



30 May 2001  
15/01

## INQUIRY REPORT

### APPLICATION A412

### MAXIMUM RESIDUE LIMIT FOR ETHYLENE OXIDE IN HERBS AND SPICES

**Note:**

This report is the “Inquiry” as referred to in Section 16 of the *Australia New Zealand Food Authority Act (1991)* and sets out the reasons for making a recommendation to the Australia New Zealand Food Standards Council under Section 18 of the Act.

## EXECUTIVE SUMMARY

The Australia New Zealand Food Authority (ANZFA) received **Application A412** on 27 April 2000, from the National Registration Authority for Agricultural and Veterinary Chemicals (NRA) seeking to amend the Australian *Food Standards Code* to establish a maximum residue limit (MRL) of 20 mg/kg for ethylene oxide (EtO) in herbs and spices.

ANZFA decided, pursuant to section 37 of the *Australia New Zealand Food Authority Act 1991*, to progress this application as a matter of urgency in order to avoid compromising the objective set out in subsection 10(1)(a) of the Act, namely the protection of public health and safety. Accordingly, ANZFA completed a Full Assessment of the application, prepared draft variations to the *Food Standards Code*, and proposed recommendations to be considered by the Australia New Zealand Food Standards Council (ANZFSC).

On 28 July 2000, ANZFSC agreed to the recommendations to amend Standard A14 – Maximum Residue Limits, and agreed also that the date of implementation of the amendment would coincide with the date of gazettal of the variation to the standard. The variation commenced on the 17 August 2000, the date of gazettal. The adoption of the draft variation to Standard A14 was recommended for the following reasons:

- The MRL for EtO was recommended by the NRA after the granting of an Emergency Use Permit for fumigant use of EtO on herbs and spices on 20 April 2000.
- The MRL is due to expire on 30 September 2001, which is the date of expiration of the Emergency Use Permit.

- The use of EtO on herbs and spices is currently required to reduce microbial contamination.
- The MRL of 20 mg/kg is set at a level consistent with good agricultural practice.
- On the basis of the report entitled *Cancer Risk Assessment of Ethylene Oxide Residues in New Zealand Spices* prepared by the New Zealand Institute of Environmental and Scientific Research (ESR), there is negligible cancer risk to consumers from EtO residues in spices.
- The conclusion from the Full Assessment Report stated that on the basis of the data available, an MRL of 20 ppm for ethylene oxide in herbs and spices is justified and does not pose any additional public health and safety risk.

There are no additional issues arising from this Inquiry that would justify amendment to the Ministerial Council decision in July 2000, which established the temporary MRL of 20 mg/kg ethylene oxide in herbs and spices. Any extension to the Emergency Permit to use EtO beyond the expiry date is the responsibility of the NRA. ANZFA would give appropriate consideration to the need for regulatory measures able to be supported by additional scientific assessment of toxicological and monitoring data.

## **BACKGROUND TO THE APPLICATION**

### *Treatment of herbs and spices*

Selected herbs and spices (particularly paprika, pepper and cinnamon) imported into Australia can be contaminated with *Salmonella* and require treatment prior to sale and use. The Australian Quarantine and Inspection Service (AQIS) test for *Salmonella* in imported herbs and spices and, if found, require decontamination of the shipment. Currently, treatment with ethylene oxide (EtO) is the standard method to control microbial contamination of herbs and spices. AQIS subsequently tests the spices for ethylene oxide residues according to the provisions of the *Food Standards Code*.

### *Legality of the use of ethylene oxide on domestic and imported foods*

Until recently, there was no registered agricultural use of ethylene oxide in Australia. In January 2000, AQIS sought advice from ANZFA about the status of EtO in relation to the *Food Standards Code* and was informed that there was no MRL for EtO and that therefore no residues of EtO (or its metabolites) were permitted in foods imported into or produced in Australia.

Subsequently, an import company applied to the NRA for an emergency use permit for ethylene oxide on herbs and spices (Application No. 3589). This permit was granted on 20 April 2000 until 30 September 2001. The NRA subsequently made an application to ANZFA to have a maximum residue limit of 20 ppm for ethylene oxide in herbs and spices. The residue definition is ethylene oxide and does not include any metabolites.

