actually) go to, what is the anticipated turnaround time, and cost?
 - a. The submission goes to the client services officer who logs the submission and passes it to review staff (the staff person depends on topic) who review and provide recommendation.
 - b. Turnaround time can be as little as two weeks but could be much longer dependent on complexity and extent of detail and rationale provided.
 - c. First hour is free, and then standard MOE review fees apply (hourly rate at \$165/hr).
4. Is preapproval intended for the use of the tool and/or the resulting data interpretation?
 - a. It was clarified that preapproval is for use of the tool(s) only; judging the results of related data interpretation is the job of the AP.

Use of Risk Assessment Tools under P6

A. Toxicity Testing:

1. Is it possible to define certain standard tests or interpretation that could allow for limited use of toxicity testing without having to obtain pre-approval?
 - a. While it was pointed out that selection of toxicity tests should be based on what is most defensible for a particular site, there were some suggestions around what might be considered to fit within a P6 “box” of allowable use of toxicity tests. The discussion was not conclusive, but there was a desire to explore this further.
2. Which “parts” of toxicity testing do we need to get preapproval for (type of test, test endpoints, data quality, approach/process/interpretation, ECx)?

- a. MOE wants to see a conceptual model (CM) in the submission which demonstrates (along with rationale) why the tests chosen are appropriate based on the receptors, conditions, and pathways at the site.
- b. MOE is not looking for a high level of detail; rather, they want to see a reasonable approach and clear rationale. It was suggested that submittal of a Problem Formulation (PF) may be useful - this might be too much detail but if multiple tools and WOE are being used, it might be appropriate (or at least provide a subset of key PF sections in a briefer document).

B. Modification of a TRV

1. If you are using TRVs published by the agencies/sources identified in TG7 in the manner recommended by those agencies/sources, MOE would not consider this to be modifying a TRV.
2. MOE wants to see rationale that explains why the values chosen are the most appropriate values from the sources listed in TG7 based on receptors, conditions, and pathways at the site. For example, if a less than chronic exposure scenario is being evaluated, use of a sub-chronic TRV may be appropriate, with rationale provided.
3. Use of Protocol 1 uncertainty factors was discussed, particularly whether they are still current. Use of Protocol 1 uncertainty factors was not considered to be modification of a TRV because this was an extrapolation from an underlying toxicity value to a different species, not a modification of the underlying value or re-interpretation of the toxicity study on which it was based. If a more current and scientifically defensible uncertainty factor were applied, and if the uncertainty factor was less conservative than the Protocol 1 default, pre-approval would be required, whereas if the factor was more conservative, pre-approval would likely not be required. In either case, rationale would need to be provided in a report.
4. CSAP society should consider developing guidance for AP reviews to define modification of a TRV in more detail.

C. Food Chain Modelling

1. Small mammals and birds are applicable receptors at most, if not all terrestrial contaminated sites. Consumption of contaminated food is generally an operable exposure pathway. Therefore, if a terrestrial site is contaminated, a pre-approval is necessary in order to conduct a risk assessment, even for a relatively small, and simple (not diverse) terrestrial environment. Is it possible to define a “simple” application of a food chain model using TG 7-approved references that could be allowed under P6 without having to obtain pre-approval?
 - a. A simple example was presented to illustrate the question raised

- b. As for the other RA tools, there is a desire to explore what may be allowed under P6 without preapproval, and the options for developing some guidance include those listed under :Summary and Recommendations”
2. Similar to TRV modification, preapproval should be straight forward, provided your rationale is reasonable and based on recommendations from TG7.

D. Weight-of-Evidence

1. Is it possible to define a “simple” application of a weight-of-evidence that could be allowed under P6 without having to obtain pre-approval?
 - a. Clarification was provided that the restriction on the use of WOE was carried over from the previous version of TG7. Now that DERA is available (although not MOE policy yet), some relaxation may be prudent to consider.
 - b. There was some discussion of what shape this may take, but it was recognized that this would have to be developed further, with input from MOE, CSAP and practitioners.
2. Currently preapproval is required. The preapproval would likely involve submitting the PF. AS above, it is the use of the tool require preapproval (it has to be used in a way that is defensible for the site); and not the interpretation that will result from using the tool (which is the conclusion of the risk assessment).

E. What constitutes “Assessments of the aquatic receiving environment”?

1. We did not get to discuss this point.
2. It is noted that the recent preapproval form posted on MOE’s website now describes this tool as “higher order assessments of population, food chain modelling and ecological succession aspects of the aquatic receiving environment.”