CHLOROPROPANOLS IN FOOD

An Analysis of the Public Health Risk

TECHNICAL REPORT SERIES NO. 15

FOOD STANDARDS AUSTRALIA NEW ZEALAND
October 2003

ISBN 0642 345 97 X
ISSN 1448-3017
Published October 2003

Food Standards Australia New Zealand

Australia	New Zealand
PO Box 7186	PO Box 10599
Canberra BC ACT 2610	Wellington
Australia	New Zealand
Tel +61 2 6271 2241	Tel + 64 4 473 9942
Fax +61 2 6271 2278	Fax +64 4 473 9855
Email info@foodstandards.gov.au	Email info@foodstandards.govt.nz

TABLE OF CONTENTS

ACKNOWLEDGEMENTS

FSANZ gratefully acknowledges the following organisations that have contributed to this paper:

The Australian Government Analytical Laboratories (AGAL)
Virotec Global Solutions Pty Ltd
Queensland Health Department

FSANZ also thanks Dr Wendy Matthews from the UK's Food Standards Agency who undertook a comprehensive peer review of this technical paper.

ABBREVIATIONS

1,3-DCP	1,3-dichloro-2-propanol
3-MCPD	3-chloro-1,2-propanediol
AGAL	Australian Government Analytical Laboratories
ANZFA	Australia New Zealand Food Authority (now FSANZ)
ANZFSC	Australia New Zealand Food Standards Council
AOAC	Association of Official Analytical Chemists
AQIS	Australian Quarantine Inspection Service
ATDS	Australian Total Diet Survey
CCFAC	Codex Committee on Food Additives and Contaminants
CSL (UK)	Central Science Laboratory (United Kingdom)
DIAMOND	Dietary Modelling of Nutritional Data (FSANZ computer software program)
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
FSA	Food Standards Agency (United Kingdom)
FSANZ	Food Standards Australia New Zealand
GMP	Good manufacturing practice
HVP	Hydrolysed vegetable protein
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	Limit of detection
LOEL	Lowest observable effect level
LOR	Limit of reporting
mg/kg bw/day	milligrams per kilogram of body weight per day
ML	Maximum limit
NNS	National Nutrition Survey
NOEL	No observable effect level
PMTDI	Provisional maximum tolerable daily intake
SCF	European Commission's Scientific Committee on Food
TDI	Tolerable daily intake
µg/kg bw/day	micrograms per kilogram body weight per day
WHO	World Health Organization

EXECUTIVE SUMMARY

In recent years there has been increasing scientific interest in a class of chemicals known as chloropropanols. The formation of chloropropanols in foods is not fully understood, although they are known to be formed during the production of hydrolysed vegetable protein in the presence of hydrochloric acid. The World Health Organisation (WHO) has identified potentially adverse health effects resulting from exposure to chloropropanols. This paper examines the public health and safety risk associated with the consumption of food containing chloropropanols, based on both the results of food surveys conducted in Australia in 2001 and 2002 and the toxicological evaluation of their health impact undertaken by the Joint FAO/WHO[1] Expert Committee on Food Additives (JECFA) in 2001.

The overall conclusion of this report is that, in relation to exposure to chloropropanols from food, adequate regulatory measures are now in place in Australia and New Zealand to protect consumers, and any risk associated with the levels of chloropropanols remaining in food is considered to be very low.

The major chloropropanols are 3-chloro-1,2-propanediol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP), both of which can be found in a number of foods. Whilst it has been known for several years that chloropropanols can occur in soy and oyster sauces, a UK survey of soy and oyster sauces released in 2001 indicated the presence of high levels of 3-MCPD in some products. This prompted a re-examination of the toxicology data on chloropropanols by JECFA, as well as the commencement of further survey work in both the UK and Australia.

In relation to 3-MCPD, JECFA in 2001 established a provisional maximum tolerable daily intake (PMTDI) of up to 2 μg/kg bw/day based on potential renal effects. For 1,3-DCP, JECFA identified some evidence for potential carcinogenicity and has not established a safe level of intake. JECFA noted, however, that the margin between the estimated dietary intake and the level that results in tumour formation in animal studies is very large.

To assess any potential public health concerns, FSANZ has conducted two surveys of chloropropanols in food in Australia, one in soy and oyster sauces (2001) and one in a broader range of other foods (2002). The results of the first survey confirmed the presence of both 3-MCPD and 1,3-DCP in some soy and oyster sauce products. Levels of 3-MCPD were very high (up to 150 mg/kg) in some individual soy sauce products and this resulted in the recall of these particular products from the Australian market. In order to ensure that low levels of chloropropanols were maintained in these foods, FSANZ also recommended a change to the *Food Standards Code* to include maximum levels of 0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP for soy and oyster sauces, based on 40% dry matter content. In addition, FSANZ advised the Australian Quarantine and Inspection Service to introduce import testing for soy and

[1] Food and Agricultural Organization of the United Nations/World Health Organization

oyster sauce products and to release only those products that complied with the new maximum levels.

The second survey, in 2002, detected generally very low levels of both 3-MCPD and 1,3-DCP (up to 0.083 mg/kg and up to 0.11 mg/kg, respectively), in some samples of minced beef, sausages, ham, battered fish, beef steak and lamb chops. In some cases, 1,3-DCP was detected in the absence of 3-MCPD, indicating that 1,3-DCP may be formed independently of 3-MCPD. Although the sample size of this survey was relatively small, the samples were sufficiently random and representative to clearly indicate the presence of low-level chloropropanols in certain foods. In contrast to soy and oyster sauces, 3-MCPD in other foods were very low.

FSANZ estimated the dietary exposure to 3-MCPD and 1,3-DCP from a wide range of foods based on the Australian survey data together with food consumption data from the 1995 National Nutrition Survey. In the first scenario, exposure estimates were determined using the mean concentrations for 3-MCPD and 1,3-DCP found in soy and oyster sauces from the 2001 Australian survey data. In the second scenario, exposure estimates were determined using the newly established maximum levels for 3-MCPD (0.2 mg/kg) and 1,3-DCP (0.005 mg/kg) in the *Food Standards Code.* Total estimated dietary exposure to 3-MCPD was well below the PMTDI established by JECFA in both scenarios at both mean and 95th percentile exposure levels.

Since the predominant contributors to the dietary exposure to 3-MCPD for all age groups were soy and oyster sauces, the dietary exposure to 3-MCPD was estimated for the smaller group of consumers specifically exposed through consumption of soy and oyster sauces. Estimated dietary exposure to 3-MCPD for these consumers at the 95th percentile, using the 2001 survey data, was up to 400 % of the PMTDI. However, when the dietary exposure was estimated using the newly established maximum level for 3-MCPD of 0.2 mg/kg in the *Food Standards Code*, the 95th percentile exposure was only up to 5% of the PMTDI.

Total estimated dietary exposure for consumers of 1,3-DCP from a wide range of foods was also low, the major food contributors being minced meat, sausages, bread, soy and oyster sauce, ham and bacon for both scenarios. Although no tolerable daily intake has been established for 1,3-DCP, the margin between the level of exposure for high consumers and the level causing tumour formation in animal studies is extremely large (approximately 200,000 fold). Under these circumstances, the public health and safety risk for consumers is considered to be very low and therefore did not warrant any regulatory action.

The formation of chloropropanols in food is not fully understood and government agencies will be liaising with relevant industry sectors to determine the source of chloropropanols in food. In addition, government agencies will work with relevant industry sectors to monitor the food supply for chloropropanols to ensure that the levels are kept as low as practically achievable.

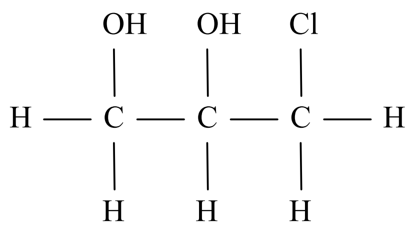
1.0 INTRODUCTION

1.1 What are chloropropanols?

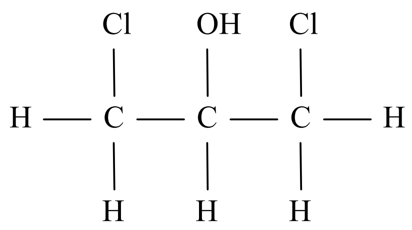
Chloropropanols are chemicals formed when glycerol reacts with chlorine under acidic conditions. The major chloropropanols are 3-chloro-1,2-propanediol (3-MCPD; CAS No. 96-24-2) and 1,3-dichloro-2-propanol (1,3-DCP; CAS No. 96-23-1), both of which are formed in foods. The chemical structures of 3-MCPD and 1,3-DCP are shown below. 3-MCPD is also known as chlorohydrin, glycerol chlorohydrin, 3-chloropropan-1,2-diol and 1-chloropropane-2,3-dihydroxypropane.

1,3-DCP is also known as dichlorohydrin, 1,3-dichloropropan-2-ol and *sym*-glycerol dichlorohydrin.

3-chloro-1,2-propanediol (3-MCPD)



1,3-dichloro-2-propanol (1,3-DCP)



1.2 How do chloropropanols form in foods?

The exact conditions required for the formation of chloropropanols in foods are still unclear although model systems suggest that 3-MCPD can form when glycerol reacts with hydrochloric acid at high temperatures. 3-MCPD may also form when glycerol reacts with sodium chloride in the presence of other acids, such as citric and acetic acids, at high temperatures (Hamlet et al, 2002).

