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To: standards management
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Subject: Submission: APPLICATION A1041

Categories: Blue Category

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Public Submission on

APPLICATION A1041:
FOOD DERIVED FROM SDA SOYBEAN LINE MON87769
1ST ASSESSMENT REPORT

Despite the extension of the submission deadline in response to the Queensland floods, MADGE has not had enough time to sufficiently review this crop to make a full submission on all technical details. However MADGE have read enough to ask that food from SDA Soybean Line MON87769 be rejected for the reasons listed in this interim submission:

1. FSANZ listed 27 references in its safety assessment document that it did not cite. This looks like reference padding and it does not add to the credibility of the FSANZ assessment process. Also, FSANZ failed to reference 16 citations in the same document. MADGE does not have the confidence that FSANZ has applied serious scientific process necessary for the review of the safety of this crop, and asks that approval be withheld until a more credible assessment is conducted.

2. MADGE has counted 17 studies received by FSANZ from Monsanto to support their application. Only 5 of these studies reported compliance with Good Laboratory Practice associated with US regulation. None of these studies mentioned compliance with OECD standards, and the FSANZ made no mention of their compliance in its assessment. This food safety assessment overrides this 13 April 2010 statement by the FSANZ CEO:

> "It is a requirement that the data relied upon to establish the safety of a GM food be generated according to internationally accepted quality assurance guideline (i.e. approved methodology and Good Laboratory Practice (GLP)) and that this has been sugjected to external scrutiny (i.e. independent audit and documentation trail). [..] Studies that do not make the grade will not be accorded any weight in the safety assessment"

Most of the Monsanto studies should not have been given any weight in this assessment, and this includes studies investigating potential allergencity. The data provided is insufficient according to FSANZ's stated standards, and this crop should not be approved.

3. In this assessment FSANZ failed to comply with the Auditor General's recommendations made in its ANAO Audit Report No.15 2010–11. MADGE requests that FSANZ redo this first assessment document complying with the Auditor General's recommendations so the public can make an appropriate assessment of FSANZ process in their assessment of the food safety of the crop.

4. On a more technical issue, describe what FSANZ has done to determine whether the chimeric sequences in this crop are capable of immunostimulatory activity, as discussed in the European Food Safety Authority's "Scientific Opinion on the assessment of allergenicity of GM plants and microorganisms and derived food and feed" EFSA Journal 2010; 8(7):1700, giving particular attention to the codon-altered gene originally sourced from Neurospora crassa.

5. The protein characterization tests showed specifically raised antibodies reacting with a wide range of proteins, not only the intended proteins. Even if these proteins were aggregates and degradation products of the intended proteins the EFSA scientific opinion above says these novel products represent separate risks of allergenicity. Please explain why FSANZ ignored these novel products, despite particular reference to them. MADGE requests that each of the protein products that were recognized by the specific antibodies be identified and tested.

   We alert FSANZ to Section 1 of the ANNEX:ASSESSMENT OF POSSIBLE ALLERGENICITY of the Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants, CAC/GL 45-2003, being

   "All newly expressed proteins in recombinant-DNA plants that could be present in the final food should be assessed for their potential to cause allergic reactions."

   FSANZ has not treated these identified proteins with sufficient seriousness.

6. The EFSA scientific opinion above indicated that the SGF and SIF digestibility tests are inappropriate for low-acid, low-pepsin infant gastrointestinal systems. Describe what FSANZ has done to determine the infant gastrointestinal safety of this GM crop, in light of the newly collected scientific opinion on the issue.

7. In light of the wide range of alternative non-GM sources of omega 3 oils, including Paterson's Curse and the primula juliae gene source as referred to in the FSANZ assessment, MADGE does not consider the risks associated with this GM crop outweigh the benefits, and asks for the rejection of this GM crop application.

MADGE will continue to review the crop and will make a submission at the second public review stage.

Yours faithfully,

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