

EXECUTIVE DIRECTOR

Parma, 27 March 2008
Ref : SM/shv (2008) 2658625

Mr Robert Madelin
Director-General
DIRECTORATE-GENERAL
HEALTH AND CONSUMER
PROTECTION
200 rue de la Loi
1040 Bruxelles
Belgium

Subject : Interplay between Directive 2001/18/EC and Directive 91/414/EEC – Approach for the Environmental Risk Assessment of GM Herbicide Tolerant crops

Dear Mr Madelin,

As you know, Commission Decision 2002/623/EC (dated 24 July 2002) supplementing Annex II of Directive 2001/18/EC regarding the deliberate release of Genetically Modified Organisms (GMOs) into the environment requires that potential adverse effects on the environment due to changes in cultivation and management (e.g. changes in agricultural practices) of GM crops be properly assessed. In concrete terms it implies a thorough assessment of the potential environmental impact of the combination '*GM herbicide tolerant crop + associated herbicide*'.

Since the entry into force of Directive 2001/18/EC, the interplay between Directive 2001/18/EC and Directive 91/414/EEC concerning the placing of plant protection products on the market is thus an important matter of discussion of Member States and the European Commission in the framework of the environmental risk assessment of GM Herbicide Tolerant (GMHT) crops. So far no agreement as regards a common approach to be followed for the risk assessment of GMHT crops was found.

Against this background, facing related comments from Member States in the course of its environmental risk assessment of applications for GMHT crops, the concern of EFSA and its GMO Panel was to strengthen the assessment of the indirect environmental impact (e.g. on biodiversity) of the herbicides associated with these crops. EFSA and its GMO Panel therefore propose that:

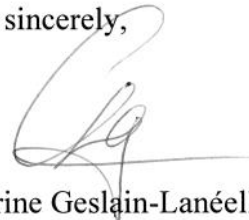
1. the borderline between the risk assessment of plant protection products and the risk assessment of GMOs be clearly defined;

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2. a scientific and yet pragmatic approach be considered as regards the environmental risk assessment and possible subsequent environmental impact of GMHT crops due to management practices (e.g. herbicides treatments) rather than to the GMO per se.

Due to the high variability of agricultural management practices as well as the multitude of agro-ecosystems throughout Europe and even within a region, the EFSA GMO Panel has proposed an approach which is described in the attached document. I would appreciate to receive your feedback on the proposed approach.

Yours sincerely,



Catherine Geslain-Lanéelle

Annex: Working document on “The Environmental Risk Assessment of genetically modified herbicide tolerant plants and the interplay between Directive 2001/18/EC and Directive 91/414/EEC”

Copy: M.P. Carl Director - General Directorate General Environment