

RCEN Delegate Report

Technical Expert Group on Screening Assessment of Living Organisms on the DSL Meeting Sep 20, 2007, Ottawa

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The TEG consists of 3 industry representatives, 2 NGO representatives (myself for the ENGOs and Paul Hasselback for the Canadian Lung Association representing Health NGOs), 2 members from academia, as well as representatives from government departments other than the NS program, i.e. CFIA, NRCAN.

The Mandate

EC will be undertaking screening assessments of living organisms on the DSL.¹ The mandate of the TEG is to make recommendations to the New Substances Program on issues related to the proposed scientific approach, including scientific and technical work, data gathering, external review, guidance documents, stakeholder engagement, external experts, transparency etc.

The Work

45 living organisms are currently listed on the DSL. All are microorganisms: 44 microbial strains and one consortium consisting of at least 9 and possibly many more strains. It is known that considerably more microorganisms were in commerce in Canada between 1984 and 1986, and it is unclear why not more were nominated to the DSL. This means that the list remains dynamic, as late nominations are still possible.

All currently listed microorganisms, including the consortium, are naturally occurring; one of them is a strain selected by exposure to specific growing conditions. None are genetically modified.

It is EC's intent that *all* 45 organisms on the DSL will undergo a screening assessment. To manage the workload, EC staff have prioritized these microorganisms in order of potential hazard and grouped them into Priority groups A, B and C through review of national and international databases and literature. It is expected that completion of the assessments and publication of assessment reports will take place in order of prioritization. Data is sketchy in some areas, and TEG members made suggestions on where additional data might be accessed. This is unlikely to change the order of prioritization. The TEG suggested moving the consortium (which is naturally occurring in the Gulf of Mexico) to Priority Group A, because not all microorganisms in the culture have been identified and can therefore not be classified. It is recognized that the

¹ The screening assessment is a risk assessment; the term "screening" was chosen to avoid confusion with the risk assessments undertaken under the NSNR.

prioritization list is dynamic, as new additions to the DSL are possible, and new data may become available.

EC proposes that the assessments will take place in 3 steps:

Step 1: Assessment of hazard. For those microorganisms that are deemed to pose a negligible hazard, no further action is taken. All those posing a non-negligible hazard will move to step 2.

Step 2: Assessment of exposure. Based on the assessment of hazard and exposure, microorganisms will be categorized as CEPA “toxic” or “non-toxic”. For the non-toxic ones, either no further action is taken, or SNAC provisions are recommended. Those deemed CEPA toxic move to Step 3.

Step 3: further data gathering and analysis to reduce uncertainty. Risk management options are explored.

The TEG recommended that the risk estimation for microorganisms of high hazard, but negligible exposure potential (e.g. in full containment) be upgraded from “negligible” to “low” to account for accidental exposure through human error, natural disasters, etc.

Once the screening assessment for a given microorganism is complete, a draft assessment report will be posted on the project’s website for public consultation, before a final assessment report is published in Canada Gazette.

The Challenges

It is clear to everyone that data collection for this project will in many cases present considerable, and perhaps insurmountable challenges.

- Scientific data on hazard is often lacking for vulnerable human populations, never mind a representative sample of non-human life or habitats.
- Taxonomic identification of microbial strains is very difficult, both because different technologies can yield different results, and because many microorganisms are genetically somewhat unstable, so that genetic fingerprints change over time.
- Data on use patterns and quantities are currently non-existent, and present a considerable challenge to collect. Even identifying companies that are commercially involved with these microorganisms constitutes a major hurdle. This field is characterized by many small, new and emerging players and is very dynamic. Many of these companies are far too small to have departments, or even personnel dedicated to regulatory issues and are completely unaware of these developments. They often don’t even have the needed data, or may find the administrative burden of providing it overwhelming. All the larger manufacturers are based in the US. Most imports are for finished products, with the importer

having no access to e.g. formulations. EC has so far identified about 800 companies in Canada for first contact.

The screening assessment currently directly affects only 45 organisms, half of which are probably not even in use anymore and none of which are likely to present a high hazard. However, there is an expectation that the experience gained from this exercise will inform the review of the NSNR for microorganisms which is planned. In addition, because Canada is one of the very few jurisdictions even having regulations for naturally occurring organisms, it may find itself in the role of an international standard-setter. Many of the applications for these microorganisms have environmental value, e.g. in the area of bioremediation. The costs and benefits of the extent of the regulatory burden may have to be carefully weighed up.