Ethylene oxide is volatile and dissipates quickly during the first few days after treatment. Cooking further reduces the level of EtO. Residues of EtO, itself, therefore, would be expected to be low and the data available in Australia and New Zealand supports this position. EtO,

however, is also reactive and it readily forms the less toxic metabolites ethylene chlorohydrin and ethylene bromohydrin upon reaction with available chlorine and bromide, and higher levels of these residues are readily found in herbs and spices.

#### *Safety of EtO and its residues*

Ethylene oxide is regarded as a highly toxic chemical. It has been shown to cause cancer in experimental animals and has strong mutagenic activity in both bacterial and mammalian assays. It is currently in Schedule 7 of the Uniform Schedule of Drugs and Poisons and thus requires special precautions in manufacture, handling, storage and use. There is a significant potential risk to workers handling this chemical.

EtO reacts with available chlorine and bromide to form detectable residues of ethylene chlorohydrin and ethylene bromohydrin in treated food. The residues of EtO itself decrease rapidly (usually <20 ppm) but residues of chlorohydrin may persist for much longer periods (up to 1500 ppm). The available data indicates that ethylene chlorohydrin is significantly less mutagenic than EtO and, as such, presents a significantly reduced public health and safety risk. There is no mutagenicity data available on ethylene bromohydrin.

#### *Consideration of EtO in New Zealand*

In New Zealand, until recently, EtO has been permitted for use on herbs and spices under a food notice that permits residues of EtO of 50 ppm. There has been on-going concern regarding the use of EtO in New Zealand since 1993. Following consideration of a recent report entitled *Cancer Risk Assessment of Ethylene Oxide Residues in New Zealand Spices* prepared by the New Zealand Institute of Environmental and Scientific Research (ESR), the New Zealand Ministry of Health recommended an MRL of 20 ppm EtO residues in spices. This regulation came in force on 23 April 2000. This MRL does not include ethylene chlorohydrin.

The agreement between the Commonwealth of Australia and the Government of New Zealand, 1995 to establish a system for the development of joint food standards (the Treaty) excluded MRLs for agricultural and veterinary chemicals in food from the joint Australia New Zealand food standards setting system. Australia and New Zealand separately develop MRLs for agricultural and veterinary chemicals in food.

Following the commencement of the Trans Tasman Mutual Recognition Arrangement (TTMRA) between Australia and New Zealand on 1 May 1998:

- Food produced in Australia that complies with volume 1 (Standard A14) or Volume 2 (Standard 1.4.2) of the *Food Standards Code* can be legally sold in New Zealand; and
- Food produced in New Zealand that complies with the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard, 1999* can be legally sold in Australia.

#### *Progress of application*

Under section 37 of the *Australia New Zealand Food Authority Act 1991*, ANZFA may decide to progress an application as a matter of urgency in order to avoid compromising the objectives set out in section 10 (1)(a) of the Act which relate to the protection of public health and safety.

This application was progressed under section 37 in response to the NRA recommendation to establish a MRL for EtO following their issue of an Emergency Use Permit on 20 April 2000, for the use of EtO as a fumigant on herbs and spices. There is apparently no effective alternative to the use of EtO at this time in Australia.

Following completion of a Full Assessment Report, ANZFA made a recommendation to the Australia New Zealand Food Standards Council (ANZFSC) to permit the use of EtO. At the meeting on 28 July 2000, the Ministerial Council agreed to the draft variation to the standard to establish a MRL for EtO in herbs and spices. The date of gazettal, 17 August 2000, was agreed to be the date of implementation. The provision for the MRL will expire on 30 September 2001, which is the date of expiry of the Emergency Use Permit.

The current temporary MRL of 20 mg/kg is set at a level consistent with good agricultural practice and is supported by the conclusions of the scientific assessment which did not identify health risks associated with residues of EtO at the levels expected to occur in spices.

## **PUBLIC CONSULTATION**

As required under section 37, ANZFA released a Notification of Inquiry (on 29 November 2000), seeking public comment on the variation to Standard A14 – Maximum Residue Limits. The closing date for submissions was 10 January 2001.

