October 1998

FULL ASSESSMENT REPORT
AND REGULATORY IMPACT ASSESSMENT

SUBJECT: P150 - ANZ STANDARD FOR FOOD ADDITIVES

EXECUTIVE SUMMARY

The policy paper "The Regulation of Food Additives", published in March 1996, was used as the basis for the development of a proposed draft Australia New Zealand General Standard on Food Additives. The proposed draft standard - P150 - was released for public comment from March 1997 to September 1997. A total of 65 submissions were received. The overwhelming majority of submissions supported the proposed draft standard, and comments received were related to:

- omissions from the schedules of additive uses currently permitted in Australia and/or New Zealand;
- inconsistencies in the permitted use of various additives; and
- requests for extensions to recognise established additive uses permitted by Codex or allowed in the EU or Northern America.

A small number of submissions raised concerns related to the general policy for the regulation of food additives being applied.

At full assessment a draft general standard for food additives has been prepared which introduces a consistent policy to the use of the additives. The standard has been developed by applying risk analysis to ensure that the dietary exposure to food additives from the food supply does not present an unacceptable risk to public health and safety and that consumers are not exposed unnecessarily to high levels of food additives. Thereafter, it facilitates both consumer choice and innovation in food technology by applying the minimum restriction on use consistent with Good Manufacturing Practice (GMP).

The safety of food additives has been assessed in accordance with the ANZFA policy paper "Framework for the assessment and management of food-related health risks". Safety evaluations undertaken by ANZFA, the National Health and Medical Research Council (NHMRC), the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the Scientific Committee on Food of the European Commission (SCF), Health and Welfare Canada, and the US Food and Drug Administration (FDA) were considered in the identification of acceptable levels of consumption.

The DIAMOND system was used in accordance with the ANZFA draft policy paper "Dietary Modelling: principles and procedures" to assess potential dietary exposure to food additives and ensure that acceptable levels of consumption as defined, for example, by the acceptable daily intake (ADI), would not be exceeded.

It is proposed that the use of food additives be regulated by reference to the technological function being performed. This is consistent with the approach taken in

the European Union directives on food additives and by the Codex Committee on Food Additives and Contaminants in developing the Codex general standard for food additives.

BACKGROUND AND ISSUES

In March 1996 the National Food Authority published a paper for Australia entitled "The Regulation of Food Additives". This paper was prepared as part of the Review of the Food Standards Code. ANZFA subsequently advertised and circulated the paper in New Zealand in the third quarter of 1996. The comments received from New Zealand indicated that it was a suitable policy document on which to base the development of a joint Australia New Zealand general standard for food additives. Therefore, the policy paper "The Regulation of Food Additives" was used as the basis for the development of a proposed draft Australia New Zealand General Standard on Food Additives.

A proposal for joint Australia New Zealand General Standard on Food Additives - P150 - was released for public comment in March 1997, initially for a three month period until 30 June 1997. However, as a result of the size of the proposal and the number of food additives and foods potentially affected, a large number of stakeholders requested extensions of time to comment. In the event the paper was available for comment for a period in excess of six months from March-September 1997.

OBJECTIVES

In developing or reviewing food standards, the Authority must have regard to the objectives outlined in section 10 of the *National Food Authority Act 1991*[1] (now the *Australia New Zealand Food Authority Act 1991*).

Consistent with these statutory objectives and the policies of the Authority, the review will, where possible:

- reduce the level of prescriptiveness of standards to facilitate innovation by allowing wider permission on the use of ingredients and additives, but with consideration of the possible increased need for consumer information;
- develop standards which are easier to understand and make amendment more straightforward;
- replace standards which regulate individual foods with standards that apply across all foods or a range of foods;
- consider the possibility of industry codes of practice as an alternative to regulation; and
- facilitate harmonisation of food standards between Australia and New Zealand.

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[1] Section 10 states that the Authority, in developing standards and variations of standards, must have regard to the following objectives in descending order:

(a) the protection of public health and safety;
(b) the provision of adequate information relating to food to enable consumers to make informed choices about food and to prevent fraud and deception;
(c) the promotion of fair trading in food;
(d) the promotion of trade and commerce in the food industry; and
(e) the promotion of consistency between domestic and international food standards where these are at variance.

The Review is also being carried out in accordance with the competition policy principles established by the Council of Australian Governments in 1995.

The ANZFA Policy paper on the regulation of food additives published in March 1996 as a part of the Review set out criteria for accepting food additives as follows:

- it poses no unacceptable risk to health when used in amounts up to the approved limits even after a lifetime of consumption;

- there is a demonstrable need for the substance and that it fulfils established criteria for technological function which, in effect, provide benefits to consumers; and

- the substance is used in any food only up to the level that achieves the technological function, regardless of the fact that higher levels might pose no threat to health. This is the concept of limited use according to good manufacturing practice (GMP).

The way in which the objectives are to be achieved is also discussed in detail in the policy paper. The paper also sets out three aims, in priority order, for a revised food additive standard.

1. To ensure that the dietary exposure of food additives from the food supply does not present a risk to public health and safety.

The standard should establish maximum permitted levels for food additives in relevant foods where a potential risk to public health and safety may be identified. The levels of additives which may be added should be established on the basis of a risk analysis. This should take into account appropriate measures of safety (such as the acceptable daily intake of the additive), levels of addition required to achieve relevant technological functions, and estimated daily intakes from all relevant foods.

2. To ensure that consumers are not exposed unnecessarily to high levels of food additives.

The establishment of limits may be appropriate where there is seen to be a risk of fraud and deception from the use of a food additive in particular foods or categories of foods.

3. To facilitate both the consumers' desire to exercise choice and innovation in food technology by applying the minimum restriction on use consistent with GMP.

RELEVANT PROVISIONS

The Food Standards Code regulates the use of food additives in Standard A3 - Food Additives, A4 - Preservatives, A5 - Colourings, A6 - Flavourings and Flavour Enhancers, A7 - Antioxidants, A8 - Artificial Sweetening Substances, A10 - Modifying Agents. In addition, permissions for the use or presence of additives are listed against the relevant food in commodity standards B to T. In some cases these duplicate entries the permissions already given in the 'A' Standards, however, in other case the entries are additional. Standard A3 expressly prohibits the addition of a food additive to food except where expressly permitted by the Code.