3-MCPD is known to occur in hydrolysed vegetable protein (HVP) when produced using hydrochloric acid. Some components of fats and oils in the starting material for HVP become chlorinated at high temperatures resulting in the formation of chloropropanols (Ministry of Agriculture, Fisheries and Food, 1999). The formation of chloropropanols in HVP is dependent on the production process and the concentrations can be reduced markedly with suitable process modifications (Hamlet et al, 2002). Soy and oyster sauces produced using an acid hydrolysis process have been found, in some cases, to contain very high levels of 3-MCPD. In contrast, traditionally fermented soy sauces do not appear to contain detectable levels of chloropropanols.

Certain types of fermented sausage such as salami have also been shown to contain 3-MCPD, possibly as a result of the interaction between fat and sodium chloride in the product and/or due to the presence of 3-MCPD in the resins used in the sausage casings (CCFAC, 2001). Bacon has also been found to sometimes contain 3-MCPD and this is possibly the result of the smoking process used (Hamlet et al, 2002). 1,3-DCP was not measured in these studies.

The mechanisms for the formation of 1,3-DCP are less clear. One route of formation of 1,3-DCP is believed to be from 3-MCPD and this has been shown to occur in soy sauces (Crews et al, 2000; Food Standards Agency, 2001c). However, it is likely that 1,3-DCP also can be formed in food via other routes.

Some studies have been conducted to investigate the effect of cooking on the formation of 3-MCPD in food. These studies have shown that elevated levels of 3-MCPD can occur in toasted bread, some grilled cheeses and fried batters. However, these studies have also shown that 3-MCPD was undetectable or present only at very low levels in cooked meat, gravy, sauces and stocks. These differing results may be related to the high water activity in the latter foods and the limited formation of 3-MCPD under food manufacturing conditions where there is a high water activity (Crews et al, 2001).

1.3 Health concerns in relation to chloropropanols

The safety of chloropropanols was first examined by JECFA in 1993 (FAO/WHO 1993). At this meeting, the potential renal toxicity of 3-MCPD was recognized, as well as a carcinogenic potential for both 3-MCPD and 1,3-DCP. It was concluded that these substances are undesirable contaminants in food and that their levels in HVP should be reduced as far as is technically possible. In 1996, the United Kingdom (UK) Food Advisory Committee recommended that the levels of 3-MCPD should be reduced to the minimum detected by the most sensitive assay method, namely, 0.01 mg/kg. The proposed EU limit at this time for 3-MCPD was 0.02 mg/kg. There was no proposed EU limit for 1,3-DCP.

The issue of chloropropanols was raised more recently in the UK following the release in 1999, 2001 and 2002 (MAFF 1999;FSA 2001a, 2001b, 2001c, 2001d) of survey results on soy sauces, food ingredients and related food products such as cereal-based products, soups, meat, and dairy products. A more detailed description of these surveys is included in Appendix **A**. The surveys on soy and oyster sauces found levels of 3-MCPD that were significantly higher than the levels considered to be technically achievable using good manufacturing practice.

The unexpectedly high levels of 3-MCPD found from the 2001 UK survey of soy and oyster sauces prompted the Codex Committee on Food Additives and Contaminants (CCFAC) to request JECFA to re-evaluate the toxicity of both chloropropanols on the basis of new data which had become available since they were previously considered in 1993. The UK results also prompted further survey work both in the UK and in Australia.

This paper examines the public health and safety risk associated with consumption of food containing chloropropanols. It presents the results of the Australian survey work on chloropropanols and a summary of the JECFA review, as well as discussing the public health implications of exposure to chloropropanols in food and the subsequent risk management action taken.

2.0 HAZARD IDENTIFICATION AND CHARACTERISATION

The 32nd session of CCFAC requested that JECFA examine the available toxicological data on chloropropanols with a view to establishing a tolerable daily intake (TDI) for these contaminants (CCFAC 2000). As a result, JECFA requested member states to provide relevant information on the toxicity, epidemiology, levels and patterns of contamination, food consumption and analytical methods, generated since its previous evaluation of chloropropanols. JECFA evaluated this information at its 57th meeting in June 2001.

A detailed report of the toxicology data is available (FAO/WHO 2002a). A summary of the toxicology data is given in the Report of the 57th meeting (FAO/WHO 2002b), which is duplicated in **Appendix B**.

The outcome of the hazard characterisation undertaken by JECFA in 2001 is given below:

2.1 3-Chloro-1,2-propanediol (3-MCPD)

The following is extracted from the Report of the 57th meeting of JECFA held in 2001 (FAO/WHO 2002b).

> *The Committee chose tubule hyperplasia in the kidney as the most sensitive end-point of deriving a tolerable intake. This effect was seen in the long-term study of toxicity and carcinogenicity in rats in a dose-related manner, although the effect did not reach statistical significance at the lowest dose. The Committee concluded that the lowest-observable-effect level (LOEL) was 1.1 mg/kg of body weight per day and considered this to be close to a NOEL.*
>
> *The Committee established a provisional maximum tolerable daily intake (PMTDI) of 2 μg/kg of body weight for 3-chloro-1,2-propanediol on the basis of the LOEL of 1.1 mg/kg of body weight per day and a safety factor of 500, which included a factor of 5 for extrapolation from a LOEL to a NOEL. This factor was considered to be adequate to allow for the absence of a clear NOEL and to account for the effects on male fertility and inadequacies in the studies of reproductive toxicity.*

2.2 1,3-Dichloro-2-propanol (1,3-DCP)

The following is extracted from the Report of the 57th meeting of JECFA held in 2001 (FAO/WHO 2002b).

> *Although only a few studies of kinetics, metabolism, short- and long-term toxicity and reproductive toxicity were available for evaluation, the results clearly indicated that*

1,3-dichloro-2-propanediol was genotoxic in vitro, was hepatotoxic and induced a variety of tumours in various organs in rats. The Committee concluded that it would be inappropriate to estimate a tolerable intake because of the nature of the toxicity observed:

- *The results of the long-term study of toxicity and carcinogenicity showed significant increases in the incidences of both benign and malignant neoplasms in at least three different tissues.*

- *It has been shown unequivocally that this contaminant can interact with the chromosomes and/or DNA; however, the tests were confined to bacterial and mammalian test systems in vitro, and there were no data on intact mammalian organisms or humans.*

3.0 FSANZ SURVEYS OF CHLOROPROPANOLS IN FOODS

FSANZ commissioned two major studies on the presence and levels of both 3-MCPD and 1,3-DCP in foods.

Firstly, in July 2001, FSANZ commissioned a survey of 3-MCPD and 1,3-DCP in selected soy and oyster sauces available at Australian retail outlets (for details, see **Appendix C**). This was commissioned as a direct result of the findings of the June 2001 UK survey that there were high levels of 3-MCPD in some soy and oyster products. Samples collected consisted of those imported products identified by the UK results as containing high levels of 3-MCPD, as well as Australian-made soy and oyster sauces. Subsequently, the Queensland Department of Health initiated surveys of soy and oyster sauces for 3-MCPD in 2001.

Secondly, in 2002, FSANZ conducted a survey of 3-MCPD and 1,3-DCP in a range of other foods (for details, see **Appendix C**). This latter survey was conducted in three stages with the foods of major interest being refined at each stage.

3.1 Soy and oyster sauces

The results of testing of soy and oyster sauces are presented in **Table 1** below and individual results in **Appendix D**. These values represent levels measured in products sampled in 2001 and may not represent levels present in products currently available.

Table 1: Levels of 3-MCPD and 1,3-DCP in a targeted range of soy and oyster sauce products available in Australia in 2001

Product description	No. of samples	No. of detects 3-MCPD	Range of concentrations 3-MCPD (mg/kg)	No. of detects 1,3-DCP	Range of concentrations 1,3-DCP (mg/kg)
Chicken marinade	1	1	0.017	0	<0.01
Oyster sauce	6	0	<0.01	0	<0.01
Soy sauce	12	6	<0.01 – 3.9	2	<0.01 – 0.11
Soy sauce - dark	2	1	<0.01 – 0.028	0	<0.01
Soy sauce - light	2	1	<0.01 – 0.014	0	<0.01
Soy sauce - mushroom flavour	2	0	<0.01	1	0.005# – <0.01
Soy sauce - salty	2	0	<0.01	0	<0.01
Soy sauce - shrimp flavour	1	1	0.025	0	<0.01
Soy sauce - sweet	2	1	<0.01 – 0.044	0	<0.01
Soy sauce - thin	1	0	<0.01	0	<0.01
Soy seasoning sauce	8	7	<0.01 – 150	7	<0.01 – 0.6

limit of reporting was decreased from 0.01mg/kg to 0.005 mg/kg during the course of the survey.

The majority of soy and oyster sauces surveyed did not contain detectable levels of either 3-MCPD or 1,3-DCP. A small number of samples contained high levels of 3-MCPD. The highest level was 150 mg/kg which was similar to the highest level of 93 mg/kg reported in the UK. 1,3-DCP was detected only in those sauces that also contained 3-MCPD and was present at lower levels than 3-MCPD. These results indicated a similar prevalence of chloropropanols and at similar levels to those reported in the UK.

