



Secretariaat
Secrétariat

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Title: Advice of the Belgian Biosafety Advisory Council on the revised molecular characterisation of RF3 oilseed rape submitted by Bayer CropScience

Context

In February 2009, Bayer CropScience informed the Belgian competent authority that on the basis of recent experiments, using more precise methods, the previous molecular characterisation of the RF3 insert of the genetically modified (GM) oilseed rape lines was revised. They provided the competent authority of Belgium a revised molecular characterisation package, more specifically an updated bio-informatic analysis of the 5', 3' and internal junction region sequences.

RF3, as well as the hybrid (MS8 x RF3) are authorised in the European Union since 2000 for food (processed oil) under article 5 of Regulation (EC) No. 258/97, and since 2007 for feed, import and processing under Directive 2001/18/EC¹. Belgium was the rapporteur member state for dossier C/BE/96/01 (MS8 x RF3) and conducted the risk assessment of the GM oilseed rape².

On 10 February 2009 the Belgian competent authority requested the advice of the Belgian Biosafety Council about the revised molecular characterisation. As rapporteur member state and in the frame of Article 5 of Directive 2001/18/EC, Belgium has to analyse the new information and to verify whether the conditions of the authorisation should be amended.

The Belgian Biosafety Advisory Council, under the supervision of a coordinator and with the assistance of its Secretariat, contacted experts chosen from the common list of experts drawn up by the Biosafety Advisory Council and the Division of Biosafety and Biotechnology (SBB) to evaluate the new information and specially to evaluate if the new data could raise any safety concern leading to change the risk evaluation of this GM oilseed rape. One expert answered positively to this request and formulated the comments which, together with the evaluation done by the coordinator himself, form the basis of the scientific evaluation given below.

¹ see Community Register of genetically modified food & feed:
<http://ec.europa.eu/food/dyna/gm_register/index_en.cfm>

² Document BAC_2004_SC_084 available at <http://www.bio-conseil.be/bac_advices.html>

Scientific evaluation

The new results demonstrate that the initial interpretation of the T-DNA insert of oilseed rape RF3 was not completely correct.

Insertion of the T-DNA and its regulatory sequences might affect the integrity and expression of the plant genome. Conceptually, this could lead to insertional inactivation of plant genes or to the expression of novel polypeptides.

In the case of event RF3, taken into account the new information provided on the insert structure, there is no evidence for the inactivation of a plant gene by the insertion of the T-DNA. Expression of cryptic open reading frames at a significant level is unlikely, as the corresponding mRNA was not detected and the context of the initiation codons is not appropriate for high level expression. In addition, no significant homology was found between the potential new open reading frames and known proteins, in particular toxic and allergenic proteins.

In addition, comparison of the phenotypic, agronomic and compositional properties of RF3 with related control lines, as reported in the original dossier (C/BE/96/01) did not reveal significant changes.

In conclusion, the new molecular data, using up-to-date molecular analysis tools and databanks do not alter the risk evaluation of event RF3. There are no new data that would influence negatively the previous safety evaluation of the transgenic line RF3.

However for completeness, we would like to receive information on the genetic relationship between 06GEBN000684 (Pedigree BC6S2) and 07GEBN000040 (Pedigree BC6S2) used by Moens and Criel (2008) for Southern Blot and PCR analysis of RF3, seedlot 99XEC00846 of Moens (2008) used PCR amplification and sequence determination, and the plant material (seedlot 98EN104908) used by Berghman and De Beuckeleer (2001).

Conclusion

Based on the scientific assessment, the Belgian Biosafety Advisory Council concludes that the new data do not influence negatively the previous safety evaluation of event RF3 and the hybrid MS8 x RF3. However, the Biosafety Advisory Council requests information on the genetic relationship between the plant material used in 2001 and 2008.

A handwritten signature in black ink, appearing to read 'p.o. Reheul', is written over a horizontal line.

Prof. D. Reheul
President of the Belgian Biosafety Advisory Council