Clout, Lisa

From: Clout, Lisa
Sent: Thursday, 22 September 2011 4:27 PM
To: FOI
Subject: FW: re antibiotics in seafood issue [SEC=IN-CONFIDENCE]

Classification: IN-CONFIDENCE

IN-CONFIDENCE

From: Butow, Barbara
Sent: Tuesday, 17 July 2007 5:09 PM
To: 'Ian McKay'
Cc: PLO; Brent, Paul
Subject: re antibiotics in seafood issue [SEC=IN-CONFIDENCE]

Hello Ian,
Further to last weeks CIB on "Antibiotics in Seafood" we have been asked to provide some words for AQIS to include in a minute to their Minister (as follows):

FSANZ is not in a position to definitively advise on the risk to public health and safety of the residues at this time. However, based on the low levels (ppb amounts), the residues are unlikely to represent a significant risk to public health and safety. In addition, the possible health risk due to antimicrobial resistance would need to be considered by the NHMRC, so FSANZ cannot advise on this issue.
On the basis of the limited data, FSANZ would support AQIS obtaining more information on the use of these chemicals in other countries and having this information considered collectively with the States and Territories, and other agencies. This will enable a comprehensive, risk-based, defendable strategy to be developed for ensuring that that all imported seafood complies with the *Australia New Zealand Food Standards Code.*

Please phone me if you have any further questions.

Kind regards,
Barbara

Dr Barbara Butow,
Food Safety Section,
Food Standards Australia New Zealand,
PO Box 7186,
Canberra,
ACT 2610

Tel: 61 2 62712283

Barbara.Butow@foodstandards.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Office of the Chief Executive Officer

Ms Rona Mellor
Deputy Secretary and
Executive Director
Australian Quarantine and Inspection Service
GPO Box 858
CANBERRA ACT 2601

Dear Rona

Thank you for your letter of 3 September 2010 regarding the discussion of the management of food safety risks associated with the import of apples potentially treated with antibiotics and other chemicals.

As you pointed out, fresh fruit and vegetables are currently classified by Food Standards Australia New Zealand (FSANZ) as low risk, or surveillance food, as categorised by the Australian Quarantine and Inspection Service (AQIS). At the inter-agency meeting on 25 August 2010, the risk of development of antimicrobial resistance from the use of antibiotics in agriculture was discussed and we can confirm that we have had preliminary discussions with the National Health and Medical Research Council regarding further work on this emerging issue. This would build on the investigation on the presence of antimicrobial resistance carried out under the Food Regulation Standing Committee in 2007.

In the upcoming months, FSANZ will address this emerging issue by reviewing the use of antimicrobials in imported apples and undertake a risk assessment to establish whether there are any potential food safety issues.

FSANZ will also collate information on the general processes and timelines involved in setting maximum residue levels for chemicals, monitoring domestic compliance and setting of import sampling and testing protocols.

~~A questions and answer information sheet will also be developed by FSANZ, in liaison with~~ the Department of Agriculture, Fisheries and Forestry, with regard to present arrangements and areas for potential improvement.

We will be happy to arrange a follow-up meeting involving all agencies within the month.

Yours sincerely

Steve McCutcheon
Chief Executive Officer

6 September 2010

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel +61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Office of the Chief Executive Officer

Ms Rona Mellor
Deputy Secretary and
Executive Director
Australian Quarantine and Inspection Service
GPO Box 858
CANBERRA ACT 2601

Dear Ms Mellor

I refer to your letter of 1 September 2010, regarding discussion of the management of food safety risks associated with the import of apples and other fresh fruit and vegetables potentially treated with antibiotics.

Further to my interim response sent on 6 September 2010, this letter provides an inter-agency co-ordinated response from Food Standards Australia New Zealand's (FSANZ) consultations with the Australian Quarantine and Inspection Service (AQIS), the Department of Agriculture, Fisheries and Forestry (DAFF), and the Australian Pesticide and Veterinary Medicines Authority (APVMA) on the three points outlined in your letter.

1. FSANZ to undertake a risk assessment for antibiotic residues in fresh fruit based on good agricultural practice overseas, with a view to advising DAFF whether to include specific antibiotics in the current testing regime for apples or other fresh fruits and vegetables. This should be commenced forthwith.

FSANZ has commenced risk assessments to establish whether residues of gentamycin and streptomycin in imported apples may pose a risk to human health. In addition, FSANZ is working with the National Health and Medical Research Council and clinical experts on antimicrobial resistance issues, including whether the use of antibiotics on fruit could promote an increase in antibiotic resistant pathogens that may present a risk to human health. It is anticipated that initial scoping of this work will be complete by the first quarter of 2011.

2. FSANZ to provide, for low risk and medium to high risk foods, information on the general processes and timelines involved in the setting of maximum residue levels for chemicals not currently covered in the Australia New Zealand Food Standards Code (the Code), monitoring of domestic compliance, and setting of import sampling and testing protocols. The goal of collating this information is to make clear the differences in the way each category of food is assessed and managed.

i) The FSANZ processes for considering the inclusion maximum residue limits (MRLs) in the Code are the same for low, medium and high risk imported foods. FSANZ may

consider new MRLs for inclusion in the Australia New Zealand Food Standards Code (the Code) through raising a Proposal or through assessment of an Application.

Proposals are generally raised in response to decisions made by the APVMA to register chemicals and promulgate MRLs for various food commodities used domestically in the production and/or processing of food. A Proposal may also address industry or other regulatory agency requests to seek recognition of Codex MRLs or exporting country MRLs for foods imported into Australia. FSANZ may receive a paid Application from industry or another party formally applying for the MRL standard in the Code to be amended.

The process for including MRLs in the Code involves: public notification that a Proposal has been raised or an Application is being considered, assessment of the Proposal (including conducting a dietary risk assessment), preparation of a draft food regulatory measure (or MRL for inclusion in the Code), public consultation on the draft regulatory measure, approval of the draft food regulatory measure and notifying the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) of the approved food regulatory measure[1].

In accordance with the *FSANZ Act 1991*, FSANZ is required to complete its assessment of Applications for MRLs either within 9 months (GENERAL Procedure) or 12 months (MAJOR Procedure) and this does not include approximately 6 – 8 weeks of preparatory work. For MRL-related Proposals, FSANZ does not have a statutory timeframe to complete its assessment, however the same timeframes that apply for Applications are established for reporting and planning purposes. FSANZ considers both paid and unpaid Applications, noting work on paid Applications commences earlier than for unpaid Applications.

ii) The State and Territory Governments and AQIS share responsibility for enforcing MRLs for all food available for sale, including both imported and domestically produced food. The domestic compliance with MRL levels is monitored through individual State and Territory residue monitoring programs. Additional monitoring of residues occurs through Component 1 of the Implementation Sub Committee National Coordinated Food Surveillance and Monitoring Program specifically, The Australian Total Diet Survey. Other Australian Government programs such as the National Residue Survey also monitor residue levels particularly in exported foods and MRLs are under constant review as part of the APVMA Chemical Review Program.

iii) As you are aware, the import sampling and testing protocols for surveillance (low risk) foods, including fruit and vegetables, are currently determined by AQIS on the basis of advice provided by FSANZ in accordance with the Memorandum of Understanding between FSANZ and AQIS which was reviewed in 2007. However, FSANZ and AQIS are currently commissioning an independent review of the arrangements for advising on the monitoring, inspection and testing regimes under the Imported Food Inspection Scheme (IFIS). This review will include consideration of appropriate measures and procedures for the management of risks associated with agricultural and veterinary chemical residues on foods imported into Australia.

---

[1] Noting that a new approach has been proposed: (i) that ANZFRMC will no longer decide on APVMA MRLs and (ii) other MRLS will continue to be processed such that ANZFRMC is the final decision maker.

3. Jointly develop questions and answers covering issues that are likely to be raised, in order to test the robustness of the present arrangements and if necessary, to identify areas of improvement.

Please find attached a set of questions and answers (Q&A) that have been drafted by FSANZ in consultation with AQIS, APVMA and Biosecurity Australia. The Q&A investigates the import of fruit and vegetables into Australia, the IFIS, use of chemicals in fruit and vegetable production, and the use of antibiotics in fruit and vegetable production. Comments on the robustness of the present arrangements at the border have not been included in the Q&A as the independent review will make recommendations on areas for improvement.

I await your advice on whether you think a follow up meeting between FSANZ, DAFF, the Australian Government Attorney-General's Department, and the Department of Foreign Affairs and Trade will be required.

Yours sincerely

Steve McCutcheon
Chief Executive Officer

17 November 2010

1. Import of fruit and vegetables into Australia

1.1 What is the risk assessment process for allowing fruit and vegetables to be imported into Australia?

When Australia receives a market access request from another country to allow the import of a plant or plant product, Biosecurity Australia undertakes an import risk analysis (IRA). An IRA is a thorough, science-based analysis of the quarantine risks associated with a particular product. Australia's IRA process is specified in the Quarantine legislations and detailed in the *Import risk analysis handbook 2007 (update 2009)*, which is available on the Biosecurity Australia website at www.daff.gov.au/ba. Briefly, the process is transparent and subject to independent scrutiny, including comments by the public, review by the Eminent Scientists Group and the Import Risk Analysis Appeals Panel. These checks and balances have been implemented to ensure that quarantine decisions are scientifically sound and based on the highest standards of administrative practice. The regulated IRA process must be strictly followed by Biosecurity Australia.

Under the current Memorandum of Understanding (MoU), Food Standards Australia New Zealand (FSANZ) provides the Australian Quarantine and Inspection Service (AQIS) with risk assessment advice in relation to foods which pose a medium to high risk to public health. FSANZ uses specific criteria for risk list assessments. The Australian Customs Service refers 100% of risk category foods to AQIS for inspection and testing against a published list of potential hazards determined by FSANZ. Food is automatically categorised as 'surveillance' if it is not categorised as 'risk' i.e. if it is low risk food.

The arrangement between FSANZ and AQIS in relation to the provision of risk assessment advice for foods in all categories is currently under review and both agencies are working closely together on improving the overall imported food surveillance program.

1.2 Are the risks associated with chemical and antimicrobial residues assessed in the biosecurity import risk assessment?

No

1.3 How is the use of chemicals and antimicrobials in countries that export fruit and vegetables to Australia monitored?

Use of chemicals overseas isn't monitored. FSANZ and other government agencies in Australia and New Zealand monitor the food supply to ensure that it is safe, and that foods comply with standards for microbiological contaminants, pesticide residue limits and chemical contamination. They also monitor food safety incidents worldwide. If FSANZ becomes aware of concerns about possible residues in imported foods and assesses the risk of that food as a medium or high risk, they can advise AQIS who can elevate inspection and testing of that food for that chemical to the risk category.

Food imported into Australia is subject to the Imported Food Control Act. Inspection of imported food occurs under the Imported Food Inspection Scheme (IFIS). Fresh fruit and

vegetables are classified by FSANZ as low risk foods and consignments have a 5% chance of being referred for a inspection by AQIS. When referred they are tested for 49 pesticide residues. The chemicals tested for are based on their greater public health significance.

1.4 How can imported fruit or vegetables be traced back to their country and region of production?

All imported fresh fruit and vegetables must be accompanied by a phytosanitary certificate from the exporting country. This contains information which allows the traceback of product to the country and region of production.

2. The Imported Food Inspection Scheme (IFIS)

2.1 How does the Imported Food Inspection Scheme work?

Foods imported into Australia must comply with the requirements of both the *Quarantine Act 1908* and the *Imported Food Control Act 1992 (IFCA)*. The enforcement of the legislative requirements in the Act is implemented through the Australian Government's Imported Food Inspection Scheme (IFIS). All food available for sale in Australia, including imported food, must comply with the *Australia New Zealand Food Standards Code* (the Code).

FSANZ provides risk assessment advice in relation to food which poses a high or medium risk to public health and AQIS then 'risk' categorise this food and determines a food's inspection regime. The types of foods that are categorised as risk foods are listed on the 'risk list' and include foods such as meat, seafood and dairy produce. AQIS has operational responsibility for inspecting food for compliance with the Code and this can include sampling and testing of imported food at the border.

Rates of inspection of foods under the IFIS are risk-based and focus on foods with food safety concerns, with higher rates of inspection applying to foods with the potential for the greatest risk to public health. When food is imported into Australia, it is placed into one of two inspection categories: risk or surveillance.

The Australian Customs Service refers 100% of risk category foods to AQIS for inspection and testing against a published list of potential hazards published in Imported Food Notices. Risk category foods are initially inspected and tested at a rate of 100%. Once five consecutive consignments have passed inspection, the rate is reduced to 25%; after a further 20 consecutive passes, the rate is further reduced to 5%. Regardless of the manufacturer's history of compliance, any consignments that fail will increase the rate of inspection and testing until a history of compliance is re-established.

Food is automatically categorised as 'surveillance food' if it is not categorised as 'risk' and 5% of all consignments of random surveillance foods are referred to AQIS for inspection. The inspection rate for surveillance food that fails inspection is increased to 100 per cent until a history of compliance is established for the producer or importer of the food. The process for increasing inspection of surveillance food is referred to as applying a Holding

Order. A holding order remains in place until favourable test results are received (following five consecutive passes), then the rate of referral returns to 5 per cent of consignments.

AQIS and FSANZ are currently commissioning an independent expert review of the arrangements for determining the monitoring, inspection and testing regimes for foods categorised as surveillance foods[2] under the *Imported Food Control Act 1992*. This review will consider appropriate measures and procedures for the management of risks associated with agriculture and veterinary chemicals residues on foods imported into Australia which are monitored and inspected under the Imported Food Inspection Scheme (IFIS).

2.2 How does FSANZ provide AQIS with advice on the low, medium and high risk category foods?

There is a MoU between FSANZ and AQIS that reinforces the cooperative partnership that exists between the two agencies in managing Australia's IFIS. The MoU describes FSANZ's role in providing risk assessment advice to AQIS, and AQIS's role in enforcement and operational policy. The current MoU states that FSANZ provides risk assessment advice in relation to medium to high risk foods (i.e. the 'risk' category), while AQIS determines enforcement and inspection priorities for low to medium risk foods in the 'random surveillance' category.

FSANZ provides risk assessment advice to AQIS in response to emerging food safety issues for which there may be a risk to public health and safety. Emerging food safety issues may be identified through testing of foods by State and Territory enforcement agencies under the national Food Surveillance Program, through notification of food safety issues being experienced in international countries that export food to Australia, and through the testing of imported food by AQIS under the IFIS.

2.3 What category do fruit and vegetables fall into?

Imported fresh fruit and vegetables are surveillance category foods. Upon arrival in Australia 5% of fruit and vegetables are referred to AQIS for inspection and possible testing.

2.4 What chemicals are tested for on imported foods?

When referred imported fresh fruit and vegetables are tested for the 49 pesticide residues identified as having potential public health implications. If they fail inspection, their inspection rate increases to 100% until compliance history has been demonstrated in 5 consecutive consignments. Tests applied to imported foods are listed at Attachment 1.

2.5 Are there any food/residue combinations on the risk list?

In general, chemical residues do not pose a medium to high risk public health and safety and thus with few exceptions, FSANZ have not advised AQIS they pose a medium-high risk. The majority of foods on the risk list are meat, seafood and dairy food products subject to

[2] All foods that are not categorised as 'risk' foods fall into this category.

microbiological testing; fish and seafood mixes are also tested for natural histamines and toxins.

Other food/hazard combinations include coconut, sesame seeds and pepper, which are all tested for *Salmonella*. Also, peanuts and pistachios and products that contain them like sauces are tested for aflatoxins, seaweed is tested for inorganic arsenic and iodine and ready to eat cassava chips are tested for hydrocyanic acid.

2.6 Do AQIS test for agricultural and veterinary chemical residues for products that are illegal in Australia?

Yes, some of the pesticides AQIS screens for are not permitted for use in Australia. These chemicals include Aldrin, DDT(Dichloro-Diphenyl-Trichloroethane), Dieldrin, Endrin, Heptachlor epoxide. These chemicals are listed as 'persistent organic pollutants' under the Stockholm Convention. The Stockholm Convention on Persistent Organic Pollutants came into force on 17 May 2004, with Australia ratifying the Convention on 20 May 2004 and becoming a Party on 18 August 2004.

2.7 Why does AQIS only test for the chemicals listed in Attachment 1 and why doesn't FSANZ suggest AQIS test for more chemicals?

The imported food inspection scheme does cover all foods but the level of testing is risk based. As it is a cost recovered scheme with importers paying for compliance testing, it is not feasible or cost effective to test for chemicals where it has been estimated there would be a low likelihood of exposure or where there are no triggers for safety concerns.

If FSANZ becomes aware of concerns about possible residues in imported foods and assesses the risk of that food as a medium to high risk, FSANZ advises AQIS so that they can take action at the border.

Imported food is also monitored in surveys done domestically by food regulators under the Food Surveillance Network. If issues are identified with a food product, state and territory regulators can take action on those foods as they have responsibility for all foods at point of sale.

2.8 How could fruit and vegetables be subject to more testing at the border?

If FSANZ or AQIS becomes aware of concerns about possible food safety issues related to imported fruit and vegetables, FSANZ will conduct a risk assessment to assess the risk the fruit or vegetables pose. FSANZ may advise that the fruit or vegetables are medium to high risk in which case AQIS may decide to elevate the food to the risk category where 100% of the fruit or vegetable of concern are referred to AQIS for testing.

3. The use of chemicals in food production

3.1 Why are chemicals used in food production?

Farmers may use chemical products, such as pesticides and veterinary medicines, to control pests and diseases. This helps them produce wholesome foods from healthy plants and animals. Farmers around the world may use chemicals differently as pests and diseases, climate, and agricultural methods differ between countries.

3.2 What is a Maximum Residue Limit (MRL)?

Residues of agricultural and veterinary chemicals are permitted in certain foods provided that they comply with specific limits in the Code. These limits are known as maximum residue limits or MRLs, and apply to both domestic and imported foods. The MRL is the highest amount of a residue of a particular chemical that may occur in a food following the proper use of that chemical.

The APVMA determines the residue level which would be present if a farmer used the greatest amount of the chemical likely to be necessary to do its job, and then determines whether this level is safe by comparing expected residues with health standards established by the Department of Health and Aging. Thus, MRLs are set to reflect the legal use of a chemical and to ensure public health and safety.

3.3 How does the government make sure that the chemicals used in food are safe?

In Australia, FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA) work together to comprehensively assess the safety of chemicals used in food production and any residues of these chemicals that may occur in food.

APVMA sets the conditions of use for chemical products and registers chemicals for use in Australia. The APVMA conducts dietary exposure assessment to ensure that chemicals used in food production are safe and effective and that any residues that may occur in food are below standards set to protect human health. The APVMA will set an MRL for the highest amount of a residue of a particular chemical that may occur in a food following the proper use of that chemical. No chemical may be used for food production unless the foods produced using the chemical are safe for people to eat.

Currently, the APVMA notifies FSANZ that a chemical has been permitted for use in Australia and advises FSANZ that an MRL has been established for that chemical. FSANZ will review the dietary exposure assessment conducted by the APVMA and if FSANZ agrees with the assessment and the established MRL, FSANZ will raise a Proposal for the MRL to be included in the Code. However, from next year these arrangements will change. FSANZ will continue to review the dietary exposure assessments but new MRLs will be automatically adopted into the Code.

A chemical company, importing country or other applicant may apply to FSANZ for an MRL to be included in the Code in situations where a chemical is legitimately permitted for use

overseas and an MRL has been establish for use internationally. In these situations FSANZ may consider the MRLs for inclusion in the Code. However FSANZ will still conduct a dietary exposure assessment of the chemicals to ensure that any residues that may occur in food are below standards set to protect human health.

FSANZ and the APVMA review the exposure of consumers to chemical residues according to international best practice methods. The assessments examine the total amount of a particular chemical which may be present in foods in Australia, to make sure that the total amount a person is exposed to is safe.

FSANZ will not permit an MRL to be included in the Code for a chemical residue for a chemical that would pose a risk to public health and safety. When an MRL is exceeded, it usually indicates a chemical is being misused. However, MRLs are normally set well below the level that would be harmful, so a residue slightly above the limit is unlikely to pose a health risk.

3.4 Why are specific chemicals approved for use overseas but are not permitted for use in Australia?

Some chemicals are permitted for use in other overseas countries but are not permitted for use in Australia. There are a number of reasons for this, including; the crop they are used on overseas may not be grown Australia, the pest the chemical is used to control may not be present in Australia or a chemical company may make an economic decision not to apply for a chemical to be registered in Australia.

3.5 Does Australia have more residues in food than say, food in Europe?

Making international comparisons can be difficult as many factors must be considered. These include climate, types and prevalence of pests, and agricultural production methods. Australia has a temperate climate and many of our animals are grass-fed and live outdoors all year. We have a mixture of some pests from warmer and wetter climates and some from cooler and drier environments.

Seasons also vary, and this can have an effect on the types and numbers of pests in the environment (just as it does with non-pest insects and plants). This difference in pest types and numbers means the range and usage of agricultural compounds will also be different.