3.2 Foods other than soy and oyster sauces

A survey of 3-MCDP and 1,3-DCP levels in foods other than soy and oyster sauces was conducted in three sequential stages, each stage taking into account earlier findings. The sampling was planned so that the survey results could be used to estimate dietary exposure to the chloropropanols. Foods and food groups chosen for analysis were guided by the available information, including the results of a survey on 3-MCPD undertaken in the UK (See Appendix A) and consideration of foods likely to contain chloropropanols as a result of processing or storage conditions. Stages 1 and 2 used composite retail samples while in stage 3 individual retail samples were analysed.

In Stage 1 of the survey 19 of the 136 samples were found to contain concentrations at or above the limit of reporting (LOR) for 1,3-DCP (0.003 mg/kg) and 23 samples were reported to contain concentrations at or above the LOR for 3-MCPD (0.005 mg/kg).

The very high levels of 3-MCPD present in some soy sauces were not observed in other foods. While the highest level in soy sauces was 150 mg/kg 3-MCPD, the highest level in other foods was found in crumbed fish at 0.083 mg/kg; more than 1000 times lower. Other foods found to contain 3-MCPD included bacon, hamburgers, sausages and lamingtons. **Table 2** provides a summary of the results and **Appendix D** contains a list of results for each of the individual foods sampled.

1,3-DCP was detected in minced beef, sausages, leg ham and battered fish fillets, albeit at low levels. In order to confirm these results, another ten samples each of minced beef and of sausages and five samples each of leg ham, fish fingers and battered fish fillets were purchased and analysed raw and after thorough cooking in stage 2 of the study. The range of concentrations of chloropropanols in these samples are summarised in **Table 3**. More detailed information on individual samples is provided in **Appendix D**.

Table 2: Levels of 3-MCPD and 1,3-DCP in Australian foods analysed in 2002 – Stage 1

Food Samples*	3-MCPD No. of samples	3-MCPD No. of detects	3-MCPD Concentration range (mg/kg)	1,3-DCP No. of detects	1,3-DCP Concentration range (mg/kg)
Baked Beans	3	0	<0.005	0	<0.003
Bacon	6	3	<0.005 – 0.022	0	<0.003
Beef, minced	8	0	<0.005	6	<0.003 – 0.063
Biscuits, savoury	3	1	<0.005 – 0.007#	0	<0.003
Biscuits, sweet	3	1	<0.005 – 0.005#	0	<0.003
Bread, white	8	0	<0.005	1	<0.003 – 0.004#
Bread, multigrain	6	1	<0.005 – 0.007#	1	<0.003 – 0.004#
Breakfast cereal, mixed grain	3	0	<0.005	0	<0.003
Breakfast cereal, single grain	3	0	<0.005	0	<0.003
Cheese, cheddar	6	0	<0.005	0	<0.003
Cheese, processed	6	0	<0.005	0	<0.003
Coffee, instant	3	0	<0.005	0	<0.003
Dim sim	6	0	<0.005	0	<0.003
Doughnuts, cinnamon	5	0	<0.005	0	<0.003
Eggs, boiled	8	0	<0.005	0	<0.003
Fish fillets, battered, fried	10	0	<0.005	2	<0.003 – 0.024
Fish portions, crumbed	6	5	<0.005 – 0.083	0	<0.003
Hamburger	6	6	0.007 – 0.049	0	<0.003
Infant cereal	3	0	<0.005	0	<0.003
Infant dinner	3	0	<0.005	0	<0.003
Infant formula	3	0	<0.005	0	<0.003
Lamingtons	3	2	<0.005 – 0.030	0	<0.003
Leg ham	6	1	<0.005 – 0.005#	2	<0.003 – 0.059
Margarine	1	0	<0.005	1	0.003#
Noodles, instant	3	0	<0.005	0	<0.003
Peanut butter	3	0	<0.005	0	<0.003
Potato crisps	3	0	<0.005	0	<0.003
Sausages, meat	6	3	<0.005 – 0.069	6	0.015 – 0.066
Tuna, canned	3	0	<0.005	0	<0.003

* All samples were in ready-to-eat form.
\# These samples contained levels below the LOR and therefore the reported values are associated with a greater degree of uncertainty than those values above the LOR.

Stage 2 of the study confirmed the findings in Stage 1, that 1,3-DCP may be present in minced beef, sausages, leg ham and battered fish and that it may be present in foods in which the proposed precursor, 3-MCPD, is not detected.

In order to characterise the results further, whole cuts of meat were sampled and analysed to determine if 3-MCPD and 1,3-DCP were also present in these cuts. For the third stage of the survey, five random samples of beef steak and six random samples of lamb chops were purchased and analysed both before and after cooking. One sample of raw beef steak and one sample of raw chops were found to contain low concentrations of 1,3-DCP. Only one sample (cooked lamb chops) was found to contain 3-MCPD above the LOR. No cooked samples contained detectable levels of 1,3-DCP. The range of concentrations of chloropropanols in these samples are summarised in **Table 4**. More detailed information on the results is in **Appendix D**.

While the majority of foods tested contained no detectable levels of chloropropanols, low concentrations of 1,3-DCP were reported in some samples in the absence of 3-MCPD. Existing information had indicated that 3-MCPD is a precursor for the formation of 1,3-DCP (CCFAC 2001) and that 1,3-DCP, if present, is found at levels lower than 3-MCPD (Food Standards Agency 2001c). The results revealed that 1,3-DCP may be present in food without the presence of 3-MCPD or at levels substantially higher than those of 3-MCPD. This suggests that 3-MCPD is not necessarily a precursor to 1,3-DCP formation although further studies would be necessary to confirm this and to confirm whether or not cooking meat changes the amount of 1,3-DCP present.

Table 3: Levels of 3-MCPD and 1,3-DCP in Australian foods analysed in 2002–Stage 2

		3-MCPD		1,3-DCP	
Food samples	No. of samples	No. of detects	Concentration range (mg/kg)	No. of detects	Concentration range (mg/kg)
Beef, minced, raw	10	0	<0.005	9	<0.003 – 0.11
Beef, minced, cooked	10	5	<0.005 – 0.012	9	<0.003 – 0.043
Sausages, meat, raw	10	3	<0.005 – 0.013	7	<0.003 – 0.069
Sausages, meat, cooked	10	2	<0.005 – 0.012	5	<0.003 – 0.036
Leg ham	5	2	<0.005 – 0.027	2	<0.003 – 0.021
Battered fish, fried	5	1	<0.005 – 0.009#	1	<0.003 – 0.006
Fish fingers, fried	5	0	<0.005	0	<0.003

\# This sample contained levels below the LOR and therefore the reported values are associated with a greater degree of uncertainty than those values above the LOR.

Table 4: Levels of 3-MCPD and 1,3-DCP in Australian foods analysed in 2002–Stage 3

		3-MCPD		1,3-DCP	
Food samples	No. of samples	No. of detects	Concentration range (mg/kg)	No. of detects	Concentration range of (mg/kg)
Steak, beef, raw	5	0	<0.005	1	<0.003– 0.070
Steak, beef, cooked	5	0	<0.005	0	<0.003
Chops, lamb, raw	6	0	<0.005	1	<0.003– 0.091
Chops, lamb, cooked	6	1	<0.005 – 0.03	0	<0.003

4.0 DIETARY EXPOSURE ASSESSMENT

Dietary exposure assessment determines the amount of a chemical a population receives through the consumption of food and beverages. Dietary exposure assessment is conducted using dietary modelling techniques that combine food consumption data with food chemical concentration data.

Dietary exposure assessments for chloropropanols were conducted using FSANZ's dietary modelling computer program, DIAMOND. This program contains dietary survey data for Australia from the 1995 National Nutrition Survey (NNS). This survey has results for 13 858 people aged 2 years and above, using a 24-hour food recall method.

Each individual's exposure to chloropropanols was calculated using their individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of chloropropanols by the total amount of the food consumed (eaten 'as is' plus consumption from mixed foods) to estimate the exposure from each food group for each individual. The total exposure for each individual is calculated by summing the exposure from each food group that may contain chloropropanols. Population statistics (mean and high percentile dietary exposures) are then derived from the ranked individuals' dietary exposures.

Where estimated dietary exposures are expressed per kilogram of body weight, each individual's total dietary exposure is divided by their own body weight, the results ranked, and population statistics derived.

Where estimated exposures are expressed as a percentage of the reference health standard, the PMTDI, each individual's total exposure is calculated as a percentage of the reference health standard (using total exposure in units per kilogram of body weight per day), the results are then ranked, and population statistics derived.

Percentage contributions of each food group to total estimated exposures are calculated by summing the exposures from a food group for each individual in the population group who consumed a food from that group and dividing this by the sum of the exposures of all individuals who consumed from any of the food groups containing chloropropanols and multiplying this by 100.

Three dietary exposure assessments have been conducted for chloropropanols. The first dietary exposure assessment, conducted in 2001, was for 3-MCPD in soy and oyster sauces. This assessment was based on UK survey data on the levels of 3-MCPD in soy and oyster sauces (Food Standards Agency 2001d; Appendix A), together with Australian consumption data for these foods.

The second dietary exposure assessment, conducted in 2002, was for both 3-MCPD and 1,3-DCP and was based on Australian survey data in a wide range of foods and Australian food consumption data. For this second assessment, two concentrations of both 3-MCPD and 1,3-DCP were used for soy and oyster sauces, one based on Australian survey data (scenario 1) and one based on the maximum limit (ML) from the *Food Standards Code* (scenario 2). The third dietary exposure assessment was conducted for the smaller group of consumers specifically exposed to chloropropanols from soy and oyster sauces. For this third assessment, the same two concentrations of both 3-MCPD and 1,3-DCP were used.

