

| Application EFSA-GMO-UK-2004-08 (Sugar beet H7-1) Comments and opinions submitted by Member States during the three-month consultation period | | | | ANNEX G |
|--|-------------------------------|------------------|--|--|
| Reference | Country | Organisation | Comment | EFSA GMO Panel response |
| Comments from National Competent Authorities under Directive 2001/18/EC | | | | |
| Austria | Ministry for Health and Women | General comments | Concerning the range of uses the notifier states that “this sugar beet will be identical to the full range of equivalent uses of conventional sugar beet”. Therefore in the risk assessment these different types of products have to be taken into consideration. As documented on p.94 of part I of the dossier, regional special products of sugar beet exist (like beet syrup), silage of roots and leaves, that have also to be examined in the RA. Only focusing in the risk assessment on refined sugar cannot be regarded as satisfactory. | In a letter to the European Food Safety Authority, dated 14 February 2006, the applicant confirms that the application is for authorization to place on the market food and feed produced from H7-1 sugar beet. The scope does not include beet leaves and small pieces of roots derived from root processing for fermentation to produce silage for animal feed. |
| Austria | Ministry for Health and Women | General comments | Labelling and Unique identifier Part IV should contain all relevant information on labelling and the unique identifier because only insufficient information about the UID is provided. Moreover this information has to be provided before market introduction. Furthermore the notifier should be obliged to transmit also all legal obligations on traceability and labelling to the first operator within the EU. | Outside the remit of the GMO Panel. |
| Austria | Ministry for Health and Women | General comments | Post-market monitoring of GM-food According to Art. 5 (3) k) of EU-Regulation 1829/2003 a post-market monitoring-plan should be added to the dossier. | See section 4.2.7 of the scientific opinion: <i>No risks to human and animal health were identified in studies of the CP4 EPSPS protein expressed in sugar beet H7-1, and in studies of the genetically transformed sugar beet itself. Thus, foods and feeds produced from sugar beet H7-1 is as safe and as nutritious as foods and feeds derived from conventional sugar beets. Dietary intake of products from sugar beet is not expected to increase on introduction of the genetically modified sugar beet H7-1 on the market, as products</i> |

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|--|-------------------------------|---|--|--|
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| | | | | <p>from sugar beet H7-1 varieties will only replace a portion of the products produced from conventional sugar beet. The GMO Panel has, therefore, not identified any issue that would require post market monitoring of sugar beet H7-1.</p> <p>The GMO Panel is of the opinion that PMM should be required only in specific cases where there is no traditional comparator. Those cases could include GM (functional) foods with altered nutritional composition and modified nutritional value and/or with specific health claims. See also section 7.11 of the GMO Panel Guidance Document (2006).</p> |
| Austria | Ministry for Health and Women | D, 02 Information on the sequences actually inserted or deleted | On page 49, part I of the dossier it is quoted "...the DNA sequence integrated in H7-1 sugar beet is identical to the T-DNA sequence contained in PV-BVGT08, except for four mismatches. One mismatch occurred in the cp4epsps coding region..." Even if it is silent in terms of the deduced amino acid sequence, clarification is needed in this respect. | <p>The GMO Panel has assessed the DNA sequence integrated in H7-1 sugar beet. Section 2.2.2. in the opinion:</p> <p><i>The sequence inserted corresponds exactly to the sequence of the cp4 epsps gene cassette in the plasmid except of four mismatches, one of them in the cp4 epsps coding region. However, this alteration at the molecular level does not change the CP4 EPSPS amino acid sequence or the activity of the protein.</i></p> |
| Austria | Ministry for Health and Women | D, 07.08 Toxicology | In one of its latest studies the Austrian Federal Environment Agency developed recommendations for a standardized and harmonized approach to the generation, presentation and interpretation of data concerning allergenicity and toxicology of GM products. These recommendations are based on in depth scientific studies, performed by experienced scientists in the field. The proposed tests should be performed by the notifier and the resulting data provided in order to guarantee a high level of safety | <p>The GMO Panel emphasises that it assesses the safety and potential allergenicity of the GM Products on a case-by-case basis following the criteria laid down in EFSA's Guidance Document on GM Plants (EFSA, 2006a). The EFSA guidance document is in line with the Recommendation of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (CAC, 2003)</p> <p>In a letter to the European Food Safety Authority, dated</p> |