The important thing in any country is to ensure that agricultural compounds are used responsibly. This means following good agricultural practice and the requirements of use, such as withholding periods.

In Australia our comprehensive testing program provides us with confidence that the level of residues in food is very low. For example, the 19th, and 20th Australian Total Diet Surveys revealed the levels of pesticide residues and contaminants in all cases were within acceptable safety limits where reliable dietary exposure estimates could be calculated.

The European Union published an Annual Report on Pesticide Residues in 2010 which provided an overview of pesticide residues in food in the European Union during 2008. The report revealed that 96.5% of the food samples analysed complied with the MRLs of pesticides permitted for food products in the EU.

3.6 How are levels of residues of chemicals in food monitored and enforced?

Regulatory agencies monitor health, agricultural and environmental issues associated with chemical product use. The use of chemical products and MRLs are under constant review as part of the APVMA Chemical Review Program. Residues in food are monitored through State and Territory monitoring activities.

FSANZ monitors the food supply to ensure that existing food regulatory measures adequately protect consumer health and safety. Pesticide residues in the food supply are assessed in diet studies such as the Australian Total Diet Study. These studies estimate dietary exposure to a range of pesticide residues and contaminants and have consistently shown that the residues of chemicals in foods sold in Australia (whether domestically produced or imported) are well below levels that ensure consumer safety.

For imported food, fresh fruit and vegetables, being low risk foods, have a 5% chance of being referred for inspection by AQIS. When referred they are tested for residues of 49 agricultural chemicals. The chemicals tested for are based on their public health significance.

State and Territory Governments also share responsibility for enforcing MRLs for all food available for sale, including both imported and domestically produced food.

3.7 What about imported food from New Zealand?

Most food from New Zealand is not subject to inspection at the border and can legally contain residues according to New Zealand's own residue standard.

Australia and New Zealand independently develop standards for chemical residues in food to suit their different environments and crops and livestock farmed. The New Zealand Government enforces its own chemical residue levels in food sold in New Zealand. However, the Governments of Australia and New Zealand have agreed as part of the Trans Tasman Mutual Recognition Arrangement (TTMRA) that food produced in New Zealand that complies with New Zealand's chemical residue standards may be sold in Australia, and food produced in Australia under Australian standards may be sold in New Zealand. These foods are exempt from inspection at the border for compliance with food standards.

4.0 The use of chemicals in fruit and vegetable production

4.1 What happens if a chemical of concern is identified in food which may be imported and there is no MRL in the FSC?

RAPID ALERT SYSTEM FOR FOOD AND FEED

The current legal basis of the system is Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (O.J. No L 31 of 1 February 2002). The purpose of the rapid alert system for food and feed (RASFF) is to provide the control authorities with an effective tool for exchange of information on measures taken to ensure food safety.

To assist the members of the network, information is classified under two different headings :

- ALERT NOTIFICATIONS
  Alert notifications are sent when the food or feed presenting the risk is on the market and when immediate action is required. Alerts are triggered by the Member State that detects the problem and has initiated the relevant measures, such as withdrawal/recall. The notification aims at giving all the members of the network the information to verify whether the concerned product is on their market, so that they also can take the necessary measures.

  Consumers can be reassured that products subject to an alert notification have been withdrawn or are in the process of being withdrawn from the market. The Member States have their own mechanisms to carry out such actions, including the provision of detailed information through the media if necessary.

- INFORMATION NOTIFICATIONS
  Information notifications concern a food or feed for which a risk has been identified, but for which the other members of the network do not have to take immediate action, because the product has not reached their market. These notifications mostly concern food and feed consignments that have been tested and rejected at the external borders of the EU.

  Consumers can be reassured that products subject to an information notification have not reached the market or that all necessary measures have already been taken.

The Commission is now publishing a weekly overview of alert and information notifications. In doing so, it is necessary to strike the balance between openness and protection of commercial information. Therefore trade names and the identity of individual companies are not published. This way of proceeding is not detrimental to consumer protection, as a RASFF notification implies that measures have been or are in the process of being taken. The public must be aware that the Commission is not in a position to give more information than what is published here. However, in circumstances where the protection of human health requires greater transparency, the Commission takes the necessary actions through its usual communication channels.

WEEK 2003/43

TABLE 1: ALERT NOTIFICATIONS

Notifications in blue typeface concern feed, all other notifications concern food.

DATE:	NOTIFIED BY:	REF. :	REASON FOR NOTIFYING:	COUNTRY OF ORIGIN:
20/10/2003	FRANCE	2003.331	Salmonella typhimurium in eggs	FRANCE
20/10/2003	BELGIUM	2003.332	colour Sudan 1 in cayenne powder containing contaminated paprika powder	SPAIN
21/10/2003	ITALY	2003.333	Salmonella typhimurium in frozen pork preparations	SPAIN
21/10/2003	GERMANY	2003.334	cypermethrin and Piperonylbutoxide in sheep/goat casings	IRAN
21/10/2003	ITALY	2003.335	Salmonella in pork shoulder	GERMANY
22/10/2003	SWEDEN	2003.336	Salmonella in salted pork meat (frying bacon)	DENMARK
23/10/2003	FINLAND	2003.337	Salmonella Gold Coast in pork hips	GERMANY
23/10/2003	FRANCE	2003.338	Escherichia coli, Staphylococcus aureus, aerobic mesophiles and Clostridium perfringens in game meat	UNITED KINGDOM
23/10/2003	GERMANY	2003.339	colour Sudan 1 in Tandoori masala	UNITED KINGDOM; INDIA
24/10/2003	ITALY	2003.340	Listeria monocytogenes in smoked salmon	DENMARK
24/10/2003	GERMANY	2003.341	Listeria monocytogenes in frozen profiteroles	BELGIUM
24/10/2003	GERMANY	2003.342	Salmonella in deep frozen fish mousse	VIETNAM

TABLE 2: INFORMATION NOTIFICATIONS

Notifications in blue typeface concern feed, all other notifications concern food.

DATE:	NOTIFIED BY:	REF. :	REASON FOR NOTIFYING:	COUNTRY OF ORIGIN:
20/10/2003	UNITED KINGDOM	2003.CBN	colour Sudan 1 in nehari masala	THE UNITED ARAB EMIRATES; PAKISTAN
20/10/2003	ITALY	2003.CBO	aflatoxins in pistachios in shell	IRAN
20/10/2003	ITALY	2003.CBP	aflatoxins in pistachios in shell	IRAN
20/10/2003	ITALY	2003.CBQ	aflatoxins in pistachios in shell	IRAN
20/10/2003	ITALY	2003.CBR	aflatoxins in pistachios in shell	IRAN
20/10/2003	ITALY	2003.CBS	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CBT	aflatoxins in pistachio kernels	IRAN
20/10/2003	GERMANY	2003.CBU	aflatoxins in pistachio kernels	IRAN
20/10/2003	GERMANY	2003.CBV	aflatoxins in pistachio kernels	IRAN
20/10/2003	GERMANY	2003.CBW	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CBX	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CBY	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CBZ	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CCA	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CCB	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CCC	aflatoxins in pistachios in shell	IRAN
20/10/2003	GERMANY	2003.CCD	aflatoxins in pistachios in shell	IRAN
20/10/2003	ITALY	2003.CCE	chromium in table knives	CHINA
21/10/2003	SPAIN	2003.CCF	cadmium in frozen cuttlefish	CHINA
21/10/2003	UNITED KINGDOM	2003.CCG	colour Sudan 1 in canned meat products (containing contaminated chilli)	UNITED KINGDOM
21/10/2003	SPAIN	2003.CCH	cadmium in frozen squid	CHINA
21/10/2003	DENMARK	2003.CCI	irradiation of dietary supplement-ginger capsules	THE UNITED STATES

DATE:	NOTIFIED BY:	REF. :	REASON FOR NOTIFYING:	COUNTRY OF ORIGIN:
21/10/2003	SPAIN	2003.CCJ	nitrofuran (metabolite) - nitrofurazone (SEM) in frogs' legs	INDONESIA
21/10/2003	GERMANY	2003.CCK	dioxins in Copper-(II)-Oxide - CUO	MALAYSIA
21/10/2003	GERMANY	2003.CCL	colour Sudan 1 in spice mix	INDIA
22/10/2003	GERMANY	2003.CCM	aflatoxins in dried fig paste	TURKEY
22/10/2003	GERMANY	2003.CCN	aflatoxins in pistachios in shell	IRAN
22/10/2003	GERMANY	2003.CCO	aflatoxins in pistachios in shell	IRAN
22/10/2003	PORTUGAL	2003.CCP	Listeria monocytogenes in frozen boneless beef and veal	BRAZIL
22/10/2003	GERMANY	2003.CCQ	aflatoxins in pistachios in shell	IRAN
22/10/2003	GERMANY	2003.CCR	aflatoxins in pistachios in shell	IRAN
22/10/2003	GERMANY	2003.CCS	aflatoxins in pistachios in shell	IRAN
22/10/2003	NETHERLANDS	2003.CCT	aflatoxins in groundnut kernels	ARGENTINA
22/10/2003	GERMANY	2003.CCU	sulphur dioxide in dried apricots	TURKEY
22/10/2003	UNITED KINGDOM	2003.CCV	Salmonella in tahini	CYPRUS
23/10/2003	SPAIN	2003.CCW	total Enterobacteriaceae in cuttlefish	INDONESIA
23/10/2003	GREECE	2003.CCX	sulphonamides sulphamerazine in mixed flower honey	BULGARIA
23/10/2003	GREECE	2003.CCY	sulphonamides sulphamethazine, sulphonamides sulphamethoxine, sulphonamides sulphathiazole and streptomycin in mixed flower honey	BULGARIA
23/10/2003	GREECE	2003.CCZ	sulphonamides sulphamerazine in mixed flower honey	BULGARIA
23/10/2003	ITALY	2003.CDA	insufficient labelling of Plastic objects for food	CHINA
23/10/2003	ITALY	2003.CDB	ochratoxin A in cocoa powder	THE NETHERLANDS
24/10/2003	ITALY	2003.CDD	migration in enamelled cast-iron teapots	CHINA
24/10/2003	ITALY	2003.CDE	absence of sanitary certificate for Brazil nuts	BRAZIL
24/10/2003	NETHERLANDS	2003.CDF	polycyclic aromatic hydrocarbons in hangover formula	THE UNITED STATES
24/10/2003	SPAIN	2003.CDG	chloramphenicol and tetracycline - hydrochloride in honey	VIETNAM
24/10/2003	SPAIN	2003.CDH	aerobic mesophiles in frozen baby octopus	INDIA
24/10/2003	FRANCE	2003.CDI	Salmonella in Cynoglossus cynoglossus	SENEGAL
24/10/2003	FRANCE	2003.CDJ	Salmonella in frozen pawns tails	BANGLADESH

Attachment 1

Testing Protocol under the FS

(a) Tests applied to imported foods.

Food	Tests	Code
Meat (Beef, Pork, Sheep, Goat, Offal, Pig & Poultry fat; salted, dried or smoked meat and offal)	Pesticide screen	1.4.2
Fish (including fresh, salted, dried or cooked)	Malachite Green Fluoroquinolones	1.4.2
Crustaceans	Nitrofurans Fluoroquinolones	1.4.2
Butter and other milk fats	Pesticide screen	1.4.2
Honey	Pesticide screen Chloramphenicol Nitrofurans Streptomycin Tetracycline Sulphonamides	1.4.2
Vegetables (Fresh, chilled, frozen)	Pesticide screen Cadmium	1.4.2 1.4.1
Vegetables (Dried or preserved)	Pesticide screen	1.4.2
Fruits (Fresh and dried)	Pesticide screen (Some products tested for lead)	1.4.2 1.4.1
Condiments, preserves, juices, seasonings	Pesticide screen	1.4.2
Selected Spices	Ethylene chlorohydrin	(indicator of Ethylene oxide now prohibited as a processing aid)
Cereals (Unprocessed or semi processed)	Pesticide screen (Some products tested for Cadmium)	1.4.2 1.4.1
Oil Seeds, Misc Plants and Seaweed	Pesticide screen	1.4.2
Peanuts	Pesticide screen Cadmium	1.4.2 1.4.1
Animal and Vegetable fats, oils, waxes	Pesticide screen (Some products tested for Erucic acid)	1.4.2 1.4.1
Meat, Fish, Crustacean, Mollusc Extracts	Pesticide screen	1.4.2
Confectionery	Colour screen	1.3.1 Schedule 4 (maximum levels permitted)
Cocoa Products	Pesticide screen Cadmium	1.4.2 1.4.1

The State and Territories and AQIS are the enforcement agencies that monitor and sample foods to determine compliance with Standard 1.4.2 - Maximum Residue Limits. If a chemical residue is detected in a food and that residue is not covered by an MRL in the Code, then the enforcement agencies may deem the food to be non-compliant with the Code and take enforcement action.

4.2 How is an MRL set in the FSC for a chemical of concern?

If a chemical was assessed as unsafe by the APVMA or by FSANZ, an MRL for that chemical would not be included in the Code.

5.0 The use of antibiotics in fruit and vegetable production

5.1 Are antimicrobial residues tested for in fruit and vegetables?

Antimicrobial residues are not currently tested for in fruit and vegetables. Antimicrobial residues are tested for in other foods such as meat products as part of the Australian Total Diet Surveys.

5.2 What are the requirements in Australia for use of antimicrobials in fruit and vegetables? Are there any requirements in the FSC?

Standard 1.4.2 of the Code does not have any specific requirements related to usage of antibiotics but may list relevant MRLs for residues arising from the use of antibiotics. There are currently no MRL limits for gentamycin or any other antibiotics permitted in fruit and vegetables listed in the Code.

The APVMA conducts a rigorous exposure assessment process before an antibiotic is permitted for use in foods. Any application would be subject to rigorous evaluation with regard to consumer safety. The APVMA currently does not have any applications seeking to use gentamycin or any other antibiotics in fruit and vegetables.

5.3 What about imported food - could they contain antimicrobial residues in fruit and vegetables?

If from New Zealand, yes, as NZ has its own MRL standard which permits the use of streptomycin in stone fruit, pome fruit and tomato seedlings.

If antimicrobials other than those listed as MRLs were used on imported food, that food would be non compliant unless the importer had made an application to FSANZ to enable a residue of an antibiotic to be included in the Code and FSANZ included an MRL in the Code giving permission for the residue to be allowed to be present in the food. As outlined in 5.2 there are currently no MRL limits for gentamycin or any other antibiotics permitted in fruit and vegetables listed in the Code.

(b) Pesticide Screen

Agricultural chemical	Agricultural chemical
Acephate	Fenoxycarb
Aldrin	Fenthion
Azinphos-methyl	Fipronil
Benalaxyl	Heptachlor epoxide
Captan	Imazalil
Carbaryl	Malathion
Chlorfenvinphos (cis & trans)	Metalaxyl
Chlorpyrifos	Methidathion
DDD (2,4- and 4,4-)	Mevinphos
DDE (2,4-and 4,4-)	Monocrotophos
DDT (2,4- and 4,4-)	Omethoate
Deltamethrin (cis, trans)	Oxyfluorfen
Diazinon	Parathion-ethyl
Dichlorvos	Parathion-methyl
Dicofol	Permethrin (cis, trans)
Dieldrin	Phorate
Difenoconazole	Phosmet
Dimethoate	Piperonyl butoxide
Disulfoton	Pirimicarb
Endosulfan (α, β & sulfate)	Pirimiphos-methyl
Endrin	Procymidone
Ethoprofos	Prothiophos
Fenamiphos	Tebufenpyrad
Fenarimol	Triadimefon
Fenitrothion	

(c) Food colour screen tests

Food colours
Allura Red AC (129)
Amaranth (123)
Azorubine (122)
Brilliant Blue FCF (133)
Erythrosine (127)
Green S (142)
Indigotine (132)
Ponceau 4R (124)
Sunset Yellow FCF (110)
Tartrazine (102)

(d) Seafood Antimicrobial Tests

Test Code	Group	Veterinary Compound
MALAG	Malachite green	Malachite green
		Leucomalachite green
NITROFU	Nitrofurans	Furaltadone
		Furazolidone
		Nitrofurantoine
		Nitrofurazone
FLUORO	Fluoroquinolones	Ciprofloxacin
		Enrofloxacin
		Gatifloxacin
		Levofloxacin
		Moxifloxacin
		Norfloxacin
		Ofloxacin
		Sarafloxacin

IMPORTED SEAFOOD SURVEY

There has been considerable media and public interest in the standards and testing applied to imported seafood products. Globally, there is concern over the presence of residues in seafood and the effects of these residues on the health of the consumer. Australian consumers have expressed concerns to the Australian Government regarding the fitness for human consumption of imported seafood.

In response to these concerns, AQIS conducted a survey on imported seafood products from April 2006 to March 2007. AQIS designed this survey to provide a 'snapshot' on the potential presence of residues of agricultural and veterinary compounds in imported seafood and whether the current testing done under the Imported Food Inspection Scheme was up to date.

- Seafood Testing Update – April 2008
- Public Seafood Survey Report – April 2008
- FSANZ – Seafood Survey Risk Assessment Advice PDF [823kb]
- Questions and Answers - Imported Seafood Survey PDF [13kb]

Contact: Email AQIS Imported Food Program
About AQIS and Contact details
Media Inquiries

Last reviewed: 22 Apr 2010

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai - Ahitereitia me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Office of the Chief Executive Officer

Mr Stephen Hunter
Executive Director
Australian Quarantine and Inspection Service
GPO Box 858
CANBERRA ACT 2610

Dear Mr Hunter

I refer to recent correspondence between Food Standards Australia New Zealand (FSANZ) and the Imported Food Program, Australian Quarantine and Inspection Service (AQIS), in relation to a survey of antimicrobial and pesticide residues in imported seafood products (fish, crabs, eels and prawns) undertaken by AQIS from April 2006 through to March 2007. The results of the survey, provided to FSANZ in July 2007, indicated that some seafood products entering Australia contained low-level residues of antimicrobial compounds that do not comply with Standard 1.4.2 – Maximum Residue Limits in the *Australia New Zealand Food Standards Code* (the Code).

In our letter of 3 August 2007 to the Acting Manager of the Imported Food Program, FSANZ agreed to provide formal advice to AQIS concerning the risks to public health and safety posed by non-compliant antimicrobial residues detected in imported seafood. In conducting a risk assessment, FSANZ has focussed specifically on the thirteen compounds detected in the survey, which represent at least six antimicrobial chemical groups – the sulphonamides, fluoroquinolones, phenicols, tetracyclines, β-lactams, and triphenyl methane dyes (malachite green). The risk assessment involved comparing estimated dietary exposures with the established reference health standard (Acceptable Daily Intake) for each chemical. For malachite green, FSANZ has used a margin of exposure approach as used in a previous assessment completed in 2005. The completed risk assessment is Attachment 1 to this letter.

Based on the dietary modelling, the FSANZ assessment has not identified any major safety concerns associated with the low levels of antimicrobial residues detected in some imported seafood. On these grounds, the residues do not constitute a medium or high risk to public health and safety.

You would be aware that FSANZ has received advice from the Expert Advisory Group on Antimicrobial Resistance (EAGAR) of the National Health and Medical Research Council in relation to antimicrobial resistance and human health. A copy of the EAGAR advice relating to the AQIS survey of antimicrobial compounds in imported seafood is enclosed with this letter.

In considering the results of the AQIS survey in terms of antimicrobial resistance, EAGAR has expressed concerns about the presence of fluoroquinolone residues in seafood. The fluoroquinolones include flumequine, ciprofloxacin and enrofloxacin which, in this survey, were found predominantly in prawns. EAGAR notes that use of the fluoroquinolones has never been permitted in animal food production in Australia, due to the potential for generating resistance in pathogenic bacteria. The existing prohibition on the use of these antimicrobial compounds in food production is important because EAGAR considers that any development of resistance to fluoroquinolones would constitute a high risk to their efficacy in clinical medicine.

On the basis of the EAGAR advice regarding the possibility that low-level residues of antimicrobial compounds, such as the fluoroquinolones, could be present in domestically produced seafood as a result of off-label use, FSANZ encourages an active, coordinated management approach involving the States, Territories and AQIS. FSANZ notes that several key strategies are already occurring in this area. A national survey of antimicrobial resistant microorganisms, coordinated by the Department of Health and Ageing, is underway. In addition, FSANZ is aware that the Imported Food Program has initiated discussions of the survey results through the Implementation Sub-Committee and the Food Surveillance Network. Collaboration between enforcement agencies through such mechanisms should ensure that ongoing efforts to monitor compliance of seafood products with relevant standards in the *Australia New Zealand Food Standards Code* achieve the desired compliance goals.

In summary, FSANZ concludes that the levels of antimicrobial compounds detected in the AQIS survey of a range of imported seafood are all very low and do not raise safety concerns. Acknowledging the concerns expressed by EAGAR in relation to the potential for developing antimicrobial resistance through chemical residues in seafood, the preferred risk management approach would be to enhance collaboration between the relevant authorities, to optimise effective enforcement measures and ensure ongoing protection of consumer health.

