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DRAFT RISK ANALYSIS REPORT

SECTION 37

PROPOSAL P243

MAXIMUM LIMIT FOR CHLOROPROPANOLS IN SOY AND OYSTER SAUCES

Note:

This report is the "Full Assessment" as referred to in Section 23 of the *Australia New Zealand Food Authority Act (1991).*

This Full Assessment was considered as a matter of urgency, under section 37 of the *Australia New Zealand Food Authority Act (1991)* and has been recommended to the Ministerial Council. ANZFA will conduct an inquiry into this Proposal as soon as practicable.

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SUMMARY

A recent survey conducted by the United Kingdom's Food Standards Agency in 2000 identified some soy sauces (22% of those tested) that contained chloropropanols. Of the samples containing the chloropropanol 3-MCPD, approximately two thirds also contained the genotoxic carcinogen 1,3-dichloropropanol (1,3-DCP). 1,3-DCP is formed from its precursor 3-MCPD. There are reports of a linear correlation between the levels of these two chloropropanols with a ratio of at least 20:1, however, this ratio has been observed to vary widely. Mixed foods other than soy and oyster sauces have been shown to contain 3-MCPD, but generally at substantially lower levels.

Based on the extensive toxicological data on 3-MCPD and 1,3-DCP that indicate human and health safety concerns with their presence in food, particularly in soy sauces, ANZFA has raised an emergency Section 37 proposal to amend Standard A12 of Volume 1 and Standard 1.4.1 of Volume 2 of the *Food Standards Code* to set maximum levels (MLs) for 3-MCPD and 1,3-DCP in soy and oyster sauces.

The available toxicological data, together with ANZFA's own dietary exposure modelling indicate that MLs of 0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP based on 40% dry matter, would be acceptable from a human health and safety perspective. A Joint FAO/WHO Expert Committee on Food Additives report concludes that evidence indicates the presence of 1,3-DCP is associated with high concentrations of 3-MCPD in food.

OBJECTIVE OF THE PROPOSAL

The objective of the proposal is to protect public health and safety by minimising the exposure to the potentially cancer causing chloropropanols that may be present in some soy and oyster sauces.

SECTION 37 CONSIDERATION

On 22 June 2001, ANZFA issued a media release advising consumers that certain soy and oyster sauces have been found to contain high levels of potential cancer-causing agents, based on the results of the United Kingdom's Food Standards Agency (FSA) survey which disclosed that some (but not all) soy sauces made by acid hydrolysis contain chemicals called chloropropanols.

On the basis of the UK study, it is proposed that an amendment be made to the *Food Standards Code* to include a maximum limit for the chloropropanol 3-MCPD in soy sauce and oyster sauce products of **0.2 mg/kg** (based on a 40% dry weight basis). Additionally, it was considered that 1,3-DCP should not be present in the food and therefore a maximum limit was proposed at the current limit of quantification, **0.005 mg/kg**.

The recommendation was made pursuant to section 37 of the *Australia New Zealand Food Authority Act 1991* (the Act). Section 37 provides that if the Authority considers that a recommendation should be made to the Council as a matter of urgency, in relation to a proposal under section 21, in order to avoid compromising the objectives set out in section 10, the Authority may decide, in writing, to omit to carry out one or more of the matters required by Part 3 of the Act. This usually, but not always, means that at least one round of public consultation and the full assessment step in the process laid down in the Act to deal with applications and proposals is not undertaken by the Authority.

The Authority is also required by section 37, as soon as practical after the adoption of the draft variation of the standard by the Council, to hold an inquiry under section 24 into the variation as adopted by the Council in the same manner as if the variation has been the subject of a full assessment under section 23 and were a draft variation prepared under that section.

BACKGROUND

On 20 June 2001, the UK Food Standards Agency (FSA) reported on potentially cancer causing chemicals, 3-chloro-1,2-propanediol (3-MCPD) and 1,3-dichloro-2-propanol (1,3-DCP), present in some soy sauce products. The UK FSA stated that the chemical contaminants may cause cancer if consumed on a regular basis over a long period of time. Some soy sauce products contained levels well in excess of the 0.02 mg/kg limit[#] that was adopted by the European Community (for 3-MCDP) and which is currently due to become effective in April 2002. The non-compliant products are being removed from sale in the UK. The sauces affected in the UK are imported from Thailand, China, Hong Kong and Taiwan. Some products from the brands implicated in the UK FSA survey are currently also sold in Australia and New Zealand.

In 1999, the Canadian Food Inspection Agency (CFIA) introduced measures to reduce the level of the contaminants in soy and oyster sauces. Their level of 1 mg/kg for 3-MCPD (1 ppm) is a provisional guideline set by Health Canada.

1. Chloropropanols in Soy Sauce and Oyster Sauce

3-MCPD and 1,3-DCP belong to a group of chemical contaminants known as chloropropanols. They can be formed in foods as a result of processing/storage conditions. Although the mechanisms for their formation are not fully understood, 3-MCPD has been shown to be a precursor for 1,3-DCP formation[1] and 1,3-DCP is a known genotoxic carcinogen in animals.

3-MCPD is a well-known contaminant of acid-hydrolysed vegetable protein (acid-HVP)[2,3], which is a commonly used savoury ingredient. Acid-HVP is frequently used in foods such as soups, prepared meals, savoury snacks, gravy mixes and stock cubes. Acid-HVP is produced by treating proteins from vegetables, such as soy, with hydrochloric acid. This treatment of defatted vegetable proteins by traditional hydrochloric acid hydrolysis can also lead to the formation of chloropropanols.

[#] Note: The European Community are currently reconsidering this limit. An EC meeting held in early-July considered whether, following recent scientific assessments that have indicated that 3-MCPD is not a genotoxic carcinogen, the EC limit should be revised upwards. No consensus was reached at this meeting and member states will consider the issue again in October 2001.

3-MCPD has been found to occur in a range of other foods and ingredients but most notably in soy sauce [4,5] made by non-traditional methods. 1,3-DCP has also been detected in acid-HVP[2] and in soy sauce[4,17] but its presence in other foods and ingredients has not been investigated to the same extent. 1,3-DCP is formed from its precursor 3-MCPD in a possible linear correlation, at a ratio of at least 20:1[14,15]. This ratio has been observed to vary widely.

2 Testing and methodology for Chloropropanols

2.1 What products are targeted/captured?

Soy and oyster sauce products contain primarily HVP, whether derived from naturally brewed or non-traditional methods. Consequently, those soy products derived from acid-HVP processes or have added acid-HVP may contain the contaminants at unacceptable levels more so than those from naturally fermented sources.

ANZFA is currently undertaking a survey of soy and oyster sauces in order to determine the extent of contamination in products available in Australia. Soy sauce products implicated in the recent UK survey will be assessed as well as products randomly chosen from supermarkets from both domestic and imported origins. All products sampled will be tested for 3-MCPD and 1,3-DCP. Results from these surveys will be released to the public once completed and assessed.

Validated testing methodology is available from the United Kingdom for measuring 3-MCPD and 1,3-DCP in food to levels of 0.02 mg/kg and 0.005 mg/kg respectively. These tests are currently being validated for use in Australian laboratories.

2.2 3-MCPD

The most widely used analytical method is based on gas chromatography with mass spectrometric detection. Samples are prepared by extraction on to a column packed with diatomaceous earth and subsequent elution of 3-MCPD with diethyl ether. The concentrated extract is taken for derivatisation and analysis by gas chromatography. Quantification is achieved using the intensity of a characteristic peak against that of the internal standard.

This is a fully validated analytical method capable of measuring 3-MCPD in food and food ingredients to 0.01 mg/kg and has been developed by the UK's Central Science Laboratory (CSL)[5]. This method has been validated through an international collaborative trial and has been accepted as a first action status by the Association of Official Analytical Chemists (AOAC).

2.3 1,3-DCP

Compared with 3-MCPD, there has been relatively little work published on 1,3-DCP in recent years. The method that has been developed for measurement of 3-MCPD in foods and food ingredients (AOAC 2000) cannot be automatically applied to 1,3-DCP. It is considerably more volatile than 3-MCPD and significant amounts are lost during the concentration stages. However, a modification of the method has been successfully used to quantify 1,3-DCP down to 0.025 mg/kg in soy sauces (FDA 2000). This involves partitioning the ether/hexane extract with acetonitrile, which can then be concentrated without losing the extracted DCP. The DCP is derivitised with heptafluorobutryrlimidazole (HFBI) prior to gas chromatography and mass spectrometric detection.

An alternative method that is capable of detecting DCP in soy sauce at levels below 0.005 mg/kg has been reported[11]. This uses headspace gas chromatography with mass spectrometric detection and a deuterated internal standard.

In Australia, a small number of laboratories have the capability to measure 3-MCPD and 1,3-DCP using standardised methods.

3. Summary of Surveys Undertaken on Chloropropanols

Surveys of 3-MCPD and 1,3-DCP levels in food and food ingredients have been conducted in the UK, USA and Canada.

3.1 UK Surveys

i) Acid-HVP and Soy Sauce

Surveys of acid-HVP products on the UK market were conducted in 1990, 1992, and 1998. Results show that the median 3-MCPD contamination levels fell from more than 10 mg/kg in 1990 to 0.01-0.02 mg/kg in 1992. In 1999, the UK completed a survey of 3-MCPD in a range of soy sauces and related products. Significant levels of 3-MCPD were found in some products. Relevant industries were advised by the FSA to take steps to reduce the concentration of 3-MCPD in all foods and food ingredients to the lowest technologically achievable.

Another UK survey was conducted and published in June 2001 as a follow up to the 1999 survey to ascertain the progress manufacturers had made in addressing the level of the contaminants. Soy sauce and related products (100 samples) were analysed by the UK CSL using validated methods of analysis with a limit of quantification of 0.01 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP.

This most recent survey assessed the levels of 3-MCPD (and 1,3-DCP) in soy sauces available in the UK against the proposed EU limit of 0.02 mg/kg, based on 40% dry matter content (which is to be adopted in April 2002). Of the samples analysed, 22% contained levels of 3-MCPD equal to or above the EU limit compared with 32% of the samples analysed in the 1999 survey. The highest level of 3-MCPD was 93.1 mg/kg.

In addition, 1,3-DCP was quantified in 17% of samples soy sauce and HVP based on a 40% dry matter content. All samples with quantifiable levels of 1,3-DCP were those samples that also contained levels of 3-MCPD above 0.02 mg/kg for 3-MCPD.

ii) Food Additives

By analogy with acid-HVP, it is possible that the use of acid treatments in the manufacture of food additives could lead to the generation of 3-MCPD from fats or oils in the starting materials. A recent UK survey 20 products found 3-MCPD in 2 of 7 samples of modified starch, the highest level detected in a sample of yellow dextrin (0.49 mg/kg). In the same survey, 3-MCPD was not detected (less than 0.01 mg/kg) in samples of caramel colours.

iii) Other products

3-MCPD can be detected at low levels in certain cereal products, including malted cereals and malt extracts which are produced using high temperature treatments – so-called “dark” malts and malt extracts, which have a more pronounced flavour and colour. These malts and malt extracts are used in a wide range of foods such as bread, biscuits, breakfast cereals, beers, sauces and gravies.

