Proposed Guidelines for the Prioritization of Living Organisms on the Domestic Substances List (DSL) Prior to the Screening Assessment Specified Under Section 74(b) of the Canadian Environmental Protection Act, 1999

The purpose of prioritizing the living organisms on the Domestic Substances List (DSL) is to identify organisms of higher concern earlier in the screening assessment process. Prioritization is not used to determine risk to the environment or to human health. Any such risks will be determined only through a formal screening assessment of the living organism, as provided for under Section 74(b) of the *Canadian Environmental Protection Act*, 1999 (CEPA, 1999).

The New Substances Program of Environment Canada (EC) and Health Canada (HC) reached a consensus on the criteria to be used for prioritization and the strategy to be implemented.

The criteria considered are:

(i) pathogenicity or toxicity for humans.
(ii) pathogenicity or toxicity to non-human species.
(iii) invasiveness.

Pathogenicity is the ability of a micro-organism to infect humans and/or aquatic and terrestrial organisms (invertebrates and vertebrates), establish itself, multiply, inflict injury or damage or cause disease or adverse immunological effects that may or may not lead to death. The effect on the host depends on the virulence of the pathogen as well as on host resistance or susceptibility. Virulence refers to the degrees of pathogenicity on a host organism and/or its ability to invade the tissue of the host.

Toxicity refers to the ability of a micro-organism to cause adverse effect(s) on humans, plants, animals and invertebrates due to toxin production, and/or metabolite or its structural components.

Invasiveness refers to the ability of a living organism to establish itself in a new environment, persist, outcompete indigenous species, take over the new environment and threaten biological diversity.

Prioritization of Living Organisms Currently on the DSL (as of May 2006)

There are currently 43 microbial strains and 1 complex microbial culture (i.e., consortium) on the DSL. We propose to prioritize them according to the following rationale:

1) Laboratory Biosafety Guidelines from the Public Health Agency of Canada (PHAC) are used to identify micro-organisms of higher concern for human health and the environment. For the purposes of the EC/HC guidelines for the prioritization of living organisms on the DSL, micro-organisms listed by the PHAC as Risk Group 2 or higher are assigned Priority Level A.

Background Information on Risk Groups from the Public Health Agency of Canada

The factors used by the Public Health Agency of Canada to determine which risk group an organism falls into is based on the particular characteristics of the organism, such as:

▪pathogenicity
▪infectious dose
▪mode of transmission
▪host range
▪availability of effective preventive measures
▪availability of effective treatment

These classifications presume ordinary circumstances in the research laboratory or growth in small volumes for diagnostic and experimental purposes, which may be different from the circumstances of use for the micro-organisms on the DSL. Four levels of risk have been defined by the Public Health Agency of Canada, as follows:

Risk Group 1 (Low Individual and Community Risk)
Any biological agent that is unlikely to cause disease in healthy workers or animals.

Risk Group 2 (Moderate Individual Risk, Low Community Risk)
Any pathogen that can cause human disease but, under normal circumstances, is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures rarely cause infection leading to serious disease; effective treatment and preventive measures are available, and the risk of spread is limited.

Risk Group 3 (High Individual Risk, Low Community Risk)
Any pathogen that usually causes serious human disease or can result in serious economic consequences, but does not ordinarily spread by casual contact from one individual to another, or that causes diseases treatable by antimicrobial or anti-parasitic agents.

Risk Group 4 (High Individual Risk, High Community Risk)
Any pathogen that usually produces very serious human disease, often untreatable, and may be readily transmitted from one individual to another, or from animal to human or vice-versa, directly or indirectly, or by casual contact.

2) EC/HC uses additional tools to identify micro-organisms of special concern for the environment which may not be captured by the classification scheme used by the PHAC. Some of these tools are:

   a) The lists of regulated pests of member countries of the International Plant Protection Convention (including Canada), as found on the International Phytosanitary Portal (IPP) at http://www.ippc.int .

   b) The Global Invasive Species Database, developed by the Invasive Species Specialist Group (ISSG) as part of the global initiative on invasive species led by the Global Invasive Species Programme (GISP). This programme is coordinated by the Scientific Committee on Problems of the Environment, the World Conservation Union (IUCN), CAB International and the United Nations Environment Program (UNEP); it comprises members from several countries,

including Canada. This database is found at http://www.issg.org/database/welcome/ .