Yours sincerely

DEAN STOCKWELL
Acting Chief Executive Officer

17th September 2007

cc. Dr Nora Galway

An Assessment of the Public Health Risk Associated with Low Residues of Antimicrobial Compounds in Imported Fish and Shellfish

Food Standards Australia New Zealand

August 2007

1. Introduction

The Australian Quarantine and Inspection Service (AQIS) recently conducted analytical surveys on chemical residues in imported fish and shellfish. The results indicate residues of a number of antimicrobial compounds present in some fish and shellfish samples from a variety of countries including New Zealand. There is no corresponding maximum residue limit (MRL) in the Code for 13 of the compounds identified in the survey results, and therefore the residues are technically non-compliant.

AQIS has requested advice from FSANZ on the risk to public health and safety of low residues of the 13 antimicrobial compounds detected in the seafood survey. The information will be used by AQIS to institute the appropriate monitoring regime under the Imported Food Control Act which will determine whether a 'random' or 'risk' rate of inspection will be applied. The advice from FSANZ will also be used by AQIS in discussions with the States and Territories to determine an overall strategy for management of non-compliant chemical residues in imported seafood.

The antimicrobial compounds included in this assessment are listed in Table 1. FSANZ has combined basic safety information with dietary exposure data to characterise the risk to human health posed by each of the chemicals when present in seafood at the levels detected in the AQIS survey.

2. Risk Assessment

2.1 Reference health standards

FSANZ has referred to the published literature to obtain, wherever possible, a reference health standard for each chemical. For the majority of compounds, an Acceptable Daily Intake (ADI) was available for comparison with the estimated dietary exposure. The published ADI used in the modelling was based on a scientific assessment of data by The Joint FAO/WHO Expert Committee on Food Additives (JECFA) or the Office of Chemical Safety (OCS).

Where a published reference health standard was not available, information was sought on the clinical use of the antimicrobial compounds for treating bacterial infections in humans. With the exception of malachite green, all of the compounds without an ADI had been used therapeutically at some point in time.

In calculating an ADI from this information, the lowest therapeutic dose was taken as the Lowest Observed Effect Level (LOEL), and a safety factor of 100 was applied; a factor of 10 to account for the absence of a No Observed Effect Level (NOEL), and an additional factor of 10 to account for inter-individual variability in humans.

The calculated ADI values are considered to be conservative and protective of human health because they are based on doses used in clinical practice. Furthermore, it is anticipated that intakes of seafood containing traces of antimicrobial compounds will only occur over a short time interval. An ADI is usually calculated on the basis of a lifetime of daily exposure.

Sulfonamides

The sulfonamides include a number of distinct compounds with bacteriostatic properties. They are classed as either short- or long- acting antimicrobials with therapeutic uses in humans and animals, including food producing livestock species. The long-acting sulfonamides are no longer the drugs of choice to treat various infections in humans because of unwanted side effects, however they are used widely in veterinary medicine. Five sulfonamide compounds were detected in the survey.

Sulfamethazine

Sulfamethazine has been used to treat bacterial diseases in human and veterinary medicine and to promote growth in cattle, sheep, pigs and poultry. The OCS has established an ADI of 0.02 mg/kg bw for sulfamethazine (sulfadimidine) which was used in this assessment. JECFA established an ADI of 0.05 mg/kg bw (published in 2006).

Sulfadimethoxine

A long-acting sulfonamide used predominantly in veterinary applications. There was no published ADI available however the lowest human therapeutic dose is usually 15 mg/kg bw/day (Hughes *et al.*, 1996). Applying the safety factor of 100, the calculated ADI is therefore 0.2 mg/kg bw.

Sulfamethoxypyridazine

Long-acting sulfonamide with similar usage pattern to sulfamethoxine. No published ADI was available, therefore an ADI of 0.2 mg/kg bw was calculated from the lowest therapeutic dose in humans of 15 mg/kg bw/day.

Sulfameter

The alternative name is sulfamethoxydiazine, a long-acting sulfanilamide, first used clinically in the 1960s, for example to treat urinary tract infections. The therapeutic dosage depends on the nature of the infection however was generally in the order of 500 mg/day. Based on this level of usage, an ADI of 0.1 mg/kg bw was calculated.

Sulfamethoxazole

Currently in widespread clinical use for the treatment of bacterial and protozoan infections, predominantly in combination with other drugs. An ADI of 0.2 mg/kg bw is calculated from a therapeutic dose in adults of 1600 mg/day.

Oxytetracycline

JECFA has evaluated tetracycline, chlortetracycline and oxytetracycline and has assigned a group ADI of 0.03 mg/kg bw, established at the 50th meeting (1998).

Beta-lactams

Ampicillin and amoxicillin are broad-spectrum antibiotics that have been used extensively to treat bacterial infections since 1961. The OCS has established an ADI for amoxicillin of 0.2 mg/kg bw. Ampicillin has no corresponding ADI, however is used in medicine both orally and for injection. Using a typical dosage of 1 g/day, the calculated ADI for ampicillin is 0.2 mg/kg bw.

Fluoroquinolones

Quinolones, including the subset fluoroquinolones, are bacteriocidal compounds, actively killing bacteria by inhibiting DNA replication and transcription. Quinolones can enter cells easily and therefore are often used to treat intracellular pathogens such as *Legionella pneumophila*.

Flumequine

Flumequine is a fluoroquinolone compound with antimicrobial activity against Gram-negative organisms and is used in the treatment of enteric infections in food animals in overseas countries. It also has limited use for the treatment of urinary tract infections in humans. Flumequine has been evaluated by JECFA on previous occasions (at the forty-second, forty-eighth, fifty-fourth and sixtieth meetings). After consideration of new data on genotoxicity, the Committee recently re-established an ADI for flumequine of 0.03 mg/kg bw.

Ciprofloxacin and Enrofloxacin

Enrofloxacin and its bioactive metabolite ciprofloxacin are fluoroquinolone antibiotics. Enrofloxacin is used in animal husbandry as a treatment for disease to control and prevent infection, and for growth promotion in some overseas countries but not in Australia. JECFA has evaluated the hazard of enrofloxacin and ciprofloxacin and established a group ADI of 0.002 mg/kg bw based on a microbiological endpoint.

Florfenicol

An ADI for florfenicol of 0.001 mg/kg bw derived from a microbiological endpoint has been published by the OCS.

2.2 Malachite Green

FSANZ completed a risk assessment of malachite green in September 2005, following positive detections in domestic and imported aquacultured fish samples tested as part of the ISC Coordinated Survey Plan. Malachite green has been previously used in other countries to treat fungal and protozoan infections on fish and fish eggs, but is not permitted in aquaculture in Australia. Leucomalachite green can also be found in fish as a metabolite of malachite green.

JECFA and the International Agency for Research on Cancer (IARC) have not evaluated the safety of malachite green or leucomalachite green, and there is no established ADI. In conducting the risk assessment, FSANZ reviewed the available toxicological data for malachite green including studies on absorption, metabolism and excretion in fish and rats; acute toxicity in rats and mice; reproductive and developmental toxicity in rabbits; and genotoxicity.

The National Toxicology Program (NTP) in the USA performed a 2-year study on toxicity and carcinogenicity in rats and mice with both malachite green and leucomalachite green (NTP, 2005). Long-term studies in rats and mice found treatment related liver toxicity. Leucomalachite green resulted in adverse effects at lower doses than malachite green. The NTP concluded that there was 'equivocal' or 'some' evidence that malachite green or leucomalachite green might produce tumours in experimental animals at levels of 5 mg/kg bw/day and above. The overall conclusion on carcinogenicity was that there is only limited evidence that malachite green and leucomalachite green could cause tumours in rodents.

In relation to the relevance for human health, the carcinogenicity and genotoxicity data together suggest that malachite green is a very low risk. Taking the non-neoplastic lesions in the rat liver as the most sensitive endpoint, the LOEL is 5 mg/kg bw/day.

3. Dietary Exposure Assessment

Dietary modelling is a tool used to estimate dietary exposure to food chemicals, including nutrient intakes, from the diet as part of the FSANZ risk assessment process. To estimate dietary exposure to food chemicals, records of what foods people have eaten are needed along with reports of how much of the food chemical of interest is in each food. The accuracy of these dietary exposure estimates depends on the quality of the data used in the dietary models. Sometimes, not all of the data needed are available or their accuracy is uncertain so assumptions have to be made, either about the foods eaten or about chemical levels, based on previous knowledge and experience. The models are generally set up according to international conventions for food chemical dietary exposure estimates. However, each modelling process requires decisions to be made about how to set the model parameters and what assumptions to make. Different decisions may result in different answers. Therefore, FSANZ documents clearly all such decisions, model assumptions and data limitations to enable the results to be understood in the context of the available data.

3.1 Chemical concentration data

The survey found residues of 13 different antimicrobial compounds above the Limit of Reporting (LOR) in imported seafood. Table 2 shows the range of seafood products containing antimicrobial compounds. For further details on sampling and levels of reporting, refer to **Attachments 1 and 2** respectively.

3.2 Dietary exposure assessment approach

Dietary exposure assessments were undertaken to estimate dietary exposures to the antimicrobial compounds detected in the survey (see Table 1).

Dietary Exposure = chemical concentration x food consumption amount

Exposures were estimated by combining usual patterns of food consumption, as derived from NNS data, with the concentration of the chemical in imported seafood. Except for malachite green, dietary exposures to the chemicals were then compared to reference health standards, in this case ADIs[1].

For all chemicals except malachite green, the amount of seafood that could be consumed before the ADI is exceeded was estimated for fish and crustacea, assuming the highest detected residues of chemicals in seafood reported in these analytical data. This calculation was based on the concentration of the chemical in the seafood in question, an adult mean body weight, and the published or calculated ADI. In calculating the maximum amount of seafood, it was assumed that there was no exposure to that chemical residue from non-food sources or other foods.

$$\text{Amount of seafood before ADI exceeded} = \frac{\text{ADI x body weight}}{\text{Highest chemical concentration in seafood}}$$

Seafood included in the testing for chemical residues included:

- Fish (excluding shark)
- Crustacea (prawns and crab)
- Eels

Canned, dried, battered or mixed seafood products were not included in this survey.

Specific processing parameters for sampled seafood included:

- Wild caught and farmed
- Cooked and uncooked
- Chilled and frozen

[1] An ADI is "an estimate of the amount of a substance in food or drinking-water, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable risk" (Joint FAO/WHO Expert Committee on Food Additives, 2007).

Table 1: Summary of seafood surveyed and chemical detections

Species	No. of Samples	No. of detections	Chemicals detected
Barramundi	3	1	Amoxicillin
Basa	3	0	N/A
Catfish	1	0	N/A
Crab	10	2	Oxytetracycline, Amoxicillin
Eel	2	4	Sulfadimethoxine, Sulfamethazine, Sulfameter, Sulfamethoxypyridazine
Fish not further specified	6	3	Sulfamethoxazole, Amoxicillin, Enrofloxacin
Garfish	1	1	Oxytetracycline
Gourami	1	0	N/A
Hairtail	3	1	Amoxicillin
Hake	3	0	N/A
Ling	6	2	Amoxicillin, Ampicillin
Mackerel	6	1	Flumequin
Opaka	1	0	N/A
Orange Roughy	2	1	Ampicillin
Prawn	39	6	Sulfamethoxazole, Oxytetracycline, Flumequine, Ciprofloxacin, Enrofloxacin, Florfenicol
Perch	1	2	Oxytetracycline, Malachite Green
Red Emperor	1	0	N/A
Shark	1	0	N/A
Silverfish	3	0	N/A
Spanish Mackerel	5	1	Flumequine
Swordfish	4	2	Amoxicillin, Ampicillin
Tilapia	1	0	N/A
Tuna	4	0	N/A

3.3 Scenarios for dietary modelling

Three scenarios were assessed for the purposes of this dietary exposure assessment and were as follows:

- *Fish only* – dietary exposure to chemical residues from all fish species excluding tuna, trout and salmon
- *Crustacea only* – dietary exposure to chemical residues from all crustacea species and included crabs, lobsters and prawns
- *Fish and Crustacea* – dietary exposure to chemical residues from all crustacea and fish (excluding tuna, trout and salmon)

3.4 Assumptions in the dietary modelling

The aim of this dietary exposure assessment was a worst-case scenario estimate for dietary exposure. Where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary exposure assessment did not underestimate exposure.

The assumptions made in the dietary modelling were:

- each chemical was present in all fish (where chemical residues were detected in fish) at the highest residue detected for that chemical (excluding tuna, trout and salmon which were not included in this dietary exposure assessment)
- each chemical was present in all crustacea (where chemical residues were detected in crustacea) at the highest residue detected for that chemical

These assumptions are likely to lead to a very conservative estimate for chemical residue dietary exposures and assume a worst case scenario as not all species of fish included in the model will contain residues and even for species with detected residues, it is unlikely that every sample of fish would contain this level of residue or that the same species of fish would be consumed every day.

3.5 Estimated mean consumption levels

The estimated mean consumption for consumers of the seafood types analysed for this exposure assessment (derived from the 1995 Australian NNS data) was 100 grams/day. The mean daily consumption is 75 grams for prawns, and 35 grams for crab. For fish only (species assessed for the purposes of this analysis), estimated mean consumption was 95 grams.

3.6 Estimation of seafood consumed to exceed reference health standard

Table 3 shows calculated estimates of the amount of seafood species that would need to be consumed before the reference health standard (ADI) is exceeded. These calculations are based on the assumption that there is no exposure to chemical residues from non-food sources or any background exposure from other foods.

Table 2: Chemical detections above the Limit of Reporting (LOR) for fish and crustacea

	Sulfadimethoxine	Sulfamethazine (Sulfadimidine)	Sulfameter	Sulfamethoxazole	Sulfamethoxypyridazine	Oxytetracycline	Malachite green	Amoxicillin	Ampicillin	Flumequin	Ciprofloxacin	Enrofloxacin	Florfenicol
Barramundi								✓					
Crab						✓		✓					
Eel, dried	✓	✓	✓		✓								
Fish not further specified				✓				✓				✓	
Garfish						✓							
Hair tail								✓					
Ling								✓	✓				
Mackerel										✓			
Orange Roughy									✓				
Prawn				✓		✓				✓	✓	✓	✓
Perch, climbing						✓	✓						
Spanish Mackerel										✓			
Swordfish								✓	✓				

Table 3: Estimated maximum dietary exposures to chemical residues with concentrations above the LOR for consumers of seafood only*

Chemical	Estimated Mean Dietary Exposure for Consumers					
	(µg/day)			(%ADI*)		
	Fish Only	*Crustacea Only*	*Fish and Crustacea*	*Fish Only*	*Crustacea Only*	*Fish and Crustacea*
Sulfamethazine (Sulfadimidine)	0.9	n/a	0.9	<1	n/a	<1
Sulfadimethoxine	0.3	n/a	0.3	<1	n/a	<1
Sulfamethoxypyridazine	1.2	n/a	1.2	<1	n/a	<1
Sulfameter	1.2	n/a	1.2	<1	n/a	<1
Sulfamethoxazole	0.5	0.4	0.5	<1	<1	<1
Oxytetracycline	0.6	0.7	0.7	<1	<1	<1
Amoxicillin	12.9	29.5	19.9	<1	<1	<1
Ampicillin	12.9	n/a	12.9	<1	n/a	<1
Flumequine	0.8	1.3	1.1	<1	<1	<1
Ciprofloxacin	n/a	0.2	0.2	n/a	<1	<1
Enrofloxacin	3.3	10.1	5.9	3	8	5
Florfenicol	n/a	0.9	0.9	n/a	1	1

* Assumes maximum concentration level reported

3.7 Malachite green margin of exposure

In the case of malachite green, no ADI is available on which to base estimates of safe levels of consumption. To estimate the health risk from potential exposure of malachite green relative to the observed effect level (taken previously as 5 mg/kg bw/day), a margin of exposure approach has been used.

The survey found malachite green at 7.8 µg/kg in climbing perch. Based on mean daily consumption of fish, this residue equates to a level of exposure of approximately 0.011 µg/kg bw/day. The level of exposure reported in the survey is therefore 450,000 times below the Lowest Observed Effect Level (LOEL). At this level of dietary exposure, the health risk from malachite green residues in fish is extremely small.

Table 4: Estimate of seafood consumption required to exceed the ADI

Chemical	Commodity	Maximum detected concentration (µg/kg)	ADI (mg/kg bw)	Approximate consumption amounts required to exceed ADI (kg/day)
Sulfamethazine (Sulfadimidine)	Eel	8.6	0.02	155
Sulfadimethoxine	Eel	3.4	0.20	3,941
Sulfamethoxy-pyridazine	Eel	12	0.2	1,116
Sulfameter	Eel	12	0.1	558
Sulfamethoxazole	Fish (NFS)	5	0.2	2.680
	Prawns	5.4	0.2	2.481
Oxytetracycline	Crab	6.7	0.03	300
	Garfish	2	0.03	1.005
	Prawn	8.6	0.03	233
	Climbing perch	5.9	0.03	340
Amoxicillin	Barramundi	35	0.2	382
	Crab	380	0.2	35
	Fish NFS	58	0.2	231
	Hairtail	130	0.2	103
	Ling	71	0.2	188
	Swordfish	51	0.2	262
Ampicillin	Orange Roughy	10	0.2	1.340
	Ling	16	0.2	837
	Swordfish	130	0.2	103
Flumequine	Mackerel	2	0.03	1,005
	Prawns	17	0.03	118
	Spanish Mackerel	8.2	0.03	245
Ciprofloxacin	Prawn	3.1	0.002	43
Enrofloxacin	Fish NFS	33	0.002	4
	Prawns	130	0.002	1
Florfenicol	Prawns	11	0.001	6

Notes: No other background exposure from other foods considered.
(NFS) = Not further specified
Mean body weight of 67 kg used for Australians aged 2 years and above.

4. Risk Characterisation

Based on the calculations performed using appropriate reference health standards for each chemical (ADIs) and a worst-case scenario, the quantities of a particular seafood that would need to be consumed before reaching levels of exposure that would exceed the acceptable daily intake are very large. In the majority of cases, the upper limit is not reached unless hundreds of kilograms of a particular seafood were to be consumed each day over a lifetime (see Table 4).

The most significant level of exposure is to the fluoroquinolone antimicrobial enrofloxacin, where, based on the maximum concentration found in the survey, exposure would represent only 8% of the ADI. Consumption of at least 1 kg of prawns per day would be required to exceed the acceptable daily intake level for this compound. While it would be possible for an individual to reach this level of consumption, it is very unlikely that this quantity of prawns would be consumed on a daily basis over a lifetime. In addition, enrofloxacin residues are very unlikely to be present at the detected level in every serve of seafood consumed, in every sitting over a lifetime. Given the low level of detection and these qualifying conditions, the levels of enrofloxacin residues detected in the survey do not represent a safety risk.

A previous risk assessment for malachite green (and leucomalachite green) in 2005 indicated a wide margin of exposure between the intake of malachite green residues from fish and the observed effect dose. The level of malachite green residues detected in climbing perch in this survey leads to a similarly wide margin of exposure, and is therefore not considered to pose a safety concern.

5. Conclusion

The chemical residues detected in various species of fish and other types of seafood included in the AQIS survey are not permitted in the Code. In some cases, the residues may arise from the illegal use of antimicrobial compounds to treat protozoa and fungal infections on fish, fish eggs and crustacea particularly under aquaculture conditions.

On the basis of information available to FSANZ and at the levels of dietary exposure to chemical residues estimated in this assessment, the risk to public health and safety from the consumption of various types of fish and crustacea is considered to be very low.

6. References

Hughes, W.T., and Killmar, J. (1996) Monodrug Efficacies of Sulfonamides in Prophylaxis for *Pneumocystis carinii* Pneumonia. Antimicrobiol. Agents and Chemotherapy 40 (4): 962-965.

JECFA Food Additive Series 51 (2006)
http://www.inchem.org/documents/jecfa/jecmono/v51je03.htm

National Toxicology Program. (2004). NTP Technical report on the toxicity studies of malachite green chloride and leucomalachite green (CAS Nos. 569-64-2 and 129-73-7) administered in feed to F344/N Rats and B6C3F1 Mice. National Toxicology Program Toxicity Report Series Number 71.
http://ntp.niehs.nih.gov/ntp/htdocs/ST_rpts/tox071.pdf. Accessed on 19 August 2005.

National Toxicology Program. (2005). TR-527 Toxicology and carcinogenesis studies of malachite green chloride and leucomalachite green (CAS Nos. 569-64-2 and 129-73-7) in F344/N rats and B6C3F$_1$ mice (feed studies).
http://ntp.niehs.nih.gov/index.cfm?objectid=070B74C5-C780-E272-6721383F7A1113BC. Accessed on 19 August 2005.