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|--|---------|--------------|---|--|
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| | | | <p>and public confidence in the approach taken [Spök A., Hofer H., Lehner P., Valenta R., Stirn S. Gaugitsch H. (2005). Risk Assessment of GMO Products in the European Union. Umweltbundesamt Wien, Band 253]. The additional 90-day oral toxicity feeding study in rats was carried out with pulp. This can be regarded as one component of the toxicological risk assessment. No test with portions of roots, which are often mixed with molasses and fed as pellets have been carried out. Such tests are considered as important, because they contain the genetic modification, whose effect should be tested. The pulp mainly consists of dried fibre residue and some sugar and cannot be regarded as representative. The three-week feed performance study, conducted with sheep cannot be regarded as representative as well, because it is not clear how the sheep have been “physically examined” or whether toxicological relevant parameters have been assessed (p. 109, part I). Concerning the conclusions on p. 94 of part I of the dossier, that “the human exposure to the introduced protein [...] will be negligible”, it has to be stated that in the literature attached no scientific proof exists for this postulate: Klein et al. (1998, technical dossier, part I, p. 93) tested the presence of proteins in sugar but not the EPSPS-protein, which has been inserted. Furthermore in a study of Potter et al. 1990 it is mentioned that proteins could be detected in sugar (ng/g). The attached study which should proof that no EPSPS-protein can be detected in sugar and molasses (Silvanovich & Lee 2003) only consists of a protein-characterization of the</p> | <p>14 February 2006, the applicant confirms that the application is for authorization to place on the market food and feed produced from H7-1 sugar beet. In this context, the GMO Panel finds no reason to be critical to the choice of test material in the 90-day feeding study in rats. The Panel is of the opinion that the three week feeding study of sugar beets to sheep is an integral part of the nutritional assessment of the genetically modified sugar beet. The molecular characterization and the comparative compositional analysis did not indicate the occurrence of any unintended effects due to the genetic modification. In addition the applicant provided a 90-day rat feeding study which did not indicate any adverse effect.</p> <p>The GMO Panel also notes that the applicant has the task to demonstrate the safety of the new proteins that are expressed in the genetically modified plant, not their absence in derived products.</p> |

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|--|-------------------------------|------------------|---|--|
| Reference | Country | Organisation | Comment | EFSA GMO Panel response |
| | | | EPSPS-protein produced from GM-sugar beet as well as a comparison of this protein with E. coli derived EPSPS-protein. An additional study (Lee et al. 2001) shall proof, that DNA can not be detected in sugar of transgenic sugar beet. This study is an intern Monsanto study and consists of an abstract of two pages. This can not be regarded as state of the art. | |
| Austria | Ministry for Health and Women | D, Allergenicity | 07.09 The assessment of any potential allergenic and toxic effects of the genetically modified H7-1 Roundup Ready sugar beet is reduced to the allergological assessment of the isolated proteins produced from the newly inserted genes. This was done primarily through literature review and research in data-bases for comparison of the introduced sequence with known allergens (p. 51, part I). Concerning allergenicity, no experimental tests with the GMO itself have been conducted. These studies carried out with an isolated protein are not a convincing proof of potential harmless. The risk of an unintended enhancement of the allergenic potential is therefore not thoroughly foreseeable. Potential secondary effects resulting from the event of insertion, which might lead to new unexpected allergenic qualities should be studied in depth. In one of its latest studies the Austrian Federal Environment Agency developed recommendations for a standardized and harmonized approach to the generation, presentation and interpretation of data concerning allergenicity and toxicology of GM products. These recommendations are based on in depth scientific studies, performed by experienced | See section 7.9 of the GMO Panel Guidance Document (2006a): <i>The specific allergy risk of GMOs is associated with i) exposure to newly expressed protein(s) that can be present in edible parts of the plants or in the pollen... and ii) with alterations to the allergenicity of the whole plant and derived products e.g. due to over-expression of natural endogenous allergens as an unintended effect of the genetic modification.</i> i) Given this lack of complete predictability of allergenicity of a newly expressed protein, it is necessary to obtain, from several steps in the risk assessment process, a cumulative body of evidence which minimises any uncertainty with regard to the protein(s) in question. This approach is internationally accepted and has been conducted as described in section 4.2.5 of the scientific opinion. ii) The issue is to demonstrate that the GM crop will not be more allergenic than the non GM comparator because of an unintended effect of the insertion of the |

