

9 May 2001
14/01

PRELIMINARY ASSESSMENT REPORT

APPLICATION A435 TRIACYLGLYCEROL LIPASE AS A PROCESSING AID

Applicant: Novo Nordisk A/S

Date received: 06 February 2001

1. BACKGROUND:

An application has been received from Novo Nordisk A/S seeking an amendment to Standard 1.3.3 – Processing Aids, in Volume Two of the *Food Standards Code*. The proposed amendment is to include triacylglycerol lipase sourced from the host organism *Aspergillus oryzae*, which carries the gene coding for a lipase isolated from donor organism *Fusarium oxysporum* in the Table in clause 17 of Standard 1.3.3.

2. OBJECTIVE:

The objective of the proposed amendment is to allow the use of an improved triacylglycerol lipase. This enzyme is used to improve yield in the degumming process, to increase the purity of vegetable oils and to improve the emulsifying properties of lecithin and egg yolk. Advantages of using this triacylglycerol lipase over other lipases are improved storage stability of oil and improved taste/quality and improved performance of emulsifiers.

3. REGULATORY IMPACT STATEMENT (RIS)

This RIS is preliminary only and based on available information or on information provided by the applicant. The RIS identifies the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include information from public submissions. This preliminary RIS invites public comment on these areas.

Objective of the RIS

To assess the costs and benefits associated with adopting the proposed regulatory change to permit the use of triacylglycerol lipase produced by *Aspergillus oryzae* carrying the lipase gene from *Fusarium oxysporum*.

The regulatory options are as follows:

Option 1. Not approve the use of triacylglycerol lipase produced by *Aspergillus oryzae* carrying the lipase gene from *Fusarium oxysporum*.

Option 2. Approve the use of triacylglycerol lipase produced by *Aspergillus oryzae* carrying the lipase gene from *Fusarium oxysporum*.

Identification of affected parties

Parties affected by the options outlined above include:

1. Food industry wishing to use this lipase to improve the yield in de-gumming of oils during oil purification process, and improve emulsifying properties of lecithin and egg yolk.
2. Consumers using the oils and other products prepared using lipase.
3. Government agencies enforcing the food regulations.

Potential regulatory impacts

An assessment of the potential regulatory impacts will be made after the receipt of public submissions.

4. CONSIDERATION OF ISSUES UNDER SECTION 13 OF THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY ACT 1991 (ANZFA Act)

Subsection 13(1) of the ANZFA Act requires the Authority to make a preliminary assessment of an application. In making that preliminary assessment, subsection 13(2) requires the Authority to have regard to a number of matters set out in paragraphs 13(2)(a) to (e). Each of those matters is discussed below.

Paragraph 13(2)(a)

This application relates to a matter that warrants a variation of a food regulatory measure because the application seeks an amendment of a standard. A standard by definition under the ANZFA Act, is a food regulatory measure.

Paragraph 13(2)(b)

The application is not so similar to any previous application that it ought not be accepted.

Paragraph 13(2)(c)

On its face, the application does not suggest that the proposed amendment would present any further costs on the community, Government or industry, provided that there are no adverse health effects. The costs would be neutral. The proposed amendment is to allow for a new processing aid technique in the preparation of food. The cost of using that proposed new technique would be borne by the manufacturer.

Paragraph 13(2)(d)

The nature of the application is such that only a variation to a standard (ie a food regulatory measure) can bring about what the applicant is seeking. No other measures are available.

Paragraph 13(2)(e)

Other relevant matters for consideration by the Authority are as follows - (i) to (v).

(i) World Trade Organization (WTO) Implications

The World Trade Organization (WTO) was created on 1 January 1995 to provide a forum for facilitating international trade. The WTO does not engage in any standard-setting activities but is concerned with ensuring that standards and procedures for assessment of and conformity with standards do not create unnecessary obstacles to international trade.

Both Australia and New Zealand are members of the World Trade Organization (WTO) and signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS agreement) and on Technical Barriers to Trade (TBT agreement). Within Australia, the Council of Australian Governments (COAG) has put a memorandum of understanding in place binding all States and Territories to the agreements.

The WTO agreements are predicated on a set of underlying principles that standards and other regulatory measures should be:

- based on sound scientific principles;
- developed using consistent risk assessment practices;
- transparent;
- no more trade-restrictive than necessary to achieve a legitimate objective;
- recognise the equivalence of similar measures in other countries;
- not used as arbitrary barriers to trade; and
- consistent, wherever possible, with international standards, guidelines and recommendations, such as those established by Codex.

As members of the World Trade Organisation (WTO) both Australia and New Zealand are obligated to notify WTO member nations where proposed regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The *Food Standards Code* is mandatory legislation applying to both domestic and imported food products. Suppliers of food products are not required to take up permissions granted through amendments to the Code, however food products not complying with the Code cannot legally be supplied in Australia.

Amending the Code to allow the use of triacylglycerol lipase as a processing aid is unlikely to significantly effect trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at full assessment and, if necessary, notification will be made in accordance with the WTO TBT or SPS agreements.

(ii) Australian Food Standards Code

Currently Standard 1.3.3 - Processing aids, Table to clause 17 – Permitted Enzymes of Microbial Origin does not include triacylglycerol lipase produced by *Aspergillus oryzae* carrying the lipase gene from *Fusarium oxysporum*.

(iii) New Zealand Food Regulations

253 (2d) Food conditioners, permits the use of lipase without any reference to host organisms.

(iv) Codex

There is no Codex Standard for lipase produced by *Aspergillus oryzae* carrying lipase gene from *Fusarium oxysporum*.

(v) Approval in other Countries

A petition for approval in Denmark is in preparation by the applicant. Submission of a GRAS notification to the US FDA is also underway but no approval has yet been sought from any other countries.

5. WORKPLAN CLASSIFICATION

ANZFA's initial assessment of this application for placement on the Work-Plan was Group 3, Category 3'. Following preliminary assessment it is recommended that this classification be confirmed.

6. CONCLUSIONS

This application does relate to a matter that may be developed as a food regulatory measure, or warrants a variation of a food regulatory measure, as provided for in section 13 of the ANZFA Act. The identification of any further costs and benefits arising from any food regulatory measure so developed will be made at full assessment (as required under section 15 of the ANZFA Act) and having taken into account public submissions.

Accordingly, the Authority has decided to accept Application A435 and will now proceed to make a full assessment of it.

The amendment of the *Food Standards Code* being sought would allow the use of lipase produced by *Aspergillus oryzae* as host organism and *Fusarium oxysporum* as donor organism. Conditions of use may be required (eg requirement to comply with specifications for identity and purity, and with a maximum percentage addition to specific foods).

7. FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand (*Maximum Residue Limits of Agricultural Compounds*) *Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the *New Zealand Fair Trading Act 1986* and all food sold in Australia must comply with the *Australian Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the *Australian Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

8. INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A435** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by **20 June 2001**.

Submissions may be sent by Email to slo@anzfa.gov.au. However, ANZFA cannot guarantee accurate transmission and it is suggested that you also forward a hard copy by mail.

Queries regarding procedural aspects of this matter can be directed to the Standards Liaison Officer at the above address or by Email on slo@anzfa.gov.au. Requests for more general information on ANZFA can be directed to the Information Officer at the above address or by Email on info@anzfa.gov.au.