Levels up to 0.5 mg/kg of 3-MCPD have been found in these ingredients[20]. This is similar to the levels found in roasted barley, which is a characteristic ingredient in certain beers. These products are typically used as ingredients making up between 1 and 10% of the final food, so the resulting 3-MCPD concentration in the final foods will be one or two orders of magnitude lower.

A range of foods were analysed for the presence of 3-MCPD in a recent UK survey[21]. These analyses mainly concentrated on products where fat and chloride are present in acidic conditions and where the food is processed at high temperatures and/or has a long shelf-life at ambient temperature. Where quantifiable levels were found, 3-MCPD was present at low levels. Only one sample in this survey exceeded 0.1 mg/kg.

3.2 US survey

A survey of 21 samples of soy sauce purchased in the US found that 9 samples exceeded 1 mg/kg of 3-MCPD, with the highest being 85 mg/kg[19]. 1,3-DCP was detected (i.e. > 0.025 mg/kg) in 6 of 21 samples, at levels between 0.07 and 1.9 mg/kg. All of the samples containing 3-MCPD at levels above 1 mg/kg [19] also contained 1,3-DCP.

3.3 Canadian survey

Analyses of 90 soy sauce products in Canada found concentrations of 3-MCPD ranging from not detectable (less than 0.01 mg/kg) to 329 mg/kg[18].

3.4 Distribution Curves

Surveys of acid-HVP and soy sauce have found that the distribution of 3-MCPD is markedly skewed, with a large number of products having low or undetectable levels, and a relatively small number having high levels. In the case of the UK surveys[3], caution should be exercised in interpreting the results of these surveys since the sampling was dependent on the provision of samples by selected food manufacturers and may not have been representative of all the products currently on the market. The Canadian survey[18] also showed that the distribution of contamination was markedly skewed, the median level being 0.5 mg/kg and the mean being 18 mg/kg.

4. Summary of Safety Studies Undertaken on Chloropropanols

4.1. United Kingdom

The most recent assessments of the toxicology of 3-MCPD (and 1,3-DCP) have been conducted in the UK by the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM)[6] and the Committee on Carcinogenicity (COC)[7]. Summaries of these documents can be found at Attachment 4 and 5.

One of the main conclusions from the Committee was that 3-MCPD can be regarded as having no significant genotoxic potential *in vivo*.

4.2 European Community

In the European Commission, discussions began in December 1999 on a proposal to set a limit for 3-MCPD in certain foods and food ingredients. The Commission adopted a regulatory limit of 0.02 mg/kg based on 40 per cent dry matter content in soy sauce and acid-HVP which is to come into effect in April 2002.

The European Commission's Scientific Committee on Food (EC SCF) met and adopted its opinion on 3-MCPD on 30 May 2001[16]. The EC SCF concluded on the basis of all new data available that there was adequate evidence that the genotoxic activity *observed in vitro* for 3-MCPD was not expressed in vivo. The EC SCF also agreed that the additional information supported the view that the increase in benign tumours observed in the long-term carcinogenicity assay in rats is the result of non-genotoxic mechanisms, either through chronic hormonal imbalance or sustained cytotoxicity and chronic hyperplasia. The EC SCF reviewed their opinion establishing a Provisional Tolerable Daily Intake (PTDI) for 3-MCPD of 0.002 mg/kg body weight/day[16], based on a Lowest Observable Effect Level (LOEL) of 1.1 mg/kg with a safety factor of 500. This level was in agreement with that proposed by JECFA in June 2001[14,15].

4.3 Canadian risk analysis

Based on the results of a chronic rat study, Health Canada established a PTDI of 0.0011 mg/kg body weight/day based on the LOEL and an uncertainty factor of 1000. This is apparently a preliminary strategy, with the ultimate objective being to reduce 3-MCPD levels to concentrations that are as low as reasonably achievable. The Canadian Food Inspection Agency is currently conducting preliminary investigations to verify the effectiveness of compliance measures taken to date.

4.4 USA risk analysis

Based on technological feasibility and a preliminary quantitative cancer risk assessment by the Food and Drug Administration (FDA), specifications of 1 mg/kg (1 ppm) for 3-MCPD and 0.005 mg/kg (50 ppb) for 1,3-DCP in acid-HVP (on a dry basis) were established by the Food Chemicals Codex (FCC) in 1997. Following discussions with FDA, the US industry has voluntarily complied with these FCC specifications which appear to provide a significant margin of safety to protect public health from the diverse range of products using acid-HVP. FDA's Center for Food Safety and Applied Nutrition (CFSAN), Cancer Assessment Committee and Quantitative Risk Assessment Committees have recently finished their formal evaluations of 3-MCPD and are providing these assessments to the Joint FAO/WHO Expert Committee on Food Additives (JECFA), which will assist Codex in establishing an international specification. CFSAN is currently monitoring chloropropanol levels and evaluating its risk management options to lower levels of chloropropanols in Asian soy sauces in order to eliminate any significant human health risk from these products.

4.5 Joint FAO/WHO Expert Committee on Food Additives (JECFA)

JECFA establishes safe levels of intake for food additives and contaminants, and chemical specifications for food additives. JECFA decisions are accepted internationally and used by governments to establish national food standards. JECFA also provides advice to the Codex Committee on Food Additives and Contaminants (CCFAC).

JECFA most recently considered chloropropanols at its 57th meeting (June 2001). Information on the concentration of 3-MCPD in food, food ingredients, and protein hydrolysates was submitted to JECFA by the UK, the USA, and the International Hydrolyzed Protein Council. The USA supplied a national estimate of the intake of 3-MCPD and three countries (Australia, Japan and the USA) provided information on the consumption of soy sauce.

Both 3-MCPD and 1,3-DCP were previously evaluated by the Committee at its forty-first meeting in 1993, when it concluded that 3-MCPD and 1,3-DCP were undesirable contaminants in food and considered that their concentrations in hydrolysed proteins should be reduced to the lowest level technically achievable.

Information obtained from recent JECFA assessment report (June 2001).

A summary of the JECFA report can be found at Attachment 5.

JECFA derived a provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 0.002 mg/kg body weight/day, choosing tubular hyperplasia in the kidney as the most sensitive toxicity end-point using a Lowest Observable Effect Level LOEL of 1.1 mg/kg body weight/day and a safety factor of 500 based on a long-term study of toxicity and carcinogenicity in rats.

The committee indicated that 1,3-DCP was genotoxic *in vitro*, was hepatotoxic, and induced a variety of tumours in various organs in rats[8]. The Committee concluded that the estimation of a tolerable intake was inappropriate because of the nature of the toxicity based on the following considerations:

- The results of the long-term study showed significant increases in the incidences of both benign and malignant neoplasms in at least three independent studies;
- It has been shown unequivocally that this contaminant can interact with 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.

4.6. Previous ANZFA consideration of 3-MCPD

JECFA considered toxicology data on 3-MCPD in 1993 and concluded that this substance was an undesirable contaminant in food and expressed the opinion that its level in acid-HVP should be reduced as far as is technically possible. Consistent with this approach, the UK Food Advisory Committee in 1996 indicated that 3-MCPD should be reduced to the minimum detectable by the most sensitive method (ie 0.01mg/kg). At this time, ANZFA contacted companies and urged them to adopt manufacturing practices that would reduce the levels of 3-MCPD in their products.

4.7 Consideration of Chloropropanols in New Zealand

On the basis of the report released on 20 June 2001 by the UK FSA, the New Zealand Ministry of Health, warned consumers on 21 June 2001 to avoid consuming products containing soy sauce until the situation has been clarified. New Zealand health protection officers revealed on 22 June 2001 that a number of implicated brands are available in New Zealand. None of the batches that had been tested positive in the UK survey were found, but the Ministry believe it is possible that there are some contaminated batches in the country.

The Ministry has established an emergency food measure and is working with New Zealand Customs to institute border controls to stop and test soy and oyster sauces and products that contain substantive amounts of soy and oyster sauces as ingredients. These products will be withheld from distribution, pending either confirmation that they are manufactured by natural fermentation and thus less likely to contain the contaminants or are cleared by testing in an accredited laboratory. Products that are tested must not contain levels of 3-MCPD above 0.02 mg/kg.

Importers and manufacturers that can prove that their products are manufactured using natural fermentation without the addition of acid-HVP will have no restrictions placed upon their products. Importers must obtain a declaration letter from the relevant government authority in the country of origin (manufacturer declarations will not be accepted).

5. Estimation of Dietary Exposure

ANZFA considers a dietary exposure assessment is necessary to determine an estimated dietary exposure to 3-MCPD as well as to assist in setting a ML for the Food Standards Code. The full exposure assessment can be found at Attachment 7.

Setting a ML needs to take into consideration the estimated dietary exposures, the theoretical maximum allowable level (TMAL) and analytical data on the products in question. The ANZFA dietary modelling results indicate that if an ML for 3-MCPD was set at 0.02 mg/kg, or 0.1 mg/kg:

- this would be acceptable from a public health and safety perspective, with respect to exposure to 3-MCPD from dietary intake of soy and oyster sauces;
- the 0.02 mg/kg level could result in more products possibly being non-compliant with such a standard, with products potentially being withdrawn unnecessarily; and
- the 0.1 mg/kg level could see the vast majority of products in the UK survey that do comply with this level, also not containing detectable levels of 1,3-DCP.

For observed levels of 3.7 mg/kg (i.e. the mean residual level from the 100 samples tested in the UK survey):

- this level would be acceptable from a public health and safety perspective, with respect to exposure to 3-MCPD from dietary intake of soy and oyster sauces, but is very close to the calculated TMAL. It does not take into consideration intake of 3-MCPD from other sources in the diet and the aim for regulators of contaminants to set regulations according to ALARA and GMP principles; and
- at this level of 3-MCPD some of these products may also contain detectable levels of 1,3-DCP.

A level of 16.9 mg/kg (i.e. the mean residual level from the 22 samples tested in the UK survey, found to contain levels of 3-MCPD above 0.005/kg) would be unacceptable due to the potential risk to public health and safety from the consumption of soy and oyster sauces.

Thus a ML of 0.2 mg/kg for 3-MCPD (proposed Australian ML) would be acceptable from a public health and safety perspective, with respect to exposure to 3-MCPD from dietary intake of soy and oyster sauces.