Specifications for permitted food additives are listed in Standard A11 - Specifications for Identity and Purity of Food Additives, Processing Aids, Vitamins, Minerals and Other Added Nutrients. In the majority of cases the standard reference specifications for food additives prepared by US National Academy of Sciences and published in the Food Chemical Codex or specifications prepared by JECFA and published by the FAO.

Prescribed names for food additives and the numbering system by which they may be alternatively identified are reproduced in the schedule to Standard A1 - Labelling and Advertising.

The New Zealand Food Regulations regulate the use of food additives in PART IV FOOD ADDITIVES. In addition, permission for the use of food additives in individual foods is given against those foods in PART II STANDARDS AND PARTICULAR LABELLING REQUIREMENTS and generally in PART III FOOD NOT ELSEWHERE STANDARDISED.

Specifications to be met by food additives are given in PART IV (6) of the New Zealand Food Regulations. The regulations' references are, in priority order, the Food Chemicals Codex, Food and Nutrition Papers (FAO), Japanese Standards of Food Additives, or the British Pharmacopoeia, or The Pharmaceutical Codex.

The identification of food additives is addressed in the TWELFTH SCHEDULE - FOOD ADDITIVE CODE NUMBERS, to the New Zealand regulations.

PUBLIC CONSULTATION

During the preparation of the policy paper "The Regulation of Food Additives", a concept paper was prepared and released for public comment for 3 months from April-July 1995. Eleven submissions were received during this period. The submissions generally supported the need to review the regulation of additives and the policy direction proposed although a number of consumers expressed concern about the "unnecessary" use of food additives. The policy paper was finalised between August 1995 and January 1996 and was accepted by the NFA in February 1996.

However, in view of progress on the Treaty between Australia and New Zealand establishing the joint food standards system, ANZFA advertised and circulated the final NFA policy paper in New Zealand for an additional period of public comment in the third quarter of 1996. The comments received from New Zealand indicated that it was appropriate that the paper be revised in due course to recognise the implementation of the joint Australia New Zealand food standards arrangements but it was, in the meantime, a suitable policy document on which to base the development of a joint Australia New Zealand general standard for food additives.

Therefore, the policy paper "The Regulation of Food Additives" was used as the basis for the development of a proposed draft Australia New Zealand General Standard on Food Additives.

The proposed draft Australia New Zealand General Standard for Food Additives - P150 - was released for public comment in March 1997, initially for a three month period until 30 June 1997. However, as a result of the size of the proposal and the number of food additives and foods potentially affected, a large number of stakeholders requested extensions of time to comment. The paper was available for comment for a period in excess of six months from March-September 1997. A total of 65 submissions were received in this period. While a small number presented raised objections to the policy proposed in *The Regulation of Food Additives*, the overwhelming majority strongly supported the policy and presented variations to the proposed draft standard either to recognise additive uses already permitted in Australia or New Zealand but omitted from the draft, or to apply the policy more consistently by removing inconsistencies in approach.

OPTIONS including alternatives to regulation

There are many options and combinations of options that could be considered. However, in view of the potential health risks arising from the use of unknown and potentially unsafe substances for technical purposes in food, the only practical options which the Authority has considered involve the maintenance of an underpinning regulation:

Option 1
Adopt the current New Zealand permissions for food additives as the joint standard;

Option 2
Adopt the current Australian permissions for food additives as the joint standard; or

Option 3
Develop a standard based on the sum of food additive permissions from the Australian and New Zealand regulations; or

Option 4
Develop a new regulatory regime involving the development of a general standard for food additives which introduces a consistent policy to the use of the additives. The regime would apply risk analysis to ensure that the dietary exposure to food additives from the food supply does not present an unacceptable risk to public health and safety and that consumers are not exposed unnecessarily to high levels of food additives, but thereafter would facilitate both consumer choice and innovation in food technology by applying the minimum restriction on use consistent with Good Manufacturing Practice (GMP).

ASSESSMENT

<u>Development of the proposed draft standard</u>

The proposed draft Australia New Zealand General Standard on Food Additives - P150 - was released for public comment in March 1997. Because of the complexities involved and in recognition of the extensive policy development already undertaken, it was considered productive to release a detailed draft as a proposal under the *ANZFA Act 1991* at an early stage of the statutory process and to seek public input on individual additives. To facilitate the development of the proposed

draft standard, additives were arranged into 5 groupings based upon previous safety evaluations undertaken by ANZFA as well as by other relevant agencies including the National Health and Medical Research Council (NHMRC), The Joint FAO/WHO Expert Committee on Food Additives (JECFA), The Scientific Committee on Food of the European Commission (SCF), Health and Welfare, Canada and the US Food and Drug Administration (FDA).

The 5 groups comprised:

Group 1. Miscellaneous additives, currently permitted extensively in Australia and/or New Zealand, for which a numerical acceptable daily intake (ADI) is currently considered not necessary on account of a lack of observed toxicity or which have a numerical ADI that is unlikely to be approached from all technically justified uses. These additives were listed in Schedule 2 of the proposed draft.

Group 2 Colours for which an ADI has been deemed unnecessary on account of their lack of observed toxicity or which have a numerical ADI that is unlikely to be approached from all technically justified uses. These additives were listed in Schedule 3 of the proposed draft.

Group 3 Colours which have numerical ADIs which are sufficiently high to enable their inclusion at a technologically useful level in all processed foods when tested on a dietary budget model. These additives were listed in Schedule 4 of the proposed draft.

Group 4 Food additives which have specific uses for which they can be generally considered as safe (may include some additives also Groups 1 or 2 for specific food uses). These additives are listed in Schedule 1 of the proposed draft.

Group 5 Additives with numerical ADIs, which preliminary estimates of potential intake indicate could be exceeded by unrestricted use, and individual colourings additives from Group 3 in specific foods. These additives were permitted, subject to defined limits, under the individual categories of food in which they are permitted Schedule 1 of the proposed draft.

A full list of the additives, sorted by alphabetical and numerical order, is included at Appendix 1.

Scientific Evaluation

Safety

The safety for use of the additives included in the draft standard has been assessed in accordance with the ANZFA policy paper "Framework for the assessment and management of food-related health risks".