4.1 Dietary exposure for consumers of chloropropanols from soy and oyster sauces using UK survey data

The dietary exposure assessment was conducted in 2001 using two levels of 3-MCPD in soy and oyster sauces from the UK FSA 2000 survey, because no data on the levels of 3-MCPD in soy and oyster sauce products in Australia were available at the time. The first level of 3.7 mg/kg was the mean residual level from the 100 samples tested in the UK survey (assuming 'not detected' results had a zero concentration of 3-MCPD), and the second level of 16.9 mg/kg was the mean residual level from the 22 samples found to contain levels of 3-MCPD above the LOR of 0.05 mg/kg in the same survey. This higher level is more representative of the dietary exposure for those consumers that consistently consume the soy and oyster sauce brands that contain higher levels of 3-MCPD. Dietary exposure estimates assume all soy and oyster sauces contain 3-MCPD at these levels.

4.1.1 Estimated exposures to 3-MCPD for consumers of soy and oyster sauces

Summary food consumption statistics were produced from the DIAMOND program as a part of the exposure assessment. The consumption of soy and oyster sauces in Australia was estimated to be 9.5 grams per day at the mean level for consumers of these sauces and 29.1 grams per day for 95th percentile level consumers. There were 1060 consumers of soy and oyster sauces (7.6% all survey respondents) including consumers of foods that contain these as ingredients.

The estimated dietary exposure for Australian consumers (aged 2 years and above) to 3-MCPD from soy and oyster sauces at different concentration levels is shown in **Table 5**. Figures are presented for consumers only of 3-MCPD. A survey respondent is only considered to be a 'consumer' when they have consumed foods that have been assigned a chloropropanol level in the model at the time of the NNS (i.e. during the 24 hours in which they participated in the NNS).

At a concentration level of 3-MCPD of 3.7 mg/kg, the estimated mean exposure for consumers of 3-MCPD only, was 35.2 µg /day (0.5 µg/kg bw/day) and 107.5 µg/day (1.8 µg/kg bw/day) for 95th percentile consumers. At a concentration level of 3-MCDP of 16.9 mg/kg, estimated consumer mean exposures were 160.7 µg /day (2.5 µg/kg bw/day) and at the 95th percentile exposure for consumers only, 491.2 µg/day (8.1 µg/kg bw/day).

Table 5: Estimated dietary exposure for Australian consumers of 3-MCPD (aged 2 years and above) from soy and oyster sauces using different concentrations from the UK survey

		Level of 3-MCPD (mg/kg)	
Population	Exposure Units	3.7	16.9
Consumers only - mean	µg/day	35.2	160.7
	µg/kg bw/day	0.5	2.5
	% PMTDI	27	125
Consumers only - 95th %ile	µg/day	107.5	491.2
	µg/kg bw/day	1.8	8.1
	% PMTDI	89	406

Note: Number of respondents = 13858, number of consumers of 3-MCPD = 1060.
Mean body weight = 67kg.
PMTDI = 2 µg/kg bw/day

4.2 Dietary exposure for consumers of chloropropanols from a wide range of foods, using Australian concentration data

Following completion of the FSANZ surveys on 3-MCPD and 1,3-DCP levels, a second dietary exposure assessment was undertaken to estimate exposure for Australian consumers of chloropropanols from a wide range of foods.

The dietary exposure was estimated by combining usual patterns of food consumption, as derived from NNS data, with concentrations of chloropropanols in a wide range of foods including soy and oyster sauces as determined from the FSANZ analytical surveys conducted in 2001 (soy and oyster sauces only) and 2002, and the 2001 Queensland Health survey of soy and oyster sauces.

4.2.1 Chloropropanols concentrations in foods

Mean concentrations of 3-MCPD and 1,3-DCP were calculated for each food for which Australian analytical data were available for inclusion in the dietary exposure assessment. FSANZ normally derives median concentrations for contaminants in foods, however, as some of the analyses were of composite samples, which results in some averaging of chemical concentrations, medians could not be derived. Some meat samples were analysed raw and cooked, in which case data for cooked samples were used to derive mean chloropropanol concentrations for the dietary exposure assessment, as this is the form of the food that people eat. A summary of the concentration data used in the dietary exposure assessment is shown below in **Table 6**. The individual concentration data from the surveys are shown in **Appendix D**.

Table 6: Summary of chloropropanols concentration data used for the dietary exposure assessment using Australian concentration data

Food group	3-MCPD (mg/kg)		1,3-DCP (mg/kg)		Number of samples used to derive the mean for the exposure assessment*	Sample source**
	Lower bound mean	Upper bound mean	Lower bound mean	Upper bound mean		
Cheese and cheese products	0	0.005	0	0.003	12 (C)	FSANZ 2002
Margarine & table spreads	0	0.005	0.003	0.003	1 (C)	FSANZ 2002
Baked beans	0	0.005	0	0.003	3 (C)	FSANZ 2002
Peanut butter	0	0.005	0	0.003	3 (C)	FSANZ 2002
Soy and oyster sauce (scenario 1)	14.9	14.9	0.069	0.077	68 MCPD (I); 37 DCP (I)	FSANZ 2001, QLD Health
Soy and oyster sauce (scenario 2)	0.2	0.2	0.005	0.005	– #	Food Standards Code
Breakfast cereals, single and mixed grain	0	0.005	0	0.003	6 (C)	FSANZ 2002
Noodles	0	0.005	0	0.003	3 (C)	FSANZ 2002
Breads	0	0.005	0.001	0.003	14 (C)	FSANZ 2002
Biscuits, cakes and pastries	0.004	0.007	0	0.003	14 (C)	FSANZ 2002
Raw meat, poultry & game, cooked	0.003	0.007	0	0.003	11 (I)	FSANZ 2002
Minced meat, cooked	0.004	0.007	0.023	0.023	10 (C)	FSANZ 2002
Ham and cooked bacon	0.008	0.011	0.003	0.006	11 (C)	FSANZ 2002
Sausages, cooked	0.002	0.006	0.015	0.017	10 (C)	FSANZ 2002
Fish fillets	0.002	0.006	0.001	0.004	5 (C)	FSANZ 2002
Processed fish portions	0	0.005	0	0.003	5 (C)	FSANZ 2002
Canned fish	0	0.005	0	0.003	3 (C)	FSANZ 2002
Eggs	0	0.005	0	0.003	8 (C)	FSANZ 2002
Coffee, prepared with water	0	0.005	0	0.003	3 (C)	FSANZ 2002
Potato crisps	0	0.005	0	0.003	3 (C)	FSANZ 2002
Dim sim/spring roll/chiko roll, cooked	0	0.005	0	0.003	6 (C)	FSANZ 2002
Hamburgers, whole	0.015	0.015	0	0.003	6 (C)	FSANZ 2002

**FSANZ 2001 = 2001 soy sauce survey by FSANZ; FSANZ 2002 = samples from the 2000 Australian Total Diet Survey supplemented by samples purchased in 2002; QLD Health = 2001 soy sauce survey by Queensland Department of Health.
*I = individual samples; C = composite samples.
= Scenario 2 used ML values and not survey data.
Lower bound mean is the value calculated where not detected results were assigned a level of 0 mg/kg; upper bound mean is the value calculated where not detected results were assigned a level equivalent to the LOD.

For 3-MCPD and 1,3-DCP, two dietary exposure assessments were conducted using two different concentrations for soy and oyster sauces. The first scenario used the mean concentration determined from Australian analytical survey data for soy and oyster sauces from 2001 (3-MCPD mean 14.9 mg/kg; 1,3-DCP lower bound mean of 0.069 mg/kg and upper bound mean of 0.077 mg/kg), which were collected prior to the introduction of the MLs in the *Food Standards Code*. Although the majority of samples were less than 1 mg 3-MCPD/kg the mean value was influenced by the high numerical value of a few results. The use of a mean concentration derived from a positively skewed distribution of 3-MCPD analyses may result in an estimated exposure that is unrealistically high.

Where concentrations of the chemicals were below the limit of reporting, a range of concentrations was used to calculate estimated dietary exposures. Non-detected results were either assigned a zero to determine the lower bound mean, or the limit of detection (LOD) (0.005 mg/kg for 3-MCPD and 0.003 mg/kg for 1,3-DCP) to determine the upper bound mean. While upper bound values are usually generated using the limit of reporting (LOR), in this case it was considered that use of the LOD would provide a more refined estimate of dietary exposure. The mean concentration level was calculated accordingly for each food or food groups whether all, or only some, of the samples had results that were not detected. For example, where there were ten samples for cooked sausages, and five of these were not detected results, a zero was substituted for the five not detected samples, and the mean for the lower bound result was calculated.

For the second scenario, soy and oyster sauces were assigned the ML from the *Food Standards Code* of 0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP. No soy and oyster sauces for sale in Australia at the present time should exceed these MLs. This scenario is likely to produce a more realistic estimate of exposure to 3-MCPD and 1,3-DCP following the introduction of the MLs into the *Food Standards Code*.