SCIENTIFIC ASSESSMENT

The basis for the recommended ML for the chloropropanol contaminants 3-MCPD and 1,3-DCP in soy and oyster sauces are the results of the following reports:

- UK FSA survey results of 3-MCPD and 1,3-DCP in soy sauce and related products;
- UK Committee on Mutagenicity of Chemicals in Food, Consumer products and the Environment (2000);
- UK Committee on Carcinogenicity of Chemicals in Food, Consumer products and the Environment (2000);

- EC Scientific Committee on Food. Opinion on 3-MCPD (2001);
- JECFA Report 2001. 3-Chloro-1,2-propanediol;
- JECFA Report 2001. 1,3-Dichloro-2-propanol; and
- ANZFA consumption data.

The results of the review of the available reports and toxicological data conclude that:

- Certain chlorinated propanols occur as contaminants in hydrolyzed vegetable proteins. Processing of defatted vegetable proteins by traditional hydrochloric acid hydrolysis leads to the formation of significant amounts of 3-MCPD and 1,3-DCP;
- It has been reported that 3-MCPD gives rise to formation of 1,3-DCP in a ratio of approximately 20:1, although this ratio has been observed to vary widely.
- Available toxicological studies undertaken and evaluated by several committees (SCF, COC, JECFA) on 3-MCPD provided adequate evidence that the genotoxic activity observed *in vitro* was not expressed *in vivo.* The toxicological information also supports the view that the increase in benign tumours observed in long-term carcinogenicity assay in rats with 3-MCPD is the result of non-genotoxic mechanisms, either through chronic hormonal imbalance (mammary gland fibromas, Leydig cell tumours) or sustained cytoxicity and chronic hyperplasia (renal tumours);
- A PMTDI of 0.002 mg/kg body weight/day has been recommended for 3-MCPD by both JECFA and the SCF based on consideration of ALL available toxicological data;
- The ANZFA consumption modeling data indicate that an ML of 1.0 mg/kg for 3-MCPD would not exceed the PMTDI.

PUBLIC CONSULTATION

Under section 37, ANZFA is required as soon as practicable to hold an inquiry into the standard as adopted. A targeted round of consultation will be conducted that involves domestic manufacturers and importers of soy and oyster sauces.

OPTIONS

In the course of developing regulations suitable for adoption in Australia and New Zealand, the Authority is required to consider the impact of various options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments.

Option 1– *Do not set any MLs for 3-MCPD and 1,3-DCP and rely upon guideline limits in conjunction with the general requirements of food legislation that make it an offence to sell food that is injurious to health (US approach).*

Option 2 – *Amend the Food Standards Code to include a ML of 0.02 mg/kg for 3-MCPD (ie the UK approach for MCPD) and a ML of 0.005 mg/kg for 1,3-DCP.*

Option 3 – *Amend the Food Standards Code to include a ML of less than 0.02 mg/kg for 3-MCPD and a ML of 0.005 mg/kg for 1,3-DCP.*

Option 4 – *Amend the Food Standards Code to include a ML of greater than 0.02 mg/kg for 3-MCPD and a ML of 0.005 mg/kg for 1,3-DCP.*

REGULATORY IMPACT ANALYSIS

Parties affected by the options listed above include:

1. Consumers in Australia and New Zealand
2. State, Territory, Commonwealth and New Zealand Health Departments
3. Australian Quarantine and Inspection Service
4. Domestic manufacturers, producers and retailers of food (soy and oyster sauces and acid-HVP) products
5. Importers of food (soy and oyster sauces and acid-HVP) products

Risk-benefit analysis

Risks and benefits arising from any new or varied food regulatory or other measure as a result of this proposal are considered below.

Option 1– Do not set any MLs for 3-MCPD and 1,3-DCP and rely upon guideline limits in conjunction with the general requirements of food legislation that make it an offence to sell food that is injurious to health (US approach).

Benefits

- There is a benefit to government in relying upon food legislation which provides a very responsive and flexible means to protect public safety.
- The benefit to consumers is that they will have a supply of soy and oyster sauces that contain low level of chloropropanols.
- There is no obvious benefit to consumers in not providing a clear mechanism for protection of the public from possible exposure to chloropropanols.
- There would be a minor administrative saving to government and industry of not having to comply with MLs and not requiring testing (or certification) of products to determine the levels of chloropropanols in soy and oyster sauce products.
- There would a benefit to industry if they have additional time to develop manufacturing processes (GMP) that reduce the levels of chloropropanols without loss of trade.

Risks

- There is a risk to government that reliance upon food legislation is not as open and transparent a mechanism for establishing a limit in law as would be including a level for chloropropanols.
- The risk to government of not setting MLs for chloropropanols may be a perception that public health is not protected.
- The risk to consumers is the potential exposure to cancer causing contaminants if significant levels of these carcinogens were found to be present in soy and oyster sauces if this option does not provide the necessary protection.
- The risk to industry is the loss of consumer confidence in the safety of implicated soy and oyster sauce products leading to significant economic losses. There could also be a

reduction in the demand for any soy and oyster sauce products due to perceived dangers associated with any of these products.

Option 2 – Amend the Food Standards Code to include a ML of 0.02 mg/kg for 3-MCPD (ie the UK approach for 3-MCPD) and a ML of 0.005 mg/kg for 1,3-DCP.

Benefits

- The benefit to government of setting an ML of 0.02 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP is that a clear, open and transparent mechanism is in place to protect public health and reduce exposure to potential cancer causing agents in the food supply.
- The benefit to consumers is that they will have a supply of soy and oyster sauces that contain low level of chlorpropanols.
- This would have the benefit of setting a clear guideline to industry of the levels of chloropropanols that good manufacturing processes should be achieving and that quality programs should meet.

Risks

- There may be significant costs to industry and consumers to alter manufacturing processes in order to reduce chloropropanol levels in soy and oyster sauces. Additionally, provided 1,3-DCP levels do not exceed the proposed ML of 0.005 mg/kg, then the ML for 3-MCPD can be much higher before dietary exposure exceeds the PMTDI. Thus setting the level of 0.02 mg/kg for MCPD may be unduly onerous on industry and cause unnecessary costs for industry that flow on to consumers.
- There is a risk that industry may have significant ongoing testing costs in proving products comply with the MLs for both 3-MCPD and 1,3-DCP. If setting a very low ML for 3-MCPD essentially controls the presence of 1,3-DCP, then the testing for 1,3-DCP may be an unnecessary burden upon industry.

Option 3 – Amend the Food Standards Code to include a ML of less than 0.02 mg/kg for 3-MCPD and a ML 0.005 mg/kg for 1,3-DCP.

Benefits

- The benefits to government, consumers and industry of setting a ML of less than 0.02 mg/kg for 3-MCPD and a ML of 0.005 mg/kg for 1,3-DCP would be consistent with those of Option 2.
- There would be additional benefits to consumers if the ML for 3-MCPD is set at less than 0.02 mg/kg as this level would reduce even further any exposure to 3-MCPD from soy or oyster sauce.
- Higher levels of public confidence in soy and oyster sauce and the regulator could also be expected.

Risks

- The risks to government, consumers and industry of setting a ML of less than 0.02 mg/kg for 3-MCPD and a ML Of 0.005 mg/kg for 1,3-DCP would be consistent with those of Option 2.

- The cost to industry of achieving a ML for 3-MCPD of less than 0.02 mg/kg may be greater than for an ML of 0.02 mg/kg or higher.
- Trade dispute issues may arise from the adoption of a ML for 3-MCDP lower than 0.02 mg/kg if the Codex Alimentarius Commission develops an international standard of 0.02 mg/kg based on the JECFA findings.

Option 4 – *Amend the Food Standards Code to include a ML of greater than 0.02 mg/kg for 3-MCPD and a ML Of 0.005 mg/kg for 1,3-DCP.*

Benefits

- The benefits to government, consumers and industry of setting a ML of greater than 0.02 mg/kg for 3-MCPD and a ML of 0.005 mg/kg for 1,3-DCP would be consistent with those of Options 2.
- The benefits to industry and consumers of including a ML of greater than 0.02 mg/kg for 3-MCPD are greater than those of Option 2, as this level would be more readily achievable and there would even less impact on trade.

Risks

- The risks to government, consumers and industry of setting a ML of greater than 0.02 mg/kg for 3-MCPD and a ML of 0.005 mg/kg for 1,3-DCP would be consistent with those of Options 2.
- There may be perceived risk to public health if the ML for 3-MCPD is set at a level greater than 0.02 mg/kg.

RECOMMENDATION

The ML selected for 3-MCDP should ensure that the objective of protecting public health and safety are met while resulting in minimal disruption to the food supply or negative impact on industry. It should provide an incentive to industry to reduce the levels of chloropropanols in soy and oyster sauce to levels that as low as is achievable.

Consequently, it is recommended that:

- a ML of 0.2 mg/kg is set for 3-MCPD; and
- a ML of 0.005 mg/kg is set for 1,3-DCP (Option 4).

WORLD TRADE ORGANISATION NOTIFICATION

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

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

Amending the *Code* to set a Maximum Level for Chloropropanols in soy and oyster sauces is likely to have a significant effect on trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at Final Risk Assessment and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

CONCLUSIONS

On the basis of the data available and the ANZFA dietary exposure assessment, a ML of 0.2 mg/kg for 3-MCPD and a ML of 0.005 mg/kg for 1,3-DCP based on 40 per cent dry matter content in soy sauce and hydrolysed vegetable protein is recommended and does not pose any additional public health and safety risk.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

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

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

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

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand*

Food Standards Code) of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

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

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

INVITATION FOR PUBLIC SUBMISSIONS

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

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

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

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

All correspondence and submissions on this matter should be addressed to the **Project Manager – Proposal P243** at one of the following addresses:

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

Submissions should be received by the Authority by: **12 September 2001**.

ATTACHMENTS

1. Draft variation to the Australian Food Standards Code
2. Statement of Reasons
3. Survey reports prepared by the UK Food Standards Agency on 3-MCPD and 1,3-DCP in soy sauce and related products
4. UK Committee on Mutagenicity report on 3-MCPD and 1,3-DCP
5. UK Committee on Carcinogenicity report on 3-MCPD and 1,3-DCP
6. JECFA reports on 3-MCPD and 1,3-DCP
7. SCF opinion report on 3-MCPD

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4. JFSSG (1999). Survey of 3-monochloropropane-1,2-diol (3-MCPD) in soy sauce and similar products. Food surveillance Information Sheet No. 187.
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7. Committee on Carcinogenicity Food, Consumer products and the Environment (2000). Statement on carcinogenicity of 3-monochloropropane-1,2-diol (3-MCPD). Statement available at http://www/doh.gov.uk/mcpd1.htm.
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13. Food Advisory Committee 2000. Press Release 8/00 108th meeting of the Food Advisory Committee: 26 October 2000. Statement available at **http://www.foodstandards.gov.uk/committees/fac/summary.htm**.
14. 3-Chloro-1,2-propanediol. JECFA Report 2001.
15. 1,3-Dichloro-2-propanol. JECFA Report 2001.
16. Opinion of the Scientific Committee on Food on 3-MCPD (adopted on 30 May 2001). European Commission.
17. Crews, C., Le Brun, G., Hough, P., Harvey, D., and Brereton, P. (2000). Chlorinated propanols and laevulinic acid in soy sauces. Czech J. Food Sci., 18, 276-277.
18. Health Canada (2000). Survey of soy sauces and similar products, summary results reported to FAO by the US Food and Drug Administration (memorandum dated 20 April 2000).
19. FDA (2000). Submission to FAO dated 14 December 2000.
20. FSA (2001a). Survey of 3-MCPD in food ingredients. Food Safety Information Sheet 11/01, February 2001.
21. FSA (2001a). Survey of 3-MCPD in food ingredients. Food Safety Information Sheet 12/01, February 2001.