Office of Chemical Safety (OCS) http://www.tga.gov.au/chemicals/ocs/index.htm
Accessed on 14 August 2007.

Sampling and testing

In April 2006, AQIS conducted imported seafood sampling from regions around Australia to test for chemical residues, namely antimicrobial and pesticide residues. In July 2007, FSANZ was provided with the results for 100 imported seafood samples from various regions, which were based on import data from 2005. See Table below for details of sampling.

Summary of seafood data provided to FSANZ by AQIS based on species and region caught

State	Commodity	Sample numbers	Total
New South Wales	Fish	20	44
	Prawn	15	
	Crab	4	
	Eel	5	
Victoria	Fish	20	30
	Prawn	10	
	Crab	0	
	Eel	0	
Queensland	Fish	10	16
	Prawn	2	
	Crab	4	
	Eel	0	
Western Australia	Fish	5	10
	Prawn	3	
	Crab	2	
	Eel	0	
Total	Fish	55	**100**
	Prawn	30	
	Crab	10	
	Eel	5	

ATTACHMENT 2

Following is a list of antimicrobial compounds assessed and the respective Limit of Reporting (LOR).

Antimicrobial Compounds			
Group	**Chemicals**		**Limit of reporting (mg/kg)**
Malachite green	Malachite green	Leucomalachite green	0.002
Quinolones	Oxolinic Acid		0.002
Phenicols	Florfenicol	Thiamphenicol	0.02
Macrolides	Tylosin	Erythromycin	0.002
Fluoroquinolones	Ciprofloxacin	Ofloxacin	0.002
	Enrofloxacin	Gatifloxacin	
	Levofloxacin	Moxifloxacin	
	Flumequine	Norfloxacin	
	Sarafloxacin		
Tetracyclines	Chlortetracycline	Tetracyclines	0.002
	Doxycycline	Oxytetracycline	
Sulphonamides	Sulphamerazine	Sulphamethoxazole	0.002
	Sulphadimethoxine	Sulphamethoxypyridazine	
	Sulphachlorpyridazine	Sulphapyridine	
	Sulphadiazine	Sulphaquinoxaline	
	Sulphadoxine	Sulphathiazole	
	Sulphamethaziine	Sulphatroxazole	
	Sulphameter	Sulphisoxazole	
Penicillin	Ampicillin	Benzyl penicillin	0.01
	Amoxycillin	Cloxacillin	
Other antibiotics	Trimethoprim		0.01

References

Akinbowale O, Peng H, Barton M (2006) Antimicrobial Resistance in Bacteria Isolated from Aquaculture Sources in Australia. *Journal of Applied Microbiology*, 100(5): 1103-13.

Duran G, Marshall L (2005) Ready to Eat Shrimp as an International Vehicle of Antibiotic-Resistant Bacteria. *Journal of Food Protection*, 68(11): 2395-2401.

Robicsek A, Jacoby GA, Hooper DC (2006) The worldwide emergence of plasmid-mediated quinolone resistance. *Lancet Infectious Diseases*, 6(10): 629-40.

Zhao S, McDermott PF, Friedman S, Qaiyumi S, Abbott J, Kiessling C, Ayers S, Singh R, Hubert S, Sofos J, White DG (2006) Characterisation of antimicrobial-resistant Salmonella isolated from imported foods. *Journal of Food Protection*, 69(3): 500-7.

COPY

Ms Melanie Fisher
Acting CEO
Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610

Dear Ms Fisher

The Australian Quarantine and Inspection Service (AQIS) wrote to the National Health and Medical Research Council (NHMRC) on 31 July 2007 seeking advice on the safety associated with the residues of antimicrobial chemicals detected in a survey of imported seafood. The survey was conducted from April 2006 to March 2007.

I am providing the NHMRC's advice directly to you so it can be included in the full toxicological risk assessment of the survey results being undertaken by Food Standards Australia New Zealand (FSANZ). It is my understanding that the risk assessment will inform AQIS's approach given that its legislation (including the *Quarantine Act 1908* and the *Imported Food Control Act 1992*) depend on advice from FSANZ.

The NHMRC has consulted with members of its Expert Advisory Group on Antimicrobial Resistance (EAGAR) in formulating its advice on the implications of the survey results for antimicrobial resistance and human health.

The survey found a number of antibiotic residues in both raw and cooked seafood samples, albeit at low levels. Of these, the two classes of antibiotics of greatest concern are the quinolones and the fluoroquinolones. The EAGAR *Importance ratings and Summary of Antibiotic Uses in Humans in Australia* (NHMRC website, 2006) classifies quinolones and fluoroquinilones as being of medium and high risk to human health respectively. A high risk rating indicates that if resistance were to develop, there are limited or no alternatives available to treat serious bacterial infections in humans. Neither quinolones nor fluoroquinolones are licensed for use in animal food production of any kind in Australia. The presence of these two classes of antibiotics at any level in the seafood samples tested is of concern.

Transfer of quinolone and fluoroquinolone resistance genes between bacteria is being described with increasing frequency. Robicsek et al (2006) say "Their insidious promotion of substantial resistance, their horizontal spread and their coselection with other resistance elements indicate that a more cautious approach to quinolone use... [is] needed". There is obviously a risk of either potentially pathogenic human bacteria that are quinolone or fluoroquinolone resistant contaminating the seafood, or of resistance being transferred from non-pathogenic bacteria to pathogenic bacteria in the environment and in those handling the raw seafood.

.../3

GPO Box 1421, Canberra ACT 2601
Level 5, 16 Allara Street, Canberra City ACT
T. 1300 NHMRC (13 000 64672) or +61 2 6217 9000 F. +61 2 6217 9100 E. nhmrc@nhmrc.gov.au
ABN 92 838 054 284

The AQIS survey contained samples of both cooked and raw seafood. Although it might be assumed that cooked, ready to eat frozen products such as prawns would not contain live pathogens, this is not always the case. For example, Duran and Marshall (2005) were able to isolate numerous resistant human pathogens, including *Escherichia coli*, *Enterococcus* spp, *Salmonella, Shigella flexeri*, *Staphloccocus* spp; and *Vibrio* spp., from frozen ready to eat shrimp imported into the US, while Zhao et al (2006) isolated *Salmonella* with resistance to eight antimicrobials from a sample of frozen squid imported into the US from Taiwan.

There is a lack of testing in locally farmed seafood for unlicensed antimicrobials. Although no antibiotics are registered for use in aquaculture in Australia, there is evidence for significant off label use and support for the view that there is a risk of transfer of resistant bacteria to humans from consumption of aquaculture products (Akinbowale et al. 2006).

In light of the above mentioned studies, the NHMRC would encourage FSANZ in future surveys to include both domestic and imported samples and to monitor not only the presence of antibiotic residues but to assess the patterns of resistance in the microbes present. Given that some of the wild caught samples in the survey were detected with antimicrobial residues, it is possible that there has been misidentification of those samples, or that the antimicrobials may have been used post catch.

Please do not hesitate to contact Dr David Abbott at the NHMRC (02 6217 9330 or david.abbott@nhmrc.gov.au) if you require further information.

Yours sincerely

Professor Warwick Anderson
Chief Executive Officer

3 September 2007

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Office of the Chief Executive Officer

Dr Narelle Clegg
National Manager
Animal & Plant Exports & Imported Food Safety Branch
Export Division
Australian Quarantine and Inspection Service (AQIS)
GPO Box 858
CANBERRA ACT 2601

Dear Narelle

Food Standards Australia New Zealand (FSANZ) recently received a letter from the Australian Honey Bee Industry Council Inc. (AHBIC) in relation to testing of imported honey.

The letter raises the issue of the detection of chloramphenicol residues in imports of Chinese honey. Previous risk assessments undertaken by FSANZ have concluded that honey containing chloramphenicol residues does not pose a high risk to public health and safety. Therefore I have suggested that AHBIC liaise with Australian food enforcement agencies, in terms of any potential non-compliance. I also advised AHBIC that I would draw this issue to AQIS' attention.

I have attached the letters exchanged between AHBIC and FSANZ for your information. Please contact Dr Mark Salter on 02 6271 2228 if you need to discuss this issue further.

Yours sincerely

Steve McCutcheon
Chief Executive Officer

17 September 2008

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Office of the Chief Executive Officer

Mr Stephen Ware
Executive Director
Australian Honey Bee Industry Council Inc
PO Box R838
ROYAL EXCHANGE NSW 1225

Dear Mr Ware

Thank you for your letter dated 5 August 2008 in relation to the testing of imported honey.

Inspection and testing of imported honey at the border is undertaken by the Australian Quarantine and Inspection Service (AQIS) under the Imported Food Inspection Scheme (IFIS). The roles and responsibilities of Food Standards Australia New Zealand (FSANZ) and AQIS under the IFIS were revised in 2007. Under these arrangements, FSANZ provides advice to AQIS on the level of public health risk posed by specific imported foods while AQIS has operational responsibility for inspection and sampling of imported food. In practice, this means that FSANZ provides risk assessment advice in relation to high risk foods (i.e. the 'risk' category), while AQIS determines enforcement priorities for other aspects of the Code (i.e. low risk foods in the surveillance category).

In addition to the role of AQIS at the border in relation to imported foods, State and Territory food enforcement agencies are responsible for enforcing the requirements of the Code for all food available for sale within their jurisdiction, including both imported and domestically produced food.

Based on previous risk assessments, FSANZ does not consider that chloramphenicol residues in honey pose a high risk to public health and safety, although the presence of residues is not permitted. I note that AQIS currently tests 5% of honey imports for chloramphenicol residues, as well as testing for other antibiotic and pesticide residues. I have drawn this issue to AQIS' attention and suggested they contact you.

I can see value in the industry working more closely with the enforcement agencies when instances of non-compliance occur in order for them to better target their enforcement activities.
Thank you for bringing this matter to my attention.

Yours sincerely

Steve McCutcheon
Chief Executive Officer

17 September 2008

Crerar, Scott
From: Crerar, Scott
Sent: Friday, 26 November 2004 1:28 PM
To: Tony Redrup (E-mail)
Cc: Ron Southgate (E-mail)
Subject: Recent failure by AQIS of Capilano honey shipment for semicabazide (SEM)

Tony

FSANZ has been consulted by industry on this recent failure due to detection of SEM and asked to give an opinion. From the FSANZ perspective, whilst it probably can't be definitely shown, it is very likely the semicarbazide (SEM) detected in the honey has leached from the plastic sealing gasket of the lid. This is also supported by prior testing of this product by Capilano before it was exported to Canada. Furthermore, since SEM residue can originate from sources other than a nitrofuran drug contamination, the failure to detect either parent nitrofuran and/or the metabolite AOZ is suggestive of this residue not being the result of nitrofuran antibiotic use.

On the public health and safety side, there is no evidence that SEM causes cancer in humans and there has been no action taken worldwide with respect to the detection of SEM in any foods. Much higher SEM levels have been detected in a range of different foods and have been attributed to leaching from plastic seals.

Given the significant uncertainty over the source of the SEM, previous industry test results, the extremely low concentration, and the fact that this does not represent a significant risk to public health, the FSANZ view is that this product should not be failed.

If you would like to discuss this further, please do not hesitate to call me.

Thanks

Dr Scott Crerar
Manager, Post Market Operations
Food Standards Australia New Zealand
PO Box 7186 Canberra BC ACT 2610
E-mail: scott.crerar@foodstandards.gov.au
Website: www.foodstandards.gov.au
Phone: +61 2 6271 2235
Fax: +61 2 6271 2278
Mobile: +61 (0[redacted]

Crouch, Kelly

From: Crouch, Kelly
Sent: Wednesday, 12 May 2004 12:19 PM
To: 'Kim Leighton (WA Health) (E-mail)'; 'trent.brady@daff.gov.au'; 'Brian Delroy (SA) (E-mail)'; 'Eric Johnson (TAS) (E-mail)'; 'Kerry Bell (QLD) (E-mail)'; 'Jim Wilson (NZ) (E-mail)'; 'Chris Chan (NSW) (E-mail)'; 'Bill Porter (SFO/NSW/Recalls) (E-mail)'; 'Peter Sutherland (E-mail)'; 'hodgem@health.qld.gov.au'; 'Kerry Boulton (AQIS/Recalls) (E-mail)'; 'terry.oughtred@dhs.vic.gov.au'; 'Victor Di Paola (VIC) (E-mail)'; 'Tracy Ward (NT/SFO) (E-mail)'; 'vojkan.stefanovic@act.gov.au'; 'Ron Southgate (AQIS) (E-mail)'; 'Sonia Nielsen (DAFF/RML c'tee) (E-mail)'; 'Sally Johnston (NZ/TAG/Recalls) (E-mail)'; 'Mark Hansen (QLD Health) (E-mail)'; 'david.hook@foodauthority.nsw.gov.au'; 'john_van_den_beuken@nzfsa.govt.nz'; 'scott.mckenzie@daff.gov.au'; 'tom.black@daff.gov.au'; 'dougall.mclachlan@daff.gov.au'
Cc: Buchtmann, Lydia; Brent, Paul; Stanley, Glenn; Jamieson, Craig; Crerar, Scott; Keane, Rob; Peachey, Graham; Pontin, Claire; Fladun, John; Boyd, Bob
Subject: Nitrofurans - Outcome Papers - Teleconferences - 22 and 30 April 2004

Att A - Draft Teleconference o... Att B - Outcome Paper - TAG Te...

Hi Folks

Please find attached the following documentation:

a) Outcome paper for teleconference on nitrofurans/honey dated 22 April 2004 (5 pages)
b) Outcome paper for teleconference on nitrofurans dated 30 April 2004 (2 pages)

Please contact me if you would like further information.

Regards
Kelly Crouch
Food Recall Coordinator
Food Standards Australia New Zealand
(ph) 02 6271 2610
(fax) 02 6271 2278
(a/hrs recall mobile) 0412 166 965

Tracking:

Recipient	Delivery	Read
'Kim Leighton (WA Health) (E-mail)'		
'trent.brady@daff.gov.au'		
'Brian Delroy (SA) (E-mail)'		
'Eric Johnson (TAS) (E-mail)'		
'Kerry Bell (QLD) (E-mail)'		
'Jim Wilson (NZ) (E-mail)'		
'Chris Chan (NSW) (E-mail)'		
'Bill Porter (SFO/NSW/Recalls) (E-mail)'		
'Peter Sutherland (E-mail)'		
'hodgem@health.qld.gov.au'		
'Kerry Boulton (AQIS/Recalls) (E-mail)'		
'terry.oughtred@dhs.vic.gov.au'		
'Victor Di Paola (VIC) (E-mail)'		
'Tracy Ward (NT/SFO) (E-mail)'		
'vojkan.stefanovic@act.gov.au'		

Recipient	Delivery	Read
'Ron Southgate (AQIS) (E-mail)'		
'Sonia Nielsen (DAFF/RML c'tee) (E-mail)'		
'Sally Johnston (NZ/TAG/Recalls) (E-mail)'		
'Mark Hansen (QLD Health) (E-mail)'		
'david.hook@foodauthority.nsw.gov.		
'john_van_den_beuken@nzfsa.govt.		
'scott.mckenzie@daff.gov.au'		
'tom.black@daff.gov.au'		
'dougall.mclachlan@daff.gov.au'		
Buchtmann, Lydia	Delivered: 12/05/2004 12:20 PM	Read: 12/05/2004 12:24 PM
Brent, Paul	Delivered: 12/05/2004 12:20 PM	
Stanley, Glenn	Delivered: 12/05/2004 12:20 PM	
Jamieson, Craig	Delivered: 12/05/2004 12:20 PM	
Crerar, Scott	Delivered: 12/05/2004 12:20 PM	
Keane, Rob	Delivered: 12/05/2004 12:20 PM	Read: 12/05/2004 12:21 PM
Peachey, Graham	Delivered: 12/05/2004 12:20 PM	
Pontin, Claire	Delivered: 12/05/2004 12:20 PM	
Fladun, John	Delivered: 12/05/2004 12:20 PM	
Boyd, Bob	Delivered: 12/05/2004 12:20 PM	

Senior Food Officers Teleconference – Nitrofurans/Honey

Thursday 22 April 2004
1.30pm AEDST

Chair: Rob Keane (FSANZ)

Attendees: Kim Leighton (WA); Trent Brady (part)(DAFF); Brian Delroy (SA); Eric Johnson (TAS); Kerry Bell (QLD); Jim Wilson (NZFSA); Chris Chan (NSW Food Authority); Bill Porter (NSW Food Authority); Peter Sutherland (NSW Food Authority); Mary Hodge (QLD); Kerrie Boulton (AQIS); Terry Oughtred (VIC); Lydia Buchtmann (FSANZ); Paul Brent (part)(FSANZ); Glenn Stanley (FSANZ); Craig Jamieson (FSANZ).

Apologies: Vojkan Stefanovic (ACT); Scott Crerar (FSANZ); Victor DiPaola (VIC); Tracy Ward (NT).

Background

The teleconference was organised at the request of the NSW Food Authority to develop an agreed strategy relating to low-level residues of nitrofurans that had been detected in honey. Prior to the teleconference the NSW Food Authority provided a draft strategy proposal for discussion (attached) and results from testing indicating low level residues in three (of ten) sampled honey products (attached).

Summary of Current Situation

Rob Keane provided a written overview of the current situation with regard to nitrofuran residues being found in imported honey and prawns. Rob also indicated that nitrofuran residues may also have been detected in scallops and that this was being considered for testing.

Imported prawns are currently being tested at the border and testing of honey will be starting on Tuesday 27 April 2004. Testing will be done by one of two laboratories. Testing will be for the parent compounds and the four metabolites.

Food Safety Status of Nitrofuran Residues

Rob, Glenn and Paul reiterated the FSANZ view that the residues of nitrofurans reported in some prawns and honey are very low and the public health risk associated with these residues is low. This was agreed and it was also agreed that the risk assessment should be updated and peer reviewed.

Legal Aspects on the Nitrofuran Residues

Prior to the teleconference, Victoria provided an alternative interpretation of Standard 1.4.2 indicating that this Standard did not apply to residues of nitrofurans as they were not currently registered agricultural and veterinary chemicals. FSANZ agreed to consider this interpretation and NSWs interpretation, and any other interpretations that other jurisdictions may have, to develop a position on the regulatory status of nitrofuran residues in food. In the meantime and subject to the interpretation being clarified, it was

agreed that the other matters would be discussed on the basis that nitrofuran residues were not permitted in any food.

It was noted that at the TAG meeting, the issue of low-level non-complying residues in food was discussed and that a policy position on these residues needed to be developed.

NSW proposal

The proposal put forward by NSW was discussed and it was agreed that recalls were not considered necessary. It was agreed that the suppliers of non-complying products should be written to about the non-compliance. While not agreed unanimously, there was broad support for the other aspects of the NSW proposal including the need to request suppliers to withdraw non-complying products from the market. It was noted that this approach was consistent with the approach taken by Queensland Health in relation to nitrofuran residues in prawns in late 2003.

The need for a nation-wide survey was considered and it was agreed that at this stage there was enough data to demonstrate the levels in honey but that the survey option be reconsidered once additional data becomes available through border testing. Broad support was expressed for the testing of honey for nitrofurans under the Imported Food Inspection Scheme.

It was noted that media attention may be possible on this issue and it was agreed that the public affairs officers in FSANZ and the NSW Food Authority would liaise to ensure any media comments were consistent.

Semicarbazide

In relation to residues of semicarbazide, it was noted that the seals on jars could have been the source and that therefore withdrawals of these products would not be sought, unless it could be shown that the seals were not the source of the semicarbazide residues.

Summary

It was agreed that:

- FSANZ would update the risk assessment on nitrofurans in prawns to reflect the latest data for prawns and seek a peer review of this assessment.
- FSANZ would consider the regulatory status of nitrofuran residues in food, specifically the interpretation of Standard 1.4.2.
- on the data available, the residues of nitrofurans reported in some prawns and honey are very low and the public health risk associated with these residues is low.
- there was broad support for the imminent testing of imported honey for residues of nitrofurans.
- recalls of honey containing residues of nitrofurans were not considered necessary given the low risk to public health.
- the suppliers of honey found to contain nitrofurans would be advised of the results and advised to take corrective action. While not unanimously agreed, there was support for the additional action of seeking withdrawal of non-complying products from the market.

- no action would taken against residues of semicarbazide in honey, unless it could be shown that the seals were not the source of the semicarbazide in the honey.
- there was no need for a nationwide survey at this time but to reconsider this once more data becomes available from border testing.
- the public affairs officers in FSANZ and the NSW Food Authority would liaise to ensure any media comments were consistent.
- a policy position on the issue of low-level non-complying residues in food needed to be developed.