The dietary exposure assessment was conducted using food groupings based on the food classification system from Standard 1.3.1 Food Additives of the *Food Standards Code,* which is used in the DIAMOND program. Foods are classified according to major food types as raw and processed foods and analytical concentrations fit easily to these food groupings. The DIAMOND program assigns chloropropanols concentrations to food groups for foods eaten ‘as is’, as well as where they are used as ingredients in mixed foods, for example, soy sauce in a stir-fry.

Where a single food from a food group was analysed, the chloropropanols concentration was assigned to the whole group, assuming that like foods would have similar concentrations. For example, the concentration for doughnuts and biscuits were assigned to all biscuits, cakes and pastries; that for canned tuna to all canned fish; and minced beef concentrations were used for all minced meat. This is likely to result in the dietary exposures being overestimated, but assumes a worst-case scenario. Food groups that were not analysed, including fresh fruits and vegetables, were assumed to have a zero chloropropanols concentration.

4.2.2 Population groups assessed

The dietary exposure assessment was conducted for consumers of chloropropanols, as a subset from all NNS respondents aged 2 years and above or from various population subgroups. Children aged 2-12 years were assessed as children generally have higher estimated exposures than adults due to their lower body weight and the larger amount of food they consume per kilogram of body weight. Teenagers aged 13-19 years were assessed as they have high food consumption due to demands of growth and development. Adults 20 years and above were also assessed as a separate group.

4.2.3 Assumptions and limitations

A number of assumptions were made in the dietary exposure assessment, including:

- all foods within the group contain the specified concentration of chloropropanols;
- only the food groups included in the exposure assessment contain chloropropanols;
- a whole group of like foods have similar concentrations of chloropropanols; and
- food consumption patterns measured in the 1995 NNS represent current food consumption patterns.

A limitation of estimating chloropropanol dietary exposure is that only 24-hour recall NNS data were available, therefore the dietary modelling is unable to give an estimation of exposure over a longer period of time. Twenty four-hour food recall data tend to over-estimate habitual food consumption amounts for high consumers. Therefore predicted high percentile exposures are likely to be higher than actual high percentile exposures over a lifetime.

The mean chloropropanols concentrations are derived from a small number of samples for some foods and may not be truly representative of the total market. Use of composite samples does mean that there are actually more individual units represented than number of analyses. However these were the best data available for dietary exposure assessment purposes. Larger sample numbers of soy and oyster sauces were analysed, although the samples were not collected in a way that represents current market share in Australia.

4.2.4 Dietary exposure results

4.2.4.1 Estimated exposure for consumers of 3-MCPD and 1,3-DCP from a wide range of foods

Estimated dietary exposures for consumers of 3-MCPD are shown below in **Table 7a** (scenario 1, where soy and oyster sauces were assigned the mean concentration from analytical surveys of 14.9 mg/kg) and **Table 7b** (scenario 2, where soy and oyster sauces were assigned the maximum limit from the *Food Standards Code* of 0.2 mg/kg). Estimated dietary exposures for consumers of 1,3-DCP are shown below in **Table 8a** (scenario 1, where soy and oyster sauces were assigned the lower bound mean of 0.069 mg/kg and the upper bound mean of 0.077 mg/kg) and **Table 8b** (scenario 2, where soy and oyster sauces were assigned the maximum limit from the *Food Standards Code* of 0.005 mg/kg). Results are reported for 'consumers only' of the chloropropanols, remembering that a survey respondent is only considered to be a 'consumer' when they have consumed foods assigned a chloropropanol level in the model at the time of the NNS i.e. during the 24 hours in which they participated in the NNS. The mean results for all respondents (i.e. all persons in the specified age group, regardless of whether they were exposed to chloropropanols through the diet or not) were very similar to those for consumers only because nearly all respondents consumed at least one food that contains chloropropanols.

Estimated upper bound mean dietary exposure for scenario 1 for consumers only of 3-MCPD from the Australian population group aged 2 years and above was 13.1 μg/day (0.20 μg/kg bw/day) and did not exceed 15 μg/day (0.21 μg/kg bw/day) for any population group assessed. Estimated 95th percentile exposure for consumers of 3-MCPD did not exceed 63 μg/day (or 0.72 μg/kg bw/day) for any population group assessed. Estimated upper bound mean dietary exposure for scenario 2 for consumers only of 3-MCPD from the Australian population group aged 2 years and above was 3.4 μg/day (0.05 μg/kg bw/day) and did not exceed 3.9 μg/day (0.05 μg/kg bw/day) for any population group assessed. Estimated 95th percentile exposure for consumers of 3-MCPD did not exceed 10 μg/day (or 0.13 μg/kg bw/day) for any population group assessed.

Estimated upper bound mean dietary exposure for scenario 1 for consumers only of 1,3-DCP from the Australian population group aged 2 years and above was 2.6 μg/day (0.041 μg/kg bw/day) and did not exceed 2.9 μg/day (or 0.039 μg/kg bw/day) for any population group. Estimated 95th percentile exposures for consumers of 1,3-DCP did not exceed 7.4 μg/day (or 0.101 μg/kg bw/day) for any population group assessed. Estimated upper bound mean dietary exposure for scenario 2 for consumers only of 1,3-DCP from the Australian population group aged 2 years and above was 2.6 μg/day (0.041 μg/kg bw/day) and did not exceed 2.8 μg/day (0.039 μg/kg bw/day) for any population group assessed. Estimated 95th percentile exposure for consumers of 1,3-DCP did not exceed 7.3 μg/day (or 0.099 μg/kg bw/day) for any population group assessed.

In some cases the estimated dietary exposures based on the lower bound means are higher than the estimated dietary exposures based on the upper bound means. This is because of the way DIAMOND is programmed, and how consumers of chloropropanols are counted. Where food groups have been assigned the lower bound level of a zero concentration of chloropropanols, people who may have consumed foods from that food group in the NNS are not considered to have been exposed to the chloropropanols and are therefore not counted as a 'consumer of chloropropanols'. However, where the upper bound model assigned a numerical concentration at the LOD to foods, people who ate foods from those groups in the NNS would be counted as a 'consumer of chloropropanols'. DIAMOND ranks the consumer's individual exposures to chloropropanols before deriving summary statistics (mean and 95th percentile estimated exposures). The estimates based on the lower bound and upper bound means are derived from different numbers of consumers of chloropropanols and therefore, different distributions of individual exposures result in different means and 95th

percentile exposures being derived. The results based on the lower bound and upper bound concentrations cannot therefore be presented as a range.

4.2.4.2 Highest contributing foods to estimated dietary exposures

Foods may be high contributors (>5%) to estimated dietary exposures to food chemicals because there is a high concentration of the chemical in the food and/or a large amount of the food is consumed.

The major contributors to estimated dietary exposures to 3-MCPD for Australia for all age groups assessed for scenario 1 were soy and oyster sauces (ranging from 86% for children to 94% for adults). When soy and oyster sauces were assigned the lower more realistic concentration of 3-MCPD in scenario 2, the major contributors were meat & poultry (28%), biscuits, cakes and pastries (21%), soy and oyster sauce (16%), ham and bacon (13%) and hamburgers (10%).

Major contributors to estimated dietary exposures to 1,3-DCP for scenario 1 for the Australian population were minced meat (45%), sausages (25%), bread (10%), soy and oyster sauce (6%), and ham and bacon (6%). Results for children and teenagers were similar. For scenario 2, major contributors were similar being minced meat (48%), sausages (27%), bread (10%), ham and bacon (6%) and margarine (5%).

4.3 Dietary exposure for those consumers specifically exposed to chloropropanols from soy and oyster sauces, using Australian concentration data

The exposure estimate in Section 4.2 is based on exposure from all foods in the diet for the whole population. It was considered appropriate to also assess the dietary exposure to 3-MCPD for those consumers specifically exposed to chloropropanols from soy and oyster sauces, since these were the predominant contributors to the dietary exposure of 3-MCPD for all age groups.

Estimated dietary exposure to 3-MCPD for these consumers was calculated using the Australian survey concentrations for 3-MCPD (14.9 mg/kg). The estimated dietary exposure to 3-MCPD for these consumers was also calculated using the newly established ML of 0.2 mg/kg for 3-MCPD in the *Food Standards Code*.

Results are shown for 3-MCPD in **Table 9a** using analytical data for the concentration in soy and oyster sauces, and **Table 9b** using the ML. Estimated mean exposures for those consumers specifically exposed to 3-MCPD from soy and oyster sauces were 138 μg/day (2.1 μg/kg bw/day) from the Australian population group aged 2 years and above and up to 146 μg/day (2.1 μg/kg bw/day) for the age group with the highest exposure (3-MCPD consumers aged 20 years and above). On a per kilogram body weight basis, the consumers of 3-MCPD in the 2-12 years group had the highest exposure at 2.8 μg/kg bw/day. Estimated

95^{th} percentile dietary exposures were 416 µg/day (7.0 µg/kg bw/day) for consumers of 3-MCPD from the population group aged 2 years and above and up to 451 µg/day (7.0 µg/kg bw/day) for the group with the highest exposure (3-MCPD consumers aged 20 years and above). On a per kilogram body weight basis, the consumers of 3-MCPD in the 2-12 year old age group had the highest 95^{th} percentile exposure at 8.1 µg/kg bw/day.

Estimated exposures to 1,3-DCP for those consumers specifically exposed to chloropropanols from soy and oyster sauces, are not reported here in detail as these sauces were not the major contributors to 1,3-DCP exposure. Indeed, using either the Australian survey data or the ML of 0.005 mg/kg, the estimated exposures to 1,3-DCP from soy and oyster sauces only, were considerably lower than the dietary exposures for consumers of 1,3-DCP from a range of food, including soy and oyster sauces.