ATTACHMENT 1

DRAFT VARIATION TO THE FOOD STANDARDS CODE

P243 - MAXIMUM LEVELS FOR CHLOROPROPANOLS IN SOY AND OYSTER SAUCES

To commence: On gazettal

[1] ***Standard A12*** *of Volume 1 of the Food Standards Code is varied by inserting the following immediately after clause (6) -*

(6A) The proportion of 3-chloro-1,2-propanediol in soy sauce and oyster sauce must not be greater than (0.2 mg/kg).

(6B) The proportion of 1,3-dichloro-2-propanol in soy sauce and oyster sauce must not be greater than 0.005 mg/kg.

[2] ***Standard 1.4.1*** *of Volume 2 of the Food Standards Code is varied by inserting the following into Columns 1 and 2 respectively of the Table to clause 3 –*

3-chloro-1,2-propanediol	
Soy sauce and oyster sauce	0.2
1,3-dichloro-2-propanol	
Soy sauce and oyster sauce	0.005

ATTACHMENT 2

STATEMENT OF REASONS – DRAFT

PROPOSAL P243

FOR RECOMMENDING A VARIATION TO STANDARD A12 – METALS AND CONTAMINANTS IN FOOD (VOLUME 1) AND 1.4.1 CONTAMINANTS AND NATURAL TOXICANTS (VOLUME 2)

The Australia New Zealand Food Authority has before it Proposal P243 to amend the *Food Standards Code* to establish maximum limits (ML) of 0.2 mg/kg for 3-MCPD and 0.005 mg/kg for 1,3-DCP in soy and oyster sauces.

ANZFA has completed a full assessment of the application, prepared draft variations to the Australian *Food Standards Code* and conducted an inquiry into the draft variation. ANZFA has decided, pursuant to section 37 of the *Australia New Zealand Food Authority Act 1991,* to progress this application as a matter of urgency.

The Australia New Zealand Food Authority recommends the adoption of the draft variation to Standard A14 for the following reasons:

- The proposed MLs for the chloropropanols are considered to reduce the risk of exposure to these potential cancer-causing agents present in soy and oyster sauces.

- The proposed ML for 3-MCPD is based on available toxicological evidence and is consistent with good manufacturing practice.

- The proposed ML for 1,3-DCP (0.005 mg/kg soy sauce on 40% dry weight basis) is based on reducing the level to as low a level as is technologically feasible, given that it is a genotoxic carcinogen. This level is the current limit of quantification and is considered to be as close as is possible to zero presence.

The commencement date of the draft variation is to be from the date of gazettal.

ATTACHMENT 3

UK FOOD STANDARDS AGENCY SURVEY REPORTS

14/01 June 2001

SURVEY OF 3-MONOCHLOROPROPANE-1,2-DIOL (3-MCPD) IN SOY SAUCE AND RELATED PRODUCTS

Key Facts

- 3-monochloropropane-1,2-diol (3-MCPD) is a chemical contaminant which is known to occur at low levels in many foods and food ingredients.
- 3-MCPD is known to cause cancer in animals, but recent studies have shown that it does not directly damage genetic material. Expert committees are currently evaluating data on 3-MCPD to establish a safe level of consumption.
- This survey repeats an earlier survey of 3-MCPD in soy sauce and similar products published in 1999. It was undertaken to measure the progress by industry in reducing levels of 3-MCPD.
- In March 2001, the European Commission adopted a regulatory limit of 0.02mg/kg based on 40 per cent dry matter content for 3-MCPD in soy sauce and hydrolysed vegetable protein (HVP), to come into force in April 2002.
- 22 per cent of the 100 samples of soy sauce and related products analysed in this survey contained levels of 3-MCPD above the European Union (EU) limit.
- Consumers are advised to avoid products identified in this survey as containing 3-MCPD levels above the agreed EU limit.
- The Agency is working with Local Authorities to ensure that products identified in this survey as containing unacceptable levels of 3-MCPD are not available in the UK.
- The Agency will conduct a further survey of 3-MCPD levels in soy sauces shortly. This will target those products found to have unacceptable levels of 3-MCPD to assess the progress made by manufacturers in reducing levels.

Summary

A survey of 3-MCPD in a range of soy sauces and related products available in the UK has been completed. A similar survey was reported in 1999.[1] 100 samples of soy sauce and related products were purchased by Ventress Technical Ltd. from retail outlets in the UK. The analysis of the samples was conducted by the Central Science Laboratory (CSL) using a validated method of analysis with a limit of quantification of 0.01 mg/kg for 3-MCPD. This survey assessed the levels of 3-MCPD in soy sauces currently available in the UK against the EU limit of 0.02 mg/kg, based on 40 per cent dry matter content which will come into force in April 2002.[2]

In this survey, 22 per cent of samples analysed contained levels of 3-MCPD equal to or above the EU limit compared with 32 per cent of the samples analysed in the 1999 survey. The highest level of 3-MCPD was 93.1 mg/kg.

Background

3-MCPD is one of a group of chemical contaminants known as chloropropanols. 3-MCPD was originally identified as a contaminant of the savoury ingredient acid-HVP,[3] which is produced by treating proteins from vegetables, such as soya, with hydrochloric acid. In acid-HVP, components of fats and oils in the starting materials are chlorinated at high temperature to form chloropropanols.

In 1994, following a review of the available data, the EC Scientific Committee for Food (SCF) concluded that "3-MCPD should be regarded as a genotoxic carcinogen".[4] 3-MCPD has since been found to occur at low levels in many foods and food ingredients,[5-8] though the origin and formation of 3-MCPD in these is not yet fully understood. In line with the SCF's opinion, the FAC recommended in 1996 that 3-MCPD should not be found in any food or ingredients using a validated method of analysis capable of measuring down to 0.01 mg/kg.[9]

An earlier survey of 3-MCPD in soy sauce and similar products[1] found significant levels of 3-MPCD in some products and the companies concerned were contacted. They were urged to take action to reduce the levels of 3-MCPD in line with the FAC's advice.

In October 2000, the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM), considered two new toxicological studies and has advised that 3-MCPD need no longer be considered as mutagenic *in vivo*; nevertheless, it is still carcinogenic in animals.[10] The FAC considered the COM's new opinion at its meeting in October 2000 and advised industry "that they should continue to take all steps necessary to reduce concentrations of 3-MCPD in foods and food ingredients to the lowest technologically achievable."[11]

The toxicological data and the statements and conclusions of the COM,[10] and the UK Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC)[12] will be reviewed by the SCF and by the Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives (JECFA) in 2001. It is anticipated that this will ultimately lead to an estimate of the amount of 3-MCPD which can be consumed daily over a lifetime without appreciable harm to health (Tolerable Daily Intake, TDI) being set.

This survey was commissioned to monitor changes in levels of 3-MCPD in soy sauce and related products since the previous survey. During the course of the survey, the European Commission adopted a regulatory limit of 0.02 mg/kg for 3-MCPD in soy sauce and HVP[12] based on a 40 per cent dry matter content. The levels of 3-MCPD in these sauces have been assessed against this new EU level, with the limit of quantification in this survey being set at 0.01 mg/kg,

This regulation was adopted in March 2001 and is due to come into force in April 2002, although the level in the regulation may be revised before coming into force, following the new advice from the SCF.

In line with the guidelines for planning, conducting and reporting surveys,[13] manufacturers and distributors of products found to contain levels of 3-MCPD, at or above 0.02 mg/kg were sent details of their individual results. They were invited to submit comments of up to 200 words. These are reported in Annex 1.

3-MCPD has been shown to be a precursor of 1,3-dichloropropanol (1,3-DCP) formation and 1,3-DCP has been shown to occur in soy sauces.[14] In light of this information and the continuing toxicological evaluation of this substance, the concentrations of 1,3-DCP were measured in the samples collected for this survey. Further to their consideration of 3-MCPD, the COM and COC have recently considered 1,3-DCP.[15,16] The results of the analyses will be assessed and interpreted against the COM and COC advice and published concurrently in Food Survey Information Sheet 15/01.

Sampling

100 samples of soy sauces and related products were purchased from retail outlets in four areas of the UK; London, Leeds, Manchester and Cambridge during August 2000. Of these samples 67 were soy sauces and the remainder were various other related sauces e.g. mushroom soy, oyster and teriyaki. The details of each sample were recorded on receipt and descriptions are reported in Table 1. The absence of a particular brand from this table means only that the product was not included in the survey. 34 of the products sampled had been analysed in the 1999 survey so that a comparison could be made. Products found in the 1999 survey to have levels of 3-MCPD above 0.01 mg/kg are listed in Table 2. The sample plan aimed to include as many of the products tested in the previous survey as possible. The remaining samples were selected at random to reflect the wide range of products available and included own brands as well as proprietary brands.

Methodology

Analyses were carried out using a validated and accredited gas chromatographic method (GC-MS) for the determination of 3-MCPD[17] with a limit of quantification of 0.01 mg/kg. The method uses deuterated 3-MCPD (d_5-3-MCPD) as an internal standard. This is added to a known amount of sample followed by saline solution and the mixture is blended to achieve homogeneity. After sonication, the contents of a diatomaceous earth refill pack are added and mixed thoroughly. This mixture is transferred to a glass chromatography column and the non-polar components are eluted using a mixture of hexane and diethyl ether. The 3-MCPD is eluted using diethyl ether and the sample extract is concentrated under rotary evaporation to a small volume. A portion of this extract is subsequently derivatised using N-heptafluoro-butyrylimidazole (HFBI). The derivatised sample is analysed by gas chromatography-mass spectrometry (GC-MS).

Quantification was based on a calibration series of 3-MCPD standard solutions, equivalent to a range of concentrations 0.006 to 1.88 mg/kg 3-MCPD, measured with each batch. Samples that were found to contain 3-MCPD at levels higher than 1.88 mg/kg were diluted and re-analysed. The samples were analysed in batches. Each batch included a reagent blank and at least one spiked sample fortified at a level of 0.010 mg/kg. All results were corrected for recovery.

