



OIA12-344

24 APR 2013

Frank Rowson
bacsithuy63@yahoo.co.nz

Dear Frank Rowson

OFFICIAL INFORMATION ACT REQUEST

I refer to your official information request originally made on 4 March 2013 relating to advice and information provided to the Minister for Food Safety in relation to Food Standards Australia New Zealand Application A1073 Food derived from Herbicide-tolerant Soybean DAS-44406-6.

As discussed by telephone with Howard Staveley on 7 March 2013, your original request has been split into two separate requests. The two requests are for:

1. Any advice and information provided by the Ministry for Primary Industries (MPI) to the Minister for Food Safety (or her predecessor) concerning FSANZ Application A1073 – Food derived from Herbicide-tolerant Soybean DAS-44406-6, and the information on which MPI will base its advice to the Minister for Food Safety to inform her decision in respect of A1073.
2. The advice and information that the Ministry for Primary Industries provided to the Minister for Food Safety in order for the Minister, as a member of the Legislative and Governance Forum on Food Regulation, to make a decision on A1073 – Food derived from Herbicide-tolerant Soybean DAS-44406-6. The request also includes the names and qualifications of the MPI staff that prepared the advice for the Minister. This request is to be dated 25 March 2013.

This response is in relation to the second of these requests.

The following information is released to you under the Official Information Act 1982:

Ref	Description
1	B12-545, briefing to the Minister for Food Safety dated 22 March 2013: Trans-Tasman decision on the acceptance of a new genetically modified food

You have also asked for the names and qualifications of the MPI officials that prepared the advice for the Minister. The names, qualifications and roles in providing the advice of the relevant officials are detailed in the table below. As agreed by telephone with Howard Staveley on 21 March 2013, the name of one MPI official is withheld on request from that official.

Role in preparing advice for the Minister for Food Safety on A1073	Name	Position	Qualifications
Primary scientific reviewer	Andrew Pearson	Senior Adviser Toxicology, Food Science & Risk Assessment	<ul style="list-style-type: none"> • BSc(Hons) Biochemistry (Toxicology), University of Surrey, UK. • Currently enrolled in an MSc Environmental Chemistry
Scientific reviewer	John Reeve	Principal Adviser Toxicology, Food Science & Risk Assessment	<ul style="list-style-type: none"> • MSc (Hons Biochemistry) Victoria University of Wellington • MSc (Toxicology) University of Surrey, UK. • Member of the Australasian College of Toxicology and Risk Assessment. • Member of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Roster of Toxicological and Epidemiological Experts 2011 – 2015 • 36 years experience in regulatory toxicology
Drafter/principal author (role is to compile scientific advice and write briefings)	[withheld as per agreement]	Senior Adviser, Food Science & Risk Assessment	<ul style="list-style-type: none"> • BHSc (First Class Hons, Food Science) • MHSc (Food Science) • Professional Member NZIFST
Manager review	Jenny Reid	Manager, Science & Risk Assessment	<ul style="list-style-type: none"> • MPublic Health • MPublic Administration • NZ Registered Dietitian
Director sign out	Dr Steve Hathaway	Director, Science & Risk Assessment	<ul style="list-style-type: none"> • BVSc., Ph. D., FRCVS

You have the right under section 28(3) of the Official Information Act to seek an investigation and review by the Ombudsman of our response to your request. A request must be made in writing to:

The Ombudsman
Office of the Ombudsmen
PO Box 10 152
WELLINGTON

Yours sincerely



Chris Carson
Director, International Policy

Distribution
Minister
Minister's Advisor
Minister's Office

Ministry for Primary Industries
Manatū Ahu Matua



22 March 2013

Document Number: B12-545

Trans-Tasman decision on the acceptance of a new genetically modified food

Purpose:

Food Standards Australia New Zealand (FSANZ) has “approved” the standard for food derived from herbicide-tolerant soybean DAS-44406-6 (a new genetically modified food) and referred it to the trans-Tasman Ministerial Legislative and Governance Forum on Food Regulation (the FoFR) for a decision on whether to “accept it” or to “seek a review” (a diagram on the decision process for new genetically modified (GM) foods is included in Appendix 1). This briefing also provides background information on the regulation of GM food in New Zealand.

This briefing provides you with advice to assist your decision as New Zealand’s member of the FoFR. Your response is required by 8 April 2013.

MPI’s advice is that the FSANZ approval is appropriate.