The decrease in estimated exposures when looking at exposure from soy and oyster sauces only, reflects the considerable contribution to exposure from other foods for 1,3-DCP.

4.4 Comparison of Australian and JECFA dietary exposure estimates for 3-MCPD and 1,3-DCP

The dietary exposure estimates for Australian consumers of chloropropanols from a range of foods including soy and oyster sauces were compared with those reported by JECFA for 3-MCPD and 1,3-DCP.

For 3-MCPD, JECFA (FAO/WHO 2002a) only reported estimated exposures from soy sauce alone. Estimated exposures by JECFA for the USA were 140 µg/day for the mean consumer and 290 µg/day for the 90^{th} percentile consumer; for Australia they estimated exposure at 200 µg/day at the mean and 400 µg/day for the 90^{th} percentile; for Japan the mean was 540 µg/day and 1100 µg/day for the 90^{th} percentile consumer. This was based on a mean concentration of 3-MCPD of 18 mg/kg from a USA survey. Estimated exposure to 3-MCPD from a range of foods for the Australian population for scenario 1 (based on analytical data for soy and oyster sauces) did not exceed 54.9 µg/day (equivalent to 0.75 µg/kg bw/day). The JECFA estimated exposures for soy sauce alone were much higher than the Australian estimate for a range of foods.

For 1,3-DCP, Australian estimates for exposure from a range of foods including soy and oyster sauces (not more than 0.14 µg/kg bw/day at the 95^{th} percentile of exposure for scenario 1 using analytical concentrations for soy and oyster sauce), were much lower than those reported by JECFA (FOA/WHO 2002a) from soy sauce alone for Japan which was the highest soy sauce consuming population (1 µg/kg bw/day).

The different methods and assumptions used in DIAMOND, and those employed by JECFA for their calculations may explain the differences in the estimated exposures. The estimated dietary exposure for consumers of chloropropanols from the population group aged 2 years and above from DIAMOND is based on a distribution of exposures from individuals, not a mean derived from a point estimate. The individual exposures could range from an individual that ate foods from only one food group in the model (that may or may not have had a not detected result), to an individual that may have eaten from nearly all the food groups in the model. As the mean food consumption amount in the point estimate (such as that used in the JECFA assessment) is affected by high numerical values for a few high consumers, it is to be expected that the DIAMOND method would result in a lower estimated exposure, even if based on the same chloropropanols concentration data, because it is based on actual food consumption amounts for individuals, where the median of the distribution of exposures tends to be less than the mean due to the positively skewed distribution of food consumption.

For 1,3-DCP for example, JECFA used the highest exposure from soy sauce from any country. This was derived from the 90th percentile consumption of soy sauce for Japan of 60 g/day with a concentration of 1,3-DCP at 0.9 mg/kg. The 95th percentile soy sauce consumption for Australia was much lower (approximately 30 g/day) and the concentration of 1,3-DCP allocated for soy sauce in the DIAMOND exposure assessment was 0.07 mg/kg, more than ten times lower. The Japanese mean body weight is 55 kg, whereas for Australia (2 years and above) it is 67 kg. These three factors result in a much lower estimated exposure for consumers of chloropropanols from the Australian population group aged 2 years and above per kilogram body weight than that predicted by JECFA, even when other foods are included in the exposure assessment.

Table 7a. Estimated dietary exposure to 3-MCPD for Australian consumers only from various food sources when the 3-MCPD concentration in soy and oyster sauces is based on Australian survey data (mean 14.9 mg/kg)

Population group	Number of consumers	Exposure	Lower bound mean	Upper bound mean	Lower bound 95th %ile*	Upper bound 95th %ile*
All (2+ years)	LB 12878	µg/day	10.5	13.1	47.6	41.7
	UB 13838	µg/kg bw/day	0.16	0.20	0.71	0.65
		% PMTDI	8	10	36	32
2-12 years	LB 1918	µg/day	3.4	4.5	2.5**	4.8
	UB 2077	µg/kg bw/day	0.13	0.17	0.11	0.18
		% PMTDI	6	9	5	9
13-19 years	LB 976	µg/day	10.0	11.5	62.5	43.4
	UB 1063	µg/kg bw/day	0.16	0.19	0.73	0.65
		% PMTDI	8	9	36	33
20+ years	LB 9984	µg/day	11.8	14.9	60.3	54.9
	UB 10698	µg/kg bw/day	0.17	0.21	0.81	0.75
		% PMTDI	8	10	41	37

*95th percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.

** The finding of a 95th percentile exposure less than the mean exposure reflects a highly skewed distribution of 3-MCPD exposures in this population group.

PMTDI: provisional maximum tolerable daily intake of 2 µg/kg bw/day.

LB = lower bound, where not detected results are assigned zero mg/kg; UB = upper bound, where not detected results are assigned the LOD.

Total number of respondents per population/age group: All years = 13858; 2-12 years = 2079; 13-19 years = 1063; 20+years = 10716.

Table 7b. Estimated dietary exposure to 3-MCPD for Australian consumers only from various food sources when the 3-MCPD concentration in soy and oyster sauces is the maximum level from the *Food Standards Code* (0.2 mg/kg)

Population group	Number of consumers	Exposure	Lower bound mean	Upper bound mean	Lower bound 95th %ile*	Upper bound 95th %ile*
All (2+ years)	LB 12878	µg/day	0.83	3.43	2.55	9.25
	UB 13838	µg/kg bw/day	0.01	0.05	0.04	0.13
		% PMTDI	1	3	2	6
2-12 years	LB 1918	µg/day	0.53	1.38	1.61	2.90
	UB 2077	µg/kg bw/day	0.02	0.05	0.06	0.11
		% PMTDI	1	3	3	6
13-19 years	LB 976	µg/day	0.94	2.42	3.27	6.29
	UB 1063	µg/kg bw/day	0.02	0.04	0.05	0.10
		% PMTDI	1	2	2	5
20+ years	LB 9984	µg/day	0.9	3.92	2.74	9.99
	UB 10698	µg/kg bw/day	0.01	0.05	0.04	0.13
		% PMTDI	1	3	2	7

*95th percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.

PMTDI: provisional maximum tolerable daily intake of 2 µg/kg bw/day.

LB = lower bound, where not detected results are assigned zero mg/kg; UB = upper bound, where not detected results are assigned the LOD.

Total number of respondents per population/age group: All years = 13858; 2-12 years = 2079; 13-19 years = 1063; 20+years = 10716.

Table 8a. Estimated dietary exposure to 1,3-DCP for Australian consumers only from various food sources when the 1,3-DCP concentration in soy and oyster sauces is based on Australian survey data (0.069 mg/kg (lower bound) & 0.077mg/kg (upper bound))

Population group	Number of consumers	Additive exposure	Lower bound mean	Upper bound mean	Lower bound 95th %ile*	Upper bound 95th %ile*
All (2+ years)	LB 13246	µg/day	0.7	2.6	3.2	6.9
	UB 13838	µg/kg bw/day	0.012	0.041	0.055	0.105
2-12 years	LB 2044	µg/day	0.6	1.3	2.5	3.4
	UB 2077	µg/kg bw/day	0.022	0.051	0.103	0.136
13-19 years	LB 1010	µg/day	0.9	2.1	3.9	5.6
	UB 1063	µg/kg bw/day	0.014	0.035	0.064	0.094
20+ years	LB 10232	µg/day	0.7	2.9	3.3	7.4
	UB 10698	µg/kg bw/day	0.009	0.039	0.044	0.101

*95th percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.

LB = lower bound, where not detected results are assigned zero mg/kg; UB = upper bound, where not detected results are assigned the LOD.

Total number of respondents per population/age group: All years = 13858; 2-12 years = 2079; 13-19 years = 1063; 20+years = 10716.

Table 8b. Estimated dietary exposure to 1,3-DCP for Australian consumers only from various food sources when the 1,3-DCP concentration in soy and oyster sauces is the maximum level from the *Food Standards Code* (0.005 mg/kg)

Population group	Number of consumers	Additive exposure	Lower bound mean	Upper bound mean	Lower bound 95th %ile*	Upper bound 95th %ile*
All (2+ years)	LB 13246	µg/day	0.6	2.6	3.1	6.8
	UB 13838	µg/kg bw/day	0.011	0.041	0.054	0.104
2-12 years	LB 2044	µg/day	0.6	1.3	2.5	3.4
	UB 2077	µg/kg bw/day	0.022	0.050	0.103	0.135
13-19 years	LB 1010	µg/day	0.8	2.1	3.9	5.4
	UB 1063	µg/kg bw/day	0.014	0.034	0.064	0.094
20+ years	LB 10232	µg/day	0.6	2.8	3.2	7.3
	UB 10698	µg/kg bw/day	0.008	0.039	0.043	0.099

*95th percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.

LB = lower bound, where not detected results are assigned zero mg/kg; UB = upper bound, where not detected results are assigned the LOD.

Total number of respondents per population/age group: All years = 13858; 2-12 years = 2079; 13-19 years = 1063; 20+years = 10716.

