



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL  
ENVIRONMENT

DIRECTORATE-GENERAL  
HEALTH AND CONSUMER PROTECTION

The Director-General

08. 09. 2008

Brussels,

ENV/B3/AA/JH/YK/gm D(2008) **ARES(2008) 25125**

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**Subject: The environmental risk assessment of herbicide tolerant plants - Interplay between Directive 2001/18/EC and Directive 91/414/EEC**

Dear Ms Geslain – Lanéelle,

Thank you for your note of 27 March 2008 suggesting a specific approach to the environmental risk assessment of genetically modified herbicide tolerant (GMHT) plants.

As you rightly point out in the letter, the provisions of Directive 2001/18/EC are explicit and clear on the need to assess in the context of the environmental risk assessment the impact of the cultivation of GM crops on biodiversity, which includes the assessment of the impact of changes in the use of pesticides. A significant objective of creating GMHT plants is to modify the use pattern of the respective herbicide. As a consequence, the effects of the differences in treatment on the environment, both quantitative and qualitative, have to be evaluated according to the requirements of Directive 2001/18/EC. As you mention, Decision 2002/623/EC more precisely specifies that indirect effects such as usage of pesticides need to be evaluated as part of the environmental risk assessment.

The cultivation of herbicide tolerant crops is linked to particular concerns, such as the continued and wide spread use of a single herbicide or spraying at a different stage of plant growth than the one that would be possible for conventional crops. As also indicated in the document of the GMO Panel, there is evidence from cultivation of GMHT crops in the USA that continuous and repeated application of (for example) glyphosate is causing changes in weed flora and development of more resistant or tolerant weeds. Against this background, the need to assess the impact of the cultivation of GM crops on biodiversity is clear. To these ends, it is appropriate to clarify the regulatory framework and eliminate any ambiguities or overlaps in this regard.

As regards plant protection products, including herbicides their use is subject to an authorisation under Directive 91/414/EC. The active substance is subject to an EU authorisation while the plant protection products containing approved substances are

approved by Member States. This approach is not modified in the proposal of revision of Directive 91/414/EC that is currently examined by the European Parliament and the Council. As a consequence, the use of a herbicide on a GMHT crop in a given Member State will always be subject to an authorisation by the concerned Member State.

Under Directive 2001/18/EC, it is necessary to cover under the GMO environmental risk assessment the possible effects on biodiversity and non-target organisms which any individual GMHT crop may cause due to the change in agricultural practices (including those due to different herbicide uses). Case-specific and mid/long term studies on the possible effects on biodiversity of non-target organisms and weeds, where available, must be included in this assessment. Such an assessment has to be carried out prior to the authorisation of the GMHT at EU level.

We would like to note that Recital 26 of Directive 2001/18 already foresees that implementation of both the PPP and GM legislation be coordinated at EU and national level. Thus, the GMO panel should coordinate closely with the pesticides panel when assessing GMHT plants. Equally, the Commission will also co-ordinate these aspects at EU level.

Given the variation of receiving environments and representative uses across the EU, which you highlight in your note, we understand the GM panel's view that the focus of the risk assessment should be on the main Member States and regions where each crop is going to be cultivated. This approach is in line with the environmental risk assessment requested by Directive 2001/18/EC and ensures that the appropriate meteorological, ecological and agricultural conditions are properly reflected. In the framework of this risk assessment, it would also be necessary to consider regional and national specificities. In order to link in to the future zonal system foreseen in the proposed Regulation which will replace Directive 91/414/EEC, it might be necessary in the future to explicitly refer to all the zones for which there could be authorisations of the use of that herbicide on the respective GM crop.

With respect to post-market monitoring, general surveillance, is useful to address unanticipated effects but not adequate to monitor the specific identified effects of changes in the use of herbicides, especially in the first years of cultivation. We note that Spain, the Competent Authority designated for carrying out the risk assessment of NK 603, indicated that case specific monitoring should be carried out in relation to the HT trait. Following the same approach than the one outlined above for the risk assessment approach with regard to the variation of receiving environments and representative uses across the EU, post-market monitoring should be suggested for the most common ecosystems and farming practices.

In sum, the consequences of the change in agricultural practices due to the herbicide use on GMHT plants have to be duly considered within the environmental risk assessment under Directive 2001/18/EC. The authorisation of the relevant herbicides at national level will have to take into account, in addition to the requirements foreseen under Directive 91/414/EC, possible conditions set out in the authorisations of GMHT plants under Directive 2001/18/EC. In particular Member States<sup>1</sup> have to perform a risk assessment for the plant protection product under the conditions of use in the GM crop. This

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<sup>1</sup> Annex VI of Directive 91/414 (criteria for autorisation of products), point C5

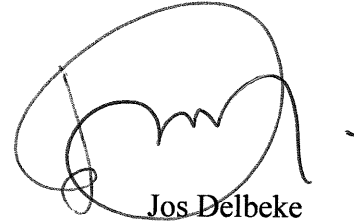
assessment shall consider whether the use of plant protection products does not have any long-term repercussions for the abundance and diversity of non-target species.

I thank you again for having sought clarification and hope the above will give the GM panel the information they require.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'R Madelin', with a long horizontal flourish extending to the right.

Robert Madelin

A handwritten signature in black ink, appearing to read 'Jos Delbeke', with a large circular flourish at the top.

Jos Delbeke