*24 August 2017*

**Submission by the EU and its Member States to CBD Notification 2017-035 on**

**Information requested in decision VIII/12 on Risk Assessment and Risk Management**

***A. Country information***

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| **Country name:** | **EU and its Member States** |

***B. Please indicate your country’s needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs)***

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|  | **Needs and priorities for further guidance on risk assessment of LMOs** | **Notes** |
| 1 |  | At this stage, no identification of specific topics in need of further guidance has taken place at the EU level. However, individual Member States may identify such topics in their national submissions and will inform the CBD Secretariat thereof directly.  |

***C. Please propose possible criteria that may facilitate the selection of topics for the development of further guidance on specific topics of risk assessment of LMOs, including a technical justification for each of the criterion proposed\****

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|  | **Criteria for the selection of topics** | **Notes and technical justification** |
| 1 | Risk assessment with regard to the topics in question is within the scope and objectives of the Protocol | The EU and its Member States think these criteria can be helpful in selecting topics for the development of further guidance. When doing this, we recommend a structured analysis of topics along the following steps:* From the range of potential topics, select clearly defined topics that could require further guidance and are within the scope and objectives of the Protocol (see criterion 1);
* Analyse available information to determine whether those topics can be covered by existing guidance (see criterion 2). This should in particular and at least involve an analysis of the applicability of the guidance that has been developed in the context of the Protocol;
* When considering developing further guidance for issues for which existing guidance has been found to be insufficient, prioritise development of further guidance based on the pace of scientific advancements, the state of development of the LMO in question and the potential risks to biodiversity and human health (see criteria 2-4).
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| 2 | Risk assessment with regard to the topics in question cannot be performed by using existing guidance documents |
| 3 | Specific topics with a high pace of scientific and technological advancement |
| 4 | Specific topics with potential adverse effects on biodiversity and/or human health |
| 5 | Specific topics might be prioritised if the LMOs in question are already, or are likely to be, commercialised and marketed somewhere in the world |

***D. Please share your views on perceived gaps in existing guidance materials***

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|  | **Perceived gaps** | **Views** |
|  |  | At this stage, no identification of gaps in existing guidance has taken place at the EU level. However, individual Member States may identify perceived gaps in their national submissions and will inform the CBD Secretariat thereof directly. |

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