Minister	Action Required:	Minister’s Deadline
Minister for Food Safety	<p>Agree that FSANZ’s approval of food derived from herbicide-tolerant soybean DAS-44406-6 is appropriate and that you do not wish to seek a review; and</p> <p>Agree to sign and send the attached out-of-session response form to the Food Regulation Secretariat.</p>	Responses to the Food Regulation Secretariat are required by 8 April 2013.

Contact for telephone discussion (if required)

	Name	Position	Work	After Hours
Responsible Manager	Jenny Reid	Manager, Food Safety	04 894 2583	029 894 2582
Principal Author	[]	Senior Advisor	04 894 2650	

name withheld as per agreement

Key Messages

1. Food Standards Australia New Zealand (FSANZ) has approved a new genetically modified (GM) food (food derived from herbicide-tolerant soybean DAS-44406-6). The approval is for human consumption and does not extend to the cultivation or production of this GM food in New Zealand.
2. The Legislative and Governance Forum on Food Regulation (FoFR), on which you are New Zealand's representative, must consider the FSANZ approval and decide if it should be accepted or sent to review. As New Zealand's representative on the FoFR, you are responsible for casting New Zealand's vote.
3. The FoFR decision is to be made by majority vote "out-of-session", that is, not at a formal meeting. Each of the ten jurisdictions' has one vote¹. Under the Food Treaty,² New Zealand has agreed to give legal effect to any amendments to the Food Standards Code agreed by the FoFR unless there are exceptional health, safety, third country trade, environmental or cultural grounds to do so³ (refer B12-524 for an example where New Zealand has 'opted out' of a joint Australia New Food Standard). Your decision as a member of the FoFR in respect to the FSANZ approval is required by 8 April 2013.
4. MPI has reviewed the FSANZ assessment and considers that the FSANZ approval of this new GM food is appropriate (refer Appendix 2 for a summary of MPI's scientific review). We also consider that if you agree to accept the approval, you can be confident that the pre-requisites for subsequently giving legal effect to the acceptance in New Zealand under the Food Act 1981 have been met (refer Appendix 3 for more detailed advice).
5. Under the Food Treaty there are limited grounds on which New Zealand may decide not to accept a joint standard. MPI does not consider any of these grounds apply to this decision.

¹ The other nine jurisdictions are: the Commonwealth of Australia; the States of New South Wales, Victoria, Queensland, Western Australia, South Australia, Tasmanian; and the Australian Capital Territory; and the Northern Territory of Australia.

² *Agreement Between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System.*

³ Subject to certain "exceptional circumstances" as set out in Annex DIII of the Food Treaty.

Recommendations

6. MPI recommends that you:

- a) **Note** that MPI advise that there are no grounds for New Zealand not to accept the FSANZ-approved standard for Food Derived from Herbicide-Tolerant Soybean DAS-44406-6.

Noted

- b) **Agree** that you *do not* wish to seek a review of FSANZ's approval.

Agreed / Not Agreed

- c) **Agree** to sign and send the attached out-of-session response to the Food Regulation Secretariat by 8 April 2013.

Agreed / Not Agreed

Steve Hathaway
Director, Science & Risk Assessment

Hon Nikki Kaye
Minister for Food Safety

/ / 2013

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Background

7. In New Zealand (and Australia), GM foods for human consumption are regulated under the Australia New Zealand Food Standards Code (the Food Standards Code). Food products are non-viable, i.e. they cannot be grown or reproduced in New Zealand.
8. FSANZ has approved a new GM food (FSANZ application A1073 Food Derived from Herbicide-Tolerant Soybean). As New Zealand's representative on the FoFR you are responsible for making a decision to accept or seek a review of FSANZ's approval.
9. Approval of genetically modified organisms (e.g. viable plants and animals for research or commercial crops) is a separate process and is the responsibility of the Environmental Protection Agency and the Minister for the Environment. There are currently no GM crops approved for commercial release in New Zealand.
10. Requirements applying to the sale of GM foods are contained in the Food Standards Code in Standard 1.5.2. Those who wish to sell newly developed foods or ingredients derived from gene technology must make an application to FSANZ providing evidence for the safety and nutritional equivalence of the food. FSANZ then undertakes a full safety assessment before referring an approval to the FoFR.
11. MPI contracts the Institute of Environmental Science and Research (ESR) to review FSANZ's pre-market safety assessments of GM foods. The ESR reviews inform MPI's submissions to FSANZ on its assessments, as well as MPI's advice to the Minister for Food Safety on whether FSANZ approvals are appropriate for New Zealand.
12. There are currently 57 varieties of GM foods accepted by the FoFR for sale in New Zealand and Australia. There are 21 varieties of corn, 13 varieties of soybean; 12 varieties of cotton; four varieties of canola; three varieties of potato; two varieties of sugar beet; one variety of rice; and one variety of lucerne. There are, on average, three or four new GM foods assessed each year.