Analytical results have a variability known as the measurement uncertainty (details are given in Annex 2). For any analytical method each result reported is the best estimate for that sample, it is always qualified by the measurement uncertainty, e.g. x mg/kg $\pm$ y mg/kg. The measurement uncertainty was assessed to be $\pm$ 0.004 mg/kg at a level of 0.01 mg/kg 3-MCPD. The analytical data showed that the analyses met the quality assurance criteria set (details are given in Annex 3).

Results

The results of the survey are summarised in Table 3 and Figure 1. A full list of results, including details of the brand names for each product is given in Table 1. 22 of the 100 (22 per cent) samples contained levels of 3-MCPD above the EU limit, these are listed in Table 4. Of the 67 samples of soy sauce, 12 (18 per cent) contained levels of 3-MCPD above the EU limit, and of the 33 samples of other similar products (such as oyster and teriyaki sauce), 7 (21 per cent) contained levels above the EU limit. The highest level of 3-MCPD was 93.1 mg/kg, in a soya bean sauce.

Interpretation

This survey was commissioned to monitor changes in levels of 3-MCPD since the previous survey. During the course of the survey, the European Commission proposed a regulatory limit of 0.02 mg/kg for 3-MCPD in soy sauce and HVP, based on 40 per cent dry matter content, which was agreed by Member States in December 2000. This regulation was adopted in March 2001 and is due to be implemented in April 2002.[12] The levels of 3-MCPD in the sauces in this survey have been assessed against this limit.

In the 1999 survey,[1] 40 samples were analysed and the reporting limit was 0.01 mg/kg based on advice from the FAC.[8] In the 1999 survey, 35 per cent of samples contained levels of 3-MCPD greater than the EU limit while in the current survey 22 per cent of samples contained 3-MCPD levels above the EU limit. Figure 2 and Table 5 show the percentage of total samples analysed in 1999 and 2000 that fall into ranges of levels of 3-MCPD. The current survey included 34 samples of products also analysed in the 1999 survey. Of these, 27 products contained levels less than the EU limit for 3-MCPD in both surveys.

A significant number of products sampled in this survey (22 per cent) still contained 3-MCPD concentrations above the EU limit. 3-MCPD was found in the range of sauces analysed and no correlation was observed between 3-MCPD levels and country of origin.

Possible sources of 3-MCPD in soy sauces are:

- The addition of acid-HVP,
- Acid hydrolysis of some or all of the soya bean/wheat and
- The toasting of the wheat component.

However, it is not possible to explore any link between method of manufacture and level of chloropropanols without further verifiable information from the producers.

Conclusion

22 per cent of samples analysed in this survey contained levels of 3-MCPD above the EU limit. The results show a decrease in frequency of contamination compared with the 1999 survey. However the current survey includes several brands of soy sauce not analysed in 1999 and some of these brands contained very high levels of 3-MCPD. The results show that sauces with unacceptable levels of 3-MCPD are still available in the UK. Indeed, the highest level found in this survey was higher than that found in the previous survey.

Those retailers responsible for selling soy sauces identified as containing high levels of 3-MCPD were asked to remove any remaining stock from the shelves. Details of all products found to have 3-MCPD levels greater than or equal to 0.05 mg/kg have been forwarded to the European Commission's Rapid Alert System. (The level of 0.05 mg/kg allows for the variation in the solid content of the products analysed). This information will then be forwarded to all Member States who may use this to arrange product recalls. The Agency is working with the Local Authorities Co-ordinating Body on Food & Trading Standards (LACOTS) to take this forward in the UK. Enforcement Officers will visit retailers whose products were shown to have high levels and inform them that a legal limit for 3-MCPD will be in force from April 2002. Retailers will also be advised to stock only those products where there is clear evidence that they have been tested for 3-MCPD and that they are within acceptable safety limits. This course of action supplements our dialogue with UK distributors of these products. Consumers are advised to avoid products identified in this survey as containing 3-MCPD levels above the agreed EU limit.

The Agency will conduct a further survey of 3-MCPD levels in soy sauces shortly to assess the progress made by industry in reducing levels of 3-MCPD in soy sauce and related products in both retail and catering establishments. Those products found to have unacceptable levels of 3-MCPD in this survey will be targeted in the follow up survey.

Summary of Units

Milligram (mg): one thousandth of a gram
Kilogram (kg): one thousand grams
Milligrams per kilogram (mg/kg)

References

1 Survey of 3-Monochloropropane-1,2-diol (3-MCPD) in soy sauce and similar products. *Food Surveillance Information Sheet no. 187*,1999.

2 Commission Regulation (EC) No 466/2001. Setting maximum levels for certain contaminants in foodstuffs. *Official Journal of the European Community*. 8th March 2001.

3 Velisek, J. D., Davidek, J., Kubelka, V., Janicek, G., Svobodova, Z and Simicova, Z. New Chlorine Containing Organic Compounds in Protein Hydrolysates. *Journal of Agricultural and Food Chemistry*, 1980, **28**, 1142-44.

4 European Commission Opinion on 3-Monochloropropanediol (3-MCPD), expressed on 16 December 1994. Reports of the Scientific Committee for Food. Food Science and Techniques, Thirty-sixth Series, 1995, 31-33.

5 Collier, P. D. Cromie, D. D. O. and Davies, A. P. (1991). Mechanism of formation of chloropropanols present in protein hydrolysates. *Journal of the American Oil Chemists Society*. **68**, 785-790.

6 Survey of 3-Monochloropropane-1,2-diol (3-MCPD) in Selected Foods. *Food Surveillance Information Sheet no.12/01*, 2001.

7 Survey of 3-Monochloropropane-1,2-diol (3-MCPD) in Food Ingredients. *Food Surveillance Information Sheet no.11/01*, 2001.

8 Survey of 3-Monochloropropane-1,2-diol (3-MCPD) in acid-hydrolysed vegetable protein. *Food Surveillance Information Sheet no. 181*, 1999.
9 Food Advisory Committee. (1996). Update on chloropropanols present in protein hydrolysates, *Press Release 13/96*.
10 http://www.doh.gov.uk/mcpd2.htm
11 http://www.foodstandards.gov.uk/committee/fac/Summary.htm
12 http://www.doh.gov.uk/mcpd1.htm
13 http://www.foodstandards.gov.uk/maff/archive/food/foodsaft.htm
14 Crews C., Le Brun G., Hough P., Harvey D. and Brereton P. Chlorinated propanols and levulinic acid in soy sauces. *Czech Journal of Food Sciences*, Vol.**18**, (2000), 276-277.
15 http://www.doh.gov.uk/comdcp.htm
16 http://www.doh.gov.uk/cocdcp.htm
17 Brereton, P *et al*. (2001). Determination of 3-Chloro-1,2-Propanediol in foods and food ingredients by gas chromatography with mass spectrometric detection: collaborative study. *Journal of AOAC International*. **84** (2), 455-465.

Further information

Further information on this survey can be obtained from:
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The full report of this survey is held in the Elsie Widdowson Library at Aviation House, 125 Kingsway, London WC2B 6NH Tel: +44 (0) 20 7276 8181. If you would like to consult a copy, please contact the Library giving at least 24 hours notice or, alternatively, copies can be obtained from the Library; a charge will be made to cover photocopying and postage.

Further copies of this Information Sheet can be obtained from:
Library and Information Service
Food Standards Agency
Room 115B, Aviation House
125 Kingsway
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Tel: +44 (0) 207 276 8187
Email: library&info@foodstandards.gsi.gov.uk

Copies of the statements from the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment and the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment the can be obtained from:
Khandu Mistry
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Fax: +44 (0) 20 7972 5156
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Further information on the work of the Food Advisory Committee (FAC) can be obtained from:
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Annex 1

COMMENTS

From Lee Kum Kee
"Following the Agency's UK survey in September 1999 about various brands of Chinese sauces and subsequent to its own reviews, Lee Kum Kee (LKK) has succeeded in eliminating any traceable level of 3-MCPD in its products produced from October 1999. LKK implemented new production techniques, product formulations and raw material sourcing to ensure that all products manufactured thereafter, while meeting or exceeding consumer expectations for quality, are also subject to rigorous testing procedures to meet or exceed stringent regulatory standards.

Working closely with internationally accredited laboratories, LKK has become the only Hong Kong food company with its own laboratory that has received Hong Kong Laboratory Accreditation Service's international accreditation for testing against 3-MCPD in raw materials and finished products.

Consensus within the scientific community about 3-MCPD effects has not been reached, and there appears to be no definitive reason to take any additional actions currently. Nevertheless, LKK is concerned enough about this issue (including the varying levels of 3-MCPD in many other food and beverage products) that it remains committed and open to constant review.

LKK takes its responsibility seriously and will continue to do whatever necessary to protect consumer trust and the long heritage of its global brand."

From Manning Impex Ltd.
"We work with our supplier and their manufacturers to meet EU regulations with regard to food safety and 3-MCPD. Our manufacturer gives surety of their Good Manufacturing Practices (GMP) certification. Furthermore, the EU mission is currently visiting our supplier's manufacturing plant to validate their Hazard Analysis and Critical Control Point (HACCP) plan and certify compliance with GMP and Sanitation Standards Operating Procedures (SSOP). We have every confidence in the systems they have in place to maintain the highest standards.

After we informed our suppliers of the EU standards for 3-mcpd, in Sept 1999, they took immediate action to obtain the Certificates of Analysis (COA) from their manufacturers to ensure that all their raw materials are below recommended levels. The results of independent analysis utilising the UK CSL methodology, confirms that the raw ingredients contain 3-MCPD at levels below 10ppb (<0.01mg/kg). In essence, the level of 3-mcpd in our product is undetectable. Moreover, our supplier will be conducting further independent testing to validate the COAs.

Our supplier and ourselves are aware and fully responsive to the health considerations of 3-MCPD. This undertaking therefore commits us to always taking the necessary precautions to maintain higher standards than those set by the EU."

From S. O. P. Edibles Ltd.
“I would like to inform you that we are working closely with our supplier in China regarding this matter, and they have been given a copy of your methodology to ensure that the tests they carry out are in line with the Food Standards Agency.”

From Chadha Oriental Foods Ltd.
“We would like to confirm that since the initial survey was undertaken by MAFF in August 1999, we have reviewed our supplier base and discontinued imports of products where levels of 3-MCPD were in excess of recommendations. Additionally, stock that was held by us was returned to suppliers.

The product that you referred to in your letter ‘Golden Mountain’ Seasoning sauce is now a discontinued product line. As such, any samples that were found on sale within the trade precedes this review.”

From S W Trading Ltd
Pearl River Bridge - Soy Sauces
We became aware of 3-MCPD in September 1999 whilst we were negotiating the 'sole agency' agreement with PRB, which we obtained in October 1999.