For the EC/HC screening assessment prioritization, micro-organisms found on these lists and/or databases are also assigned Priority Level A, regardless of their Risk Group designation established by the PHAC.

3) Consortia containing Risk Group 2 or higher micro-organisms, according to their PHAC listings, and micro-organisms known to be plant pests or invasive species are also assigned Priority Level A.

4) A preliminary survey of the literature and databases on potential hazards for human health and the environment is performed by Health Canada and Environment Canada. The following is a list of databases and search terms used for environmental and human health literature searches:

Databases	***Key Words***
Current Contents	pathogen*
PubMed	toxi*
CAB Abstracts and Global Health	immuno*
Agricola	infect*
Toxnet	disease*
Biosis	allerg*
Scopus	virul*
	resist*
Global Web Search	antibiotic*
Google	outbreak
Copernic	opportunistic
	adverse effect

Risk Group 1 micro-organisms for which one or more evidence of pathogenicity or toxicity toward human or non-human species have been reported in the related scientific literature are assigned Priority Level B. Consortia that contain such micro-organisms are assigned Priority Level B as well.

5) Risk Group 1 micro-organisms for which no evidence of pathogenicity or toxicity toward human or non-human species have been reported in the related scientific literature are assigned Priority Level C. Consortia that only contain such micro-organisms are assigned Priority Level C as well.

Table 1: Summary of Priority Levels for Micro-Organisms Currently on the DSL

Priority Level	Criteria
A	Micro-organisms belonging to Risk Group 2 (*moderate individual risk, low community risk for humans and the environment*) or above according to the PHAC. OR Micro-organisms found on a List of regulated pests in one of the member countries of the International Plant Protection Convention. OR Micro-organisms found in the database of invasive species maintained by the Global Invasive Species Programme (GISP). OR Consortia that contain such micro-organisms (as outlined in the 3 previous bullets).
B	Risk Group 1 micro-organisms (*low individual and community risk for humans and the environment*) according to the PHAC with one or more evidence of pathogenicity or toxicity in the related scientific literature. OR Consortia that contain such micro-organisms (as outlined in the previous bullet).
C	Risk Group 1 micro-organisms (*low individual and community risk for humans and the environment*) according to the PHAC with NO evidence of pathogenicity or toxicity in the related scientific literature. OR Consortia that only contain such micro-organisms (as outlined in the previous bullet).

According to the above-mentioned rationale, micro-organisms currently on the DSL would be prioritized as shown in Table 2.

Table 2: Proposed Priority Level for Micro-Organisms on the DSL as of May 26, 2006

Species	Strain	Risk Group[1]	Plant Pest/ Invasive Species	Path/ Tox Evidences for Species in Literature[2]	Priority Level
Pseudomonas aeruginosa	ATCC 31480	2	no	several	A
Pseudomonas aeruginosa	ATCC 700370	2	no	several	A
Pseudomonas aeruginosa	ATCC 700371	2	no	several	A
Bacillus cereus	ATCC 14579	2	no	several	A
Pseudomonas fluorescens	ATCC 13525	2	yes[3]	several	A
Pseudomonas fluorescens	ATCC 31483	2	yes[2]	several	A
Aspergillus niger	ATCC 9642	2	yes[2,4]	several	A
Escherichia hermannii	ATCC 700368	2	no	some	A
Enterobacter aerogenes	ATCC 13048	2	no	some	A
Pseudomonas stutzeri	ATCC 17587	2	no	some	A
Micrococcus luteus	ATCC 4698	1	no	some	B
Candida utilis	ATCC 9950	1	no	some	B
Bacillus licheniformis	ATCC 12713	1	no	some	B
Bacillus licheniformis	ATCC 55406	1	no	some	B
Bacillus thuringiensis	ATCC 13367	1	no	several[5]	B
Bacillus circulans	ATCC 9500	1	no	some	B
Pseudomonas putida	ATCC 12633	1	no	some	B
Pseudomonas putida	ATCC 31800	1	no	some	B
Pseudomonas putida	ATCC 700369	1	no	some	B
Bacillus megaterium	ATCC 14581	1	no	some	B
Bacillus subtilis	ATCC 6051A	1	no	some	B
Bacillus subtilis	ATCC 55405	1	no	some	B
Bacillus subtilis	strain 11685-3	1	no	some	B
Bacillus subtilis	ATCC 6051	1	no	some	B
Bacillus species	16970-5	1	no	some	B
Aspergillus oryzae	ATCC 11866	1	yes[3]	some	B
Chaetomium globosum	ATCC 6205	1	no	some	B
Trichoderma reesei	ATCC 74252	1	no	some	B
Pseudomonas denitrificans	ATCC 13867	1	no	some	B
Bacillus amyloliquefaciens	strain 13563-0	1	no	some	B
Saccharomyces	strain F53	1	no	no	C