### **Summary of submissions received**

A total of 6 submissions were subsequently received. A summary of these submissions is presented in Attachment 3. Except for the following comments, there were no issues raised by the submissions that had not previously been addressed in the Full Assessment Report.

#### *Use of ethylene oxide*

The majority of the submissions supported the establishment of the MRL of 20 mg/kg EtO in herbs and spices. In addition, most supported the continued use of EtO beyond the expiry date of 30 September 2001 on the grounds that there are no currently available alternative methods as effective for the fumigation of imported spices that may be contaminated with pathogenic microorganisms.

The submissions further state that the MRL, in conjunction with good agricultural practice, is sufficient to ensure negligible health risks from the continued use of EtO.

#### *Response*

Extension of the permission for use of EtO is the responsibility of the NRA. In the event that additional toxicological and residue data would support the continued use of this chemical, ANZFA will consider appropriate regulatory measures to ensure that good agricultural practice is maintained with respect to the microbiological decontamination of herbs and spices.

#### *Safety and the need for the use of ethylene oxide*

One submission, from the National Council of Women of Australia, expressed concerns about the safety of EtO and the need for its use, while acknowledging that the consumption of herbs and spices over a long period posed no apparent health risk to consumers. Strong sentiment was expressed in relation to the lack of public consultation and the decision to

progress the application under section 37 arrangements. However, no new issues that were not previously addressed by the Full Assessment Report were raised in the submission.

## **CHANGES TO THE DECISION RESULTING FROM THE INQUIRY**

There are no required changes to the variation to Standard A14 agreed by the Ministerial Council in July 2000, as a result of this inquiry. The variation adopted by the Ministerial Council is at Attachment 1.

## **CONCLUSIONS**

- The public submissions received in response to the Notification of Inquiry do not alter the validity of the recommendation to ANZFSC made previously.
- The establishment of a MRL of 20 mg/kg for ethylene oxide in herbs and spices, in parallel with the Emergency Use Permit issued by the NRA, provides assurance that herbs and spices may be treated for microbial contamination with negligible impact on public health and safety, and without affecting the quality of the product.
- The variation to Standard A14 – Maximum Residue Limits made under section 37 should remain effective until 30 September 2001.

## **WORLD TRADE ORGANIZATION (WTO) NOTIFICATION**

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter does not need to be notified to the WTO as a Sanitary or Phytosanitary (SPS) notification because it does not impact on human or animal health or a Technical Barrier to Trade (TBT) as it is not expected to significantly impact on trade of other member nations.

## **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*.

## **FURTHER INFORMATION**

**Submissions:** No submissions on this matter are sought as the Authority has completed its assessment of the matter and affirmed the variations to standards previously made .

**Further information** on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the following addresses:

PO Box 7186  
Canberra Mail Centre ACT 2610  
AUSTRALIA  
Tel (02) 6271 2258  
Email: [slo@anzfa.gov.au](mailto:slo@anzfa.gov.au)

PO Box 10559  
The Terrace WELLINGTON 6036  
NEW ZEALAND  
Tel (04) 4739942  
Email: [anzfa.nz@anzfa.gov.au](mailto:anzfa.nz@anzfa.gov.au)

Requests for copies of the full Inquiry Report or other information papers should be addressed to the Authority's Information Officer at the above address, or Email [info@anzfa.gov.au](mailto:info@anzfa.gov.au)

### **Attachments**

1. Variation to Standard A14
2. Statement of Reasons
3. Summary of Public Submissions

VARIATION TO THE AUSTRALIAN FOOD STANDARDS CODE

APPLICATION A412

MAXIMUM RESIDUE LIMIT FOR ETHYLENE OXIDE IN HERBS AND SPICES

**Explanatory note:** This is a new MRL for an agricultural chemical not previously listed in Standard A14.

**To commence:** On gazettal

*Standard A14 is varied by inserting in column 1 of Schedule 1 the chemical (shown in bold type) and inserting in column 1 and 2 respectively of Schedule 1 the food and maximum residue limit for that food, listed below -*