From that time we have instigated procedures to ensure that our customers receive only genuine PRB products which all contain:

clearly marked labelling stating:

Imported by S. W. Trading, London
Best Before end _____ , Batch Nos.

and analyse weekly by Batch Numbers to ensure that 3-MCPD is either not detected or certainly less than <10ug/kg which is now always the case.

This has been achieved by regular contact with MAFF at the outset, the Foods Standard Agency and daily contact with our manufacturers.

However, it has become apparent that random sampling by our Authorities has not produced the same results as our own analysis. There could be various reasons for this problem, but our investigations have uncovered two main reasons.

Firstly is that, unfortunately, there are counterfeit products on the market which are certainly not imported by us as our domestic sauce is 600ml and secondly we observe from the reports that the samples analysed were either not imported by us or imported before the 3-MCPD 1999 food alert was received.

Annex 2

MEASUREMENT UNCERTAINTY

Introduction

All analytical results have a variability known as the measurement uncertainty. The Eurachem/CITAC interpretation of the definition of measurement uncertainty is "the range of values that the analyst believes could be reasonably attributed to the measurand."[1] Thus, the values for 'measurement uncertainty' given in this report represent the range around the best estimate of the concentration of 3-MCPD within which the true value for the concentration of 3-MCPD is believed to lie.

Method

For this survey the measurement uncertainty was calculated from analyses of an in-house reference material containing 0.023 mg/kg and randomly selected survey samples fortified with 0.010 mg/kg 3-MCPD. The measurement uncertainty was calculated using a standard coverage factor of 2, equivalent to a confidence of approximately 95 percent. It was made up of a precision element (standard uncertainty 0.0018 mg/kg) and a bias element (relative standard uncertainty 7.3 percent). The assessment was targeted at samples containing 3-MCPD at levels close to the reporting limit and is therefore less applicable to samples containing 3-MCPD considerably in excess of 0.020 mg/kg.

Results

- Measurement uncertainty for 3-MCPD was assessed to be ±0.004 mg/kg at a level of 0.010 mg/kg 3-MCPD.

References

1. *Eurachem/CITAC Guide on Quantifying Uncertainty in Analytical Measurement*, second edition, 2000.

Annex 3

ANALYTICAL QUALITY ASSURANCE

3-MCPD

The following quality assurance criteria were set:

- The calibration line is linear and should have a correlation coefficient (r^2) of at least 0.99.
- The sample peak area ratios fall within the calibration range.
- The modification for dilution has been calculated correctly.
- The 3-MCPD peak retention times are within ± 0.3 minutes of those in the standards.
- A minimum library fit of 800 is achieved for each spectrum.

- Each analytical batch should contain the following:
- A reagent blank.
- A spike recovery sample or a quality control sample of known 3-MCPD concentration.

- The reagent blank should contain < 0.005 mg/kg 3-MCPD. Spike recoveries should fall within 50 - 130 percent and the quality control sample should be within 2 standard deviations of the true value.
- If sample concentration exceeds the linear range either less sample mass should be taken (e.g. for soy sauce take 1g instead of 8g) or the sample should be diluted and the sample mass remains the same.

Results

- The correlation coefficients of all calibration standard solutions were higher than 0.99.
- Standard solutions run at the end of each batch all had a peak area within ±15 percent of that standard run at the beginning of the batch.
- No reagent blank samples showed a response equivalent to more than 0.005 mg/kg 3-MCPD.
- All results for the soy sauce reference material all fell within 2 standard deviations of the characterised value.
- The internal standard peak area for all the calibration standards exceeded 50,000 units.
- The peak area ratios of all samples fell within the range of the calibration standards, in some cases after dilution and re-extraction of the sample.
- The mass spectra of the sample 3-MCPD peaks all exceeded a library fit of 800 against an authentic standard.
- The retention times of the sample 3-MCPD peaks were all within ±0.2 minutes of those of a standard.

15/01 June 2001

SURVEY OF 1,3-DICHLOROPROPANOL (1,3-DCP) IN SOY SAUCE AND RELATED PRODUCTS

Key Facts

- 1,3-Dichloropropanol (1,3-DCP) belongs to a group of chemical contaminants known as chloropropanols.
- 1,3-DCP is known to cause cancer in animals by directly damaging genetic material. Experts committees have recently reconsidered their opinion and confirmed that it is prudent to assume that this may also occur in humans.
- There are currently no limits for 1,3-DCP, but expert advice is that they should be present in foods at the lowest technologically feasible level, which for soy sauce equates to not present.
- 17 per cent of the 100 samples of soy sauce and related products analysed in this survey contained quantifiable levels of 1,3-DCP.
- Consumers are advised to avoid products identified in this survey as containing 1,3-DCP.
- The Agency is working with Local Authorities to ensure that products identified in this survey as containing 1,3-DCP are no longer on sale in the UK.
- The Agency will shortly commission further surveys of chloropropanols in soy sauces, in both retail and catering outlets, and a survey of 1,3-DCP in foods as soon as possible.

Summary

A survey of 1,3-DCP in a range of soy sauces and related products available in the UK has recently been completed. 100 samples of soy sauce and related products were purchased by Ventress Technical Ltd. from retail outlets in the UK. The analysis of the samples was conducted by the Central Science Laboratory (CSL) using an in-house validated method of analysis with a limit of quantification of 0.005 mg/kg for 1,3-DCP. 1,3-DCP was quantified in 17 per cent of samples. All samples with quantifiable levels of 1,3-DCP were found to contain levels of 3-monochloropropane-1,2diol (3-MCPD) above the proposed EU limit 0.02 mg/kg for 3-MCPD in soy sauce and HVP based on a 40% dry matter content.

Background

1,3-DCP is one of a group of chemical contaminants known as chloropropanols. 1,3-DCP, together with 3-MCPD, was originally identified as a contaminant of the savoury ingredient acid-hydrolysed vegetable protein (acid-HVP),[1] which is produced by treating proteins from hydrolysed vegetables, such as soya, with hydrochloric acid. In acid-HVP, components of fats and oils in the starting materials are chlorinated at high temperature to form chloropropanols.

In 1988 the EC Scientific Committee on Foods (SCF) considered chloropropanols and 1,3-DCP in particular; after considering available data, it agreed that 1,3-DCP is a genotoxic carcinogen, that is it causes cancer by directly damaging genetic material. The Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC) first considered 1,3-DCP in 1991.

They concluded that it would be prudent to regard it as a genotoxic carcinogen *in-vivo*. Following this assessment, the FAO/WHO Joint Expert Committee on Food Additives (JECFA) concluded in 1993 that, because of its carcinogenicity, 1,3-DCP is an undesirable contaminant in food and that levels should be reduced to as low as technologically achievable.[2] The Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) and COC both recently considered 1,3-DCP and concluded:

- COM statement[3]: "The committee concluded that it would be prudent to regard 1,3-DCP and 2,3-DCP as potentially genotoxic *in-vivo* and agreed that both compounds should be tested for genotoxicity *in-vivo* using the approach set out in the COM guidelines."

- COC statement[4]: "It is prudent to assume that 1,3 DCP is a genotoxic carcinogen and that exposure to 1,3 DCP should be reduced to as low a level as technologically feasible."

1,3-DCP is formed from its precursor 3-MCPD and has been shown to occur in soy sauces.[5] However, no clear relationship exits between the relative concentration of 1,3-DCP and 3-MCPD in a product except that the concentration of 3-MCPD is significantly higher than 1,3-DCP. In light of this information and the anticipated advice from the COM and COC, the samples collected for the further survey of 3-MCPD in soy sauces and related products, commissioned in 2000, were also analysed for 1,3-DCP. These data are being reported concurrently in Food Survey Information Sheet 14/01.

In line with the guidelines for planning, conducting and reporting surveys,[6] manufacturers whose products were found to contain quantifiable levels of 1,3-DCP (i.e. above 0.005mg/kg) were sent details of their individual results. They were invited to submit comments of up to 200 words. These are reported in Annex 1.

Sampling

100 samples of soy sauces and related products were purchased from retail outlets in four areas of the UK; London, Leeds, Manchester and Cambridge during August 2000. Of these samples 67 were soy sauces, the remaining samples were various other related sauces i.e. mushroom soy, oyster and teriyaki. The details of each sample were recorded on receipt and descriptions are reported in Table 1. The absence of a particular brand from this table means only that the product was not included in the survey. 34 of the products sampled had been analysed in the 1999 survey for 3-MCPD. The remaining samples were selected at random to reflect the wide range of products and included own brands as well as proprietary brands.

Methodology

1,3-DCP was measured by an automated headspace procedure with gas chromatographic separation and mass spectrometric detection. The method, which incorporated a deuterium labelled internal standard, had previously been validated in-house and shown to have a limit of quantification of 0.005 mg/kg. Quantification was based on a calibration series of 1,3-DCP standard solutions, equivalent to a range of concentrations 0.003 to 1.3 mg/kg 1,3-DCP, measured with each batch. Recovery is incorporated in the method.

Analytical results have a variability known as the measurement uncertainty (details are given in Annex 2). For any analytical method each result reported is the best estimate for that sample, it is always qualified by the measurement uncertainty, e.g. x mg/kg $\pm$ y mg/kg. The analytical data showed that the analyses met the quality assurance criteria set (details are given in Annex 3).

Results

A full list of results, including details of the brand names for each product is given in Table 1. 17 out of 100 samples (17 per cent) contained quantifiable levels of 1,3-DCP, all of which contained levels of 3-MCPD greater than 0.02 mg/kg and also greater than the level of 1,3-DCP observed. The highest level of 1,3-DCP was 0.345 mg/kg, in a soy sauce.

Interpretation

Quantifiable levels of 1,3-DCP were only found in samples that had levels of 3-MCPD above 0.02 mg/kg. This was not unexpected, as 3-MCPD has been shown to be a precursor of 1,3-DCP.[7] The results of this survey also indicate that when 3-MCPD and 1,3-DCP are found, the amount of 3-MCPD is always significantly higher. However, no direct correlation was observed between the levels of 3-MCPD and 1,3-DCP.

Expert committees have advised that it is prudent to consider that 1,3-DCP is a genotoxic carcinogen, and it should therefore be reduced to the lowest technologically feasible level in foods. It is possible to eliminate the chloropropanols from soy sauces and related products, as shown by the results of this survey and from published literature on the origin of chloropropanols in soy sauce. Hence, 1,3-DCP need not and should not be present in soy sauce and related products.

Possible sources of chloropropanols in soy sauces are:

- The addition of acid-HVP,
- Acid hydrolysis of some or all of the soya bean/wheat and
- The toasting of the wheat component.

However, it is not possible to explore any link between method of manufacture and level of chloropropanols, without further verifiable information from the producers.

