

# SURVEY REPORT



**Government of South Australia**  
Department of Health

## Chloramphenicol

**A survey of chloramphenicol in imported crab meat**

**FOOD POLICY AND PROGRAMS BRANCH, PUBLIC HEALTH**

*Project coordinated and report compiled by*

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# Chloramphenicol

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## A survey of chloramphenicol in imported crab meat

### Background

Chloramphenicol is an antibiotic drug used to treat serious diseases in humans, and to treat non-food animals. Chloramphenicol is not listed within the residue standards of the Australia New Zealand Food Standards Code and consequently there is a zero tolerance for any residues of chloramphenicol in food. Chloramphenicol is also prohibited from use in treating food producing animals under the South Australian Agricultural and Veterinary Products (Control of Use) Act 2002 & Regulations 2004.

Two forms of chloramphenicol toxicity in humans have been described. The most common adverse reaction is dose-dependent bone-marrow depression associated with a daily dose of more than 4g of chloramphenicol. Toxicity is reversible if treatment is discontinued or the dosage is reduced. Also there is an idiosyncratic reaction of aplastic anaemia observed in some people which is not dose-related. Although the incidence of aplastic anaemia has been shown to correlate with several risk factors, it is estimated to occur with a frequency of 1 in 24,000 – 40,000 courses of treatment with chloramphenicol <sup>(1)</sup>. The mortality rate associated with aplastic anaemia is greater than 50%.

Chloramphenicol also has ophthalmic uses in human medicine which represent the lowest therapeutic dose of the compound. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) considers that ophthalmic use of chloramphenicol in humans is unlikely to be associated with the development of aplastic anaemia <sup>(1)</sup>. JECFA also considers that the occasional daily dietary intake of chloramphenicol by preferential eaters of fish and shellfish which contains median levels of chloramphenicol of 0.5 µg/kg is more than one order of magnitude lower than exposure from a daily dose of a typical ophthalmic formulation used in human medicine and as stated above this is unlikely to be associated with the development of aplastic anaemia <sup>(1)</sup>.

In November 2004 Food Standards Australia New Zealand (FSANZ) highlighted, through the national Food Surveillance Network (FSN), an alert raised by the US Food and Drug Administration of the detection of low level residues of chloramphenicol in crab meat from Asian suppliers. A review of Australian Quarantine Inspection Service (AQIS) records by FSANZ revealed that the same suppliers were not supplying crab meat to Australia.

A limited survey of imported crab meat was recommended by FSANZ in an effort to determine whether chloramphenicol residues were present in imported crab meat available at wholesale or retail in Australia.

### Samples

The range of imported crab meat found available for sale in South Australia was limited. A total of 17 samples of imported crab meat products were included in the survey. Samples included frozen crab meat, frozen salted crab, soft shell crab, canned crab meat and canned crab meat in spices. Countries of origin included Vietnam, Indonesia and Thailand.

## Analysis method

Prepared samples were analysed by liquid chromatography ion trap mass spectrometry (LC-MS/MS). Duplicate samples were analysed and spike and spike duplicate samples analysed. The laboratory undertaking the analysis reported a limit of detection of 0.1µg/kg for this method. The limit of detection adopted by the United States, Canada and the European Union is 0.3 µg/kg.

## Results

Chloramphenicol was detected in 6 of the 17 samples, see Table 1.

**TABLE 1: Product details and results**

Product	No. of samples	Country of Origin	Result
Salted crab – frozen	2	Vietnam	1 @ 0.1 µg/kg 1 @ not detected*
Crab meat in spices – canned	2	Thailand	not detected*
Crab meat – frozen	7	Vietnam	2 @ 0.3 µg/kg, 1 @ 0.2 µg/kg, 1 @ 0.1 µg/kg 3 @ not detected*
Crab Meat – canned	5	Thailand (4)	1 @ 0.2 µg/kg 3 @ not detected*
		Indonesia (1)	1 @ not detected*
Soft shell crab x 1	1	Vietnam	not detected*

\* For calculation of dietary exposure estimates (Table 2) a value of 0.05µg/kg (half the limit of detection of 0.1µg/kg) was used for samples where chloramphenicol was 'not detected'

## FSANZ Risk Assessment

FSANZ has reviewed the available information on the toxicity of chloramphenicol and has assessed the potential public health risk resulting from exposure to residues of chloramphenicol in crabmeat. FSANZ has advised that the extremely low levels of chloramphenicol residues in crabmeat are very unlikely to be a health concern.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not set an acceptable daily intake (ADI) for chloramphenicol. However, JECFA considers that the intake of chloramphenicol by preferential eaters of fish and shellfish containing median levels of chloramphenicol of 0.5 µg/kg is more than one order of magnitude lower than exposure from a daily dose of a typical ophthalmic formulation used in human medicine. There is no evidence of an increased incidence of aplastic anaemia associated with ophthalmic use of chloramphenicol.

The estimated dietary exposure to residues of chloramphenicol from the consumption of the crabmeat is expected to be extremely low with the highest level of intake estimated at 0.03µg per day (see table 2); which is many orders of magnitude lower than a typical ophthalmic formulation used in human medicine where there is no evidence of increased aplastic anaemia.

Therefore the human health risk associated with the extremely low residues of chloramphenicol detected in crabmeat is considered to be extremely low.

**TABLE 2: Mean estimated daily dietary exposures to chloramphenicol from consumption of crabmeat**

Consumption of crabmeat in Australia (42 consumers)	Dietary exposure, µg of chloramphenicol a day	
	Using the mean residue in the 17 samples of 0.094 µg of chloramphenicol per kg of crab meat*	Using the maximum residue in the 17 samples of 0.3 µg of chloramphenicol per kg of crab meat
Mean consumer of crab meat who consumes 36g of crab meat a day	0.0034µg	0.01µg
High consumer of crab meat who consumes 96g of crab meat a day	0.009µg	0.03µg

\* For calculation of dietary exposure estimates (Table 2) a value of 0.05ug/kg (half the limit of detection of 0.1ug/kg) was used for samples where chloramphenicol was 'not detected'

### Notification of results to importers and AQIS

All four importers of crab meat containing residues were advised of results and encouraged to seek assurances from their suppliers that future shipments are free of residues of chloramphenicol.

AQIS were provided with sample details and results of analysis and have liaised with officials at the Thai and Vietnamese Embassies regarding the survey and trace residues found.

### Conclusion

The low levels of chloramphenicol detected in six of the seventeen samples of imported crab meat, (four below the limit of reporting adopted by the US, Canada and the EU and 2 at the limit of reporting of 0.3 µg/kg) are not considered to pose a risk to health.

Significant efforts have been made in Asia, particularly in Vietnam since 2001 to eliminate the use of prohibited antibiotics in aquaculture, including establishment of the Vietnamese National Fisheries Quality Assurance and Veterinary Directorate. The Directorate has introduced a range of measures to monitor aquaculture operations and has invested in upgrading laboratory capabilities for screening for veterinary chemical residues <sup>(2)</sup>.

The presence of the residues of chloramphenicol have been brought to the attention of exporting countries and each of the Australian importers. Surveillance of imports of crab meat by AQIS is continuing.

### References

1. WHO Food Additive Series: 53, Chloramphenicol, Joint FAO/WHO Expert Committee on Food Additives 2004.
2. Le Duy Binh, Viet Nam, "Measures applied to control forbidden antibiotics in aquaculture products in Viet Nam", Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL. 2003.  
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