A detailed database on the safety of food additives was been compiled from toxicological evaluations undertaken by ANZFA, NHMRC, JECFA, The European Scientific Committee for Food, the US FDA and other relevant published sources. Examples of the data held on individual additives is presented in Appendix 2. On the basis of these evaluations additives have either been allocated a numerical

acceptable daily intake (ADI), or a maximum tolerable daily intake (MTDI), or has been designated ADI "not specified" or "not necessary".

Potential dietary exposure to food additives has been assessed using the DIAMOND system in accordance with the ANZFA draft policy paper "Dietary modelling: principles and procedures" (Appendix 3).

A total of 397 single additives are listed in the proposed food additive standard P150. Of these, only 5 additives/additive groups (12 single additives) are considered to warrant discussion of risk minimisation options. Of the remaining additives, the 17 single additives with 'no allocated ADI' may need to be considered in the future if more information on reference health standards is made available, 205 single additives were assessed as being of no risk to human health on the basis that the ADI was 'not specified; 40 additives/additive groups with an ADI were assessed as being of no risk assuming the exclusive use of the additive in foods at maximum permitted levels (MPLs) and a further 24 additives with an ADI were assessed as being of no risk assuming actual patterns of use and manufacturers' use levels.

The additive groups sulphites, nitrites, cyclamates, saccharin and propylene glycol, have been identified as cause for concern because actual dietary exposures have the potential to exceed the ADI for either adults or schoolchildren. Risk minimisation options for these additives have been considered during the development of the draft standard.

For sulphites, the food industry is encouraged to use GMP levels at all times. Where suitable alternative methods of preservation exist, the industry is encouraged to replace sulphur dioxide and sulphites. Appropriate labelling would help to alert individuals, who cannot tolerate sulphites, of their use in specific food products (refer to P161 Specific Labelling Statements for labelling provisions).

For nitrites, draft P150 permissions have been restricted to specific processed meats.

For cyclamates, draft P150 permissions have been lowered for soft drinks and fruit juice products, deleted for tabletop sweeteners and will not be extended to spoon-for-spoon products. The food and beverage industry should be encouraged to phase out extensive use of this additive in the future, particularly in cordials, soft drinks and fruit juice drinks.

For saccharin, P150 permissions have been limited to tablets and portion control sachets. Permission for use has not been extended to spoon-for-spoon products.

For propylene glycol, permission for use on fruits and vegetables has been restricted to 4.1.3 Fruit salad only, and deleted for 4.1.2 Surface treated fruits and vegetables.

Technological function

The policy paper addressed technological function and justification for use in the following terms:

The use of a food additive should be linked to a technological function.
In practice, food additive standards allow the use of many additives, often by functional class, in broad food categories rather than on a case-by-case basis. In deciding which technological functions are appropriate in a particular food it is necessary to consider the chemical and/or physical characteristics of that food. This

process can be undertaken in isolation from consideration of individual named food additives. Once it has been decided that a function (eg the need for an emulsifier or an antioxidant) could be justified on technical grounds, a list of additives which may potentially perform this function may be drawn up. Safety considerations and the potential for fraud and deception may limit the additives which are permitted as well the levels which may be used. However, thereafter, choices about which additive to select from the list should depend upon manufacturing processes and techniques and be, therefore, properly beyond the scope of a food additive standard.

The policy paper also drew attention to the Codex Alimentarius Commission document *General Principles for the Use of Food Additives*[1] which provides guidelines to decide where and when individual technological functions are justified:

> 'The use of food additives is justified only where they serve one or more of the purposes set out from (a) to (d) and only where these purposes cannot be achieved by other means which are economically and technologically practicable and do not present a hazard to the health of the consumer:
>
> (a) to preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in sub paragraph (b) and also in other circumstances where food does not constitute a significant item in a normal diet;
>
> (b) to provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
>
> (c) to enhance the keeping quality or stability of a food or improve its organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer; and
>
> (d) to provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.'

In the preparation of the draft standard the existence of permission for the use of a food additive performing a relevant technological function in the Food Standards Code or the New Zealand Food Regulations was, in the first instance, taken as evidence of technological need. Thereafter, uses recognised specifically in Codex standards or in the regulations developed by the FDA, Health Canada or the European Union were also taken into account.

ISSUES RAISED IN PUBLIC SUBMISSIONS

A total of 65 submissions were received in response to the publication of the proposal for the ANZ general standard. The overwhelming majority of submissions generally supported the direction proposed, but raised technical matters regarding the use of specific food additives as listed in the schedules - in the main these can be summarised as relating to:

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[1] *General Principles for the Use of Food Additives* was originally adopted by the Ninth Session of the Codex Alimentarius as a Codex Advisory text (para. 295, ALINORM 72/53) and was reprinted in the Second Edition of the Codex Alimentarius, Vol I (General Requirements), pp 49–51 (1992).

- omissions from the schedules of additive uses currently permitted in Australia and/or New Zealand;
- inconsistencies in the permitted use of various additives; or
- requests for extensions to recognise established additives uses permitted in the EU, North America or by Codex.

Where the proposed amendments could be verified as relevant to food industry practice and were consistent with the policy for the review, they have been incorporated in the revised draft standard.

Additives used for other than technological purposes
A number of submissions proposed the use of additives for other than technological purposes, for example the addition of acacia gum to fruit juice as a source of dietary fibre. These requests have not been addressed in this review but referred for consideration by relevant commodity review teams.

Texts in the proposed draft standard
A number of comments addressed the texts used in the proposed draft standard, particularly with regard to potential ambiguities in intent or application. The need to make the text consistent with the same provisions in the preamble to the Codex General Standard for Food Additives was also raised. Amendments have been made to the revised draft standard to ensure that provisions are clearer and to avoid ambiguity. In addition, where these are seen to be enforceable on a national level, the relevant Codex texts have been preferred.

Objections to the food additive policy and/or the use of GMP
A number of submissions raised objections to the policy direction being proposed in the review. Particularly, with regard to changes to standards which could be seen to lead to more widespread use of food additives or to the replacement of prescriptive regulation of additives by food and level with standards which place a greater emphasis on GMP. On the basis that these submissions proposed outcomes which were inconsistent with the objectives of the review and with the policy already developed for the regulation of food additives. If implemented, they would lead to greater prescription and potentially inhibit innovation and consumer choice with no evident public health or safety benefit, and hence they were not implemented in the draft standard.

The safety of food additives
A number of submissions raised concerns about the safety of specific food additives, particularly certain colours and the sweetener aspartame.