Conclusion

This is the first survey of 1,3-DCP in soy sauce that has been reported by the Agency. Quantifiable levels of 1,3-DCP were found in 17 per cent of samples analysed and all those samples also contained levels of 3-MCPD greater than the proposed EU limit. The results show that sauces with unacceptable levels of 1,3-DCP are available in the UK. It is possible to eliminate 1,3-DCP from soy sauces and related products therefore any quantifiable amount is unacceptable. Those retailers responsible for selling soy sauces identified as containing quantifiable levels of 1,3-DCP and 3-MCPD above the proposed EU limit, were asked to remove any remaining stock from the shelves.

The Agency is working with the Local Authorities Co-ordinating Body on Food & Trading Standards (LACOTS) to take this forward as set out in Information Sheet 14/01 with enforcement officers visiting retailers whose products were shown to have high levels.

This course of action supplements our dialogue with UK distributors of these products. Consumers are advised to avoid products identified in this survey as containing 1,3-DCP.

The Agency will conduct further surveys of soy sauces shortly to assess the progress made by industry in reducing levels of chloropropanols in soy sauce and related products in both retail and catering establishments. Those products found to have unacceptable levels of 1,3-DCP in this survey will be targeted in the follow up survey. The Agency also intends to commission a survey of 1,3-DCP in selected foods as soon as possible.

Summary of Units

Milligram (mg): one thousandth of a gram
Kilogram (kg): one thousand grams
Milligrams per kilogram (mg/kg)

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23 http://www.foodstandards.gov.uk/maff/archive/food/foodsaft.htm

24 Velisek J., Davidek J.,Hajslova J., Kubelka V., Janicek G., Mankova B. *Z.Lebensmit.-Untersuch. Forsch*., 167, 241-244, 1978.

Further information

Further information on this survey can be obtained from:

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The full report of this survey is held in the Elsie Widdowson Library at Aviation House, 125 Kingsway, London WC2B 6NH Tel: +44 (0) 20 7276 8181. If you would like to consult a copy, please contact the Library giving at least 24 hours notice or, alternatively, copies can be obtained from the Library; a charge will be made to cover photocopying and postage.

Further copies of this Information Sheet can be obtained from:
Library and Information Service
Food Standards Agency
Room 115B, Aviation House
125 Kingsway
London

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Tel: +44 (0) 207 276 8186
Email: library&info@foodstandards.gsi.gov.uk

Copies of the statements from the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment and the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment the can be obtained from:
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Annex 1

COMMENTS

From Lee Kum Kee

As a manufacturer of high quality products, Lee Kum Kee is in full compliance with regulatory standards worldwide.

Lee Kum Kee takes its responsibilities to its consumers around the world very seriously. In fact, the company introduced new operating procedures following the FSA report in 1999 to ensure the highest quality of products - meeting or exceeding local regulatory standards. These procedures included changes in sourcing raw materials, changes in product formulations, and stringent testing at all stages of ingredient selection and production.

Consumers can be assured that Lee Kum Kee has eliminated any traceable levels of the reported substances, including 3-MCPD, 1,3-dichloropropan-2-ol (1,3-DCP) and 2,3-DCP in those products produced by the company after October 1999. Samples identified in the FSA reports were all products manufactured by Lee Kum Kee prior to those operating procedures introduced by the company in 1999.

Lee Kum Kee is, in fact, the only Hong Kong food company with its own laboratory that has received Hong Kong Laboratory Accreditation Service's international accreditation for testing against 3-MCPD in raw materials and finished products. In addition, Lee Kum Kee continues to work closely with internationally accredited laboratories as part of its quality assurance measures.

From JK Foods (UK)
Sample No. 60036
Tung Chun Thick Soy Sauce 250ml
We have withdrawn current stock from sale and initiated a recall for stock that has been sold within the last six months. We will put this product on hold until our supplier in Hong Kong can revise the formula to eliminate 1,3-DCP.

Sample No. 60062
Golden Mountain Soya Bean Sauce 200ml
This product is a discontinued line, the last imported consignment was received on 12th July 2000 and sold by 7th September 2000.

Sample No. 60076
Pearl River Bridge Superior Soy 150ml
We are no longer import this product. The sole importer is: SW Trading.

Annex 2

MEASUREMENT UNCERTAINTY

1,3-DCP

The measurement uncertainty was calculated from between-batch precision and mean recoveries for soy sauces containing about 0.005, 0.1 and 1 mg/kg 1,3-DCP and a sauce without detectable 1,3-DCP which had been fortified with 1,3-DCP at these levels. These were considered to be representative of levels in the survey samples. The measurement uncertainty samples were analysed in eight separate batches over a period of three weeks. The samples were analysed in batches. Each batch included a reagent blank, and reference soy sauces containing approximately 0.005 and 0.1 mg/kg 1,3-DCP.

Measurement uncertainty for 1,3-DCP was assessed to be ±0.002 mg/kg at a level of 0.005 mg/kg 1,3-DCP, ±0.085 mg/kg at a level of 0.1 mg/kg 1,3-DCP and ±0.27 at a level of 1 mg/kg 1,3-DCP.

Annex 3

ANALYTICAL QUALITY ASSURANCE

1,3-DCP

Formal quality criteria were not set for 1,3-DCP as the method has not yet been fully validated and reference materials have not been fully characterised. However batches in which the reagent blank contained detectable 1,3-DCP were to be repeated, and samples containing in excess of the calibration range were to be diluted.

Results

- In each batch the reagent blank contained less than the equivalent of 0.003 mg/kg 1,3-DCP.
- No samples contained 1,3-DCP in excess of the calibration range.
- The linearity of the calibration graphs for each batch exceeded 0.99.
- The standard deviation of the results for the reference sauce containing 0.005 mg/kg was 0.0007 and for the reference sauce containing 0.1 mg/kg was 0.0138.

ATTACHMENT 4

UK COMMITTEE ON MUTAGENICITY REPORT

Summary of the UK Committee on Mutagenicity (COM) Report on 3-MCPD and 1,3-DCP (2000)

In 1999 the COC noted in a carcinogenicity study undertaken by Sunhara et al (1993)[9] that administration of 3-MCPD to rats caused statistically significant increases in some adenomas, fibroadenomas and kidney tumours at intermediate to high dose levels in some sexes. The COC had noted in 1999 that the high dose level had exceeded the Maximum Tolerated Dose. The COC therefore asked the COM for an assessment of the mutagenicity data on 3-MCPD as part of its evaluation of the mechanism for the carcinogenic effects seen in rats.

The COM was aware that 3-MCPD had been detected as a contaminant of several foods and food ingredients, including acid-HVP and that the EU Scientific Committee for Food (SCF) had published an opinion in 1994 where it was agreed that 3-MCPD should be regarded as a genotoxic carcinogen[10]. On the basis of mutagenicity data available in 1999, the Committee's main conclusions were that:

- 3-MCPD had mutagenic activity *in vitro*;
- further negative results in an *in vivo* mutagenicity test in a second tissue namely rat liver UDS were required in order to provide adequate reassurance that the activity seen *in vitro* is not expressed *in vivo*.

In preparing its most recent assessment on 3-MCPD in 2000[6], the Committee considered two new *in vivo* mutagenicity studies commissioned in the UK. These comprised a rat bone-marrow micronucleus test and a rat liver UDS assay, both of which are widely used to assess genotoxicity *in vivo*. The Committee reached the following conclusions:

- Members agreed that 3-MCPD has a chemical structure which suggests that it may be metabolised to genotoxic intermediates. 3-MCPD was clearly mutagenic *in vitro*;
- The Committee concluded that both the rat bone-marrow micronucleus test and the rat liver UDS test had been carried out to an acceptable standard and were negative. Thus adequate reassurance had been provided that the mutagenic activity seen *in vitro* was not expressed *in vivo*;
- The two new mutagenicity studies supported the view that reactive metabolites if formed did not produce genotoxicity *in vivo* in the tissues assessed;
- The Committee concluded that 3-MCPD can be regarded as having no significant genotoxic potential *in vivo*.

ATTACHMENT 5

UK COMMITTEE ON CARCINOGENICITY REPORT

Summary report of the UK Committee on Carcinogenicity (COC) Report on 3-MCPD and 1,3-DCP (2000)

The COC reached the following main conclusions on ALL available mutagenicity and carcinogenicity data:

- that 3-MCPD had mutagenic activity *in vitro*;
- that 3-MCPD was unlikely to present a carcinogenic risk to humans, provided the exposure was 1000 times lower than the NOEL of 1.1 mg/kg bw/d for tumourigenicity in a rat study.

In light of the new toxicological status of 3-MCPD, the UK's Food Standards Agency's Food Advisory Committee advised industry in October 2000 to continue to reduce concentrations of 3-MCPD in all foods and food ingredients to the lowest technologically achievable level[13].

ATTACHMENT 6

JECFA REPORT

Summary of the 57th meeting of the Joint Fao/Who Expert Committee of Contaminants and Food Additives (JECFA) on 3-MCPD and 1,3-DCP

JECFA establishes safe levels of intake for food additives and contaminants, and chemical specifications for food additives. JECFA decisions are accepted internationally and used by governments to establish national food standards. JECFA also provides advice to the Codex Committee on Food Additives and Contaminants (CCFAC).

Both 3-MCPD and 1,3-DCP were evaluated by the Committee at its forty-first meeting in 1993, when it concluded that 3-MCPD and 1,3-DCP were undesirable contaminants in food and considered that their concentrations in hydrolysed proteins should be reduced to the lowest level technically achievable.

The Codex Committee on Food Additives and Contaminants has since asked JECFA to review the new toxicological data for both 3-MCPD and 1,3-DCP and the statements and conclusions of the COM and the COC in June 2001.

Information obtained from recent JECFA assessment report (June 2001).

Information on the concentration of 3-MCPD in food, food ingredients, and protein hydrolysates was submitted to JECFA by the UK, the USA, and the International Hydrolyzed Protein Council. The USA supplied a national estimate of the intake of 3-MCPD and three countries (Australia, Japan and the USA) provided information on the consumption of soy sauce.

3-MCPD

Information on the consumption of soy sauce in Australia, Japan and the USA was also forwarded to JECFA for review. At any level of intake that might reasonably be expected, 3-MCPD would not be expected to have acute effects. In deriving the provisional maximum tolerable daily intake (PMTDI) for 3-MCPD of 0.002 mg/kg body weight/day, JECFA chose tubular hyperplasia in the kidney as the most sensitive toxicity end-point using a LOEL of 1.1 mg/kg bw/day and a safety factor of 500 based on a long-term study of toxicity and carcinogenicity in rats[14]. The data available to the Committee indicated that the estimated mean intake of 3-MCPD by consumers of soy sauce would be at or above the PTMDI if they chose brands with 3-MCPD contamination.