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|--|-------------------------------|---|--|---|
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| | | | <p>scientists in the field. The proposed tests should be performed by the notifier and the resulting data provided in order to guarantee a high level of safety and public confidence in the approach taken [Spök A., Hofer H., Lehner P., Valenta R., Stirn S. Gaugitsch H. (2005). Risk Assessment of GMO Products in the European Union. Umweltbundesamt Wien, Band 253 , Spök et.al.: Suggestions for the Assessment of the Allergenic Potential of Genetically Modified Organisms; Int Arch Allergy Immunol 2005; 137: 167-180].</p> | <p>transgene. If the host of the introduced gene is known to be allergenic, any potential change in the allergenicity of the whole GM food should be tested by comparison of the allergen repertoire with that of the conventional non-GM variety. It should be pointed out that these approaches should be applied on a case-by-case basis depending on the available information on the allergenic potential of the host.</p> <p>Furthermore see section 4.2.5.2 of the scientific opinion: <i>Another related issue is that allergenicity of the whole crop could be increased as an unintended effect of the random insertion of the transgene in the genome of the host e.g. through qualitative or quantitative modifications of the pattern of expression of endogenous proteins. This issue does not appear relevant to the GMO Panel since sugar beet is not considered a major allergenic food and possible over expression of any endogenous protein not known to be allergenic would be unlikely to alter the overall allergenicity of the whole plant.</i></p> |
| Austria | Ministry for Health and Women | D, 07.10 Nutritional assessment of GM food/feed | <p>The compositional analysis has been carried out with the GMP and “a nontransgenic nearly-isogenic control variety similar to H7-1 sugar beet” (p. 72, part I). Therefore it has to be questioned, why the company did not carry out these tests with the isogenic line. Furthermore it has to be asked to what extend the natural range of all relevant compounds of the “similar variety” differ from the isogenic line. Additionally it has to be stated that the compositional analysis lacks data about Ca, Mg, P, Cl, oxalate,</p> | <p>See section 3.2.1. of the scientific opinion: <i>The composition of sugar beet H7-1 was compared with the composition of a non transgenic nearly isogenic control similar to sugar beet H7-1 (a non CP4 EPSPS expressing non transgenic segregant from the sugar beet H7 1) and a set of conventional sugar beet varieties, grown in the same field trials. The number of conventional sugar beet used as comparators were thirteen in 1998 and 1999, and eight in 2003. Comparisons were also made to compositional data on</i></p> |