<b>Chemical</b>	
Food	MRL
<b>Ethylene oxide</b>	
Herbs	20
Spices	20
The MRLs for ethylene oxide cease to have effect on 30 September 2001	



**STATEMENT OF REASONS**

**APPLICATION A412**

**MAXIMUM RESIDUE LIMIT FOR ETHYLENE OXIDE IN HERBS AND SPICES**

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ANZFA decided, pursuant to section 37 of the *Australia New Zealand Food Authority Act 1991*, to progress this application as a matter of urgency in order to avoid compromising the objective set out in subsection 10(1)(a) of the Act, namely the protection of public health and safety. Accordingly, ANZFA completed a full assessment of the application, prepared draft variations to Standard A14 – Maximum Residue Limits of the Australian *Food Standards Code* and made recommendations to the Australia New Zealand Food Standards Council (ANZFSC)

In July 2000, the Ministerial Council agreed to adopt the variation to the standard for the following reasons:

- The application for the MRL for EtO was made by the NRA after the granting of an Emergency Use Permit for fumigant use of EtO on herbs and spices on 20 April 2000.
- The use of EtO on herbs and spices is required to reduce microbial contamination. Effective alternative decontamination methods are not yet available.
- The MRL of 20 mg/kg is set at a level consistent with good agricultural practice.
- On the basis of the report entitled *Cancer Risk Assessment of Ethylene Oxide Residues in New Zealand Spices* prepared by the New Zealand Institute of Environmental and Scientific Research (ESR), there is negligible public health and safety risks to consumers from EtO residues in spices.
- The MRL is due to expire on 30 September 2001, which is the date of expiration of the Emergency Use Permit.

There are no additional issues arising from this Inquiry that would justify amendment to the Ministerial Council decision in July 2000, which established the temporary MRL. Any extension to the Emergency Permit to use EtO beyond the expiry date is the responsibility of the NRA. ANZFA would give appropriate consideration to the need for regulatory measures able to be supported by additional scientific assessment of toxicological and monitoring data.

## **SUMMARY OF PUBLIC SUBMISSIONS**

The Statement of Reasons – Notification of Inquiry for application A412 was advertised for public comment on 29 November 2000 for a period until 10 January 2001. A total of 6 submissions were received and are summarised below.

### **Action for Environment inc. (New Zealand)**

- Acknowledges that while ethylene oxide poses some hazards, its use in herbs and spices is preferred over other possible methods for example, irradiation.
- Claims that there is little justification for this application to be processed as a matter of urgency and that the use of ethylene oxide does not present any clear or urgent threat to public health and safety. Consequently, disagrees with the phasing out of the permission for its use.
- Supplied technical information in relation to the use of ethylene oxide.

### **Australian Food and Grocery Council**

- Supports approval of the maximum residue limit for ethylene oxide in herbs and spices of 20 mg/kg, and being consistent with good agricultural practice
- Disagrees with the limited time permission (until 30 September 2001) on the grounds that once safety is established through GAP and the MRL, approval should stand indefinitely, alongside other methods for the treatment of herbs and spices.

### **Australian Self-Medication Industry**

- No concerns raised in response to the proposal. However, expressed a desire to provide comment following a meeting between TGA/Industry Joint Herbal Task Force in February 2001.

### **National Council of Women of Australia**

- Considers that ANZFA has provided no reasons to explain why ethylene oxide is used in herbs and spices
- Expresses concerns on the safety of ethylene oxide
- Considers that the report on ethylene oxide implies that approval for the use of irradiation methods for herbs and spices is a foregone conclusion, and disagrees with approval for irradiation
- States that the public consultation process in relation to this application is a farce.

### **Food and Beverage Importers Association**

- Supports the application for a MRL of 20 mg/kg for ethylene oxide in herbs and spices
- Expresses no health concerns and states that there is a technical need for its use
- Notes that the recommended permission for the use of ethylene oxide expires on 30 September 2001, and states that the arrival of an alternative treatment method is not sufficient reason to impose a limited approval time.

### **Food Technology Association (Victoria)**

- Expresses supports for the application without further comment.