JECFA considered that as 3-MCPD is found infrequently in foods, a regulatory limit would be unlikely to have much effect on the overall intake of non-consumers of soy sauces. However, because the distribution of residual 3-MCPD in soy sauce is highly skewed and because it is likely that brand loyalty could result in regular consumption of highly contaminated brands of soy sauce, a regulatory limit on the concentration of 3-MCPD in soy sauce could markedly reduce the intake by soy sauce consumers.

1,3-DCP

In 1988 the EC Scientific Committee on Foods considered the available data on 1,3-DCP and agreed that 1,3-DCP is a genotoxic carcinogen causing cancer by directly damaging genetic material. The COC first considered 1,3-DCP in 1991. They concluded that it would be prudent to regard it as a genotoxic carcinogen *in vivo*. The COM and COC both recently considered 1,3-DCP and concluded that it would be prudent to regard 1,3-DCP as potentially genotoxic *in vivo*, and that exposure to 1,3-DCP should be reduced to as low a level as technologically feasible.

1,3-DCP is formed from its precursor 3-MCPD and has been shown to occur in soy sauces[4,17]. However, although no clear relationship exists between the relative concentration of 1,3-DCP and 3-MCPD, information supplied by the USA concerning the relationship between levels of 3-MCPD and 1,3-DCP was contained in the recent JECFA report. A linear relationship between the levels of 3-MCPD and 1,3-DCP was described, with a ratio of at least 20:1.

JECFA reviewed the available toxicological data and the statements and conclusions of the COM and the COC on 1,3-DCP at its meeting in June 2001[15] at the request of CCFAC.

Although only a few studies of kinetics, metabolism, short- and long-term toxicity, and reproductive toxicity were available for evaluation, they clearly indicated that 1,3-DCP was genotoxic *in vitro*, was hepatotoxic, and induced a variety of tumours in various organs in rats[8]. The Committee concluded that the estimation of a tolerable intake was inappropriate because of the nature of the toxicity based on the following considerations:

- The results of the long-term study showed significant increases in the incidences of both benign and malignant neoplasms in at least three independent studies;
- It has been shown unequivocally that this contaminant can interact with 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.

JECFA noted that the highest estimated intake of 1,3-DCP by consumers of soy sauce, 0.001 mg/kg body weight/day, is about 20,000 times lower than the dose that caused tumours in rats (19 mg/kg body weight/day). The Committee concluded that the available evidence suggests that 1,3-DCP is associated with high concentrations of 3-MCPD in food.

ATTACHMENT 7

DIETARY EXPOSURE ASSESSSMENT

A dietary exposure assessment was deemed necessary in order to determine an estimated dietary exposure to 3-MCPD as well as to assist in the setting of a maximum level (ML) for the FSC.

Background

A recent survey conducted by the United Kingdom's Food Standards Agency in 2000 identified some soy sauces produced by acid hydrolysis that contained chloropropanols. Of the samples found with chloropropanols, all contained 3-MCPD, and around two thirds of these also contained 1,3-Dichloropropanol (1,3-DCP), which is a potential carcinogen and should not be present at any levels in foods. Mixed foods other than soy and oyster sauces have been shown to contain 3-MCPD, but generally at lower levels.

Dietary Modelling

The dietary exposure assessment was conducted using ANZFA's dietary modelling computer program, DIAMOND. The dietary exposure was estimated by combining patterns of food consumption, as derived from national nutrition survey (NNS) data, with levels of 3-MCPD in foods at two possible MLs and analytical levels in soy and oyster sauces.

3-MCPD Levels

Four levels of 3-MCPD in soy and oyster sauces were used in the dietary modelling. The maximum limit of 0.02 mg/kg proposed by the European Commission, 0.1 mg/kg, which is a proposed ML for Australia and New Zealand, 3.7 mg/kg, the mean residual level from the 100 samples tested in the UK survey, and 16.9 mg/kg, the mean residual level from the 22 samples found to contain levels of 3-MCPD above 0.05 mg/kg in the same survey. Dietary exposure estimates assume all soy and oyster sauces contain 3-MCPD at these levels.

Additional MLs greater than 0.1 mg/kg could be modelled, but samples above this level are more likely to contain detectable 1,3-DCP, which is not considered desirable. Only one product in the UK survey with an analytical level of 3-MCPD below 0.1 mg/kg also contained a detectable level of 1,3-DCP. This sample had a level of 3-MCPD of 0.02 mg/kg and a level of 1,3-DCP of 0.006 mg/kg.

Food Consumption Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above; and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of the NNSs used a 24-hour food recall methodology.

The consumption of soy and oyster sauces in Australia and New Zealand was estimated through the DIAMOND program, and are shown in Table 1 below.

The respondent mean refers to the total consumption of soy and oyster sauce averaged over all the respondents in each NNS. The consumer mean and 95th percentile only applies to those respondents who actually consumed soy or oyster sauces.

Table 1. Consumption of soy and oyster sauces in Australia and New Zealand

	Consumption (grams per day)		
	Respondent Mean	Consumer Mean	Consumer 95th %ile
Australia	0.7	9.5	29.1
New Zealand	0.9	10.2	34.3

How were the dietary exposures calculated?

The DIAMOND program allows 3-MCPD concentrations to be assigned to food groups. 3-MCPD concentrations were assigned to soy and oyster sauces, including where soy and oyster sauces were used as an ingredient in mixed foods. The DIAMOND program multiplies the specified concentration of 3-MCPD by the amount of soy and oyster sauce that an individual consumed in order to estimate the exposure for each individual. Population statistics (mean and high percentile dietary exposures) are then derived from the individuals' dietary exposures. The dietary exposure assessment was conducted for both Australian and New Zealand populations.

Estimating Risk

In order to determine if the level of exposure to 3-MCPD is cause for concern, the exposures were compared to a Tolerable Daily Intake (TDI) of 0.002 mg/kg of body weight/day.

Results

At contamination levels of 0.02 mg/kg and 0.1 mg/kg of 3-MCPD in all soy and oyster sauces, the estimated dietary exposure is well below the TDI for all respondents and consumers only in both Australia and New Zealand (only 2% of TDI for 95th percentile consumption for both populations - see Table 1). At a contamination level of 3.7 mg/kg the estimated dietary exposure to 3-MCPD at the 95th consumption level is around 90% of the TDI for Australian and New Zealand populations. However, at a contamination level of 16.9 mg/kg of 3-MCPD in soy and oyster sauces, the consumer mean and 95th percentiles are above the TDI for both the Australian and New Zealand populations. The 95th percentile of consumers had an estimated dietary exposure to 3-MCPD in excess of 400% of the TDI for both the Australian and New Zealand populations.

Table 1. Estimated dietary exposure to 3-MCPD from soy and oyster sauces at various levels of contamination

			Level of 3-MCPD (mg/kg)			
Country	Population	Additive intake	0.02	0.1	3.7	16.9
Australia	Respondent mean	mg/day	0.0000	0.0001	0.027	0.0123
		% TDI	0.01	0.06	2	10
	Consumer mean	mg/day	0.0002	0.0010	0.0352	0.1607
		% TDI	0.2	0.7	27	125
	Consumer 95th %ile	mg/day	0.0006	0.0029	0.1075	0.4912
		% TDI	0.5	2	89	406
New Zealand	Respondent mean	mg/day	0.0000	0.0001	0.0034	0.0154
		% TDI	0.01	0.06	2	10
	Consumer mean	mg/day	0.0002	0.0010	0.0378	0.1726
		% TDI	0.1	0.7	25	115
	Consumer 95th %ile	mg/day	0.0007	0.0034	0.1270	0.5799
		% TDI	0.5	2	91	416

Note: Australia – number or respondents = 13858, number of consumers = 1060.
New Zealand – number of respondents = 4636, number of consumers = 415.

Calculating a TMAL

A theoretical maximum allowable level (TMAL) was calculated to estimate the level of 3-MCPD that may be present in soy and oyster sauces so that the TDI is not exceeded by a high consumer of soy and oyster sauces. The TMAL takes into consideration the:

- estimated dietary exposure to 3-MCPD from foods other than soy and oyster sauces (background intake);
- dietary exposure to 3-MCPD for high consumers of soy and oyster sauces; and
- TDI.

The background intake of 3-MCPD was calculated with the following assumptions. 3-MCPD may also be present in savoury foods. These savoury foods were assumed to constitute one eighth of the total diet (estimated 1500g/day of solid food), or 180g/day. The mean residual contamination of 3-MCPD in savoury foods was assumed to be 0.012 mg/kg (UK survey). The estimated dietary exposure to 3-MCPD from foods other than soy sauces was calculated to be 2 µg/kg of body weight per person per day.

The TMAL calculations for Australia and New Zealand were 4.5 mg/kg and 3.9 mg/kg respectively. These levels give an indication of the maximum level of contamination that could be present in soy and oyster sauces before the TDI would be exceeded by a high consumer, taking account of background exposure from other foods.

Interpretation of Results

If contamination levels of all soy and oyster sauces were at MLs of either 0.02 mg/kg or 0.1 mg/kg, estimated exposure to 3-MCPD would be expected to be very low (≦ 2% of TDI). The estimated dietary exposure at the 3.7 mg/kg level of contamination results in dietary exposures for high consumers of 3-MCPD close to the TDI.

This level of contamination is also approaching the TMAL. A contamination level of 19.6 mg/kg is well in excess of the TMAL and would see mean and high consumers of soy and oyster sauces exceeding the TDI. These estimated dietary exposures do not take into consideration intake of 3-MCPD from sources other than soy and oyster sauces. It should also be noted that the consumption figures are based upon a one-day recall protocol and may not reflect habitual daily intake, so that the 95th percentiles may be an overestimate. However, they may reflect the potential dietary exposure for people who habitually use soy and oyster sauces in their cuisine.

Conclusions

Setting an ML needs take into consideration the estimated dietary exposures, the TMALs and analytical data on the products in question. The dietary modelling results indicate that if an ML for 3-MCPD was set at 0.02 mg/kg or 0.1 mg/kg:

- this would be acceptable from a public health and safety perspective, with respect to exposure to 3-MCPD from dietary intake of soy and oyster sauces;
- the 0.02 mg/kg level could result in more products possibly being non-compliant with such a standard, with products potentially being withdrawn unnecessarily if ML of 0.02 mg/kg was used; and
- the 0.1 mg/kg level could see the vast majority of products that do comply with this level, also not containing detectable levels of 1,3-DCP.

For observed levels of 3.7 mg/kg (the mean analytical level):

- this level would be acceptable from a public health and safety perspective, with respect to exposure to 3-MCPD from dietary intake of soy and oyster sauces, but is very close to the calculated TMAL. It does not take into consideration intake of 3-MCPD from other sources in the diet and the aim for regulators of contaminants to set regulations according to ALARA and GMP principles;
- at this level of 3-MCPD some of these products may also contain detectable levels of 1,3-DCP.

A level of 16.9 mg/kg would be unacceptable due to the potential risk to public health and safety from the consumption of soy and oyster sauces.