[1] Risk level designation based on the Public Health Agency of Canada's Laboratory Biosafety Guidelines.
[2] Scope of search as of June 2006.
[3] *P. fluorescens* and *A. niger* (unspecified strains) are considered plant pests of quarantine importance in the Commonwealth of Dominica (Commonwealth of Dominica pest list, November 17, 2005).
[4] *A. niger* and *A. oryzae* (unspecified strains) are considered endemic (unregulated) rice pests in Cambodia (Cambodian endemic and quarantine rice pests, May 6, 2005).
[5] Toxicity toward specific insect taxa.

cerevisiae					
Arthrobacter globiformis	ATCC 8010	1	no	no	C
Bacillus polymyxa	ATCC 842	1	no	no	C
Bacillus polymyxa	ATCC 55407	1	no	no	C
Paenibacillus polymyxa	strain 13540-4	1	no	no	C
Nitrobacter species	16969-4	1	no	no	C
Nitrobacter winogradskyi	ATCC 25391	1	no	no	C
Cellulomonas biazotea	ATCC 486	1	no	no	C
Rhodopseudomonas palustris	ATCC 17001	1	no	no	C
Nitrosomonas europaea	ATCC 25978	1	no	no	C
Nitrosomonas species	16968-3	1	no	no	C
Nitrosococcus species	16971-6	1	no	no	C
Nitrococcus species	16972-7	1	no	no	C
Complex microbial culture	13637-2	1[6]	no[7]	no[8]	C

Prioritization of New Additions to the DSL:

1) Any new microbial strains and complex microbial cultures (i.e. consortia) added to the DSL will be prioritized according to the above-mentioned rationale.

2) Evaluators from the New Substances Program of Health Canada and Environment Canada will perform a preliminary literature search as soon as a new microbial strain or a new complex microbial culture (i.e. consortium) is added to the DSL and the prioritized list of living organisms will be updated accordingly.

3) Any new organisms added to the DSL that are NOT micro-organisms will be prioritized by evaluators from Health Canada and Environment Canada on a case-by-case basis.

Post Prioritization Procedure:

The prioritized list is a dynamic one, and may change when new living organisms are added to the DSL, or whenever evaluators from Health Canada or Environment Canada find additional information that changes the Priority Level of a living organism.

A screening assessment under Section 74(b) of CEPA 1999, as well as a review of decisions from other jurisdictions under Section 75 of CEPA 1999, will be conducted by the New Substances Program for all living organisms on the DSL in the order of priority specified in these prioritization guidelines.

[6] According to the applicant, all 9 strains considered as principal members of the consortium belong to Risk Group 1.
[7] None of the 9 strains considered as principal members of the consortium according to the applicant are neither invasive, nor plant pest.
[8] No report of pathogenicity, toxicity or infectivity in the scientific literature for any of the 9 strains considered as principal members of the consortium according to the applicant.

If information needed to complete a screening assessment is missing, the New Substances Program may start working on the next organism on the list of priorities until the required information is obtained.

References:

Public Health Agency of Canada. (2004). Laboratory Biosafety Guidelines. 3rd Ed. Office of Laboratory Security. Ottawa, Ontario. 113 pp. http://www.phac-aspc.gc.ca/publicat/lbg-ldmbl-04/index.html

Lists of regulated pests on the International Phytosanitary Portal (IPP): http://www.ippc.int

The Global Invasive Species databases: http://www.issg.org/database/welcome/