Bioteknologinemnda
The Norwegian Biotechnology Advisory Board

EFSA
Largo N. Palli 5/A
(on the Viale Mentana)
I-43100 Parma
Italy

Date: 16.09.2008

Comments - open consultation on GMO guidance documents from EFSA

Additional documentation - GMO assessment in Norway
Norway participates in the EU's GMO risk assessment process, but subsequently makes a final national decision following an authorization in the EU. According to the European Economic Area **(**EEA) Agreement[*], Norway is entitled to take into account other criteria in addition to health and environmental risk when evaluating an application for market placement of a GMO. Market placement of GMOs is regulated by the Norwegian Gene Technology Act[†] (the Act) and related regulations[‡].

The purpose of the Norwegian Act, as specified in its first section, is to ensure that the production and use of genetically modified organisms is ethically justifiable, socially acceptable, and in accordance with the principle of sustainable development and without adverse effects on human health, animal health, and the environment.

Section 10, second paragraph, of the Act states that the deliberate release of genetically modified organisms may only be approved when there is no risk of adverse effects on human or animal health or the environment, and that considerable weight is to be given to whether the deliberate release of genetically modified organisms will be of benefit to the society and is likely to promote sustainable development.

The Norwegian Ministry of Environment has requested the Norwegian Biotechnology Advisory Board to provide an opinion on how to implement the concepts of "sustainable development" and "benefit to the community" set out in the Act. The Norwegian Biotechnology Advisory Board published its report "*Sustainability, benefit to the community and ethics in the assessment of*

[*] http://www.efta.int/content/legal-texts/eea/FinalAct/FinalAct.pdf/at_download/file

[†] http://www.regjeringen.no/en/doc/Laws/Acts/Gene-Technology-Act.html?id=173031

[‡] http://www.regjeringen.no/en/dep/md/documents-and-publications/acts-and-regulations/Regulations/2005/regulations-relating-to-impact-assessmen.html?id=440455

Postadresse/Postal address:	Kontoradresse/	Telefon/Telephone:	Telefax:	E-mail:	Internett:
P.O.Box 522 Sentrum	Office address:	+47 24 15 60 20	+47 24 15 60 29	bion@bion.no	www.bion.no
N-0105 Oslo, Norway	Rosenkrantz' gt. 11				

genetically modified organisms. Implementation of the concepts set out in Sections 1 and 10 of the Norwegian Gene Technology Act" [§] in 1999.

For our national assessment of GMOs, additional information from applicants is therefore often required. For a given notification, for instance of a herbicide tolerant or insect resistant plant, it might be relevant to draw attention to and ask about what changes in agricultural practice the use of such a GMO may lead to compared with its conventional counterpart. Of special interest are changes in the use of pesticides and herbicides, both in terms of types and amount, which again could result in changes of exposure both to agricultural workers and the environment. The nature of these changes should be related to and discussed together with the overall possible benefit to society and contribution to sustainable development. **The Norwegian Biotechnology Advisory Board welcomes reference to our national GMO-legislation in the guidance documents provided by EFSA, as applicants most often request authorization also in Norway.**

Substantial equivalence and the importance of OECD consensus documents
The concept of substantial equivalence relies heavily on comparative analyses on the molecular level and on the evaluation of agronomic and morphological characteristics of the organisms in question. The Norwegian Biotechnology Advisory Board would like to stress that it is very important that a notifier takes into account and provides the information that is outlined in the relevant OECD consensus documents.

Transparancy, reference material, independent research
Transparancy is an important factor whenever public trust is a defined goal. The Norwegian Biotechnology Advisory Board finds it of of utmost importance that the majority of the documentation accompanying a notification is available in the public domain. In addition, sufficient reference material should be easily accessible by independent labs for further research and analysis.

Adjuvance
Recently, the issue of a possible adjuvant effect of Cry proteins in GMOs (especially maize) has been raised by Norwegian Authorities. It is obvious that maize may be eaten together with other foods containing components to which an immune response may be enhanced due to a possible adjuvant effect of Cry proteins. If Cry proteins act as adjuvants, the effect will be expected to be seen as an increase in allergies to the most commonly allergenic foods rather than to maize.

The Norwegian Biotechnology Advisory Board sees the need for further clarification regarding the possible adjuvant effect of Cry proteins and welcomes a chapter on adjuvance in the allergy section of the EFSA guidance document.

Sincerely,

Lars Ødegård, Head

Sissel Rogne, Director

Copy: Directorate for Nature Management, Norway

[§] http://www.bion.no/publikasjoner/sustainability.pdf