4. Proposed Approach to Environmental Risk Assessment of Microorganisms under the Canadian Environmental Protection Act (CEPA)

J. Beardall¹, J. Louter¹ and N. Skipper¹

Management of toxic substances is part of the current approach to pollution prevention in Canada. The Substances New to Canada provisions in CEPA ensure that no new substance is introduced into Canada before it has been assessed for whether it is "toxic" as defined in section 11 of CEPA:

"A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions

- (a) having or that may have an immediate or long-term effect on the environment;
- (b) constituting or that may constitute a danger to the environment on which human life depends; or
- (a) constituting or that may constitute a danger to human life or health."

This paper outlines Environment Canada's proposed approach to the environmental risk assessment of microorganisms within the context of the new substances program.

The information provided by the notifier as prescribed in regulation will be the basis for the assessment. The risk assessment will comprise an effects and an exposure assessment, and risk characterization. The risk characterization will integrate the assessment of potential exposure with the assessment of potential adverse effects and will conclude with a determination of whether or not the microorganism is suspected of being "toxic" as defined in section 11 of CEPA.

 $^{^{\}rm 1}$ Biotechnology Section, New Substances Division, CCEB, Environment Canada, PVM, 351 St. Joseph Blvd., Hull, Que, K1A 0H3, Canada

Information provided under regulation

Effects Assessment

- -pathogenicity
- -production of toxins
- -production of by-products
- -resistance to control agents
- -effects on biodiversity
- -effects on biogeochemical cycling

Exposure Assessment

- -levels of introduction
- -characteristics of site
- -background levels
- -receptor species
- -proliferation/persistence
- -selection
- -ecological fitness
- -dispersal
- -gene transfer

Risk Characterization

-integration of effects assessment and exposure assessment

Suspicion of "toxic"

(section 11 of CEPA)

-recommend controls

No suspicion of "toxic"

(section 11 of CEPA)

-manufacture or importation may proceed

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