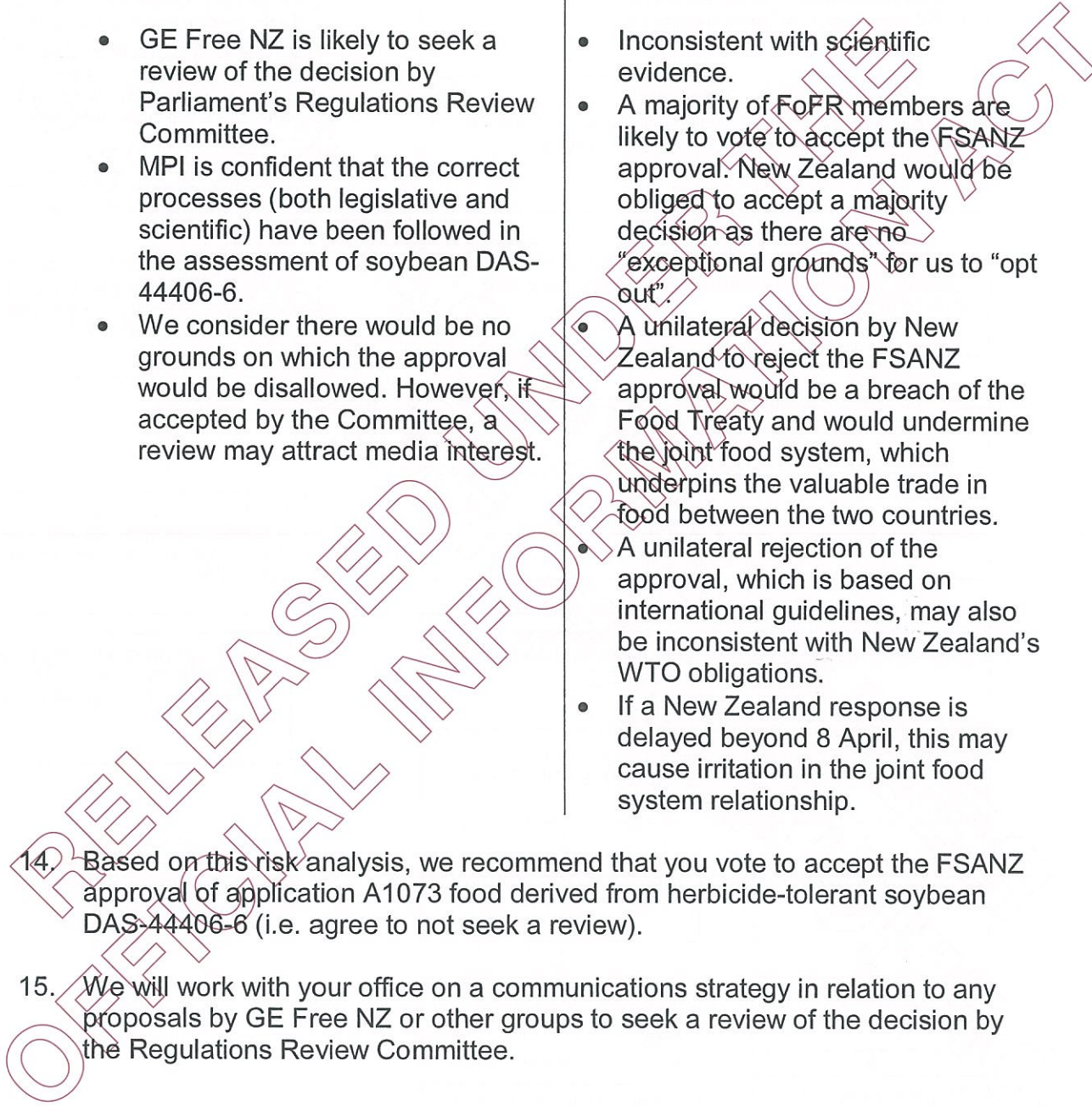
Analysis

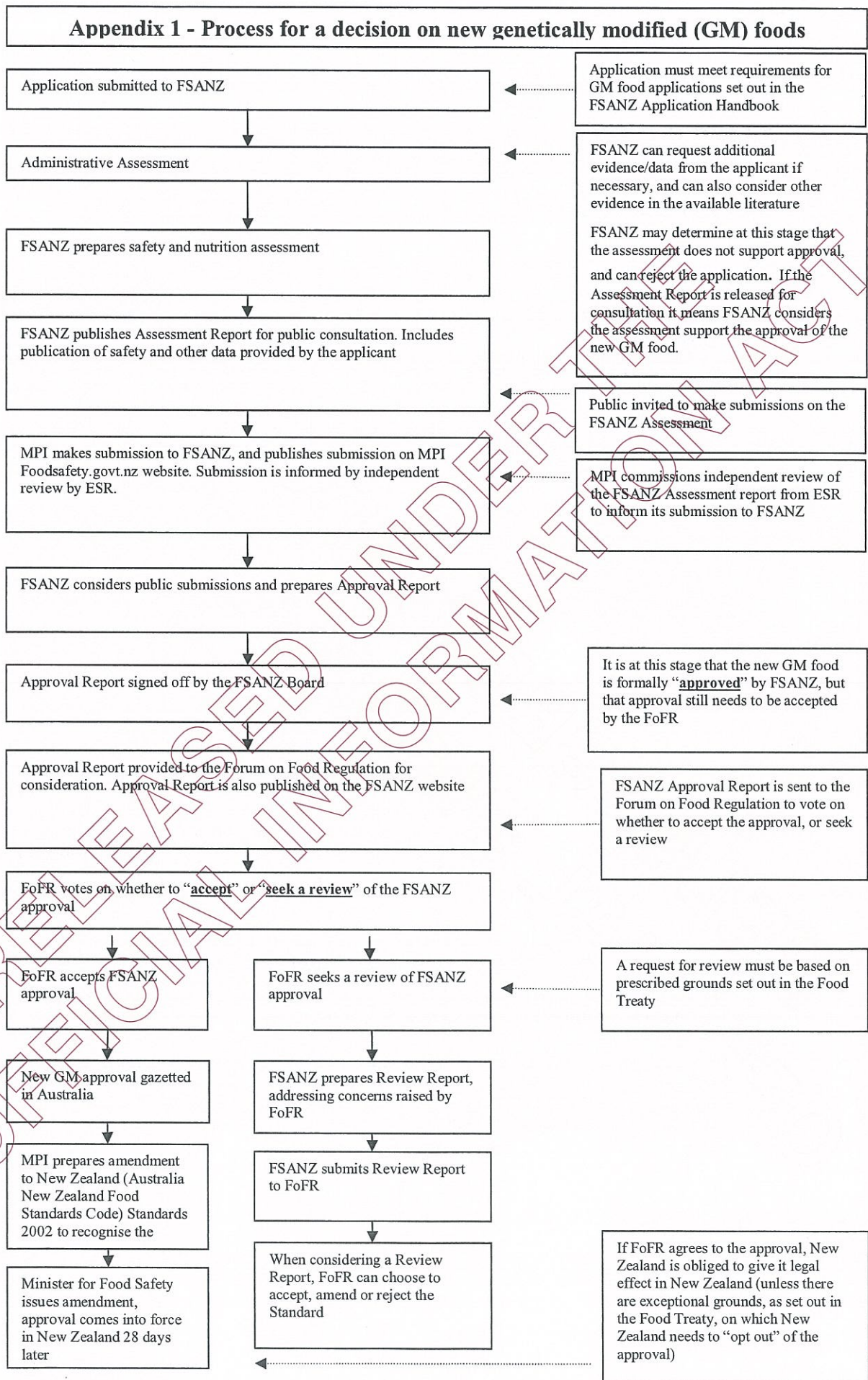
13. The regulation of GM foods is a sensitive issue. Several groups strongly oppose the presence of GM foods in the food supply, and regularly make media statements protesting FSANZ approvals of new GM foods. Risks associated with this decision are outlined in the table below:

Accepting the approval	Not accepting the approval
<ul style="list-style-type: none"> • GE Free NZ is likely to seek a review of the decision by Parliament’s Regulations Review Committee. • MPI is confident that the correct processes (both legislative and scientific) have been followed in the assessment of soybean DAS-44406-6. • We consider there would be no grounds on which the approval would be disallowed. However, if accepted by the Committee, a review may attract media interest. 	<ul style="list-style-type: none"> • Inconsistent with scientific evidence. • A majority of FoFR members are likely to vote to accept the FSANZ approval. New Zealand would be obliged to accept a majority decision as there are no “exceptional grounds” for us to “opt out”. • A unilateral decision by New Zealand to reject the FSANZ approval would be a breach of the Food Treaty and would undermine the joint food system, which underpins the valuable trade in food between the two countries. • A unilateral rejection of the approval, which is based on international guidelines, may also be inconsistent with New Zealand’s WTO obligations. • If a New Zealand response is delayed beyond 8 April, this may cause irritation in the joint food system relationship.

