

Additional advisory report on the renewal of the authorisation for import and processing of genetically modified oilseed rape GT73

COGEM advisory report CGM/130326-02

Introduction

Genetically modified (GM) oilseed rape (*Brassica napus*) GT73 expresses the *goxv247* and *cp4 epsps* genes resulting in tolerance and resistance to glyphosate containing herbicides. GT73 has been approved for import and processing, and food and feed use in the European Union (EU) since 2005.¹

In 2012, the applicant submitted an additional application for GT73 because he wanted to ensure that in the European Union (EU) the entire range of uses of GT73 (with the exception of cultivation), is authorised. Based on the information in the original application, the additional information supplied by the applicant, the scientific comments by the EU Member States, and other scientific data, the European Food Safety Authority (EFSA) recently concluded that oilseed rape GT73 is as safe as its conventional counterpart, and is unlikely to have any adverse effect on human and animal health and the environment.² In the opinion of EFSA, the monitoring plan is in line with the intended uses.

The Netherlands' Ministry of Infrastructure and the Environment asked COGEM whether the recently published EFSA opinion sufficiently answers COGEM's comments on the application for renewal of the authorisation of GM oilseed rape GT73.

Previous COGEM advisory reports

COGEM has previously issued several advisory reports concerning import and processing of GT73 oilseed rape.^{3,4,5,6,7} COGEM concluded that the post-market environmental monitoring plan of import and processing of GT73 did not fulfill the criteria of COGEM.⁷

Opinion

None of the concerns raised by COGEM in its previous advisory reports has been dealt with in EFSA's scientific opinion.

In the opinion of COGEM the general surveillance plan for import and processing of GT73 oilseed rape should be improved on several points. Most importantly, COGEM advises to include roadsides and railway beddings near oilseed rape transshipment and transport sites for monitoring on the presence of GT73, in particular if glyphosate is applied for weed control as is usual for railway beddings.

The establishment of small volunteer populations of spilled GT73 in disturbed environments where glyphosate is frequently applied cannot be excluded. Cross-fertilisation of volunteers harbouring the transgenic traits of GT73 and other GM oilseed rape events could lead to stacking of different transgenic traits in one plant. A possible combination of these transgenic traits or a possibly unanticipated interaction between products of these transgenes could potentially result in an unexpected, delayed or indirect adverse effect. COGEM is of the opinion that monitoring of GT73 volunteers along transport routes or

transshipment areas is of the utmost importance to enable the identification of a potentially adversely environmental effect.*

Additionally, the general surveillance plan could be improved by a commitment of the applicant to provide the raw obtained monitoring data and the analysis of these data to the Competent Authorities and the European Commission. Next to the European Commission, Member States should be immediately informed by the authorisation holder on identified unexpected adverse effects.

In summary, COGEM is of the opinion that approval of the application of import and processing of GT73 should depend on the inclusion of monitoring along transport routes or transshipment areas in the general surveillance plan. Special attention should be paid to the areas where viable GT73 oilseed rape seeds could be spilled unintentionally, enabling the identification of any direct or indirect, immediate, delayed or unanticipated environmental effects.

References

1. European Commission (2005). Commission decision of 31 August 2005 concerning the placing on the market,..., of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate (2005/635/EC). Official Journal of the European Union.3. 9. 2005 L 228/11-13
2. EFSA (2013). Scientific Opinion on application (EFSA-GMO-NL-2010-87) for the placing on the market of genetically modified herbicide tolerant oilseed rape GT73 for food containing or consisting of, and food produced from or containing ingredients produced from oilseed rape GT73 (with the exception of refined oil and food additives) under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 11(2): 3079-3105
3. COGEM (1998). Advies C/NL/98/11. COGEM advies CGM/980928-10
4. COGEM (2001). Advies C/NL/98/11. COGEM advies CGM/010110-01
5. COGEM (2006). Advies herbicidentolerant koolzaad (C/NL/98/11). COGEM advies GM/060828-03
6. COGEM (2012). Advice on import and processing of GT73 oilseed rape. COGEM advice CGM/120203-01
7. COGEM (2012). Advice on General Surveillance concerning import of GT73 oilseed rape. COGEM advice CGM/120521-01

*COGEM points out that new applications of stacked events, which have been obtained by conventional crossbreeding and whose parental lines already have been approved in the EU, have to be assessed for a possibly interaction between transgenes and their products because such an interaction could lead to a potentially adverse environmental effect.