MINISTRY OF
SOCIAL AFFAIRS AND HEALTH

**Board for Gene Technology**





Tuesday, 17 February 2014

Ms. Paola Testori Coggi
Director General
Directorate General for Health and Consumers
1049 Brussels
Belgium

Dear Ms. Paola Coggi,

The Board for Gene Technology, as the Finnish Competent Authority (CA) for Directives 2001/18/EC and 2009/41/EC, would like to ask the Commission's view on the regulatory status of the oligonucleotide mutagenesis (ODM) techniques.

ODM is currently widely used in research laboratories for the site-specific mutagenesis of microbial, plant and animal genes and it is also increasingly used for plant breeding purposes. The regulatory status of ODM remains, however, unclear.

The Directives 2001/18/EC and 2009/41/EC exclude mutagenesis from their scope, provided no recombinant nucleic acid molecules are used in the production of the modified organism. Unfortunately, the lack of definitions in these directives e.g. for terms "recombinant nucleic acid" and "heritable material" has led to a situation where different interpretations of the scope of the directives are possible.

This issue has been considered in the 2011 Final Report of the Commission New Techniques Working Group (NTWG), which presented the majority opinion that organisms modified with ODM are excluded from the scope of the directives. Unfortunately, this conclusion has not been formally acknowledged by the Commission nor discussed in the meetings of the Competent Authorities for Directives 2001/18/EC and 2009/41/EC, leaving the national CAs in a legally challenging position when the operators need confirmation about the legal status of their organisms modified with ODM.

The Board for Gene Technology and the supervisory authorities of the Finnish Gene Technology Act have received requests from operators concerning ODM. The Board for Gene Technology has recently expressed the opinion that plants developed with RTDSTM, which is an ODM technique, are outside the scope of Finnish Gene Technology Act which implements the Directives 2001/18/EC and 2009/41/EC.

The Board recognizes that this situation is unsatisfactory and interpretations by each individual Member State may lead to a situation where the interpretations in the Member States may differ from each other. Therefore, the Board wishes to ask the Commission about its plan and the timetable for the development of an EU wide harmonized approach and guidance on the issue.

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Moreover, the ODM issue is not a unique one, as similar problems also concern some other newly developed and developing genetic techniques. The EU gene technology legislation, laid in 1980´s, does not any longer correspond to the state-of-the art of genetic engineering, including greatly increased knowledge on molecular genetics and advanced technologies. Some of the most urgent problems are highlighted in the report of the Commission Working Group on New Technologies. As a result, there is ambiguity on the regulatory status of many techniques which seriously hampers the work of authorities and stakeholders. The authorities may also face major difficulties in the risk assessments and risk management, as the current requirements may not be suitable for the new techniques or proportional to the impacts involved in their use. It is not clear to stakeholders, such as researchers and companies, how to cope with legislation and what is expected from them. Furthermore, they may encounter different legal requirements in different Member States, which is not in line with the principle of harmonization in the EU.

We respectfully ask the Commission to clarify the regulatory status of ODM technology, preferably before the end of April 2014, because the Finnish CA is due to take a position in the matter in May 2014.

Furthermore, we would greatly appreciate putting the Final Report of the NTWG on the agenda of next CA meeting.

We are looking forward to your reply and cooperation with you on these issues.

Sincerely yours,

Matti Sarvas, prof. emer.
Chairman of the Board for Gene Technology

Kirsi Törmäkangas, PhD
Secretary General of the Board for Gene Technology

cc: Ms Dorothée André, Head of Unit Biotechnology and Plant Health