14. Based on this risk analysis, we recommend that you vote to accept the FSANZ approval of application A1073 food derived from herbicide-tolerant soybean DAS-44406-6 (i.e. agree to not seek a review).

15. We will work with your office on a communications strategy in relation to any proposals by GE Free NZ or other groups to seek a review of the decision by the Regulations Review Committee.





Appendix 2 – Summary of MPI’s scientific review of soybean DAS-44406-6

1. In April 2012, Dow AgroSciences Australia Ltd and MS Technologies LLC submitted an application to FSANZ for the approval for human consumption of food derived from herbicide-tolerant soybean DAS-44406-6 (Application A1073). This is a GM variety that is tolerant to three herbicides: 2,4-dichlorophenoxyacetic acid (2,4-D), glufosinate ammonium, and glyphosate.
2. Tolerance to these herbicides is the result of the introduction of three genes which express three different enzymes and codes three proteins (called AAD-12, PAT and EPSPS). Both the PAT and EPSPS proteins have been widely used to confer herbicide tolerance in a range of GM crop species. The AAD-12 protein has previously been assessed by FSANZ in relation to a earlier application (Application A1046 – Food derived from herbicide-tolerant soybean line DAS-68416-4, approved in October 2011).
3. A feature of this GM plant is the simultaneous introduction of three novel enzymes providing herbicide tolerance. This requires the use of a larger inserted gene than in previous plants.
4. The soybean DAS-44406-6 is not intended to be grown in New Zealand (and no application for commercial release in New Zealand has been made). The applicant states that the new soybean is intended primarily for use as a broad acre commodity (field soybean) to produce products derived from cracked soybeans. In cracked soybeans, the hull is removed to produce flakes, which in turn are used to produce soybean oil, protein concentrates and flour. The soybean oil may therefore appear in processed foods, or be sold as a cooking oil.
5. The applicant states that soybean DAS-44406-6 is not intended for vegetable or commercial garden purposes, that is, in the production of food products like tofu, soybean sprouts, soy milk, and green soybeans.

FSANZ Assessment

6. In its safety assessment FSANZ concluded that food derived from soybean DAS-44406-6 is nutritionally adequate and as safe for human consumption as food from commercially available conventional soybean varieties.
7. At the public consultation stage, MPI (in consultation with the Institute of environmental Science and Research (ESR)) reviewed the safety assessment report prepared by FSANZ. We agreed with FSANZ’s view that this new GM food does not present any public health or safety concerns.
8. On the advice of ESR, MPI provided a comment in our submission concerning data for endogenous allergens (allergenic proteins occurring naturally in the plant) associated with soybean DAS-44406-6. In response to this submission, FSANZ removed the section on endogenous allergens from its final safety assessment report, as it considered there is no scientific justification for including this data in GM food safety assessments. MPI agrees with this approach.

Labelling

9. If the FoFR agrees to accept the FSANZ approval, food derived from soybean DAS-44406-6 must be labelled as “genetically modified” if it contains novel DNA or novel protein. Some types of highly processed soy products do not contain novel protein or DNA. For example, soybean oil contains negligible levels of protein so it would not be expected to contain novel DNA and/or protein. However if the soybean was used to produce protein concentrates, protein isolates or textured flours, these are likely to contain novel protein and/or DNA so would require labelling as a GM food.

Consultation and summary of submissions

10. FSANZ conducted one round of public consultation for Application A1073. Sixty-eight submissions were sent to FSANZ. Four supported the application and forty-five submissions opposing the Application were based on a campaign letter prepared by GE Free New Zealand. The submissions included one from MPI. This like other MPI submissions was placed on its website so there is transparency of position on all submissions.
11. FSANZ has responded to the issues raised in submissions, in section 3.2.3 of the Approval Report (attached). FSANZ has separated out the issues that relate to GM food in general, and those specific to A1073. In addition, FSANZ has detailed information on its website about issues raised that are relevant to all GM food assessments.
12. In the Approval Report, FSANZ provides a detailed response to a large number of issues raised specific to Application A1073 (see pages 6 to 15). The issues include compositional equivalence to conventional crops, immune reactivity, alignment with international procedures, occurrence of unintended effects or mutations, the necessity of animal feeding studies, the reliance by FSANZ on the applicant's data, allergenicity, acrylamide production, and concerns with the levels of pesticide applied to the whole soybean.
13. MPI agrees with and supports the FSANZ responses to the issues raised in submissions.