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|--|-------------------------------|---|--|--|
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| | | | malate, citrate and betain. Especially for the use as feed, the compositional analysis should be extended. | <p><i>sugar beet available in the literature.</i></p> <p>Thus, the control sugar beet is a near-equivalent variety with background genetics representative of the tested H7-1 sugar beet. During the breeding process to produce sugar beet hybrids it is not possible to generate strict isolines due to the inherent genetic variability in the breeding lines, which are not 100% homozygous, therefore a near-equivalent variety was selected as the control.</p> <p>In relation to analysed compounds, section 3.2.2. of the scientific opinion states: <i>Leaf (top) and processed root samples (brei) of the sugar beet H7-1 and its comparators from in total sixteen field trials in Europe in 1998 and 1999, and brei samples from five field trials in the United States in 2003, were analysed for their composition. With exception of phosphorous and magnesium, which were not analysed, the set of compounds analysed corresponded to those later suggested by OECD (2002). In addition, several components not suggested by OECD were analysed.</i></p> |
| Austria | Ministry for Health and Women | D, 12 Environmental Monitoring Plan | As described under “scope of the application”, an ERA and as a consequence adequate monitoring activities according to the provisions of annex VII of directive 2001/18/EC that take into account the accidental release have to be added to the dossier. | As the scope of the application does not include living genetically modified organisms, an environmental monitoring plan for H7-1 Roundup Ready Sugar Beet is not required. |
| Austria | Ministry for Health and Women | A, 04 Scope of the application as defined in Annex II | Scope of the notification is food and feed produced from genetically modified H7-1 Roundup Ready sugar beet. But in the letter of Monsanto of 29 March 2005 it is quoted that for feed use also by-products of the root processing are used. These by-products | In a letter to the European Food Safety Authority, dated 14 February 2006, the applicant confirms that the application is for authorization to place on the market food and feed products produced from H7-1 sugar beet. |

| Application EFSA-GMO-UK-2004-08 (Sugar beet H7-1) | | | | ANNEX G |
|--|----------------|---------------------|--|--------------------------------|
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| Reference | Country | Organisation | Comment | EFSA GMO Panel response |
| | | | contain “portions of roots and sometimes leaf remnants” and are not regarded as “capable of replication and therefore do not contain or consist of GMOs” by the company. As a contrast in part II, section B2.a.i. it is mentioned by the applicant that “reproduction may also occur from vegetative tissue, crowns or portions of roots. It is possible that some regrowth in the following season may produce fertile seed”. Due to this fact the scope of this application has to be expanded to “feed containing or consisting of GM plants”. As a consequence, also an adequate ERA and monitoring (aiming at spillage) has to be considered and part VI of the dossier has to be completed. | |

| Application EFSA-GMO-UK-2004-08 (H7-1 Sugar Beet) | | | | ANNEX G |
|--|--------------------------------------|---------------------|---|--|
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| Comments from other EFSA net users | | | | |
| Germany | Federal Institute of Risk Assessment | General comments | Having assessed the dossier, the German Federal Institute of Risk Assessment (BfR) has come to the conclusion that the information and data available do not indicate that the placing on the market of foods and feeds derived from the genetically modified H7-1 sugarbeet is likely to cause adverse effects on human or animal health in the context of its proposed use. | The GMO Panel agrees with the comment. |

Comments and opinions submitted by Member States during the three-month consultation period

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|---|---------|---|--|---|
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| Greece | EFET | D. Information relating to the GM plant | <p>2. Information on the sequences actually inserted or deleted d (iii) p.51 Bioinformatics analysis of the DNA sequences flanking the 5' and 3' junctions of H7-1 sugar beet insert An experimental confirmation through transcriptional analysis should be carried out to confirm the theoretical bioinformatics analysis. 3. Information on the expression of the insert a (ii) Levels of the CP4 EPSPS protein in H7-1 sugar beet The explanation that the three-fold increase observed in the root samples from the 1999 European field trials is due to the optimization of the analytical method employed is not convincing. Had that been the case, the absolute difference between top and brei mean range observed should not have been kept constant and reflect the difference observed in 1998? The optimization of the method does not apply for the leaf samples?</p> | <p>In relation to the potential for expression of fusion proteins section 2.2.2. of the scientific opinion states: <i>Bioinformatic analysis was carried out to investigate the potential creation of newly expressed fusion proteins. No significant homologies were found to allergens, toxins or pharmacologically active proteins. The GMO Panel considers that the information from the bioinformatics analysis indicates a low probability for an unintended expression of potentially harmful proteins.</i></p> <p>In relation to the expression of the insert, section 2.2.3. of the scientific opinion states: <i>The CP4 EPSPS protein was identified in all sugar beet H7-1 samples and in both types of tissue studied. The expression levels were similar in glyphosate treated and non-treated root samples, whereas expression levels were slightly lower in non-treated tops than in tops treated with glyphosate. However, this difference was not statistically significant. No expression was detected in the non GM reference material (non CP4 EPSPS expressing, non transgenic segregants from sugar beet H7-1). Very similar average expression levels of the CP4 EPSPS protein in the tops were observed in 1998 and 1999, the levels being 0.172 and 0.161 g/mg fresh weight, respectively. In the processed root tissue (the brei) the expression was 0.053 g/mg fresh weight in 1998 and 0.181 g/mg fresh weight in 1999. The expression varied between 0.102 and 0.307 g/mg fresh weight in leaf material and between</i></p> |

