Environment Canada Environnement Canada

Executive Summary of the Canadian Regulatory System for Biotechnology (CRSB) Workshop:

Towards an Integrative Research Strategy for Organisms that are Micro-organisms under the New Substances Program

Held at the Courtyard by Marriott, Toronto, ON
May 18-19th, 2004

EXECUTIVE SUMMARY

"Biotechnology products offer significant benefits to Canadian consumers and businesses. At the same time, they require careful scrutiny and regulation. The Government is strengthening its commitment to ensure that these new technologies not only enhance health and safety, but also respect and preserve the environment." [Chapter 5-'Making Canada's Economy More Innovative', Budget Plan, Budget, 2000- http://www.fin.gc.ca/budget00/inno/inno1e.htm].

In response to urgent priorities identified during the 1998 Canadian Biotechnology Strategy consultations, the Federal Government has recognized the need to invest in the Canadian regulatory system for products of biotechnology. In its Budget 2000 announcement, the Government confirmed this commitment by allocating $90M over three years for the Canadian Regulatory System for Biotechnology (CRSB). Funds have been assigned to the CRSB initiative and EC receives part of this fund to support work in four areas, namely: a) meeting technical capacity and human resource needs; b) improving public awareness of, and confidence in the regulatory system; c) increasing efficiency, effectiveness and timeliness of the regulatory system; and d) generating knowledge to support the regulatory system.

The main responsibility of Environment Canada (EC) and Health Canada (HC) with respect to animate products of biotechnology is to administer the New Substances Notification Regulations (NSNR- http://laws.justice.gc.ca/en/C-15.31/SOR-94-260/index.html) for living organisms (LO) under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999- http://laws.justice.gc.ca/en/C-15.31/text.html) in order to ensure that the import to or manufacture in Canada of living organisms occurs in a manner that does not harm the environment and/or human health. Part 6 of CEPA 1999 covers animate products of biotechnology that encompass both micro-organisms and organisms other than micro-organisms (such as transgenic fish and livestock). This document deals specifically with micro-organisms as they constitute the bulk of animate products of biotechnology notified to EC and HC under the New Substances (NS) Program.

To better define the research agenda associated with the risk assessment and risk management of micro-organisms under EC's NS Program, a 2-day workshop was held on May 18-19, 2004 in Toronto. The CRSB/EC Workshop had three key objectives:

1. provide a forum for the identification of research needs and priorities as they pertain to micro-organisms under the NS Program, capitalizing on results from past and current research studies;
2. seek input on unsettled issues, identified data & information needs, and on tools/approaches/methods for addressing them; and,
3. improve coordination and collaboration between the different groups directly or indirectly contributing to the NS program.

A total of 43 attendees from EC, HC, Agriculture and Agri-Food Canada, Fisheries and Oceans and Industry Canada met to discuss aspects of the NS Program for micro-organisms and associated knowledge needs for Risk Assessment (RA) and Risk Management (RM) that can be addressed through research activities.

In small working groups during the workshop, participants examined and shared their views on the list of knowledge needs, identified priorities and developed recommendations for addressing the priority knowledge needs. The knowledge needs were organized under 4 main themes namely:

1) microbial consortia;
2) genetic material;
3) environmental fate and effects; and,
4) containment/confinement/emergency response.

The following table identifies the top ten research priorities, associated ranking and number of votes secured for each priority that was identified by the participants during this 2-day workshop.

Rank	**Theme**	**Issue**	**Score/votes**
1	Environmental Fate and Effects	Develop ecologically relevant tests - focus on different types of environmental matrices. It is important to perform assays in a matrix that simulates as best as possible the receiving environment into which the micro-organism will be introduced - develop criteria for assessing movement of micro-organisms. Micro-organism movement on site (e.g. water flux) should also be considered	10
2	Microbial consortia	Degree of consortia change over time (between batches) - establishing the balance between stability vs. consistency of consortia products - identification of active ingredients in a consortium	8
2	Environmental Fate and Effects	Determine what constitutes an adverse ecosystem effect - the generation of baseline information is important and depending on the baseline, the degree of change that would be acceptable should be considered	8
4	Genetic material	Develop criteria for assessing gene transfer events - such criteria could consider background levels in the environment, ecological	7

		significance of gene transfer and conditions that may enhance gene transfer	
4	Microbial consortia	Improved identification of consortia components - development of criteria for characterization of consortia	7
4	Microbial consortia	Develop environmental pathogen screening methodology - development of techniques/technologies (guidance document) to identify pathogens - development of an environmental pathogen check list that is dynamic so that additions to the list can be made periodically	7
4	Environmental Fate and Effects	More research into structure/function of microbial communities	7
8	Environmental Fate and Effects	Develop standard test methods to determine environmental fate and effects	6
8	Containment/ confinement/ emergency response	Develop knowledge on dealing with spills and inadvertent releases	6
10	Containment/ confinement/ emergency response	Change in policy to look at the need for mandatory spill reporting requirements At the policy level, changes need to be brought about to determine whether all biotechnology-related spills should be reported	5

Workshop Proceedings have been developed which summarize the information recorded in table discussions, and synthesize the recommendations for moving towards the development of a focused research strategy that will be required to successfully address the above priority knowledge needs over the next two cycles (i.e., in the next 6-10 years) of CRSB funding. Workshop participants agreed that a successful research strategy has to be built around EC's existing research activities and be coordinated with other departments and agencies that are involved in the regulation of new living organisms that are micro-organisms. The intention of this Workshop, the resulting Proceedings and the upcoming research strategy is to ensure that the RA and RM process is up-to-date and evolving to take into consideration new scientific developments in biotechnology.

The research strategy will provide direct support to regulators as well as compliance promotion and enforcement officers by enabling the development of knowledge, data and tools required for RA and RM of micro-organisms. It will also serve as the corner-stone for EC's decision-making process regarding allocation of CRSB funding and will guide the researchers in aligning their research projects to meet the identified priorities. It will be reviewed periodically taking into consideration advances in science, national priorities and international trends in biotechnology development.

The Biotechnology Division (NSB, EC) in consultation with the research, compliance promotion and enforcement community within EC will develop and manage the research strategy.

To obtain a CD of the Workshop Proceedings, please contact:

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