The additives permitted in the standard have been subjected to extensive safety evaluation by a large number of relevant bodies including ANZFA, the National Health and Medical Research Council (NHMRC), The Joint FAO/WHO Expert Committee on Food Additives (JECFA), The Scientific Committee on Food of the European Commission (SCF), Health and Welfare, Canada and the US Food and Drug Administration (FDA). Potential dietary exposure to food additives has been assessed using the DIAMOND system in accordance with the ANZFA draft policy paper "Dietary modelling: principles and procedures". Only additives found to be suitable for use have been included in the standard.

In addition, additives must be identified by name or by their number in the international numbering system for food additives and by their function on the label

of packaged foods. This enables consumers who may have concerns about sensitivities to specific additives to identify and avoid them.

Beer

Submissions from the Australian and New Zealand brewing industries opposed the general permission for Schedule 2-4 additives in beer on the basis that beer is a product with a traditional image which would be damaged by a general permission for additive use. These submissions proposed that a limited list of additives be permitted in beer in accordance with current Australian and New Zealand brewing practices. The Authority recognises that this would be consistent with the EU directives on food additives and also with a proposal foreshadowed at the Codex Alimentarius Commission to limit the use of generally permitted additives in beer. The proposal of the brewers was therefore upheld and the draft standard amended accordingly.

Wine

As an interim measure, similar restriction on additive use has been maintained in the draft standard for wine consistent with AFSC Standard P3 Wine, Sparkling Wine and Fortified Wine. This standard was amended in March 1995 to align with EU wine directives in the interests of enhancing market access. The Authority recognises that unsupported variations to the additive permissions for wine could adversely affect trade with the EU for no apparent benefit to Australian wine producers. However, New Zealand does not have a similar arrangement with the EU and New Zealand winemakers may see benefit in a wider range of additives being recognised. In addition, the current list of additives permitted in Australia may present a barrier to trade for wine makers in, for example North and South America. This matter will be addressed further in the specific context of the development of a Joint ANZ wine standard.

Preservatives

It was suggested in one submission that the use of preservatives in certain high pH foods (eg sauces and pickles) could result in the selection of pathogenic bacteria and as such could actually present a risk to public health and safety.

Regulations in NZFR, the European Union, Canada and the USA, as well as the Codex draft general standard for food additives, all allow for the use of preservatives in sauces, toppings and similar foods provided that Good Manufacturing Practice (GMP) guidelines are followed.

There are many types of sauces manufactured in Australia, New Zealand and around the world and it is apparent that while the use of preservatives in some types of sauce is not necessary, they are justified in others. Current Australian standards already permit preservatives in chilli paste, dairy and non-dairy dips, pickles, mushrooms and olive products. The presence of preservatives by carry-over from ingredients is also permitted in sauces. Furthermore, the AFSC allows the inclusion of preservatives in toppings, although chocolate and caramel toppings do not normally contain them. Under transitional arrangements, Standard T1 also allows Australian manufacturers to use preservatives in sauces which comply wholly with the New Zealand Food Regulations. There is no evidence that this has led to the abuse of preservatives in these products in Australia.

Not allowing preservatives in sauces would remove a current New Zealand permission without apparent justification and create a significant trade barrier for imports of sauces and related products. Furthermore, the possible risk of preservatives in higher pH products could potentially apply to a wide range of

products in which preservatives are permitted. In this regard it is important to note that:

- ∑ the draft food additive standard introduces the concept that a listing in the standard does not automatically confer permission for the use of the additive in the specified food. The use must also be consistent with GMP. This is not the case in the current AFSC;
- ∑ State and Territory food acts prohibit the preparation of a food which is injurious to health; and
- ∑ the preparation of a food which is not safe for consumption will be an offence under the proposed new food hygiene regulations.

In effect, there is a clear responsibility placed on manufacturers to ensure that any additive is fit for its intended purpose.

REGULATORY IMPACT ANALYSIS

Option 1 - Adopt existing NZ regulations	
Benefits	**Costs**
• Public health and safety would continue to be protected at the current level applying in New Zealand, • The cost to government to prepare the new standard would be minimal	• Australian manufacturers would be forced to revise their use of food additives to meet New Zealand permissions, with consequent cost increases and possible reduction in product quality; these cost increases would no doubt be passed on to Australian consumers, • There may be greater competition in Australia from foods manufactured in New Zealand, • Consumer choice would be limited particularly with respect to products containing additives currently permitted in Australia which do not currently enjoy the same range of permissions for use in New Zealand, • There would be a potential cost to government as the regulations were developed prior to: the establishment of the COAG principles for guidelines and regulations, and the establishment of the WTO and are not entirely consistent with the principles of the SPS and TBT agreements.

Option 2 adopt existing Australian regulations	
Benefits	**Costs**
• Public health and safety would continue to be protected at the current level applying in Australia, • The cost to government to prepare the new standard would be minimal	• New Zealand manufacturers would be forced to revise their use of food additives to meet Australian permissions, with consequent cost increases and possible reduction in product quality; these cost increases would no doubt be passed on to New Zealand consumers, • There may be greater competition in New Zealand from foods manufactured in Australia, • Consumer choice would be limited particularly with respect to products containing additives currently permitted in New Zealand which do not currently enjoy the same range of permissions for use in Australia, • There would be a potential cost to government as the regulations were developed prior to the establishment of the COAG principles for guidelines and regulations and the establishment of the WTO SPS and TBT agreements and are not entirely consistent with the principles which underpin either of them.

Option 3 a standards based on the sum of food additive permissions from the Australian and New Zealand regulations	
Benefits	**Costs**
• Public health and safety would continue to be protected at a level which represented the lowest common denominator of Australia and New Zealand regulations, • The cost to government to prepare the new standard would be greater than for options 1 and 2 but would be minimal compared to option 4	• Consumer confidence in the food supply would not be advanced and could be diminished as the current Australian and New Zealand regulations do not always require that the use of many food additives be linked to defined technological functions or be consistent with Good Manufacturing Practice, • Innovation by Australian and New Zealand manufacturers would be limited, particularly with respect to new products as only additive uses currently permitted in New Zealand and Australia would be available. Any changes would require a full application to vary the new joint standard which may not be consistent with the timely development of new products in a competitive market, • There would be a potential cost to government as both the Australian and New Zealand regulations were developed prior to : the establishment of the COAG principles for guidelines and regulations, and the establishment of the WTO and are not entirely consistent with the principles of the SPS and TBT agreements.