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|--|---------|--|--|---|
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| Comments from other EFSAnet users | | | | |
| | | | | <i>0.033 and 0.233 g/mg in root material in the respective years. The lower expression rate in roots in 1998 was observed in all analysed material. Since the protein is not known to be toxic or allergenic, the GMO Panel considers that this difference is of no particular concern.</i> |
| Greece | EFET | D, 07.10 Nutritional assessment of GM food/feed | Proximate levels in top tissue of H7-1 seem to be significantly different for not only dry matter but also protein and ash. More specifically the maximum range difference in control and H7-1 seems to be within 10 units. These values do not overlap the control and the commercial varieties values, however, they do overlap the literature range values. The same thing applies for dry matter in the proximate levels analysis of root tissue from H7-1 sugar beet. Regarding amino acids analysis of top tissue from H7-1 sugar beet and looking at the range of two amino acids (alanine, arginine), this falls outside the range of the commercial varieties. The same thing applies for tyrosine and valine in the amino acids analysis of root tissue from H7-1 sugar beet. Finally, saponin analysis shows statistically significant differences at 5% between H7-1 and the near-isogenic control for top 1999 and root 1999. Although no risk could be posed to human health, these glycosides are used as anti-feedants in animals. | The compositional comparison of H7-1 sugar beet to its near isogenic controls and a set of different commercial varieties is described in section 3.2.2. of the scientific opinion. |
| Greece | EFET | D, 12 Environmental Monitoring Plan | Considering that: 1) the wild relatives of sugar beet originated in Asia Minor, 2) sugar beet is a cross-pollinated species, 3) gene flow has been demonstrated between cultivated and wild beets | In a letter to the European Food Safety Authority, dated 14 February 2006, the applicant confirms that the application is for authorization to place on the market food and feed products produced from H7-1 |

| Application EFSA-GMO-UK-2004-08 (H7-1 Sugar Beet) | | | | ANNEX G |
|---|------------------------------|------------------------|--|---|
| Comments and opinions submitted by Member States during the three-month consultation period | | | | |
| Reference | Country | Organisation | Comment | EFSA GMO Panel response |
| Comments from other EFSA net users | | | | |
| | | | special precautions should be taken to prevent the dissemination of GM seeds and/or vegetative material with potential to grow into a viable plant. The accidental introduction of GM beet plants into the natural ecosystem where wild beets are grown might disturb the balance of the wild beets population. Therefore, it should be clarified whether seeds or processed sugar and/or syrup will be imported in the Southern EU countries. To this direction the submission of Environmental Monitoring Plan is essential. | sugar beet. |
| Spain | Ministerio de Medio Ambiente | A. General information | The National Competent Authority for Directive 2001/18/EC have analysed the dossier and considers that is not justified enough if some parts of the product left in the field could regrowth. In this case the product should be considered as a GMO. On the other hand, the point E. 2. of the summary, indicates that the GM plant is cultivated at the Czech Republic and Poland among others, if so, we would like clarification of the legal status of the GM plant at the U.E. | In a letter to the European Food Safety Authority, dated 14 February 2006, the applicant confirms that the application is for authorization to place on the market food and feed produced from H7-1 sugar beet. The scope does not include cultivation. |

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- OECD, 2002, Consensus document on compositional considerations for new varieties of sugar beet: key food and feed nutrients and antinutrients. Series on the Safety of Novel Foods and Feeds, No. 3, Organisation for Economic Co-operation and Development, Paris.