Recommendation

14. When considering a FSANZ approval, the FoFR has the option of seeking a review of that approval. A review can only be sought on one or more of the following grounds (set out in the Australian Food Regulation Agreement and the Food Treaty):
 - a. It is not consistent with existing policy guidelines set by the FoFR.
 - b. It is not consistent with the objectives of the legislation which establishes FSANZ (i.e. the FSANZ Act).
 - c. It does not protect public health and safety.
 - d. It does not promote consistency between domestic and international food standards where they are at variance.
 - e. It does not provide adequate information to enable informed choice.
 - f. It is difficult to enforce and/or comply with in both practical and resource terms.
 - g. It places an unreasonable cost burden on industry or consumers.
 - h. It is not consistent with the principles for the establishment of food standards set down in the Food Treaty, including consistency with both countries' World Trade Organization obligations and consistency with domestic laws and regulations of both countries.
 - i. It is inappropriate on the grounds of exceptional environmental or cultural factors.
15. We consider that none of the above grounds apply in the case of FSANZ's approval of soybean DAS-44406-6.
16. Under the Food Treaty, New Zealand also has the option to "opt out" of a joint food standard if there are exceptional health, safety, third country trade, environmental or cultural grounds to do so. MPI considers that there are no exceptional grounds that make it necessary to "opt out" of the FSANZ approval of soybean DAS-44406-6.
17. Based on these considerations, and review of the FSANZ assessment of the safety of soybean DAS-44406-6, we recommend that you accept the FSANZ approval (i.e. that you do not seek a review of the approval).

Appendix 3 – Pre-requisites for issuing a food standard under the Food Act

1. FSANZ approvals are given effect in New Zealand by amendments to the New Zealand (Australia New Zealand Food Standards Code) Standards 2002.
2. When deciding whether a FSANZ approval is appropriate for New Zealand, it is necessary to consider whether the pre-requisites for issuing a food standard (or an amendment to a food standard) under section 11E of the Food Act 1981 have been met for that approval.
3. In amending or making standards under the Food Act, the Minister is required to take into account several matters. These closely reflect the matters that FSANZ is required to consider in developing changes to the Food Standards Code (including new GM food approvals).⁴
4. Section 11E of the Food Act requires that
 - (1) In issuing any food standard, the Minister shall take into account the following:
 - (a) the need to protect public health;
 - (b) the desirability of avoiding unnecessary restrictions on trade;
 - (c) the desirability of maintaining consistency between New Zealand's food standards and those applying internationally;
 - (d) New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australia - New Zealand Joint Food Standards Agreement;
 - (e) such other matters as the Minister considers appropriate.
 - (2) The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation) —
 - (a) adequate and appropriate notice of the intention to issue the food standard; and
 - (b) a reasonable opportunity for interested persons to make submissions; and
 - (c) adequate and appropriate consideration of any such submissions.
5. MPI has reviewed the FSANZ assessment contained in the Approval Report for Application A1073, and considers that the application has been competently assessed by FSANZ. As such, we consider that there are no potential public health and safety concerns in permitting food derived from soybean line DAS-44406-6.
6. We also advise that, in accepting the approval, you can be satisfied that it does not impose unnecessary restrictions on trade, and maintains consistency between New Zealand's food standards and those applying internationally (FSANZ's assessment process following international guidelines and is notified to the WTO).

⁴ The matters that FSANZ must consider in the development of food standards are set out in section 18 of the Food Standards Australia New Zealand Act 1991 (Cwth).

7. We have not identified any other matters in relation to the FSANZ assessment to bring to your attention. We also consider that you can be satisfied that appropriate consultation has been carried out. As noted in Appendix 2, FSANZ undertook consultation and received 68 submissions. FSANZ also responded in detail to matters raised by submitters.
8. We consider that the proposed variations to the Food Standards Code to permit food derived from soybean line DAS-44406-6 meets the requirements for issuing a standard set out in section 11E of the Food Act. We therefore recommend that you accept the FSANZ approval of soybean DAS-44406-6 (i.e. that you do not seek a review). We anticipate that a majority of FoFR members will also agree to accept the FSANZ approval of soybean DAS-44406-6.

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