Table 9a. Estimated dietary exposure to 3-MCPD for Australian consumers of soy and oyster sauces, when the 3-MCPD concentration in soy and oyster sauces is based on Australian survey data (mean 14.9 mg/kg)

Population group	Number of consumers	Exposure	Mean	95^{th} %ile*
All (2+ years)	1060	µg/day	138	416
		µg/kg bw/day	2.1	7.0
		% PMTDI	107	351
2-12 years	103	µg/day	71	242
		µg/kg bw/day	2.8	8.1
		% PMTDI	138	404
13-19 years	92	µg/day	138	378
		µg/kg bw/day	2.2	6.0
		% PMTDI	110	301
20+ years	865	µg/day	146	451
		µg/kg bw/day	2.1	7.0
		% PMTDI	103	351

*95^{th} percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.

PMTDI: provisional maximum tolerable daily intake of 2 µg/kg bw/day.

Total number of respondents per population/age group: All years = 13858; 2-12 years = 2079; 13-19 years = 1063; 20+years = 10716.

Table 9b. Estimated dietary exposure to 3-MCPD for Australian consumers of soy and oyster sauces, when the 3-MCPD concentration in soy and oyster sauces is the maximum level from the *Food Standards Code* (0.2 mg/kg)

Population group	Number of consumers	Exposure	Mean	95th %ile*
All (2+ years)	1060	µg/day	1.9	5.6
		µg/kg bw/day	0.03	0.10
		% PMTDI	1	5
2-12 years	103	µg/day	1.0	3.3
		µg/kg bw/day	0.04	0.11
		% PMTDI	2	5
13-19 years	92	µg/day	1.8	5.1
		µg/kg bw/day	0.03	0.08
		% PMTDI	1	4
20+ years	865	µg/day	2.0	6.1
		µg/kg bw/day	0.03	0.10
		% PMTDI	1	5

*95th percentile: Only 5% of consumers had exposures above this level, 95% of consumers were exposed to lower amounts.

PMTDI: provisional maximum tolerable daily intake of 2 µg/kg bw/day.

Total number of respondents per population/age group: All years = 13858; 2-12 years = 2079; 13-19 years = 1063; 20+years = 10716.

5.0 RISK CHARACTERISATION

5.1 3-Chloro-1,2-propanediol (3-MCPD)

The most sensitive adverse effect caused by 3-MCPD is renal toxicity, and the provisional maximum tolerable daily intake (2 µg/kg bw per day) established by JECFA is based on tubule hyperplasia in animal toxicity studies. 3-MCPD is not genotoxic *in vivo* and, on balance, the available studies do not indicate carcinogenic potential.

The dietary exposure assessment conducted in 2001 for Australian consumers specifically exposed to chloropropanols from consumption of soy and oyster sauces was based on the UK survey data (FSA, 2001d) and Australian food consumption data. The estimated level of exposure for consumers of 3-MCPD was compared to the PMTDI in order to determine if the exposure from these foods was a public health concern. At a contamination level of 3.7 mg/kg for soy and oyster sauces, the estimated dietary exposure for consumers of 3-MCPD at the 95th percentile was around 90% of the PMTDI (aged 2 years and above). However, at a contamination level of 3-MCPD at 16.9 mg/kg (which, from the UK data, reflected the exposure of habitual consumers of highly contaminated sauces), the mean and 95th percentile exposures for consumers (aged 2 years and above) to 3-MCPD were above the PMTDI, with the 95th percentile exposure being in excess of 400% of the PMTDI. Although this estimate of exposure used conservative assumptions, it identified a potential public health concern for Australian consumers, particularly for habitual consumers of highly contaminated sauces.

Further dietary exposure assessments were conducted in 2002 using the 2001 and 2002 Australian survey data and the Australian food consumption data. In these dietary exposure estimations, the mean concentration of 3-MCPD in soy and oyster sauces from Australian surveys was 14.9 mg/kg. The estimated dietary exposure to 3-MCPD from a wide range of foods was below the PMTDI for both mean and 95th percentile consumers of 3-MCPD. For mean consumers of 3-MCPD in all population groups, estimated dietary exposure was 10% or less of the PMTDI and 41% or less for 95th percentile consumers of 3-MCPD. However, under this modelling scenario, approximately 2% of all NNS respondents exceeded the PMTDI for 3-MCPD. The majority of these respondents exceeding the PMTDI had consumed large amounts of soy or oyster sauce (above the 95th percentile consumption figure), or had high consumption of mixed dishes where soy and oyster sauces were an ingredient (e.g. stir fries, Asian style meals and sauces), and/or had low body weights.

Given that the predominant contributors to the dietary exposure of 3-MCPD were soy and oyster sauces, dietary exposure was also estimated for those consumers specifically consuming these foods, using the Australian concentration data. In this case, when using a mean concentration of 3-MCPD of 14.9 mg/kg, estimated mean exposure for this smaller group of consumers was 107% of the PMTDI for those aged 2 years and above, and 138% of the PMTDI for those in the 2-12 years age group. Estimated 95th percentile exposure for this group of consumers was 351% PMTDI for those aged 2 years and above, and 404% of the PMTDI for those in the 2-12 years age group.

The above dietary assessments were conducted using a mean concentration of 3-MCPD in soy and oyster sauces of 14.9 mg/kg, derived from Australian surveys undertaken in 2001. The regulatory action taken subsequent to these surveys removed many of the high chloropropanols-containing sauces from the market. Thus, no soy or oyster sauce on the market in Australia should now exceed the ML of 0.2 mg/kg for 3-MCPD prescribed in the *Food Standards Code*.

Further dietary exposure assessments were conducted in which soy and oyster sauces were assigned a concentration of 3-MCPD equivalent to the ML. In this scenario, the dietary exposure to 3-MCPD from a wide range of foods was well below the PMTDI for both mean and high consumers of 3-MCPD. For mean consumers of 3-MCPD in all population groups assessed, estimated dietary exposure was 3% or less of the PMTDI and 7% or less for 95th percentile consumers of 3-MCPD.

When dietary exposure was estimated only for those consumers specifically exposed to 3-MCPD from soy and oyster sauce, using the ML of 0.2 mg/kg, estimated exposure for the highest exposed group in the population (2-12 years age group) was 2% of the PMTDI for mean consumers and 5% of the PMTDI for 95th percentile consumers. Even the highest consumer of soy sauce identified in the NNS (204 grams in 24 hours), would not exceed the PMTDI when the maximum 3-MCPD concentration was 0.2 mg/kg. Additionally, as the exposure estimates are based on a 24-hour recall, habitual exposure is likely to be over-estimated for high consumers.

On the basis of the available data, 3-MCPD at the current levels found in food is unlikely to be a public health and safety concern for any group in the population, although the levels should be as low as reasonably achievable in all foods without compromising the availability of otherwise nutritious foods.

5.2 1,3-Dichloro-2-propanol (1,3-DCP)

The JECFA review of the toxicity data found that 1,3-DCP induced a variety of tumours in rat studies and was positive in *in vitro* genotoxicity tests. Taken together, these data, while still limited, indicate that 1,3-DCP should be regarded as a potential carcinogen in humans. Under these circumstances, it is not possible at this time to establish a tolerable daily intake for 1,3-DCP, below which there is no appreciable risk. In the future, if further data become available which allows a better understanding of the mechanism of tumour formation in animal studies, it may be possible to identify a threshold dose level for tumour formation and thus establish a tolerable daily intake for 1,3-DCP.

Although limited, the currently available data provides some evidence for a threshold for 1,3-DCP-induced tumour formation. In the one rat study, tumours occur only at the highest of the three dose levels and no dose-response relationship is apparent. Liver and kidney damage is also seen in both short- and long-term studies with 1,3-DCP at dose levels that are lower than the dose level that induced tumours – for the majority of carcinogens, tumour formation is generally linked to tissue hyperplasia.

In relation to genotoxicity, *in vivo* studies have not been conducted with 1,3-DCP – for many chemicals, positive *in vitro* studies alone are not a good predictor of carcinogenicity in animal studies.

On the basis of the currently available information, however, and in the absence of an identified threshold dose level for tumour formation, it must be assumed that 1,3-DCP may induce tumours through a genotoxic mechanism, for which the threshold is unknown and likely to be low. Therefore there may be a cancer risk, albeit a low risk, even at very low levels of exposure to 1,3-DCP. In these circumstances, the risk can be characterised only by determining the margin of exposure between the known levels of 1,3-DCP in food and the level of 1,3-DCP shown to cause cancer in animal studies.

The results of the 2001 and 2002 surveys of Australian foods were used in the dietary exposure assessment for 1,3-DCP conducted in 2002. The estimated upper bound mean dietary exposure for consumers of 1,3-DCP from a wide range of foods was 2.9 µg/day in the 20 years and above age group, the highest consuming group. The estimated upper bound 95th percentile dietary exposure for consumers of 1,3-DCP was 7.4 µg/day in the 20 years and above age group.

When the newly established ML for 1,3-DCP of 0.005 mg/kg was used in the dietary exposure assessment, the estimated dietary exposure for consumers of 1,3-DCP from a wide range of foods at the upper bound mean was 2.8 µg/day in the 20 years and above age group, the highest consuming group. The estimated upper bound 95th percentile dietary exposure for consumers of 1,3-DCP in the 20 years and above age group was 7.3 µg/day. For both of the above dietary exposure estimates, the 95th percentile dietary exposure for consumers of 1,3-DCP from the Australian diet was approximately 200,000 fold less than the level of exposure shown to cause tumours in animal studies. At this level of dietary exposure, the risk of tumour formation from exposure to 1,3-DCP, even in the absence of a threshold for tumour formation, is likely to be very small.