Attachments

1. Email from NSW Food Authority outlining proposed strategy including NSW Food Authority testing results

NSW Food Authority Proposal (received by email)

Please find attached a test report on the 10 honey samples NSWFA submitted for testing. The following points are noteworthy:

- In the sample id table (top table), where there is the word "seal", it means the sample was contained in a retail container with a plastic seal of the type that could leave semicarbazide residue.
- Samples 6, 8 and 10 contained AOZ, which is accepted as a putative metabolite of one of the nitrofurans and not from other sources.
- Samples 1,3,4,6,7,8 and 10 were detected to contain semicarbazide (SC). SC could be a metabolite of nitrofurazone, but could also have been leached from plastic bottle seals. All these samples had plastic seals in their containers. All samples negative wrt SC did not have seals. Testing of some of the seals for the presence (at significantly higher levels) of SC is being organized.
- All samples positive for AOZ contained imported honey.
- Sample 10 was (apparently) the same product as tested by Mr Taylor. Result is similar to what Mr Taylor obtained (4.3 & 4.6 ppb of AOZ).

NSW would like to put forward the following proposal in terms of course of action in regard to honey contaminated with nitrofurans. This proposal reflects our current thinking, but certainly not an entrenched position. We would value the feedback and input from other jurisdictions.

Proposal:

1. **No public recall** of contaminated honey products.

   Reasons:

   a. Very low risk to human health based on FSANZ's risk assessment and previous press releases. (We would like FSANZ to provide an update of their advice in this regard)

   b. Section 30 of the NSW Food Act provides for making a recall order only if there is reasonable ground to believe that the making of the order is necessary to prevent or reduce the possibility of a serious danger to public health .... The low levels of nitrofuran (metabolites) detected do not pose a "serious danger".

2. Advise all companies selling the implicated products to carry out (voluntary) **product retrieval** and **stop selling the products immediately** because it is in breach of the Code. Implicated products at this stage are those ones detected to contain AOZ in the attached analysis report, but not the ones containing SC, unless further evidence shows that the SC was not from bottle seals.

   Reasons:

   a. The breach is seen as more than a "technical breach" in that the chemicals involved are not harmless ones. Alt least Furazolidone has been identified by the UK and EU food authorities as possessing mutagenic and carcinogenic properties.

   b. FSANZ's Fact Sheet of 31 Mar 2004 advised that 5 consignments of prawns were found to have levels of nitrofurans and they were not permitted into Australia. Another Fact sheet dated 9 Dec. 2003 stated that "FSANZ has instructed AQIS to test imported honey and imported prawns for this antibiotic. Any products found to have levels of Nitrofuran will not be permitted for sale in Australia." A policy position is embodied in these statements of regarding food contaminated with nitrofuran (albeit at low levels) as not acceptable for sale. If food containing nitrofuran is not acceptable for import, it should not be regarded as acceptable for local

sale. A contrary position could be challenged on the ground of barrier to trade.

c. Not taking enforcement action against food (locally produced or otherwise) contaminated with nitrofuran residues would be inconsistent with the legal prohibition of the use of the drugs in food production.

d. The Food Safety Authority of Ireland recalled prawns detected to contain nitrofurans (0.4-1.17 ppb) in 2002 (http://www.fsai.ie/alerts/archive/alerts_pr_2002_4.asp).

e. The UK Food Standards Agency sought the cooperation of cold stores to remove and destroy Thai & Brazilian chicken in 2002 when these imports were found to contain low levels of nitrofurans (http://www.food.gov.uk/news/newsarchive/57091).

f. Canada recalled Australian honey products detected to contain nitrofuran residues in March 2004. (The question of the reliability of the test results in this case should be viewed as separate to the policy issue).

g. In discussing the risk of nitrofurans in food, the UK Food Standards Agency considered it "a possible increased risk of cancer in human through long term consumption".

h. While it may be argued that it is unlikely that consumers would be exposed to these residues long term because AQIS has started screening for nitrofurans in imports, the argument is hard to sustain because of the low (10%) level of AQIS monitoring. Moreover, not taking action may signal to industry that it is strictly a technical breach of no consequence and *status quo* could prevail. This would be a difficult position to defend in the light of what overseas food authorities have said and done.

i. While nitrofurans *per se* are not likely to be present in food because they are rapidly metabolized, at least one of their metabolites (AOZ) has been shown to be genotoxic as well. There is no MRL for nitrofurans, neither are there MRLs for the metabolites. So, the absence of nitrofuran residues *per se* doe not get over the breach of the Code.

3. For companies not conducting voluntary product retrieval, implicated products would be seized, and statutory samples obtained and tested. Prosecution may follow subject to test results.

4. All retrieved and seized products should be destroyed.

5. Issue warning to all honey importers of possible nitrofuran contamination and that enforcement action will be taken against illegal sale.

6. Nation-wide survey of honey products likely to be contaminated (containing imported honey)

Honey samples.doc

UNCONTROLLED COPY

Batch Number: A04/0069 **Project:** Honey Samples

Laboratory Reference	Food Type	Client Reference
A04/0069/1	Honey	Aust: Archibalds Yellow Box Honey 500g - Seal
A04/0069/2	Honey	Aust: Leabrook Farms Blue Gum Honey 400g - Squeeze
A04/0069/3	Honey	Aust: Beechworth Pure Honey 325g - Seal
A04/0069/4	Honey	Aust: Capilano100%Pure AustralianHoney 375g - Seal
A04/0069/5	Honey	Imp: Heather Creamed Honey 250g - No seal, plastic
A04/0069/6	Honey	Imp: Allowrie 500g - Seal
A04/0069/7	Honey	Imp: Capilano 750g - Seal
A04/0069/8	Honey	Imp: Bi-Lo 750g - Seal
A04/0069/9	Honey	Imp: Leabrook Pure Honey 400g - Squeeze
A04/0069/10	Honey	Imported: Home Brand 500g - Seal

Laboratory Reference: / Analysis Description	Method	Units	A04/0069/1	A04/0069/2	A04/0069/3	A04/0069/4	A04/0069/5
Nitrofuran metabolites							
AMOZ	04-041	µg/kg	<0.50	<0.50	<0.50	<0.50	<0.50
AOZ	04-041	µg/kg	<0.50	<0.50	<0.50	<0.50	<0.50
AH	04-041	µg/kg	<1.0	<1.0	<1.0	<1.0	<1.0
SC	04-041	µg/kg	6.3	<1.0	2.1	12	<1.0

Laboratory Reference: / Analysis Description	Method	Units	A04/0069/6	A04/0069/7	A04/0069/8	A04/0069/9	A04/0069/10
Nitrofuran metabolites							
AMOZ	04-041	µg/kg	<0.50	<0.50	<0.50	<0.50	<0.50
AOZ	04-041	µg/kg	1.1	<0.50	1.1	<0.50	5.0
AH	04-041	µg/kg	<1.0	<1.0	<1.0	<1.0	<1.0
SC	04-041	µg/kg	4.8	3.2	8.0	<1.0	1.1

INFORMATION ON BOTTLE SEALS, AS REQUESTED.

Advanced Analytical Australin Pty ltd
ABN 20 105 644 979
11 Julius Avenue,
North Ryde NSW 2113 Australia

Ph: +61 2 9888 9077
Fax: +61 2 9888 9577
contact@advancedanalytical.com.au
www.advancedanalytical.com.au

SFO TELECONFERENCE – 30 APRIL 2004 – 12.00 NOON

Attendees:

In person

Claire Pontin (Chair – FSANZ)
Graham Peachey (FSANZ)
Kelly Crouch (FSANZ)
Rob Keane (FSANZ)
Scott McKenzie (DAFF)
Tom Black (DAFF)
Kerry Bell (QLD)
John Fladun (FSANZ)
Lydia Buchtmann (FSANZ)
Scott Crerar (FSANZ)
Ron Southgate (AQIS)
Sonia Nielson (DAFF)
Dougall Mclachlan (DAFF)

Via telephone

Kim Leighton (WA Health)
Peter Sutherland (NSW)
Chris Chan (NSW)
Tracy Ward (NT)
Brian Delroy (SA)
Victor Di Paola (VIC)
John Van Den Beuken (NZFSA)
Bill Porter (NSW)
David Hook (NSW)
Mark Hansen (QLD)
Eric Johnson (TAS)
Terry Oughtred (VIC)
Bob Boyd (FSANZ NZ)
Sally Johnston (NZFSA)

Apologies

ACT Health

PURPOSE OF MEETING

Claire Pontin (FSANZ) thanked everyone for attending the meeting at such short notice and provided a brief outline on the purpose of this meeting.

Following a closer legal inspection of the *Food Standards Code*; in particular the text of Standard 1.4.2 FSANZ has determined that because nitrofurans are not listed in Schedule 1 of this Standard there is no prohibition on nitrofuran residues in food. FSANZ agreed to confirm this interpretation.

The effect of this interpretation was not the intent when the *Food Standards Code* was drafted. Because of the broad ramifications for all chemicals not listed, FSANZ was proposing an amendment to the *Food Standards Code* under urgency provisions to address this anomaly. This was generally supported but it was noted that the decision to make this amendment under urgency provisions was a decision for the FSANZ Board.

There was discussion on a number of issues related to chemical residues in food and it was identified that there was the general concern in relation to the prohibition in Standard 1.4.2 that FSANZ would address, subject to the FSANZ Board agreement and there was the specific concern in relation to nitrofurans.

In relation to the general concern about the prohibition in the Standard, most jurisdictions and AQIS noted that the general provisions in relation to 'unsuitable' food in Food/Health Acts provided scope to regulate chemical residues in food. However, it was noted that these provisions were untested in relation to low level chemical residues. On this basis, the use of the urgency provisions to amend the Code were supported.

Some jurisdictions raised other issues that may need to be addressed in revising the Standard, but the general view was that these supplementary issues may need to be left for a subsequent review of the Standard. This matter would be considered further by FSANZ.

In relation to the specific concern about nitrofurans, Bill Porter (NSW) stated that they had sent out letters to three companies requesting their assistance in removing product from sale. Because they had relied on the provisions of the Code in the letter, they were now planning to write back and advice them of the problems with 1.4.2. Bill agreed to provide John Fladun with a copy of the letter.

MEDIA & CONSUMER ENQUIRIES

Lydia Buchtmann (FSANZ) stated that FSANZ has received two media inquiries today in relation to nitrofurans in food. Lydia stated that she had prepared some key messages for any media inquiries. These key messages will be used in a Ministerial that is currently being prepared for our Minister. The key messages are: we are open, the levels are low and not considered a safety risk, may not be illegal for products to contain nitrofurans; that this is a technical anomaly and that FSANZ staff are advising the Board as a matter or urgency. FSANZ would like to see a consistent approach in the response to any media inquires and States and Territories are welcome to forward any media inquires to FSANZ.

OTHER BUSINESS

Nil

NEXT MEETING

It was agreed that there should be another teleconference sometime next week that will discuss the more technical issues in respect of amending the Standard. This would be managed by the Product Safety Standards Section.

Meeting closed at 1.05pm

(as at 12 05 04 – 11.30am)

Keane, Rob

From: Keane, Rob
Sent: Thursday, 22 April 2004 12:04 PM
To: 'Kim Leighton (E-mail)'; 'Trent Brady (E-mail)'; 'Craig Shadbolt (E-mail)'; 'Brian.Delroy@dhs.sa.gov.au'; 'Eric.Johnson@dchs.tas.gov.au'; 'Kerry_Bell@health.qld.gov.au'; 'jim.wilson@nzfsa.govt.nz'; 'Chris.Chan@foodauthority.nsw.gov.au'; 'Mary_Hodge@health.qld.gov.au'; 'Kerrie Boulton (E-mail)'; Terry.Oughtred@dhs.vic.gov.au
Cc: 'Tracy Ward (E-mail)'; Buchtmann, Lydia; Brent, Paul; Stanley, Glenn; Jamieson, Craig; Pontin, Claire; 'victor.dipaola@dhs.vic.gov.au'; 'Vojkan Stefanovic (E-mail)'
Subject: Teleconference - nitrofurans

Further to my email yesterday, please find attached a FSANZ summary of the current situation in terms of nitrofurans in prawns and honey. I apologise for the lateness of this document.

Nitrofurans Status.doc

You should now have the following

- an Agenda
- two emails from Chris including two sets of results (Mr Taylor's and NSW Food Authority's)
- nitrofuran status document from FSANZ

I look forward to discussing this issue at 1.30 pm AEST

Rob Keane
(02) 6271 2635

NITROFURAN RESIDUES IN PRAWNS AND HONEY

Summary

There have been reports in the media about honey and prawns containing residues of nitrofurans.

Nitrofurans are antibiotics and have been prohibited for use in most countries in the world due to public health and safety concerns in relation to the carcinogenic potential of either the parent compounds or their metabolites. The EU prohibited the use of nitrofurans in food producing animals in 1995, and Australia prohibited the use of nitrofurans in late 1992.

In October 2003, the Australian Prawn Farmers Association (APFA) provided laboratory results indicating the presence of nitrofuran residues at very low levels in certain prawns imported into Australia.

In respect of nitrofuran residues in honey, an Australian apiarist informed FSANZ on 5 December 2003 about results of nitrofuran residue testing that had been conducted on a variety of Capilano honey samples. As reported by the 'Today Tonight' Television program, five samples were found to contain trace residues of a nitrofuran residue, at levels between 0.4 and 1.4 parts per billion (ppb).

FSANZ has kept the relevant enforcement authorities in the Australian States and Territories and New Zealand informed of the reports of nitrofuran residues in prawns and honey. FSANZ has also advised the Australian Quarantine and Inspection Service (AQIS) to test consignments of imported prawns and honey for nitrofuran residues.

Testing of imported prawns for nitrofuran residues was instituted on 8 December 2003. AQIS has advised FSANZ that testing of imported honey for nitrofuran residues will be instituted from April 2004.

FSANZ has approached the Department of Foreign Affairs and Trade and requested advice from the Argentine authorities as to the residues of nitrofurans in honey, and the controls in place to prevent further contamination. To date no response has been received.

FSANZ is aware that recalls of honey have been instituted in Canada because of residues of nitrofurans. The 'No Name' brand of honey has been included in these recalls and this honey was imported into Canada from Australia. The honey is understood to be a blend of Argentine and Australian honey. The recalls have been instituted despite statements from Canadian authorities that 'the residues of nitrofurans in the honey in question are uniformly low and pose a low risk.'

FSANZ continues to keep a watching brief on international actions in relation to nitrofuran residues in prawns and honey. The current position is that the residues of nitrofurans reported in some prawns and honey are very low and the public health risk associated with these residues is low.

Risk assessment on prawns and honey

FSANZ has undertaken an assessment of the risk to public health of the very low residues of nitrofurans reported in prawns and honey.

The risk has been characterised by determining the margin of exposure between the known levels of AOZ residues in prawns and the level of the parent compound furazolidone shown to cause tumours in animal studies.

The conclusion of the risk assessment in prawns is that the public health risk is very low. This assessment is based on nitrofuran residue data provided by the Australian Prawn Farmers' Association (APFA). Using the highest detected levels in the APFA data (16 ppb) the margin between the level of exposure for high consumers of prawns and the level causing toxicity in animal studies is extremely large (approximately 400,000 fold). Additional residue data on nitrofuran residues in prawns has recently become available from the Australian Quarantine and Inspection Service (AQIS) and Queensland Health. Once these data are compiled, the risk assessment will be revised using this larger data set.

Using a similar calculation for nitrofuran residues in honey, incorporating average detected levels of 0.8ppb (available to FSANZ at that time) the level of exposure for high consumers of honey compared to the level causing animal toxicity is also extremely large (50,000,000 fold). Since this assessment was conducted, FSANZ has been informed by Capilano that the levels of nitrofuran residues reported in honey in Canada ranged from 0.5 to 1.2 ppb. These results are consistent with the levels used by FSANZ in the original calculations and the conclusion that the public health risk is very low.

Information on sites of other countries would appear to indicate that they also consider the risk associated with the residues to be low.

UK – prawns and shrimps
http://www.foodstandards.gov.uk/news/pressreleases/51434/
UK – Chicken
http://www.food.gov.uk/multimedia/webpage/nitrofurandrugsinchicken/
Canada – honey (scroll down to near the end)
http://www.inspection.gc.ca/english/corpaffr/recarapp/2004/20040312bqae.shtml

NO TARGET AT BORDER

Keane, Rob

From: Crerar, Scott
Sent: Friday, 26 March 2004 8:34 PM
To: Bill Porter (E-mail); Brian Delroy; Caroline Martin; Charlotte Channer; Chris Chan; Crerar, Scott; Dennis Bittisnich; Eric Johnson; Gary Bielby (E-mail); Gary Smith; Geoff Raven; Ian McKay; John Van Den Beuken; Kaye Coates; Kerry Bell; Kim Leighton; Melissa Langhorne; Neil Smith; Nora Galway; Peggy Douglass; Peter Merrell; Pontin, Claire; Sally Johnston; Sophe Williamson; Taylor, John; Tenille Fort; Tracy Ward; Vojkan Stefanovic
Cc: 'petrenas.elena@saugov.sa.gov.au'; Kerrie Boulton (E-mail); Keane, Rob
Subject: Update and heads up on nitrofurans

Dear TAG

There has been renewed interest by the media in the nitrofurans and honey/prawns issue, predominantly as a result of Canada issuing a recall for an Australian honey product. From the FSANZ perspective, our view has been and continues to be there is an extremely low risk from these trace levels of nitrofurans and recalls are not justified. Today Tonight will be running a story on Monday or Tuesday evening covering this issue again. An interview with FSANZ (myself) will be a part of this story. The thrust of the FSANZ message is in the talking points copied below. I have also copied an updated brief for your information around this issue.

If you have any questions, please feel free to give me a call.

Nitrofurans and honeyTT Talkin...

CIB - Nitrofuran Residues in H...

Regards

Scott Crerar
Manager, Post Market Operations
Food Standards Australia New Zealand
PO Box 7186 Canberra BC ACT 2610
E-mail: scott.crerar@foodstandards.gov.au
Website: www.foodstandards.gov.au
Phone: +61 2 6271 2235
Fax: +61 2 6271 2278
Mobile: +61 [redacted]

Nitrofurans and honey

- FSANZ is confident that imported honey and prawns currently on sale are safe. We have carried out a risk assessment, from available test results, that indicates people could consume 35 kg of honey every day for life and still have no ill effect.
- The nitrofuran that gave rise to the residues found in honey was furazolidone. Nitrofurans are a group of antibiotics that are still prescribed by doctors to treat urinary tract infections with exposure for adults being at least 2,000,000 times higher than the dietary exposure based on the levels found in the honey.
- However, this nitrofuran is no longer registered for use as a veterinary chemical in food-producing animals in Australia and there is no residue limit for it in the Food Standards Code. Although the foods are safe, they are not legal.
- Food Standards Australia New Zealand (FSANZ) has instructed the Australian Quarantine and Inspection Service (AQIS) to test imported honey for this antibiotic.
- Although some non-accredited tests for nitrofuran in honey are available, to date AQIS has been unable to use an accredited test that is legal. They are currently meeting with other food regulatory agencies in Canada to address this issue.
- Any products found to have levels of Nitrofuran will not be permitted for sale in Australia.

Nitrofurans and prawns

- FSANZ is confident that imported prawns currently on sale are safe. We have carried out a risk assessment, from available test results, that indicates people could consume 1.8kg of prawns every day for life and still have no ill effect.
- The nitrofuran that gave rise to the residues found in prawns and honey was furazolidone. Nitrofurans are a group of antibiotics that are still prescribed by doctors to treat urinary tract infections with exposure for adults being at least 2,000,000 times higher than the dietary exposure based on the levels found in the prawns.
- However, this nitrofuran is no longer registered for use as a veterinary chemical in food-producing animals in Australia and there is no residue limit for it in the Food Standards Code. Although the foods are safe, they are not legal.
- Food Standards Australia New Zealand (FSANZ) has instructed the Australian Quarantine and Inspection Service (AQIS) to test imported prawns for this antibiotic.
- Out of 56 samples of imported prawns tested to date AQIS has found only 4 with levels of nitrofurans and consignments from this supplier will not be

permitted into Australia until at least 3 consignments have proved clear of nitrofurans.

Post Market Operations
FSANZ

CURRENT ISSUES BRIEF

NITROFURANS IN HONEY

- THERE HAVE BEEN RECENT REPORTS IN THE MEDIA ABOUT HONEY CONTAINING RESIDUES OF NITROFURANS, SPECIFICALLY IN IMPORTED ARGENTINIAN HONEY.

- NITROFURANS ARE ANTIBIOTICS AND HAVE BEEN PROHIBITED FROM USE IN FOOD-PRODUCING ANIMALS IN MOST DEVELOPED COUNTRIES DUE TO PUBLIC HEALTH AND SAFETY CONCERNS IN RELATION TO THEIR CARCINOGENIC POTENTIAL AT HIGH LEVELS OF EXPOSURE.

- FSANZ BECAME AWARE OF THE POTENTIAL FOR IMPORTED HONEY TO CONTAIN NITROFURAN RESIDUES IN NOVEMBER 2003 AND ADVISED THE AUSTRALIAN QUARANTINE AND INSPECTION SERVICE (AQIS) TO TEST IMPORTED HONEY FOR NITROFURAN RESIDUES ON 14 NOVEMBER 2003.

