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Ref. SCBD/BS/MPDM/jh/67587 - Submission of information on identification of living modified organisms that are not likely to have adverse effects on conservation and sustainable use of biological diversity, taking also into account risks to human health.

This is a submission from the Centre for Integrated Research in Biosafety (INBI)[1] on paragraph 12 of decision BS-V/12 as per the request of Mr. Ahmend Djoghalf (25 January 2012):

"The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP), in paragraph 12 of its decision BS-V/12, requested Parties and invited other Governments and relevant organizations to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and (ii) the criteria that were considered for the identification of such living modified organisms."

In reply to (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health:

We note that this hypothetical category of LMOs is relevant only for the purposes of Article 7(4)[2]. We further note that Article 15 requires risk assessments of LMOs to be undertaken in accordance with Annex III which states in part 6: "Risk assessment should be *carried out on a case-by-case basis*. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the *likely potential receiving environment*" (emphasis added).

After a thorough reflection of the scientific literature on risk assessment of LMOs, we can find no examples of case-by-case risk assessments based on scientific data of adequate quality[3] that would in our opinion assist Parties in identifying LMOs that could be

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[1] The Centre for Integrated Research in Biosafety (INBI) is a multidisciplinary research centre located at the University of Canterbury, New Zealand. We are composed of primarily academic teaching and research staff. Our mission is to provide advice on the safe implementation of biotechnology, including conducting risk assessment research and performing evaluations of risk assessments. Our core audience is the public and public sector with an emphasis on those who could otherwise not access the resources to address their questions.

[2] "The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

[3] For terms, please refer to AHTEG. Guidance Document on Risk Assessment of Living Modified Organisms. http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-12-en.pdf: United Nations

considered to not likely "have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health" in environments that were not explicitly considered in the case-by-case assessment.

By their very nature, case-by-case risk assessments are not suited to making global or universal assessments. This is for various reasons. Case-by-case assessments:

- include case-specific protection goals; these protection goals vary from area to area, country to country and region to region;
- will have used assessment endpoints and measurements of these endpoints that were specific to the potential receiving environment and society; "[d]ue to the complexity and variability of environmental relations, it is not possible to predict all potential effects for all regions where a GMO might be exposed. Thus it remains uncertain whether the results of risk analysis obtained on a temporally and spatially limited basis, actually hold under conditions of commercial use on larger spatio-temporal scales"[4];
- different jurisdictions require different methods to inform their case-by-case risk assessments. For example, the European Union requires a general surveillance monitoring plan[5] and risk assessments that are not informed by such a plan will not provide the information necessary to determine whether an LMO, assessed using different procedures for different potential receiving environments, is not likely to cause an unanticipated adverse effect in the countries of the EU.
- are compatible with all articles of the Protocol, but a global assessment would not be. For example, Article 23(a)[6] of the Protocol sets requirements for "safe transfer and handling" which by necessity will be country-specific and intended use-specific for the following reasons:
    - the potential to cause an adverse effect may in part be deemed unlikely because of specific transfer and handling procedures;
    - these procedures will be informed by knowledge of the capacity and familiarity of the public and/or users of the LMO and this capacity and familiarity will differ from country to country and intended use.

In summary, it was not possible to find credible evidence to support the contention that existing case-by-case assessments are demonstrated transferable to all other, much less all, potential receiving environments, or that case-by-case assessment is compatible with the notion that they would be transferable. We are unaware of any existing LMOs that have benefited from a globally comprehensive set of case-by-case risk assessments. Without even a single such case to draw experience from, we find it premature to consider the premise that there could be a reason to expect that any particular case-by-case assessment would provide evidence that any LMO or trait derived from modern biotechnology is "not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

In reply to (ii) the criteria that were considered for the identification of such living modified organisms:

Do criteria exist that could be adopted to identify LMOs that are not likely to have an adverse effect? Given the nature of the case-by-case risk assessment process, this

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Environment Programme Convention for Biodiversity; http://www.cbd.int/doc/meetings/bs/mop-05/official/mop-05-12-en.pdf; 2010.

[4] p. 72 of Breckling, B. and Reuter, H. (2006). General surveillance of genetically modified organisms – the importance of expected and unexpected environmental effects. J. Verbr. Lebensm. *1 Supplement 1*, 72-74.

[5] Directive 2001/18/EC Annex VII.

[6] "Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health."

question is in our opinion unproductive because it is too open ended to inform a scientifically credible risk assessment process. Any given LMO would have to benefit from an environment-specific risk assessment for all potential receiving environments and then be retrospectively confirmed to not have caused an adverse effect in any potential receiving environment. Conversely, different potential receiving environments would have to be determined to be alike in all relevant ways to transfer the conclusions from one to the other. Neither of these is at present a scientific or practical possibility.

If there were LMOs which had already been evaluated by a comprehensive, or at least objectively representative, range of case-by-case risk assessments, then it would be possible to *begin* a discussion of whether any one or combination of case-by-case assessments were predictive of a global outcome. Of course, this type of discussion would not likely be productive until a statistically informative number of comprehensively assessed LMOs and traits existed.

In summary, it was not possible to find evidence of any scientifically plausible criteria for identifying LMOs not likely to cause an adverse effect.

Notwithstanding our assertion that there is no evidence of any scientifically plausible criteria for identifying LMOs not likely to cause an adverse effect, should the Parties come to form the view that they would be satisfied that such identifications could be made in some generic way, then we would suggest two criteria that should be mandatory.

Any such products should have such a high level of confidence that they can cause no adverse effects that developers of such products:

(1) assume and maintain liability for unanticipated adverse effects and bear the costs of ongoing monitoring, and
(2) assume liability for any subsequent adverse effect resulting from its intended use which results in a loss of efficacy (e.g., loss of use of a herbicide that was overused in conjunction with the LMO[7]).

In summary, it was not possible to identify any scientific basis for establishing criteria that would assist Parties in identifying LMOs "not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health." Attempts to categorise LMOs this way would be fundamentally at odds with case-by-case risk assessment.

Sincerely yours,

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and
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[7] It is clear, for instance, that the intended use of Roundup (or glyphosate-based herbicides) on Roundup Ready crops has uniquely lead to the development of glyphosate-tolerant weeds that threaten the use of glyphosate-based herbicides on LMOs and conventional crops. For references, see Heinemann, J. A. and Kurenbach, B. (2008). Special threats to the agroecosystem from the combination of genetically modified crops and glyphosate (Kuala Lumpur, Third World Network).