Option 4 - a new standard to implement the policy paper on the regulation of food additives	
Benefits	**Costs**
• Public health and safety would continue to be protected but at a level which could be justified against internationally recognised risk assessment and management criteria, • Consumer confidence in the food supply would be enhanced by a well elaborated regulatory system, • Innovation by Australian and New Zealand manufacturers would be facilitated by the removal of unnecessary regulation, • The policy underpinning the regulation of food additives in Australia and New Zealand would be consistent with the policies adopted already by Codex (for the development of the GSFA), the EU and Canada	• Certain consumers may have a concern about a reference to GMP rather than prescriptive regulation for additives which do not raise concerns for safety or deceptive practice, • The cost to government of developing a new standard would be significantly greater than for options 1, 2 or 3.

ANZFA Section 10 Objectives

- *Protection of public health and safety*

The safety of the additives permitted by the draft standard has been evaluated either by ANZFA or the NHMRC in Australia, for the Food Standards Committee in New Zealand or by other recognised regulatory bodies including JECFA, the SCF, Health and Welfare, Canada and the US FDA. On the basis of these evaluations, a draft standard has been prepared which is consistent with the ANZFA policy "Framework for the assessment and management of food-related health risks".

Potential dietary exposure to additives permitted in the standard has been determined to be within acceptable limits using the procedure set out by ANZFA in the draft policy paper "Dietary Modelling: principles and procedures".

Furthermore, the use of additives in ways which may mislead consumers about the nutritional quality of foods and, thereby, adversely affect public health, has been limited by application of the GMP principle throughout the standard.

- *Adequate consumer information*

The labelling of food additives is not the subject of this proposal, however, consumers can obtain information about the presence of additives in food from the ingredient lists or otherwise from their presence on food labels.

The draft standard also presents the permissions for the use of food additives in a single document rather than being distributed throughout the Code. This will greatly assist consumers seeking information about permitted food additives in Australia and New Zealand.

- *Promotion of fair trading in food*

The adoption of the draft standard will promote fair trading by ensuring that the provisions relating to the use of food additives will be the same in Australia and New Zealand. The draft standard applies a uniform policy throughout and removes many of the inconsistencies found in the previous Australian and New Zealand food additive regulations.

- *Promotion of trade and commerce in the food industry*

Subject to the prior objectives, the standard has been developed in line with ANZFA policy to:

- facilitate innovation by reducing the level of prescriptiveness of food additive standards and allow wider permission on the use of additives;
- develop standards which are easier to understand and make amendments more straightforward; and
- replace standards which regulate individual foods with standards that apply across all foods or a range of foods.

The draft standard also places greater emphasis on the importance of industry taking responsibility for the appropriate use of food additives by the introduction to an explicit requirement for compliance with GMP.

- *Promotion of consistency between domestic and international food standards*

The format of the standard is consistent with policy applied by the Codex Committee on Food Additives and Contaminants in the development of the Codex General Standards for Food Additives. In addition similar formats have been adopted by the European Union in its directives relating to food additives and proposed by the Health Canada in its review of food additive regulations. The consistencies between formats will allow rapid comparisons to be made between the ANZ standard and other national and international regulations.

The ANZ draft standard has been developed to apply a consistent level of protection for public health and safety and from misuse of additives in the context of the Australian and New Zealand food markets. The justification for individual additives as approved in the draft standard has been developed using a risk analysis model and applying sound scientific principles in accordance with the requirements of the WTO SPS and TBT agreements. Accordingly, therefore, while the majority of permissions are consistent with Codex and relevant overseas standards, a small number of technical variations may be expected.

OTHER RELEVANT MATTERS

Codex GSFA

In June 1997, the 22nd session of the Codex Alimentarius Commission approved to the first component of the General Standard for Food Additives (GSFA) developed by the Committee on Food Additives and Contaminants (CCFAC). This permits 170 food additives, determined by JECFA as not requiring a numerical ADI, in foods in general (except where expressly prohibited or restricted) in accordance with good manufacturing practice. This recommendation is entirely consistent with the policy elaborated by ANZFA in Proposal 150 - to develop a joint ANZ standard for food additives.

Then second element of the GSFA which permits additives with numerical ADIs by maximum level and by reference to food categories, in similar manner to that employed in the draft ANZ standard, is currently being developed by CCFAC. It is expected that a draft standard will be recommended for adoption at step 5 by CAC at it 23rd meeting in June 1999.

<u>EU directives</u>

Food additives are regulated in the EU by 3 Directives:

∑ 94/35/EC on sweeteners for use in foodstuffs,
∑ 94/36/EC on colours for use in foodstuffs, and
∑ 95/2/EC on food additives other than colours and sweeteners.

Although formatted somewhat differently, the policy adopted by the EU for the regulation of food additives is entirely consistent with that proposed in the draft joint ANZ standard. In particular, additives which are recognised as safe are permitted in foods in general in accordance with the principle of *quatum satis*. This permission is then qualified by lists of foods where the use of these generally permitted additives is prohibited or restricted. Additives of concern are permitted individually by reference to food and maximum level of use. In the directive on food additives other than colours and sweeteners, permission to use an additive is linked to it performing any one of a number of technological functions recognised in the directive.

<u>Canada</u>

Health Canada is in the process of reviewing the regulation of food additives in Canada. The policy directions for this review "*A Strategic Direction for Change*" were published by the Health Protection Branch in August, 1993. It was proposed that a positive list be established for those food additives having an "Unlimited" or "Not Specified" acceptable daily intake. Unless restricted by federal standards, the substances on this list would be able to be used in foods at levels consistent with "good manufacturing practice." Subsequently, a document which elaborated this policy and sought comment on the proposed positive list(s) was published in 1996. The policy direction developed by Health Canada is essentially the same as that proposed for the joint ANZ standard.

Associated Review projects

There are 3 associated review projects addressing:
∑ the labelling of food additives;
∑ specifications for food additives; and
∑ flavourings.

CONCLUSIONS

A draft general standard for food additives has been prepared as a result of the full assessment. This standard was based on the proposed draft standard circulated by the Authority in March 1997.