The survey data indicated that the major foods contributing to dietary exposure to 1,3-DCP for Australia were minced meat (45%), sausages (25%), bread (10%), soy sauce (7%), and ham and bacon (6%).

With one exception, 1,3-DCP was detected only in those soy sauces that contained 3-MCPD, which may suggest that, in this food, 1,3-DCP is derived from 3-MCPD, although a concentration relationship between the two substances was not apparent. In other foods, 1,3-DCP was detected in 14% of the samples tested. The levels of 1,3-DCP in the various foods were highly variable and, in a number of foods, 1,3-DCP was found in the absence of 3-MCPD, which suggests there may be more than one route of formation of 1,3-DCP.

On the basis of the available data, dietary exposure to 1,3-DCP at the current levels found in food is unlikely to be a public health and safety concern for any group in the population, although the levels should be kept as low as reasonably achievable in all foods, without compromising the availability of otherwise nutritious foods.

6.0 RISK MANAGEMENT

6.1 Australia and New Zealand

6.1.1 Soy and oysters sauces

The assessment of the public health and safety risk posed by chloropropanols in soy and oyster sauces was initially based on frequency and levels of contamination in samples from the UK survey and on Australian consumption data. Similar contamination was found in Australian samples.

The risk assessment concluded that the extent of contamination posed an unacceptable risk to public health and safety.

Subsequently risk management decisions were taken in three areas:

1. Retailers and manufacturers of a number of soy and oyster sauce products that contained unacceptably high levels of 3-MCPD undertook a recall of these products.

2. In August 2001, a maximum limit of 0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP, for soy and oyster sauces calculated on 40% dry matter content, for incorporation into the *Food Standards Code* was recommended. These recommendations were based on the application of the '*as low as reasonably achievable'* principle and were the levels that FSANZ was advised could be achieved by industry using good manufacturing practice. These limits were adopted by the Australia New Zealand Food Standards Council (ANZFSC)[2] in October 2001 and came into force in November 2001 for soy and oyster sauces imported into or manufactured in Australia and New Zealand. The maximum limit of 0.005 mg/kg for 1,3-DCP was the limit of reporting for this substance.

3. The Australian Quarantine and Inspection Service (AQIS) was advised to introduce import testing for soy and oyster sauce products on 6 July 2001.

6.1.2 Foods other than soy and oyster sauces

The assessment of the public health and safety risks posed by chloropropanols in a range of foods other than soy and oyster sauce was based on the extent and level of contamination in the Australian food supply and Australian consumption data. It is notable that the levels of 3-MPCD were very low in these foods compared to those in soy and oyster sauces. The risk assessment concluded that the current level of chloropropanols in these foods is unlikely to pose a public health and safety concern for

[2] In July 2002 the Australia and New Zealand Food Regulation Ministerial Council (formerly known as the Australia New Zealand Food Standards Council) was established. The Council comprises Health Ministers from all Australian States and Territories, the Commonwealth and New Zealand as well as other Ministers from relevant portfolios, such as Primary Industries, that are nominated by their jurisdictions.

any population subgroups. Regulatory action on foods other than soy and oyster sauces is not warranted at this time.

The level of 1,3-DCP in these foods was also very low, although above the limit of reporting in some cases. Although it would be preferable to reduce the level of 1,3-DCP to the limit of reporting for other foods, as with the soy and oyster sauces, it remains unclear how manufacturing practices would need to change to achieve this result. Until there is a better understanding of the mechanism of formation of 1,3-DCP in foods, no regulatory action is proposed.

6.2 International - Codex Alimentarius Commission

The Codex Committee on Food Additives and Contaminants (CCFAC) has been working on the elaboration of a Position Paper on Chloropropanols since 2000 (33rd Session, CCFAC, 2001), recognising that chloropropanols contamination is a food safety issue that has trade implications, and therefore a harmonised approach to control chloropropanol levels in foods is desirable. Issues proposed for discussion in the Position Paper include toxicity, epidemiology, levels and patterns of contamination, food consumption, and analytical methods generated.

CCFAC has noted that several scientific bodies, including the European Commission's Scientific Committee For Food (SCF) and JECFA have reassessed the toxicity of 3-MCPD and 1,3-DCP.

In terms of possible approaches to regulation, CCFAC has noted that while there is some evidence that controlling the level of 3-MCPD will control the level of 1,3-DCP, the evidence is not conclusive. Although the JECFA assessment on chloropropanols mentions a ratio of 20 (3-MCPD) : 1 (1,3-DCP), there is evidence that the relationship between levels of 3-MCPD and 1,3-DCP is not constant at all concentrations and the ratio has been reported to vary widely. Thus reliance upon the level of 3-MCPD to control levels of 1,3-DCP is an indirect measure. To date, CCFAC has not been able to reach consensus on the elaboration of maximum levels for chloropropanols in soy and oyster sauce. At the 35th Session of the CCFAC (2003), several delegations informed CCFAC that new studies had recently been completed on levels of chloropropanols in a range of foods, including soy sauce, and that in the coming year more data would enable a risk assessment to be conducted in the EC countries.

CCFAC agreed that the delegation of the United Kingdom would revise the Position Paper on Chloropropanols on the basis of discussions, written comments submitted and data to be made available for circulation, comment and further consideration at its next Session to be held in 2004. CCFAC also agreed that the revised document should include proposals for the elaboration of maximum levels for chloropropanols in the relevant foods.

6.3 Future Directions

The formation of chloropropanols in food is not fully understood and government agencies are liaising with relevant industry sectors to determine the source of chloropropanols in food. In addition government agencies are working with relevant industry sectors to monitor the food supply for chloropropanols to ensure that the levels are as low as practically achievable.

FSANZ is monitoring and contributing to international considerations associated with chloropropanols in food.

7. REFERENCES

CCFAC (2000) Joint FAO/WHO Food Standards Programme Codex Committee on Food Additives and Contaminants report of the 32nd Session, Codex Alimentarius Commission 24th Session July 2001, (ALINORM 01/12).

ftp://ftp.fao.org/codex/alinorm01/Al01_12e.pdf

CCFAC (2001) Joint FAO/WHO Food Standards Programme Codex Committee on Food Additives and Contaminants – 33rd Session Position paper on Chloropropanols (CX/FAC 01/31) January 2001.

Crews C, Brereton P and Davies A (2001) The effects of domestic cooking on the levels of 3-monochloropropanediol in foods. Food Additives and Contaminants, Vol 18, 271-280.

Crews C, LeBrun G, Hough P, Harvey D, and Brereton P (2000) Chlorinated propanols and levulinic acid in soy sauces. Czech Journal of Food Sciences, Vol 18, 276-277.

FAO/WHO (1993) Evaluation of certain food additives and contaminants. Report of the 41st meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series, No. 837, 1993.

FAO/WHO (2002a) *Safety Evaluation of certain food additives and contaminants.* Prepared by the 57th meeting of Joint FAO/WHO Expert Committee on Food Additives (JECFA) *WHO Food Additives Series, No 48*. WHO, Geneva.

FAO/WHO (2002b) Evaluation of Certain Food Additives and Contaminants. 57th Report of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Technical Report Series No. 909. WHO 2002.

Food Advisory Committee (1996) Press Release 6/96 Update on chloropropanols in hydrolysed vegetable protein.

Food Standards Agency (2001a) Survey of 3-Monochloropropane-1,2-diol (MCPD) in Food Ingredients. Food Safety Information Sheet No.11/01.

http://www.food.gov.uk/science/surveillance/fsis-2001/3-mcpding

Food Standards Agency (2001b) Survey of 3-Monochloropropane-1,2-diol (MCPD) in Selected Foods. Food Safety Information Sheet No12/01.

http://www.food.gov.uk/science/surveillance/fsis-2001/3-mcpdsel

Food Standards Agency (2001c), Survey of 1,3-Dichloropropanol (1,3-DCP) in Soy Sauce and Related Products Food Survey Information Sheet Number 15/01.

http://www.food.gov.uk/science/surveillance/fsis-2001/13dcpsoy

Food Standards Agency (2001d) Survey of 3-Monochloropropane-1,2-diol (MCPD) in Soy Sauce and Related Products Food Survey Information Sheet No.14/01.

http://www.food.gov.uk/science/surveillance/fsis-2001/3-mcpdsoy

Food Standards Agency (2002a) Catering soy sauce products surveyed.

http://www.food.gov.uk/news/newsarchive/soy_sauce

Food Standards Agency (2002b) Follow-up survey of chemical contaminants in shop bought soy sauce shows significant improvement Ref: 2002/0291.

http://www.food.gov.uk/news/newsarchive/soy

Hamlet CG, Sadd PA, Crews C, Velisek J, and Baxter DE (2002) Occurrence of 3-chloro-propane-1,2-diol (3-MCPD) and related compounds in foods: a review, Food Additives and Contaminants 19(7), 619-631.

Ministry of Agriculture, Fisheries and Food (1999) Survey of 3-monochloropropane-1,2-diol (3-MPCD) in acid hydrolysed vegetable protein, Food Surveillance Information Sheet 181. London.

http://archive.food.gov.uk/maff/archive/food/infsheet/1999/no181/181mcpd.htm