- ON 5 DECEMBER 2003, MR LEE DUFFIELD, AN AUSTRALIAN APIARIST, INFORMED FSANZ THAT AN OVERSEAS LABORATORY HAD REPORTED FIVE SAMPLES OF CAPILANO HONEY AS CONTAINING NITROFURAN RESIDUES OF APPROXIMATELY ONE PART PER BILLION.

- BASED UPON A SCIENTIFIC RISK ASSESSMENT FSANZ CONSIDERS THE RISK TO PUBLIC HEALTH OF THE HONEY TO BE VERY LOW AND THAT THE AFFECTED HONEY IS SAFE TO EAT.

- GIVEN THAT THERE ARE CURRENTLY NO AUSTRALIAN APPROVED USES OF NITROFURANS IN FOOD PRODUCING ANIMALS, THERE ARE NO MAXIMUM RESIDUE LIMITS AND DETECTABLE RESIDUES ARE NOT PERMITTED. FSANZ HAS THEREFORE INFORMED THE RELEVANT ENFORCEMENT AUTHORITIES IN THE AUSTRALIAN STATES AND TERRITORIES AND NEW ZEALAND OF THE REPORTS ABOUT NITROFURAN RESIDUES IN HONEY.

- ON 13 MARCH AND 23 MARCH 2004 THE CANADIAN FOOD INSPECTION AGENCY (CFIA) ANNOUNCED THAT CERTAIN BATCHES OF HONEY FROM AUSTRALIA WERE BEING RECALLED IN CANADA BECAUSE OF NITROFURAN RESIDUES.

- THE MANUFACTURER OF THE RECALLED HONEY HAS INFORMED FSANZ THAT THE LEVELS FOUND WERE APPROXIMATELY ONE PART PER BILLION. THESE LEVELS ARE CONSISTENT WITH THOSE USED IN THE ORIGINAL RISK ASSESSMENT AND FSANZ CONSIDERS THE RISK TO PUBLIC HEALTH OF THE HONEY TO BE VERY LOW AND THAT THE AFFECTED HONEY IS SAFE TO EAT.

BACKGROUND

- The nitrofuran residues reported are very low and at levels between 0.4 and 1.4 parts per billion.

- FSANZ has undertaken a scientific risk assessment of the residues reported in honey and using an average level of 0.8 ppb, FSANZ has assessed that an individual could safely consume 35kg of honey every day for life.

- While FSANZ has provided advice to AQIS to test for nitrofuran residues in imported honey, FSANZ and AQIS are not currently aware of any authorised laboratory that is capable of testing honey for low levels of nitrofuran residues. The testing undertaken for Mr Duffield was in a German laboratory that is not authorised for testing food imported into Australia. As a result, AQIS cannot institute the testing until authorised laboratories develop the analytical capability for low-level nitrofuran analysis in honey. FSANZ supports the development of a validated testing regime for nitrofuran analyses in honey within Australia.

- FSANZ has raised the issue of nitrofuran residues in honey with the enforcement authorities in the Australian States and Territories and New Zealand. However, only limited action can be taken by the jurisdictions because of the lack of a domestic capability for detecting low-level nitrofuran residues. As the analytical capability develops, jurisdictions will reconsider the situation and determine the action they consider necessary.

- The Today Tonight program has been particularly vocal on the issue of nitrofuran residues in honey and aired a story on 8 December claiming that there had been a "cover up" by regulatory agencies including FSANZ and AQIS. This is not the case as FSANZ acted appropriately once it became known that imported honey may contain nitrofuran residues by requesting AQIS to test imported honey at the border.

not cleared

PREPARED BY:	Rob Keane	6271 2635
CLEARED BY:	Scott Crerar/Steve Crossley	6271 2235/6271 2624
	Greg Roche	6271 2285

DATE: 25 March 2004

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Dr Andy Carroll
National Manager
Cargo Operations
AQIS
GPO Box 858
CANBERRA ACT 2601

Dear Dr Carroll

Antibiotic Residues in Honey

Thank you for your letter of 5 December 2003 and your advice that AQIS has commenced the process of amending the Imported Food Control Order to move honey to active surveillance (10%) for the testing of nitrofurans, sulphonamides, tetracyclines and streptomycin in honey.

You have also asked whether the testing of honey for the specified antibiotic residues is limited to honey, honey containing comb and creamed honey. FSANZ is not aware of the details of the use of these antibiotics in other countries and is therefore not aware of whether other honeybee products, such as propolis, could contain residues of these antibiotics. The EU rapid alert notice only refers to honey containing the non-complying antibiotic residues and on this basis, FSANZ considers it reasonable to only test honey, honey containing comb and creamed honey at this time. However, FSANZ is continuing to monitor the EU rapid alert notices and should other honeybee products be found to contain non-complying antibiotic residues then FSANZ will advise AQIS accordingly.

If you require further technical information on this issue please contact Mr Rob Keane on 6271 2635.

Yours sincerely

Dr Scott Crerar
Section Manager
Post Market Operations
30 January 2004

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Dr Andy Carroll
National Manager
Cargo Operations
AQIS
GPO Box 858
CANBERRA ACT 2601

Dear Dr Carroll

Antibiotic Residues in Honey

You may be aware that residues of certain antibiotics have recently been detected in honey in Europe. I have attached a copy of a recent EU rapid alert notice reporting the detection of antibiotic residues in honey. In addition, FSANZ has recently received information alleging the presence of nitrofurans in imported honey. As a result of these detections and the allegations, I am writing to provide AQIS with updated advice relating to the risk to public health and safety and the appropriate level of testing for residues of antibiotics in honey.

Nitrofurans

FSANZ has recently become aware of reports about a detection of 3-amino-oxazolidinone (AOZ), a metabolite of the nitrofuran antibiotic furazolidone, in one honey sample in the United Kingdom at 5.5 µg/kg. In addition, FSANZ has recently received information alleging the presence of nitrofurans in imported honey.

On the basis of information available to FSANZ about the toxicity of AOZ and taking into account the low levels reported, the risk to public health and safety is considered to be very low. However, nitrofurans have been prohibited from use in food-producing animals in most countries due to public health and safety concerns in relation to the carcinogenic potential of either the parent compounds or their metabolites. Australia prohibited the use of nitrofurans in late 1992.

In order to ensure that honey containing nitrofuran residues is not imported and to obtain additional data on any residues that may be present, it is advised that imported honey be tested for nitrofuran residues at the active rate of inspection (10%). This recommendation is based upon the likely low health risks associated with residues of nitrofurans and the absence of knowledge about the continued use of nitrofurans overseas. This advice is also consistent with the advice that FSANZ has provided on testing for nitrofurans in prawns.

Sulphonamides, Streptomycin and Tetracyclines

In the most recent European Union rapid alert notification that is attached to this letter, residues of a range of other antibiotics have also been reported in some European countries. The substances detected include:

- the sulphonamides sulphamerazine sulphamethazine, sulphamethoxine and sulphathiazole;
- streptomycin; and
- tetracyclines

The EU rapid alert notification did not include information on the levels detected. In order to ensure imported honey does not contain residues of these substances, it is advised that these products be tested for sulphonamides, tetracyclines and streptomycin at the active rate of inspection (10%). This recommendation is based upon the likely low health risks associated with residues of these substances, the absence of knowledge about the continued use of these substances overseas and the need for additional data on the residues of these substances to confirm the evidence base for a risk assessment.

Practical Implementation of Testing

FSANZ recognises that there may be some practical issues associated with implementing an 'active' rate of inspection for all these substances in honey. FSANZ would therefore support incremental or interim inspection measures while the practicalities of implementing the 'active' rate of inspection for all substances are addressed. FSANZ requests comment on practical inspection measures that could be adopted to ensure that testing is commenced as soon as practicable.

Limits of reporting

Recently, discussions have taken place between AQIS and FSANZ concerning the need for limits of reporting for tests on imported food. In relation to residues of antibiotics, FSANZ suggests that AQIS investigate the domestic capability for testing for these substances and the limits of reporting that are currently achievable with existing methods used by accredited laboratories. FSANZ can then provide advice as to whether these limits of reporting are sufficient.

If you require further technical information on this issue please contact Mr Rob Keane on 6271 2635.

Yours sincerely

Mr Steve Crossley
Program Manager
Monitoring and Evaluation
14 November 2003

Keane, Rob
From: Crerar, Scott
Sent: Tuesday, 8 July 2003 4:59 PM
To: 'Wayne.Riley@aqis.gov.au'
Cc: Keane, Rob
Subject: RE: Mr Breen

Wayne

Our response below. I hope that this is clear. Basically we think that this is a non-event. I am on holidays until 22 July. If you would like to discuss further, please give Rob Keane a call.

Thank you for your facsimile containing the 'significant' results from Martin Breen. FSANZ has reviewed these results and has the following comments.

Firstly, the results from the laboratories indicate that no residues of either chloramphenicol or nitrofurans have been detected. The results also indicate that 'trace' levels of tetracyclines have been reported by the analytical laboratory but that these are below the limit of quantification. The results report does not indicate whether these results are the result of the application of the screening method or the confirmatory method. In any case, as the results are below the limit of quantification, FSANZ does not consider that the results can be regarded as 'positive'. Results reported as 'trace' and below the limit of quantification may be unreliable and in FSANZ's view do not constitute a detection.

Secondly, FSANZ has considered these results in the context of existing residues that are permitted in other food commodities. MRLs currently exist for oxytetracycline and chlortetracycline as stated below.

OXYTETRACYCLINE
INHIBITORY SUBSTANCE, IDENTIFIED AS OXYTETRACYCLINE
HONEYT0.3
KIDNEY OF CATTLE, GOATS, PIGS AND SHEEP 0.6
LIVER OF CATTLE, GOATS, PIGS AND SHEEP 0.3
MEAT (MAMMALIAN) 0.1
MILKS 0.1
POULTRY, EDIBLE OFFAL OF 0.6
POULTRY MEAT 0.1
SALMONIDS T*0.2

CHLORTETRACYCLINE
INHIBITORY SUBSTANCE, IDENTIFIED AS CHLORTETRACYCLINE
CATTLE KIDNEY 0.6
CATTLE LIVER 0.3
CATTLE MEAT 0.1
EGGS 0.2
PIG KIDNEY 0.6
PIG LIVER 0.3
PIG MEAT 0.1
POULTRY, EDIBLE OFFAL OF 0.6
POULTRY MEAT 0.1

From these existing MRLs, it is apparent that the residues that may be present in prawns are below those that are already legally permitted in mammalian, poultry and fish commodities. Given that these commodities are consumed in greater amounts than prawns, the residues that may be present in prawns would be of lower significance to dietary exposure than the residues already permitted in other foods. On this basis, FSANZ considers that the residues that may be present in prawns are not of public health significance.

In summary, FSANZ considers that the reported results do not indicate the presence of any non-compliant residues and that even if the results were confirmed at the limits of quantification the residues would not represent a risk to public health and safety. Given these low and insignificant residues, FSANZ considers that a meeting to discuss the results would be of little value at this stage.

Regards

Scott Crerar
6271 2235

-----Original Message-----

From: Wayne.Riley@aqis.gov.au [mailto:Wayne.Riley@aqis.gov.au]
Sent: Tuesday, 8 July 2003 4:17 PM
To: Crerar, Scott
Subject: Mr Breen

Scott

Not pressuring. Can you give an idea if Mr Breen's antibiotics are something you need to consider.

Just putting together options for response to minister.

Regards

Wayne Riley
Client Manager
AQIS/Import Clearance/Food Safety
ph 02 6272 5515
fax 02 6272 5888
mob 0[redacted]
email wayne.riley@aqis.gov.au

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai - Ahitereiria me Aotearoa

55 Blackall St., Barton
ACT 2600 Australia
PO Box 7186
Canberra BC ACT 2610
Australia
Tel + 61 2 6271 2222
Fax +61 2 6271 2278
www.foodstandards.gov.au

Dr Andy Carroll
National Manager
Cargo Operations
AQIS
GPO Box 858
CANBERRA ACT 2601

Dear Dr Carroll

Nitrofuran Residues in Scallops

As a result of recent allegations about nitrofuran residues in scallops, I am writing to provide AQIS with updated advice relating to the appropriate level of testing for residues of nitrofurans in scallops.

FSANZ has been informed that residues of nitrofurans may be present in imported scallops. There is no information available on the likelihood or on the levels of nitrofurans that may be detected in scallops, but FSANZ has requested additional information from the informant. FSANZ considers that the matter merits investigation and monitoring. Therefore, to gather additional data, FSANZ advises that imported scallops be tested for nitrofuran residues.

FSANZ understands that the most practical application of the nitrofuran test would be to apply the test on an 'officer to assign' basis as determined at the time of inspection. At this time, this testing advice applies to all scallops regardless of how packed but does not extend to mixed foods containing scallops.

This advice will need to remain under review and is subject to change depending upon the levels reported in tested samples. To ensure that FSANZ can provide AQIS with timely advice, I would like to request that AQIS advise FSANZ of the results of non-complying samples. This will enable FSANZ to consider the public health implications of specific residue detections and revise the advice accordingly.

If you require further technical information on this issue please contact Mr Rob Keane on 6271 2635.

Yours sincerely

Dr Luba Tomaska
A/g General Manager
Office of Food Safety and Services
21 April 2004

Testing of Honey for Antibiotic Residues through the Imported Food Program

Background

The European Union (EU) recently suspended the importation of all animal-derived food products, including honey, imported from China as a result of a "lack of controls on the use of veterinary drugs". The United Kingdom Food Standards Agency (FSA) subsequently undertook testing for residues of antibiotics in Chinese honey products. Residues of chloramphenicol and streptomycin were detected in eleven out of 16 samples of Chinese honey products that were tested. The FSA then withdrew all Chinese honey from sale in the United Kingdom but indicated that the honey was withdrawn on a voluntary basis and that their "... primary concern in the consumer risk assessment was the possibility of [chloramphenicol] triggering aplastic anaemia". A FSA independent expert group subsequently at these levels this is most unlikely" The FSA was also informed by a large honey supplier within the UK who had analysed the individual components of some blended honeys, that the Chinese honey component was responsible for the chloramphenicol contamination.

The Canadian Food Inspection Agency (CFIA) issued a health hazard alert to consumers on 18 April 2002 advising them not to consume Chinese honey and blends containing Chinese honey due to the possibility they contained residues of chloramphenicol. Subsequently on 27 April 2002, the CFIA coordinated a voluntary recall of all honey from China and blends of honey containing honey of Chinese origin that were in the marketplace. In May 2002, the CFIA announced additional measures aimed at manufacturers and importers to help safeguard consumers. The measures included advice to manufacturers to discontinue using honey from China in their products and the detainment of all shipments of honey from China until proven free of chloramphenicol residues. Shipments of honey from other countries are currently being subjected to the CFIA's regular monitoring program which also includes a test for chloramphenicol.

Risk assessments

Streptomycin and chloramphenicol

In response to these events, ANZFA assessed the potential public health risk resulting from exposure to residues of streptomycin and chloramphenicol in honey. ANZFA toxicologists also reviewed the information concerning the toxicity of chloramphenicol as there was no Acceptable Daily Intake (ADI) established for this chemical. By using the results of the UK survey, dietary exposure assessments were undertaken for both streptomycin and chloramphenicol.

ANZFA concluded that the level of dietary exposure to streptomycin was well below the ADI (less than 6% of the ADI), assuming that all foods permitted to contain residues do so at the MRL, and honey (no MRL established) had the maximum residue levels from the UK survey. Therefore, it was concluded that there is a negligible public health risk posed by residues of streptomycin in honey.

The estimated dietary exposure for chloramphenicol residues was assessed and shown to be extremely low. The public health risk posed by residues of chloramphenicol in honey could

not, however, be definitively established as JECFA has not set an ADI. Although chloramphenicol use has been associated with aplastic anaemia and leukaemia, this has only occurred at high (therapeutic) and sustained doses and there is no evidence of these effects at low doses. Moreover, JECFA has considered the risk posed by residues in food to be of the same order as exposure resulting from systemic uptake following clinical ophthalmic use. In the latter case, there is no evidence of an increased incidence of aplastic anaemia or leukaemia. Thus, ANZFA considers the levels of chloramphenicol residues in honey are very unlikely to pose a health risk.

Further details on the dietary exposure assessments and toxicology can be found at Attachments 1 and 2 respectively.

Independent of the public health risk assessment for chloramphenicol, it must be acknowledged that in the absence of an ADI for chloramphenicol, residues are both illegal and undesirable to have in the food supply and therefore some testing should be undertaken on honey sourced from countries where these residues may be present.

Current risk management advice to AQIS on testing of honey

ANZFA, in a recent review of the testing of the Active and Random Surveillance Food Categories for pesticides and antibiotics, advised AQIS in October 2001 of a testing regime for honey. This consisted of the random level (5%) testing for both antibiotics (routine antimicrobial substance screen) and pesticide residues (priority pesticide list).

Additional risk management advice

As a result of the recent EU and FSA actions, ANZFA also advised AQIS on 12 March 2002 that the antimicrobial substance screen applied to honey should specifically include a test for residues of chloramphenicol at the random (5%) rate. The random level of testing for chloramphenicol was still considered appropriate because low chloramphenicol residues in honey are very unlikely to pose a health risk. Nevertheless it was recognised as desirable to test for and therefore limit exposure to potential illegal drug residues.

Attachment 1

DIETARY EXPOSURE ASSESSMENT
ANTIBIOTICS IN HONEY
25 February 2002

Purpose of Dietary Exposure Assessment
In response to the UK Food Standards Agency testing of antibiotic residues (streptoymycin and chloramphenicol) in honey, a dietary exposure assessment was conducted for Australian and New Zealand populations to determine if the levels of streptoymycin and chloramphenicol found in UK honey (of blended and Chinese origin) would be of a public health and safety concern in Australia and New Zealand.

Australian and New Zealand permissions for Streptomycin and Chloramphenicol
Streptomycin has Maximum Residue Limits (MRLs) in the Australia New Zealand Food Standards Code as follows:

Food	MRL (mg/kg)
Milk	0.2
Mammalian meat	0.3
Mammalian offal	0.3

There are no MRLs for chloramphenicol for Australia and New Zealand.

Dietary survey data used for the dietary modelling

- The 1995 Australian National Nutrition Survey (NNS) data, for 13 858 respondents aged 2 years and above.
- The 1997 New Zealand NNS data, for 4 636 respondents aged 15 years and above.

Both of these surveys used a 24-hour food recall methodology.

Dietary modelling was conducted for the whole population only.

Residue data used for honey in the dietary exposure assessment
Residue data were used from a UK Food Standards Agency survey. Summaries of the residue data are shown in Table 1.

Table 1: summary of the residue data from a UK Food Standards Agency survey of antibiotics in honey

Chemical	No samples	No samples no residues	Min (µg/kg)	Max (µg/kg)	Mean* (µg/kg)
Streptomycin	14	6	ND	500	73.57
Chloramphenicol	16	5	ND	7.2	2.06

ND = Not detected
* Assuming not detected results have a concentration of zero.

The mean and maximums were used in the dietary modelling to estimate the most likely and the worst case scenario estimated dietary exposures respectively.

Exposure to streptomycin was also estimated taking into account exposure from other dietary sources using MRL concentrations.

Estimated Dietary Exposures

Table 2: Mean estimated daily dietary exposures to Streptomycin for consumers only

Country	Exposure	Scenario				
		Honey only Mean residue	Honey only Max residue	MRL's only	MRL's + honey mean residue	MRL's + honey max residue
Australia	µg/kg bw	0.002	0.113	2.8	2.8	2.8
	%ADI*	0.003	0.2	5.6	5.6	5.6
New Zealand	µg/kg bw	0.002	0.123	2.53	2.52	2.55
	%ADI*	0.004	0.2	5.05	5.04	5.09

* ADI = acceptable daily intake of 50 µg/kg bw

Table 3: Mean estimated daily dietary exposures to Chloramphenicol for consumers only

Country	Exposure	Scenario	
		Honey only Mean residue	Honey only Max residue
Australia	µg/kg bw	0.0005	0.0016
	%ADI	*	*
New Zealand	µg/kg bw	0.0005	0.0018
	%ADI	*	*

* There is no ADI in Australia or New Zealand for Chloramphenicol

Interpretation of the results

The results assume that all honey consumed in Australia and New Zealand has the concentration specified in the model for the respective scenario. Models for streptomycin using MRL's assume all foods contain residues at the level of the MRL.

The results indicate that estimated dietary exposures for streptomycin are well below the ADI (less that 6%) assuming all foods permitted to contain residues do so at the MRL, and honey at the maximum residue.

The results based on the MRLs for streptomycin for New Zealand show a (slightly) lower estimated exposure for MRLs + honey at mean residue, than for MRLs on their own. It would be expected that the addition of honey to the model would result in an increase in the estimated exposure. However, the results are based on 2 different sets of consumers. For MRLs only there were 4605 consumers and for MRL + honey mean, there were 4609 consumers. The mean estimated exposures are derived from the distribution of estimated exposures for each individual. A different set of consumers will have a different distribution of exposures, therefore resulting in different mean estimated exposure for the population.