The standard had been prepared to be consistent with ANZFA's previously published policies on:
"The Regulation of Food Additives";
"Framework for the assessment and management of food-related health risks"; and
"Dietary modelling: principles and procedures".

This outcome is the most effective means of achieving the aim of ensuring that the intake of food additives from the food supply does not present a risk to public health and safety. This outcome also means that consumers are not exposed unnecessarily to high levels of food additives, while facilitating both the consumers' desire to exercise choice, and innovation in food technology, by applying the minimum restriction on use consistent with GMP.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION (*)

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

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

This matter does need to be advised to the WTO as a TBT Notification because it contains proposed changes to food standards, to prevent potentially deceptive uses of food additives, which could have impacts on the compositional requirements of foods imported into Australia and New Zealand.

This matter does need to be advised to the WTO as a SPS Notification because it contains proposed changes to food standards, to protect public health and safety in the use of food additives, which could have impacts on the compositional requirements of foods imported into Australia and New Zealand .

Appendices

1. Additives included in the draft ANZ standard for food additives by alphabetical (1a) and numerical (1b) order.

2. The food additive toxicology database (excerpt only).

3. Dietary exposure assessments of food additives.

Attachments to the Report:

1. Draft Variation to the Australian *Food Standards Code*

2. Draft Explanatory Notes

3. Public Comment Received

Appendix 1

SCHEDULE 1a - Food Additive numbers sorted by alphabetical order

Additive name	INS No.
4-hexylresorcinol	
Acesulphame potassium	950
Acetic acid, glacial	260
Acetic and fatty acid esters of glycerol	472a
Acetylated distarch adipate	1422
Acetylated distarch phosphate	1414
Acid treated starch	1401
Adipic acid	355
Agar	406
Alginic acid	400
Alitame	956
Alkaline treated starch	1402
Alkanet (& Alkannin)	103
Allura red AC	129
Alpha-amylase	1100
Aluminium	173
Aluminium silicate	559
Aluminium, calcium, sodium magnesium potassium and ammonium salts of fatty acids	470
Amaranth	123
Ammonium acetate	264
Ammonium adipate	359
Ammonium alginate	403
Ammonium carbonate	503
Ammonium carbonates	503
Ammonium citrates	380
Ammonium dihydrogen phosphate	342
Ammonium fumarate	368
Ammonium hydrogen carbonate	503
Ammonium lactate	328
Ammonium malate	349
Ammonium phosphates	342
Ammonium salts of phosphatidic acid	442
Annatto extracts	160b
Anthocyanins	163
Arabinogalactan (larch gum)	409
Ascorbic acid	300
Ascorbyl palmitate	304
Aspartame	951
Azorubine	122
b Carotene (synthetic)	160a
Beeswax, white & yellow	901
Beet Red	162
Bentonite	558
Benzoic acid	210

Additive name	INS No.
Bleached starch	1403
Bone phosphate	542
Brilliant black BN	151
Brilliant blue FCF	133
Bromelain	1101
Brown HT	155
Butylated hydroxyanisole	320
Butylated hydroxytoluene	321
Calcium ascorbate	302
Calcium benzoate	213
Calcium hydrogen malate	352
Calcium sulphate	516
Calcium acetate	263
Calcium alginate	404
Calcium aluminium silicate	556
Calcium carbonate	170
Calcium carbonates	170
Calcium chloride	509
Calcium citrate	333
Calcium dihydrogen phosphate	341
Calcium disodium EDTA	385
Calcium fumarate	367
Calcium gluconate	578
Calcium glutamate, Di-L-	623
Calcium hydrogen carbonate	170
Calcium hydrogen phosphate	341
Calcium hydroxide	526
Calcium lactate	327
Calcium lactylates	482
Calcium malate	352
Calcium malates	352
Calcium oleyl lactylate	482
Calcium oxide	529
Calcium phosphates	341
Calcium propionate	282
Calcium silicate	552
Calcium sorbate	204
Calcium stearoyl lactylate	482
Calcium tartrate	354
Caramel I - plain	150a
Caramel II - caustic sulphite process	150b
Caramel III - ammonia process	150c
Caramel IV - ammonia sulphite process	150d

Additive name	INS No.
Carbon dioxide	290
Carnauba wax	903
Carotenal, □-apo-8'-	160e
Carotenes	160a
Carotenoic acid, □-apo-8'-, methyl or ethyl esters	160f
Carrageenan	407
Cellulose, microcrystalline and powdered	460
Chlorophyllin copper complex, sodium and potassium salts	141
Chlorophylls	140
Chlorophylls copper complex	141
Chlorophylls, copper complexes	141
Choline salts of acetic, carbonic, hydrochloric, citric, tartaric and lactic acid	1001
Citric acid	330
Citric and fatty acid esters of glycerol	472c
Cochineal and carmines	120
Cupric sulphate	519
Curcumin	100
Curcumins	100
Cyclamates	952
Cyclohexylsulfamic acid	952
Dextrins, white & yellow, roasted starch	1400
Diacetyltartaric and fatty acid esters of glycerol	472e
Diammonium hydrogen phosphate	342
Dimethyl dicarbonate	242
Dioctyl sodium sulphosuccinate	480
Dipotassium hydrogen phosphate	340
Dipotassium tartrate	336
Disodium guanylate, 5'-	627
Disodium hydrogen phosphate	339
Disodium inosinate, 5'-	631
Disodium monohydrogen citrate	331
Disodium pyrophosphate	450
Disodium ribonucleotides, 5'-	635
Disodium tartrate	335
Distarch phosphate	1412
Dodecyl gallate	312
Enzyme treated starches	1405
Erythorbic acid	315
Erythrosine	127
Ethyl maltol	637
Fast green FCF	143
Ferric ammonium citrate	381
Ferrous gluconate	579
Ficin	1101
Fumaric acid	297

