European Food Safety Authority

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DIRECTORATE

30 APR. 2013

Parma,
Ref.: PB/EW/AC/shv(2013) out – 7343322

Ms Paola Testori Coggi
Director-General
Directorate General for Health and Consumers
European Commission
200, rue de la Loi
B-1049 Brussels – Belgium

Subject: **Application 87 for authorisation of GT73 oilseed rape**

Dear Ms Testori Coggi,

We hereby confirm the receipt, on 20 March 2013, of your letter dated 19 March 2013 (Ref. Ares(2013)372633) noting that a full risk assessment of GT73 oilseed rape is needed for you to proceed with the authorisation. Therefore you ask EFSA to complement its opinion related to GT73 oilseed rape in order to cover the safety of the isolated seed protein products, and to request the missing data to Monsanto.

EFSA agrees that no conclusion can be drawn for the full scope of the application pending the risk assessment of the isolated seed protein products. Therefore, EFSA has already asked the applicant to provide the necessary information on intake and toxicity during the risk assessment of GT73 oilseed rape with its letter dated 27 January 2012(Ref(2012)6203479, see questions 2 and 3 of the Food and Feed Working Group). However, the applicant chose to not supply the requested information.

Against this background, EFSA does not see further options for action. Should the data become available EFSA will be happy to undertake a risk assessment.

Yours sincerely,

Per Bergman
Director

Cc: E. Poudelet, D. André, S. Pelsser, J. Bollmann, M Mirazchyska
E. Waigmann, A.Christodoulidou, repro.directorate@efsa.europa.eu – EFSA
Monsanto – Applicant

Encl.: Letter EFSA to Monsanto dated 27 January 2012 (Ref. EW/ZD/AFD/lg(2012) 6203479)

efsa
European Food Safety Authority

GMO Unit

Parma 27 GEN. 2012
Ref. EW/ZD/AFD/lg (2012) 6203479

Monsanto Europe S.A./N.V.
Avenue de Tervuren 270-272
B-1150 Brussels

Dear

Subject: Your application for authorisation of genetically modified oilseed rape GT73 submitted under Regulation (EC) No 1829/2003 – Stop-the-clock (1) EFSA-GMO-NL-2010-87

The EFSA is currently in the process of reviewing your application **EFSA-GMO-NL-2010-87** for the placing on the market of genetically modified **oilseed rape GT73** and derived food and feed. In the course of the risk assessment, the GMO Panel has identified questions that would need further clarifications from you (see Annex).

Pending the requested information, the GMO Panel cannot proceed with the risk assessment. Hence, in accordance with Articles 6(1) and 18(1) of Regulation (EC) No. 1829/2003, the clock of your application EFSA-GMO-NL-2010-87 is stopped by the EFSA as of the date of the present letter.

In order to optimize the workflow of our Panel, you are requested to reply to this letter within **30 working days** by responding whether you are intending to provide additional information or not. If yes, you shall indicate in your response the exact date by when additional information will be provided by you.

The additional information specified in the Annex shall be submitted as one package answering all questions the EFSA has raised. The additional information shall be provided in the form of one paper copy, one CD-ROM and one CD ROM public version (if applicable) to the secretariat[1] of the GMO Unit.

[1] Contact: GMO_secretariat_applications@efsa.europa.eu

If it appears that the deadline can not be met, you are requested to timely contact the secretariat to propose a new deadline for submission of the additional information. In case the EFSA has not received the additional information within the deadline, a reminder will be sent to you asking to confirm your intention to submit the additional information and to provide the exact date before which you will submit the additional information requested by the EFSA. In the absence of a written response from you, the GMO Panel may adopt the scientific opinion on the basis of the available information.
EFSA would like to remind you that in accordance with Articles 6 and 18 of Regulation (EC) No. 1829/2003, the time limit of 6 months for adoption of the overall opinion shall be extended whenever the EFSA seeks supplementary information from the applicant.

Further requests for any additional information by the EFSA may arise at any stage during the risk assessment.

Yours sincerely,

Elisabeth Waigmann

Ms Elisabeth Waigmann
Acting Head of GMO Unit

c.c. Ms André, Ms Pelsser, Ms Torppa, Mr Walsh, Ms Kantorska – DG SANCO
Mr Van den Eede, Mr Mazzara – DG EURL-GMFF
Mr Divéki, Ms Ehlert, Mr Fernández Dumont, Mr Devos,
GMO_secretariat_applications – EFSA
GMO EXTRAnet for applications

Annex: Questions by the Molecular Characterisation, Food & Feed and Environment WG on Application EFSA-GMO-NL-2010-87