Estimated dietary exposures for chloramphenicol could not be directly compared with an ADI since none has been established. However, an assessment of the level of risk associated with these levels of chloramphenicol residues in honey is included in Attachment 2.

Attachment 2

TOXICOLOGY OF CHLORAMPHENICOL RESIDUES IN HONEY MARCH 2002

Chloramphenicol has been reviewed by the Joint Expert Committee on Food Additives (JECFA) on three occasions, the most recent being 1994.

Carcinogenicity

The major international concern with chloramphenicol has been the potential for exposure to lead to the development of aplastic anaemia. Aplastic anaemia is usually fatal and in those that survive there is a high incidence of acute leukaemia.

The incidence of aplastic anaemia is 1.5 cases per million per year, and the incidence of chloramphenicol-associated aplastic anaemia is 1 case per 10 million per year. The JECFA Committee considered the ophthalmic use of chloramphenicol (which is a common route of exposure) was not associated with the induction of aplastic anaemia. They also considered that exposure to chloramphenicol residues through food to be of the same order as exposure via ophthalmic use.

While there are no adequate animal studies that have examined the carcinogenicity of chloramphenicol, the available epidemiological evidence from the extensive clinical use of chloramphenicol does not indicate an association except the extremely low incidence of leukaemia as a result of aplastic anaemia.

Genotoxicity

The available data indicates that chloramphenicol is a weak inducer of chromosomal aberrations and sister chromatid exchanges in mammalian cells *in vitro*. These chromosomal effects occur only at very high dose levels. The *in vivo* micronucleus assay was negative.

There is no data to suggest that the weak in *in vitro* genotoxicity observed could lead to carcinogenicity or to genetic damage to germ cells. There is no evidence that chloramphenicol is teratogenic.

ADI

The JECFA Committee were unable to establish an ADI because the available long-term studies were not considered adequate for this purpose. Chloramphenicol has been in clinical use for many years and with little evidence of adverse effects.

Evidence of weak *in vitro* genotoxicity is not uncommon and is not generally regarded as strong evidence of potential long-term adverse effects.

Summary

JECFA suggested that the human exposure to residues of chloramphenicol in food is of the same order as exposure resulting from systemic uptake following clinical ophthalmic use. In the latter case, there is no evidence of an increased incidence of aplastic anaemia or leukaemia. Thus, the levels of chloramphenicol residues in honey are very unlikely to be a health concern.

Attachment 3

SURVEY DATA ON CONTAMINANTS IN HONEY

Internationally, there have been few surveys that have looked at the presence and levels of contaminants in honey products.

In 1994 the United Kingdom MAFF undertook a survey of domestic and imported honey products for the heavy metals lead and cadmium. The survey results showed that honey and pollen contained low concentrations of both lead (0.01-0.2 mg/kg) and cadmium (0.04-0.18 mg/kg) and concluded that consumption at these levels did not pose a risk to public health. The 19th Australian Total Diet Survey looked at lead in honey and showed there to be a maximum level of 0.11 mg/kg. Canadian testing for lead in maple syrup in 1998/1991 showed that 56% of samples tested had residues of lead, but information on the levels was not available.

In 1998/1999 the Canadian Food Inspection Agency's Residue in Agri-Foods Monitoring Program showed that 2% of domestic honey and 12% of imported honey had residues of phenol and 2% had residues of sulfonamides. No indication of the levels of these contaminants was available. However in 1999/2000 the Canadian Food Inspection Agency's Residue in Agri-Foods Monitoring Program showed a range of chemical residues in honey exceeding allowable limits that included the following violations:

- 12% phenol (maximum level of 2.32ppm, average of 0.57ppm)
- 2% sulfamethazine (maximum level of 0.04ppm)
- 3% sulfamethoxazole (maximum level of 0.08ppm)
- 10% sulfathiazole (maximum level of 0.73ppm)
- 21% tetracycline (maximum level of 0.08ppm)
- 4% oxytetracycline (maximum level of 0.01ppm)

Almost all the determined residues were at very low levels and represented violations due to a lack of established tolerances for these substances in honey.

A quality survey of Australian honeys by the Queensland Department of Primary Industries published in 2001 showed that of 60 different honeys tested, all were found to be free of antimicrobial residues, organochlorins, organophosphate type pesticides, and synthetic pyrethroids at the level of reporting.

Keane, Rob
From: Marro, Narelle
Sent: Friday, 23 May 2003 10:20 AM
To: Keane, Rob
Subject: FW: Chloramphenicol testing of Chinese honey

Rob
I found the following email when going through my IFP emails today.

May be of interest to you.

Narelle

-----Original Message-----
From: **Marro, Narelle**
Sent: Wednesday, 10 April 2002 10:35 AM
To: Salter, Mark
Subject: FW: Chloramphenicol testing of Chinese honey

Narelle

-----Original Message-----
From: **Crerar, Scott**
Sent: Tuesday, 12 March 2002 9:51
To: Peter Bignell (E-mail)
Cc: Ron Southgate (E-mail); Annette Marrington (E-mail); Peter Maple (E-mail); Kerrie Boulton (E-mail); Crossley, Steve; Roche, Greg; Marro, Narelle; Salter, Mark; Keane, Rob
Subject: Chloramphenicol testing of Chinese honey

Dear Peter

In speaking to Ron Southgate on this issue, I had flagged the fact that ANZFA would be providing some advice to you on what form of antibiotic testing we wanted for honey in view of the Chinese honey contamination issue. Please find our advice below. If there are any issues, please don't hesitate to contact me to discuss.

Thanks

CHLORAMPHENICOL RESIDUES IN HONEY

As you are aware, the United Kingdom (UK) recently released survey results of tests on imported Chinese honey for various residues of antibiotics. This testing was initiated through concerns voiced by the European Union (EU) that controls on the use of veterinary therapeutics in China were being inadequately enforced. In fact the EU recently announced a ban on all imports of Chinese products of animal origin. The ban takes effect [redacted] March. In the meantime all such imports are being rigorously tested by European authorities at the ports.

With regards to the UK test results, ANZFA has sought additional information from the UK Food Standards Agency (FSA) to determine if there is likely to be any public health risk from imported Chinese honey. The FSA has indicated to ANZFA that the honey was withdrawn on a voluntary basis and that their "... primary concern in the consumer risk assessment was the possibility of triggering aplastic anaemia. A FSA independent expert group advised that at these levels this is most unlikely". The UK FSA also received information from testing performed by industry that for the blended honeys, it was most likely the Chinese honey was the source of the chloramphenicol residues.

ANZFA toxicologists have reviewed the information concerning the toxicity of chloramphenicol in conjunction with the results of the UK survey. We have concluded that the levels of chloramphenicol residues in honey are very unlikely to be a health concern. Although chloramphenicol use has been associated with aplastic anaemia and leukaemia, this has only occurred at high (therapeutic) doses and there is no evidence of these effects at low doses. However, it is also acknowledged that these residues are both illegal and undesirable to have in the food supply and therefore some form of testing should be occurring to prevent continued exposure.

Taking into account this new information, ANZFA would like to request AQIS to undertake the following actions:

- testing for antibiotic residues in honey should be resumed, in accordance with ANZFA's previous advice. In particular, attention should be given to the testing of residues of chloramphenicol in Chinese honey.
- if tests are not available, this analyte/commodity combination should be given priority in method development.
- that the testing of residues of chloramphenicol in Chinese honey should be undertaken at the random frequency of testing.
- that positive test results for chloramphenicl/honey should be reported to ANZFA as soon as practical and the level stated.

If there are any problems with this proposed course of action, please do not hesitate to contact me on (02) 6271 2235.

Thanking you

Scott Crerar

Scott Crerar
Australia New Zealand Food Authority
Monitoring and Evaluation
PO Box 7186
Canberra MC 2610 Australia
Phone: +61 2 6271 2235
Mobile: [redacted]
Fax: +61 2 6271 2278
Email: scott.crerar@anzfa.gov.au

ANZFA
Australia New Zealand Food Authority
TE MANA WHAKARITE KAI MŌ ĀHITEREIRIA ME AOTEAROA

55 Blackall Street
Barton ACT 2600
Australia
Ph: 61 2 6271 2222

PO Box 7186
Canberra MC ACT 2610
Australia
Fax: 61 2 6271 2278

www.anzfa.gov.au

Mr Peter Maple
Manager, Import Operations
Food and Agricultural Products
Australian Quarantine and Inspection Service
GPO Box 858
CANBERRA ACT 2601

Dear Mr Maple

Amendments to the Active and Random Surveillance Categories and Pesticide Screen

I am writing to provide updated advice on the chemical testing of foods in the Random and Active surveillance categories, and the agricultural and veterinary chemical analytes that should be screened, under the *Imported Food Control Act, 1992.*

Recently, concerns have been raised regarding the appropriateness of certain chemical tests applied to foods in the Active and Random surveillance categories. In response to these concerns, ANZFA has undertaken a review of the Random and Active surveillance category lists in order to more accurately target chemical testing of foods. As a result, ANZFA recommends that amendments, as detailed in the attached document, be incorporated into the Imported Food Program's Active and Random surveillance category lists.

As a part of the review process, ANZFA also considered the agricultural and veterinary chemical analytes that should be included in the pesticide screen, as set out in the Imported Food Program Master Test Legend. ANZFA's primary responsibility is to target areas of public health and safety significance. Therefore, the analytes ANZFA has proposed for inclusion in the pesticide screen are considered to be those of greatest public health significance due to their potential for acute health effects. ANZFA recommends that the Master Test Legend pesticide screen should be restricted to the revised list of analytes, as set out in the attached document.

In order for ANZFA to respond quickly and effectively to emerging food issues it may be necessary for changes to be made at short notice to the list of analytes included in the pesticide screen. To this end, I would appreciate it if you could clarify

what mechanisms are available to amend the list of analytes to be tested for in the screen, how easily this can be done, and how long such processes are likely to take.

Thank you for your help in this matter. If you require further clarification on the advice outlined above then please contact Mary-Lou Dalzell on 6271 2227 in the first instance.

Yours sincerely

Steve Crossley
Program Manager
Food Monitoring and Evaluation
19 October 2001

bcc Greg Roche
Scott Crerar
Rob Keane

Review of Chemical Testing for the Imported Food Program Active and Random Surveillance Categories

October 2001

Introduction

The inspection of food imported into Australia is carried out by the Australian Quarantine and Inspection Service (AQIS) under the *Imported Food Control Act, 1992* (IFCA). ANZFA provides advice to AQIS on how foods should be categorised and which tests should be applied to food under the Imported Food Program (IFP). The IFP inspects food for compliance with the Food Standards Code, at varying rates, depending on its risk categorisation. Foods which do not represent a high public health and safety concern are categorised in the IFP as Random surveillance foods. These are inspected at a rate of 5%. Foods in the Active surveillance category are tested at a rate of 10%, as there is a lack of knowledge on the degree of risk these foods may pose, and further information is required to allow categorisation into either the Risk or Random surveillance categories.

Recently, concerns have been raised regarding the appropriateness of tests applied to foods for certain chemicals in the Active and Random surveillance categories. Therefore, the IFP Random and Active surveillance category food lists have been reviewed with a view to rationalise testing. This has been achieved by:

1. focusing on those chemicals which represent a potential public health and safety concern; and

2. more accurately targeting the testing of foods which, by their nature or method of production or manufacture, are likely to contain chemical residues.

For the purposes of this review, chemicals include pesticides, antibiotics and polychlorinated biphenyls (PCBs).

Methodology for the review

In recommending which tests should be applied to foods in the Active and Random surveillance categories the following methodology has been applied:

- Consistent application of tests to food commodities taking into account where agricultural practice suggests that the occurrence of chemical residues in those food commodities will be more likely.

- Targeted testing of those foods or components of food where chemical residues are likely to concentrate and persist.

- Compiling the pesticide screen to include testing for those pesticides where an acute reference dose exists due to the potential for acute toxicity.

ANZFA recommends amendments to the Active and Random surveillance categories, applying the above methodology, as detailed in Attachment 1.

Where possible, recommended amendments to the Active and Random Surveillance lists are supported by data from IFP testing results. A brief summary of the main classes of chemicals and their likely residues in food is at Attachment 2.

Pesticide Screen

Tests applied to foods inspected under the IFP are set out in the IFP Master Test Legend. The IFP Master Test Legend and the Active and Random surveillance category lists currently refer to the 'OP-OC screen'. This terminology should be amended to refer to a 'priority pesticide list'.

ANZFA recommends that reference to 'OP-OC screen' in the IFP Master Test Legend and the Active and Random surveillance category lists be amended to 'priority pesticide list'.

Currently the Master Test Legend specifies that the pesticide screen and PCB screen are applied together for the testing of food commodities. This arrangement provides a broad testing approach which does not recognise that a food, by its nature or method of production, may not contain both pesticide and PCB residues. Separating the tests for pesticide and PCB screens in the Master Test Legend will allow additional flexibility to specifically target testing of foods likely to contain pesticide residues or foods likely to contain PCB residues, or both.

ANZFA recommends that the IFP Master Test Legend be amended to allow the separate application of a pesticide screen or PCB screen for the testing of imported food.

Currently the IFP Master Test Legend screen for pesticides includes testing for a range of chlorinated organic pesticides (organochlorines or OCs) (PCBs are included in the list of OCs), organophosphorus pesticides (OPs) and fungicides, included at Attachment 3. Due to the potential for acute health effects, testing for pesticides should concentrate on those pesticides for which an acute reference dose exists for imported food, rather than undertaking a wider screen for chemicals of lower significance to public health and safety.

To ensure the continued protection of public health and safety it is important that there is the capacity to change the pesticide analytes tested for without delay, as new information on pesticide residues becomes available.

Subject to the capacity for timely amendment, ANZFA recommends that the IFP Master Test Legend pesticide screen be amended to ensure that imported food testing focuses on those pesticides set out in Table 1.

Table 1. Recommended residue analytes for the IFP Pesticide Screen.

Residue	LOR (mg/kg)
Azinphos-methyl	0.20
Carbaryl	0.10
Chlorpyrifos	0.01
Chlorfenvinphos (cis & trans)	0.05
Diazinon	0.05
Dichlorvos	0.10
Dimethoate	0.15
Disulfoton	0.05
Endosulfan (α, β & sulfate)	0.05
Ethoprofos	0.05
Fenamiphos	0.05
Fenitrothion	0.01
Fenthion	0.05
Fipronil	0.05
Malathion	0.05
Methidathion	0.05
Mevinphos	0.05
Monocrotophos	0.05
Omethoate	0.05
Parathion-ethyl	0.05
Parathion-methyl	0.05
Phorate	0.05
Phosmet	0.05
Pirimicarb	0.05
Pirimiphos-methyl	0.05

ATTACHMENT 1

RECOMMENDED AMENDMENTS TO THE IFP RANDOM CATEGORY LIST

Tariff	Description	Current chemical test requirements	Proposed Change	Justification
All		'OC-OP screen'	'priority pesticide list'	Change in name to more accurately reflect analytes being screened.
0204	Sheep/goat (fresh, chilled or frozen)	Antibiotic Screen	**Delete** antibiotic screen.	Delete antibiotic testing for these products as antibiotics unlikely to be used for this type of farming. No IFP past data is available, indicating there has been no imports under this tariff code in the previous two years.
0208	All frog, crocodile and deer (fresh, chilled or frozen)	Antibiotic Screen	**Delete** antibiotic screen	Delete antibiotic testing for these products as antibiotics unlikely to be used for this type of farming.
0209	Pig and poultry fat (fresh, chilled or frozen)	Antibiotic Screen Stilbenes	**Delete** antibiotic screen **Include** priority pesticide list & PCB screen	Delete antibiotic test as antibiotics are not generally lipophilic and will not be deposited in the fat. Include priority pesticide list and PCB screen as PCBs and some pesticides are lipophilic.
0210	Canadian pork	Antibiotic screen	**Include** 'as for all plus carbadox'	Test Canadian pork products only, to be consistent with requirements in 0203. Use of carbadox is currently being re-evaluated by Health Canada and is likely to be banned in the near future.
0409	All honey	Antibiotic screen	**Include** priority pesticide list	Retain antibiotic screen. Include priority pesticide list as pesticides used in hives to control parasites.

Tariff	Description	Current chemical test requirements	Proposed Change	Justification
0701-0714	Vegetables – fresh, preserved, frozen, dried	OC-OP & PCB screen (except onions, leeks and garlic)	**Delete** exemption for onions, garlic and leeks. **Delete** PCB screen	Onions, garlic and leeks are as likely to be contaminated with pesticide residues are other vegetables, therefore there is no reason to exempt them from these tests. Delete PCB screen as this is a contaminant which tends to be in fats and oils.
0803-0814	Fruit - Fresh	OC-OP & PCB screen	**Delete** PCB screen	As for vegetables, Delete PCB screen as this is a contaminant which tends to be in fats and oils.
1001-1008	Cereals	Aflatoxins Ergot Rice, wheat – plus cadmium	**Include** priority pesticide list	Priority pesticide list should be applied. OPs are used worldwide as post harvest grain protectants. Post harvest application can lead to very high residue levels with acute dietary effects. Residues have been found on Australian grain through the ATDS.
1101-1109	Milled cereal products	All corn/maize products only- Aflatoxins	**Include** Bran and Germ – as for all plus priority pesticide list	Milling of cereals substantially reduces residues from the raw grain. Therefore, priority pesticide list is unlikely to be necessary for most milled cereal products. However, the milled cereals should be monitored and if problems arise, reconsider applying priority pesticide list. **Bran and germ**: Priority pesticide list should be applied to bran and germ as residues are likely to be concentrated in this portion of the raw grain. Note – testing these products may be possible only if they have a separate tariff code.

Tariff	Description	Current chemical test requirements	Proposed Change	Justification
1210	Hop cones, ground, powdered or pellets	OC-OP & PCB screen	**Delete** Pesticide and PCB screen	PCB screen should be deleted, as per for fruits and vegetables. Pesticide screen should also be deleted. No IFP past data is available, indicating there has been no imports under this tariff code in the previous two years.
1702	All other sugars	OC-OP & PCB screen	**Delete** pesticide and PCB screen	Products highly processed and refined, with raw product not likely to have high levels. Therefore unlikely to be of concern.
2001	Preserved fruit and vegetables (vinegar or acid)	OC-OP & PCB screen	**Delete** PCB screen	Justification as for Fruit and Vegetables (0701-0714, 0803-0814)
2002	Preserved Tomatoes	OC-OP & PCB screen	**Delete** PCB screen	Justification as for Fruit and Vegetables (0701-0714, 0803-0814)
2003	Prepared or preserved mushrooms or truffles	OC-OP & PCB screen	**Delete** Pesticide and PCB screen	Delete pesticide screen as this is not the sort of commodity standard pesticides are likely to be used on. Not been tested for pesticides in the past, no problems identified, thus no justification.
2004	Other prepared or preserved vegetables - frozen	OC-OP & PCB screen	**Delete** PCB screen	Justification as for Fruit and Vegetables (0701-0714, 0803-0814)
2005	Other prepared or preserved vegetables, not frozen	OC-OP & PCB screen	**Delete** PCB screen	Justification as for fruits and vegetables (0701-0714, 0803-0814). Retain priority pesticide list. As preservation technique not specified, are not able to determine what the effect will be on pesticide residues. Monitor for compliance.

Tariff	Description	Current chemical test requirements	Proposed Change	Justification
2008	Other prepared fruit or nuts not elsewhere specified	OC-OP & PCB screen	**Delete** PCB screen	Justification as for fruits and vegetables above. Retain priority pesticide list pending data analysis with chemicals in new pesticide screen. As preservation technique not specified, are not able to determine what the effect will be on pesticide residues. Monitor for compliance. IFP past data indicated a total of 3 failures for pesticides out of 536 samples.
2009	Fruit or vegetable juices	OC-OP & PCB screen	**Delete** PCB screen	Justification as for Fruit and Vegetables (0701-0714, 0803-0814). Retain priority pesticide list pending data analysis with chemicals in new pesticide screen. IFP past data indicated no failures for pesticides out of 324 samples.
2103	Sauces, mixed condiments & mixed seasonings (includes mayonnaise, salad dressings & mustard)	OC-OP & PCB screen	**Delete** PCB screen	PCBs unlikely to be detected in these products. Sauces can contain oils, fruits, vegetables and animal fats which are all being screened for pesticides elsewhere. Therefore retain priority pesticide list to maintain consistency, and because past data shows some problems. IFP past data indicated a possible 106 failures from 1430 samples.