Additive name	INS No.
Gellan gum	418
Glucono delta-lactone	575
Glucose oxidase	1102
Glycerin (glycerol)	422
Glycerol esters of wood rosins	445
Gold	175
Green S	142
Guar gum	412
Gum arabic (Acacia)	414
Hydrochloric acid	507
Hydroxypropyl distarch phosphate	1442
Hydroxypropyl methylcellulose	464
Hydroxypropyl starch	1440
Indigotine	132
Iron oxide black	172
Iron oxide red	172
Iron oxide yellow	172
Iron oxides	172
Isomalt	953
Karaya gum	416
L -glutamic acid	620
L-cysteine monohydrochloride	920
Lactic acid	270
Lactic and fatty acid esters of glycerol	472b
Lactitol	966
Lecithin	322
Lipases	1104
Locust bean (carob bean) gum	410
Lutein	161b
Lycopene	160d
Lysozyme	1105
Magnesium hydrogen carbonate	504
Magnesium sulphate	518
Magnesium carbonate	504
Magnesium carbonates	504
Magnesium chloride	511
Magnesium glutamate, Di-L-	625
Magnesium hydrogen phosphate	343
Magnesium lactate	329
Magnesium oxide	530
Magnesium phosphates	343
Magnesium silicate	553
Magnesium silicates	553
Magnesium trisilicate	553
Malic acid	296
Maltitol & maltitol syrup	965

Additive name	INS No.
Maltol	636
Mannitol	421
Metatartaric acid	353
Methyl ethylcellulose	465
Methyl cellulose	461
Methyl p -hydroxybenzoate (paraben)	218
Microcrystalline cellulose	460
Mineral oil, food grade	905a
Mono- and diglycerides of fatty acids	471
Monoammonium glutamate, L-	624
Monomagnesium phosphate	343
Monopotassium glutamate, L-	622
Monopotassium tartrate	336
Monosodium glutamate, L-	621
Monosodium tartrate	335
Monostarch phosphate	1410
Natural extracts (carotene)	160a
Nisin	234
Nitrogen	941
Nitrous oxide	942
Octyl gallate	311
Oxidised starch	1404
Papain	1101
Paprika oleoresins	160c
Pectins	440
Pentapotassium triphosphate	451
Pentasodium triphosphate	451
Petrolatum (petroleum jelly)	905b
Phosphated distarch phosphate	1413
Phosphoric acid	338
Pimaricin (natamycin)	235
Polydextroses	1200
Polydimethylsiloxane	900a
Polyethylene glycol 8000	1521
Polyglycerol esters of fatty acids	475
Polyglycerol esters of interesterified ricinoleic acids	476
Polyoxyethylene (20) sorbitan monooleate	433
Polyoxyethylene (20) sorbitan monostearate	435
Polyoxyethylene (20) sorbitan tristearate	436
Polyphosphates	452
Polyvinylpyrolidone	1201
Ponceau 4R	124
Potassium ascorbate	303
Potassium benzoate	212
Potassium bisulphite	228
Potassium fumarate	366

Additive name	INS No.
Potassium malates	351
Potassium metabisulphite	224
Potassium sulphite	225
Potassium acetate	261
Potassium adipate	357
Potassium alginate	402
Potassium aluminium silicate	555
Potassium carbonate	501
Potassium carbonates	501
Potassium chloride	508
Potassium citrates	332
Potassium dihydrogen citrate	332
Potassium dihydrogen phosphate	340
Potassium ferrocyanide	536
Potassium gluconate	577
Potassium hydrogen carbonate	501
Potassium lactate	326
Potassium nitrates	251
Potassium nitrite	249
Potassium phosphates	340
Potassium polyphosphates	452
Potassium propionate	283
Potassium silicate	560
Potassium sodium tartrate	337
Potassium sorbate	202
Potassium sulphate	515
Potassium tartrate	336
Powdered cellulose	460
Processed eucheuma seaweed	407a
Propionic acid	280
Propyl gallate	310
Propyl p -hydroxybenzoate (paraben)	216
Propylene glycol	1520
Propylene glycol alginate	405
Propylene glycol esters of fatty acids	477
Protease (microbial)	1101
Proteases	1101
Pyrophosphates	450
Quinoline yellow	104
Riboflavin	101
Riboflavin -5'-phosphate sodium	101
Riboflavins	101
Saccharin	954
Saffron, crocetin and crocin	164
Shellac	904
Silicon dioxide (amorphous)	551
Silver	174

Additive name	INS No.
Sodium benzoate	211
Sodium lactylates	481
Sodium metabisulphite	223
Sodium nitrites	250
Sodium phosphates	339
Sodium acetate	262
Sodium acetates	262
Sodium alginate	401
Sodium aluminium phosphate	541
Sodium aluminium phosphate	541
Sodium aluminium phosphate, acidic	541
Sodium aluminium phosphate, basic	541
Sodium aluminosilicate	554
Sodium bisulphite	222
Sodium carbonate	500
Sodium carbonates	500
Sodium carboxymethylcellulose	466
Sodium citrates	331
Sodium cyclamate	952
Sodium diacetate	262
Sodium dihydrogen citrate	331
Sodium dihydrogen phosphate	339
Sodium erythorbate	316
Sodium ferrocyanide	535
Sodium fumarate	365
Sodium hydrogen carbonate	500
Sodium hydrogen malate	350
Sodium lactate	325
Sodium malate	350
Sodium malates	350
Sodium nitrates	252
Sodium oleyl lactylate	481
Sodium polyphosphate, glassy	452
Sodium propionate	281
Sodium sesquicarbonate	500
Sodium sorbate	201
Sodium stearoyl lactylate	481
Sodium sulphite	221
Sodium tartrate	335
Sodium, sulphate	514
Soduim ascorbate	301
Sorbic acid	200
Sorbitan monostearate	491
Sorbitan tristearate	492
Sorbitol	420
Stannous chloride	512
Starch acetate (esterified with acetic anhydride)	1420
Starch sodium octenylsuccinate	1450

Additive name	INS No.
Stearic acid	570
Succinic acid	363
Sucralose	955
Sucrose acetate isobutrate	444
Sucrose esters of fatty acids	473
Sulphur dioxide	220
Sunset yellow FCF	110
Synthetic delta-tocopherol	309
Synthetic gamma-tocopherol	308
Talc	553
Tannins	181
Tartaric acid	334
Tartaric, acetic and fatty acid esters of glycerol (mixed)	472f
Tartrazine	102
Tertiary butylhydroquinone	319
Tetrapotassium pyrophosphate	450
Tetrasodium pyrophosphate	450
Thaumatin	957
Titanium dioxide	171
Tocopherol, d-alpha-, concentrate	307
Tocopherols concentrate mixed	306
Tragacanth gum	413
Triacetin	1518
Tricalcium phosphate	341
Triethyl citrate	1505
Trimagnesium phosphate	343
Triphosphates	451
Tripotassium citrate	332
Tripotassium phosphate	340
Trisodium citrate	331
Trisodium phosphate	339
Turmeric	100
Vegetable Carbon	153
Xanthan gum	415
Xylitol	967
Zinc silicate	557