RECOMMENDED AMENDMENTS TO THE IFP ACTIVE CATEGORY LIST

Tariff	Description	Current chemical test requirements	Proposed Change	Justification
0804-0806 0811-0814	Dried edible fruit and peel of citrus fruit or melons	OC-OP & PCB screen	**Delete** PCB screen **Recommend** drop to Random list	Justification as for Fruit and Vegetables (0701-0714, 0803-0814) Drop to Random list, as is consistent with other fruit and vegetables.
1201-1208	Oil seeds and oleaginous fruits	OC-OP & PCB screen	**Retain** priority pesticide list and PCB screen **Recommend** drop to Random list	Retain priority pesticide list as is consistent for other fat or oil based foods. Past data shows very few failures (1 failure from 214 samples), therefore drop to Random category.
1507-1517	Animal or vegetable fats, oils and waxes	OC-OP & PCB screen	**Retain** priority pesticide list and PCB screen	**Retain** priority pesticide list as there have been some failures for this category in the past. IFP past data indicates 9 failures from 280 pesticide tests applied.

AGRICULTURAL AND VETERINARY CHEMICALS AND CONTAMINANTS

Background

Registered pesticides and other chemicals such as antibiotics, are intentionally applied to agricultural commodities, under approved conditions. As a result chemical residues may be present in food, although the levels should be, and in the majority of cases are, less than the specified Maximum Residue Limit (MRL). In many instances residues will be below detectable limits.

The MRL is a limit on the amount of pesticide or antibiotic residue permitted in a commodity. A commodity with a residue above the MRL cannot be legally sold in Australia.

Although MRLs are not direct health measures, the toxicology of the chemical is taken into consideration when setting the MRL. There are two types of potential human health risks associated with consumption of pesticide residues, acute and chronic toxicity. Acute toxicity is evidenced by almost immediate effects. Chronic toxicity occurs when effects are produced by long term intake of lower or intermittent doses of a chemical.

Pesticides

Chlorinated organic pesticides (organochlorines, OCs) include highly stable, non biodegradable compounds that persist in soil and concentrate in the food chain. Due to their fat solubility some are stored in the fat tissue of humans and other animals. The use of many persistent chlorinated organic pesticides in developed countries is heavily restricted.

Organophosphorus pesticides (OPs) are widely used insecticides with an array of structures, properties and agricultural uses. Organophosphorus pesticides are mostly biodegradable, and therefore do not concentrate in the food chain as is the case for chlorinated organic pesticides. Organophosphorus pesticides degrade rapidly by hydrolysis into harmless substances and do not accumulate in the human body.

Synthetic pyrethroids are artificially produced insecticides which have a similar chemical structure to natural pyrethrins. Synthetic pyrethroids are generally biodegradable and therefore do not tend to persist in the environment.

Fungicides are used to control diseases caused by fungi and may vary in structure, properties and uses. They can either be protectant or eradicant.

Antibiotics

Antibiotics are used to maintain the health and promote the growth of animals, usually in intensive farming situations. As a result of their use, low levels of antibiotics residues may be present in some foods. Antibiotics are not generally lipophilic and do not tend to accumulate in the fatty tissue of animals

The IFP Master Test Legend currently stipulates screening for the following antibiotics:

chloramphenicol
oxytetracycline
streptomycin
penicillin

Additionally, the Random surveillance category specifies that Canadian pork should be tested for Carbadox. Canada is one of the few remaining countries to permit the use of Carbadox. However, Canada Health recently placed a temporary ban on its use, pending finalisation of its safety assessment.

Polychlorinated biphenyls

Polychlorinated biphenyls (PCBs) are mixtures of synthetic organic chemicals with the same basic chemical structure and similar physical properties ranging from oily liquids to waxy solids. Unlike pesticides or antibiotics, PCBs are environmental contaminants and find their way into foods primarily through soil and water contamination. PCBs are fat soluble and tend to be deposited in fatty tissue.

ATTACHMENT 3

IMPORTED FOOD PROGRAM

CURRENT MASTER TEST LEGEND PESTICIDE AND PCB SCREEN

OCs

Aldrin and Dieldrin (combined)
BHC (other than the gamma isomer, Lindane)
DDT (total)
Chlordane
Endrin
Heptachlor and heptachlor epoxide (combined)
Hexachorobenzene (HCB)
Lindane
Total endosulphan (alpha and beta isomers and sulphate)
Sum of PCBs

OPs

Azinphos ethyl
Azinphos methyl
Chlorfenvinphos
Chlorpyrifos
Chlorpyrifos methyl
Diazinon
Dichlorvos
Dioxathion
Ethion
Fenthion
Fenitrothion
Maldison
Methamidophos
Mevinphos
Monocrotphos
Parathion
Parathion-methyl
Pirimiphos-methyl
Trithion

Fungicides

Chorothalonil
Dichloran
Iprodione
Procymidone
Vinclozolin

IMPORTED FOODS PROGRAM

RANDOM SURVEILLANCE CATEGORY FOODS

3 September 1999

Should an Authorised Officer have reasonable grounds to believe that a food may not comply with Australian food regulations, alternative or additional analysis may be ordered by the Officer.

All products are subject to visual and label inspection even if no analytical tests are required.

For the purpose of this document the term thermally processed refers to product processed by heat to prevent spoilage.

CHAPTER 2: MEAT & EDIBLE MEAT OFFAL

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
beef - fresh & chilled frozen	0201 0202	**all** - (21) antibiotics
pork - fresh chilled or frozen	0203	**all** - (21) antibiotics Canadian pork carbadox
sheep, goat - fresh, chilled or frozen	0204	**all** - (21) antibiotics
horse - fresh, chilled or frozen	0205	**PROHIBITED IMPORT**
edible offal	0206	**PROHIBITED IMPORT**
poultry (meat & offal)- fresh chilled or frozen	0207	**all** - (21) antibiotics
other (frog, rabbit, deer, crocodile) - fresh, chilled or frozen	0208	**rabbit - PROHIBITED IMPORT** **all** - (21) antibiotics
pig fat, poultry fat	0209	**all-** (21) antibiotics **pig fat** - as for 'all' plus (23) stilbenes
meat & edible meat offal - salted, in brine, dried or smoked	0210	**uncooked fermented meat - PROHIBITED IMPORT** **all** - (21) antibiotics

CHAPTER 3: FISH & CRUSTACEANS, MOLLUSCS & OTHER AQUATIC INVERTEBRATES

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
fish - fresh & chilled frozen **fish fillets & other fish meat**	0302 0303 0304	**all -** (22) metals (mercury only) (24) histamine
fish & fish meal - dried, smoked or salted	0305	**all -** (22) metals (mercury only) **ready-to-eat** - as for 'all' plus (5) staph enterotoxin
crustaceans (raw) - chilled, frozen, dried or salted	0306	**live crustaceans - PROHIBITED IMPORT** **Raw -** (22) metals (mercury only) (25) sulphur dioxide **farmed crustacea -** (21) antibiotics
molluscs (including snails) – raw, chilled, frozen, salted or dried	0307 0307.600	**unopened molluscs & live snails - PROHIBITED IMPORT** **terrestrial snails** (cooked) (1) SPC (3) *E coli*

CHAPTER 4: DAIRY PRODUCE, EGGS, HONEY & EDIBLE ANIMAL PRODUCTS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
milk & cream - liquid, not containing sugar or other sweetening matter	0401	**all -** (27) phosphatase **UHT & sterilised milk (including goats milk) -** (21) microbial growth
milk & cream - dried, concentrated or containing added sugar or other sweetening matter (includes flavoured, skim and malted milks)	0402	**dried-** (2) coliforms **(infant formula (dried)-** (2) coliforms **infant formula (sterilised)** (12) microbial growth. **condensed milk -** (21) microbial growth
fermented milk products (including buttermilk, yoghurt and sour cream)	0403	**all -** (2) coliforms
whey	0404	**all -** (2) coliforms

CHAPTER 4: Continued

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
butter and other fats or oils derived from milk	0405	**all -** (20) Pesticide & PCB screen
cheese & curd	0406	**all -** (3) *E coli*
eggs in shell **egg products** - dried or frozen	0407 0408	**eggs in shell, uncooked/ unpasteurised egg products - PROHIBITED IMPORT** **all egg products** (except thermally processed hermetically sealed product)- (28) alpha amylase **egg pulp & egg powder** as for 'all' plus - (4) *Salmonella* **thermally processed hermetically sealed product** – (13) Commercial sterility
honey	0409	**all -** (21) antibiotics
edible products of animal origin (eg royal jelly)	0410	**all -** (2) coliforms

* to be reviewed at the beginning of 1999.

CHAPTER 5: PRODUCTS OF ANIMAL ORIGIN
(Not elsewhere specified)

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
guts, bladders & stomachs, eg. sausage casings (runners, caps & sets)	0504	**No analytical tests required** **Visual and labelling**

CHAPTER 7: EDIBLE VEGETABLES & CERTAIN ROOTS & TUBERS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
vegetables -		**all -**
potatoes	0701	(20) Pesticide & PCB screen
tomatoes	0702	**leafy, root & tuber vegetables** - as
onions, garlic & leeks	0703	for 'all' plus
cabbages and other brassicas	0704	(48) cadmium
lettuce	0705	**preserved vegetables (retail packs) -**
carrots & other edible roots	0706	as for 'all' plus
cucumbers & gherkins	0707	(25) sulphur dioxide
leguminous vegetables	0708	
other vegetables	0709	
frozen vegetables	0710	
preserved vegetables (SO2, brine)	0711	
dried vegetables	0712	
dried leguminous vegetables (lentils, beans etc)	0713	
manioc, arrowroot	0714	

Note: Leafy, root & tuber vegetables include taro leaves, amaranth, potato, carrots and other edible roots such as taro and yams.

CHAPTER 8: EDIBLE FRUITS & NUTS; PEEL OF CITRUS FRUIT OR MELONS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
coconut, brazil nuts & cashews	0801	**all** (except coconut)- (26) aflatoxins
other nuts	0802	**pastes** - as for 'all' plus (4) *Salmonella*
fruit - fresh or dried		**all** -
bananas (fresh or chilled)	0803	(20) Pesticide & PCB screen
dates, figs, pineapple, mangoes	0804	**figs (fresh & dried) & dried fruit** -
citrus	0805	as for 'all' plus
grapes (fresh or dried)	0806	(47) ochratoxins
melons & pawpaws	0807	(25) sulphur dioxide
apples, pears & quinces	0808	**preserved fruit** as for 'all' plus -
apricots, cherries, peaches & plums	0809	(50) artificial sweeteners **berry fruit, stone fruit (including peaches, nectarines, apricots, plums)**
other fruits	0810	- as for 'all' plus
frozen fruits & nuts	0811	(51) captan
preserved fruits & nuts (SO_2, brine or other preservative)	0812	
dried fruit (except grapes)	0813	
citrus or melon peel	0814	

CHAPTER 9: COFFEE, TEA, MATE & SPICES

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
coffee	0901	**all-**
tea	0902	(47) ochratoxins
mate	0903	
spices -		**all** -
peppers (including capsicum & pimento)	0904	(1) coliforms
vanilla	0905	
cinnamon	0906	
cloves	0907	
nutmeg	0908	
anise, fennel, coriander, cumin, caraway & juniper berries	0909	
ginger, saffron, turmeric & all other spices	0910	

CHAPTER 10: CEREALS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
cereals -		**all** (except rice) -
wheat	1001	(26) aflatoxins
rye	1002	(32) ergot
barley	1003	**rice, wheat** - as for 'all' plus
oats	1004	(48) cadmium
maize	1005	
rice	1006	
grain sorghum	1007	
other cereals	1008	

CHAPTER 11: PRODUCTS OF THE MILLING INDUSTRY

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
milled cereal products -		**corn/maize products only** -
wheat flour	1101	(26) aflatoxins
other cereal flours	1102	
cereal grouts & meals	1103	
worked cereal grains (eg rolled oats, kibbled grain)	1104	
potato flour, meal and flakes	1105	
flour & meal of dried leguminous vegetables, sago & powdered vegetables	1106	
malt	1107	
starches	1108	
gluten	1109	

CHAPTER 12: OIL SEEDS & OLEAGINOUS FRUITS MISCELLANEOUS GRAINS, SEEDS & FRUITS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
oil seeds - soya beans copra linseed rape seed sunflower seed other oil seeds & oleaginous fruits flours & meals of oil seeds & oleaginous fruits	 1201 1202 1203 1204 1205 1206 1207 1208	**all -** (20) Pesticide & PCB screen
hop cones (ground, powdered or pellets)	1210	**all -** (20) Pesticide & PCB screen
plant & plant products (includes herbs, ginseng, liquorice)	1211	**all -** (1) SPC
other plant products used for human food (includes locust bean seeds, kernels, roots, seaweeds, algae & kava etc)	1212	**all -** (4) *Salmonella*

CHAPTER 13: LAC, GUMS, RESINS & OTHER VEGETABLE SAPS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
natural gums (eg gum arabic)	1301	**No analytical tests required** **Visual and labelling**
vegetable saps & extracts, pectin, agar and other thickeners derived from vegetables	1302	

CHAPTER 15: ANIMAL & VEGETABLE FATS, OILS & WAXES

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
animal or vegetable fats , oils & waxes -		**all -** (20) Pesticide & PCB screen
lard, rendered pig & poultry fat	1501	**rape & mustard oil -** as for 'all' plus
bovine fat (raw or rendered)	1502	(49) erucic acid
lard products	1503	
fish fats & oils	1504	
other animal fats	1506	
soya-bean oil	1507	
ground-nut oil	1508	
olive oil	1509	
other oil obtained from olives	1510	
palm oil	1511	
sunflower oil	1512	
coconut & palm kernel oil	1513	
rape & mustard oil	1514	
other vegetable oils	1515	
animal & vegetable oils (chemically modified)	1516	
margarine & other edible mixture	1517	
glycerol (glycerine)	1520	
vegetable waxes & beeswax	1521	

CHAPTER 16: PREPARATIONS OF MEAT, FISH, CRUSTACEANS, MOLLUSCS OR OTHER AQUATIC INVERTEBRATES

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
sausages & similar products of meat, meat offal or blood	1601	**thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only) (21) antibiotics
other prepared or preserved meat, meat offal or blood (includes hams, steak & kidney pies, pate)	1602	**thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only) (21) antibiotics **Canadian pork products** – carbadox
extracts and juices of meat, fish, crustaceans & molluscs (includes stock cubes, bonox etc)	1603	Pesticide & PCB

CHAPTER 16 **Continued**

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
prepared or preserved fish, caviar & caviar substitutes (includes crumbed fish, fish balls, fish cakes, canned fish)	1604	**Anchovies, caviar & cooked fish products -** (5) staph enterotoxin **thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only) (24) histamine (sardines, tuna, mackerel, salmon, fish pastes)
prepared/ preserved crustaceans & molluscs - smoked marinated mussels	1605	**all (except thermally processed hermetically sealed product) -** (5) staph enterotoxin **thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only)

CHAPTER 17: SUGAR & SUGAR CONFECTIONERY

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
cane or beet sugar	1701	**No analytical tests required**
other sugars	1702	**all -** (20) Pesticide & PCB screen
molasses	1703	**all -** (22) metals
sugar confectionery (including white chocolate, chewing gum) (not containing cocoa)	1704	**all** (except uncoloured confectionery)- (41) colour screen **confectionery containing coconut and/or high fat content -** as for 'all' plus (4) *Salmonella* **hard formed confectionery -** as for 'all' plus (22) metals (lead only)

Note: hard formed confectionery includes products such as boiled sweets etc.
High fat confectionery includes products such as white chocolate, fudge etc.

CHAPTER 18: COCOA & COCOA PRODUCTS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
cocoa beans **cocoa shells, husks & skins** **cocoa paste** **cocoa butter, fat & oil**	1801 1802 1803 1804	**No analytical tests required** **Visual and labelling**
cocoa powder	1805	(4) *Salmonella* (not further heat processed)
chocolate & other foods containing cocoa	1806	**all** - (4) *Salmonella* (48) cadmium

CHAPTER 19: PREPARATIONS OF CEREALS, FLOUR, STARCH OR MILK; PASTRYCOOKS' PRODUCTS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
malt extract & food preparations not containing >10% cocoa	1901	**all** (except pasta) - (26) aflatoxins
pasta (all) **tapioca** **precooked or swollen cereal products or grains**	1902 1903 1904	
bread, pastry, cakes, biscuits & other bakers wares (including rice paper)	1905	**Filled products –** (5) SET

CHAPTER 20: PREPARATIONS OF VEGETABLES, FRUIT, NUTS OR OTHER PARTS OF PLANTS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
preserved vegetables & fruits (by vinegar, acetic acid)	2001	**all -** (39) pH (20) pesticide screen **thermally processed hermetically sealed product pH >4.5 -** (13) commercial sterility (36) pressure testing (canned only)
preserved tomatoes (not by vinegar, acetic acid) (includes dried tomatoes in oil)	2002	**all -** (20) pesticide screen (25) sulphur dioxide **(except canned)** **thermally processed hermetically sealed product pH >4.5** as for 'all' plus - (13) commercial sterility (36) pressure testing (canned only) (22) metals (lead only in soldered cans)
prepared or preserved mushrooms & truffles (includes canned mushrooms)	2003	**all -** (5) staph enterotoxin (20) pesticide screen **thermally processed hermetically sealed product pH >4.5 -** (13) commercial sterility (36) pressure testing (canned only)
other prepared or preserved vegetables - frozen	2004	**frozen vegetables only -** (20) Pesticide
other prepared or preserved vegetables - not frozen **(includes low acid canned vegetables & olives)**	2005	**thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only) (22) pressure testing (canned only) (20) pesticide screen **non thermally processed hermetically sealed product in brine/other liquid (eg bulk barrels) -** (5) staph enterotoxin (39) pH
fruits & nuts preserved by sugar (includes glace & crystallised fruits)	2006	(5) staph enterotoxin

jams, jellies, marmalades, fruit & nut pastes	2007	**nut pastes** - (4) *Salmonella* (26) aflatoxins **thermally processed hermetically sealed product** - (13) commercial sterility (36) pressure testing (canned only)

CHAPTER 20: continued

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
other preserved fruits & nuts not elsewhere specified (includes ground nuts & other seeds, canned fruits)	2008	**thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only) (20) pesticide screen **non thermally processed hermetically sealed product in brine/other liquid (eg bulk barrels) -** (39) pH **other preserved fruits not elsewhere specified -** (50) artificial sweeteners
fruit & vegetable juices	2009	**apple & pear juice** (40) patulin (20) pesticide screen

CHAPTER 21: MISCELLANEOUS EDIBLE PRODUCTS

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
extracts, concentrates & essences of tea, coffee, mate, chicory & coffee substitutes	2101	**No analytical tests required** **Visual and labelling**
yeasts (active & inactive) & prepared baking powders	2102	**No analytical tests required** **Visual and labelling**
sauces, mixed condiments & mixed seasonings (includes mayonnaise, salad dressings & mustard)	2103	**all -** (5) staph enterotoxin **thermally processed hermetically sealed product pH >4.5 -** (13) commercial sterility (36) pressure testing (canned only) **Mayonnaise containing egg –** (4) *Salmonella* **Peanut sauces –** (26) aflatoxins
soups & broths	2104	**thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only)
ice cream & other edible ices	2105	**all -** (2) coliforms

CHAPTER 21 Continued

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
foods not elsewhere specified (includes textured protein substances, ice cream mix, syrups, royal jelly etc)	2106	**all (except thermally processed hermetically sealed product) -** (2) coliforms **thermally processed hermetically sealed product -** (13) commercial sterility (36) pressure testing (canned only) **Coagulated vegetable protein based products -** (5) *B cereus* **Pastes (tahini) –** (4) *Salmonella*

CHAPTER 22: BEVERAGES, SPIRITS & VINEGAR

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
waters (including natural or artificial mineral waters & aerated waters) not containing added sugar or other sweetening matter waters (including mineral & aerated waters) containing added sugar or other sweetening matter or flavouring, and other non-alcoholic beverages	2201 2202	**all -** (39) pH **If pH >3.5, then test for -** (2) coliforms (15) *Pseudomonas aeruginosa*
beer	2203	**No analytical tests required** **Visual and labelling**
wine	2204	**all -** (25) sulphur dioxide (if not declared on the label)
vermouth & other wine flavoured with plants or aromatic substances **other fermented beverages (including cider, perry & mead)** **spirits >80% alcohol** **spirits <80% alcohol**	2205 2206 2207 2208	**No analytical tests required** **Visual and labelling**
vinegar	2209	**No analytical tests required** **Visual and labelling**

CHAPTER 25: SALT

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS

salt (including product containing free-flow agents and/or anti-caking agents)	2501	No analytical tests required Visual and labelling

CHAPTER 35: ALBUMINOIDAL SUBSTANCES; MODIFIED STARCHES & ENZYMES

PRODUCT	TARIFF CODE	I.F. TESTING REQUIREMENTS
caseins, caseinates albumins, albuminates gelatine & gelatine products	3501 3502 3503	No analytical tests required Visual and labelling
dextrins & other modified starches	3505	No analytical tests required Visual and labelling
enzymes, prepared enzymes not elsewhere specified	3507	No analytical tests required Visual and labelling