Schedule 1b - Food Additive numbers sorted by numerical order

INS No.	Additive name
100	Curcumins Curcumin Turmeric
101	Riboflavins Riboflavin Riboflavin -5'-phosphate sodium
102	Tartrazine
103	Alkanet (& Alkannin)
104	Quinoline yellow
110	Sunset yellow FCF
120	Cochineal and carmines
122	Azorubine
123	Amaranth
124	Ponceau 4R
127	Erythrosine
129	Allura red AC
132	Indigotine
133	Brilliant blue FCF
140	Chlorophylls
141	Chlorophylls, copper complexes Chlorophylls copper complex Chlorophyllin copper complex, sodium and potassium salts
142	Green S
143	Fast green FCF
150a	Caramel I - plain
150b	Caramel II - caustic sulphite process
150c	Caramel III - ammonia process
150d	Caramel IV - ammonia sulphite process
151	Brilliant black BN
153	Vegetable Carbon
155	Brown HT
160a	Carotenes Carotene (synthetic) Natural extracts (carotene)
160b	Annatto extracts
160c	Paprika oleoresins
160d	Lycopene
160e	Carotenal, b-apo-8'-
160f	Carotenoic acid, b-apo-8Ő-, methyl or ethyl esters
161b	Lutein
162	Beet Red
163	Anthocyanins
164	Saffron, crocetin and crocin
170	Calcium carbonates Calcium carbonate Calcium hydrogen carbonate
171	Titanium dioxide
172	Iron oxides Iron oxide black Iron oxide red Iron oxide yellow
173	Aluminium
174	Silver
175	Gold
181	Tannins
200	Sorbic acid
201	Sodium sorbate
202	Potassium sorbate
204	Calcium sorbate
210	Benzoic acid
211	Sodium benzoate
212	Potassium benzoate
213	Calcium benzoate
216	Propyl p -hydroxybenzoate (paraben)
218	Methyl p -hydroxybenzoate (paraben)
220	Sulphur dioxide
221	Sodium sulphite
222	Sodium bisulphite
223	Sodium metabisulphite
224	Potassium metabisulphite
225	Potassium sulphite
228	Potassium bisulphite
234	Nisin
235	Pimaricin (natamycin)
242	Dimethyl dicarbonate
249	Potassium nitrite
250	Sodium nitrites
251	Potassium nitrates
252	Sodium nitrates
260	Acetic acid, glacial
261	Potassium acetate
262	Sodium acetates Sodium acetate Sodium diacetate
263	Calcium acetate
264	Ammonium acetate
270	Lactic acid
280	Propionic acid
281	Sodium propionate
282	Calcium propionate
283	Potassium propionate
290	Carbon dioxide
296	Malic acid
297	Fumaric acid
300	Ascorbic acid

INS No.	Additive name
301	Soduim ascorbate
302	Calcium ascorbate
303	Potassium ascorbate
304	Ascorbyl palmitate
306	Tocopherols concentrate mixed
307	Tocopherol, □-alpha-, concentrate
308	Synthetic gamma-tocopherol
309	Synthetic delta-tocopherol
310	Propyl gallate
311	Octyl gallate
312	Dodecyl gallate
315	Erythorbic acid
316	Sodium erythorbate
319	Tertiary butylhydroquinone
320	Butylated hydroxyanisole
321	Butylated hydroxytoluene
322	Lecithin
325	Sodium lactate
326	Potassium lactate
327	Calcium lactate
328	Ammonium lactate
329	Magnesium lactate
330	Citric acid
331	Sodium citrates Sodium dihydrogen citrate Disodium monohydrogen citrate Trisodium citrate
332	Potassium citrates Potassium dihydrogen citrate Tripotassium citrate
333	Calcium citrate
334	Tartaric acid
335	Sodium tartrate Monosodium tartrate Disodium tartrate
336	Potassium tartrate Monopotassium tartrate Dipotassium tartrate
337	Potassium sodium tartrate
338	Phosphoric acid
339	Sodium phosphates Sodium dihydrogen phosphate Disodium hydrogen phosphate Trisodium phosphate
340	Potassium phosphates Potassium dihydrogen phosphate Dipotassium hydrogen phosphate Tripotassium phosphate
341	Calcium phosphates Calcium dihydrogen phosphate Calcium hydrogen phosphate Tricalcium phosphate
342	Ammonium phosphates Ammonium dihydrogen phosphate Diammonium hydrogen phosphate
343	Magnesium phosphates Monomagnesium phosphate Magnesium hydrogen phosphate Trimagnesium phosphate
349	Ammonium malate
350	Sodium malates Sodium hydrogen malate Sodium malate
351	Potassium malates
352	Calcium malates Calcium hydrogen malate Calcium malate
353	Metatartaric acid
354	Calcium tartrate
355	Adipic acid
357	Potassium adipate
359	Ammonium adipate
363	Succinic acid
365	Sodium fumarate
366	Potassium fumarate
367	Calcium fumarate
368	Ammonium fumarate
380	Ammonium citrates
381	Ferric ammonium citrate
385	Calcium disodium EDTA
400	Alginic acid
401	Sodium alginate
402	Potassium alginate
403	Ammonium alginate
404	Calcium alginate
405	Propylene glycol alginate
406	Agar
407	Carrageenan
407a	Processed eucheuma seaweed
409	Arabinogalactan (larch gum)
410	Locust bean (carob bean) gum
412	Guar gum
413	Tragacanth gum
414	Gum arabic (Acacia)
415	Xanthan gum
416	Karaya gum
418	Gellan gum
420	Sorbitol
421	Mannitol
422	Glycerin (glycerol)

INS No.	Additive name
433	Polyoxyethylene (20) sorbitan monooleate
435	Polyoxyethylene (20) sorbitan monostearate
436	Polyoxyethylene (20) sorbitan tristearate
440	Pectins
442	Ammonium salts of phosphatidic acid
444	Sucrose acetate isobutrate
445	Glycerol esters of wood rosins
450	Pyrophosphates Disodium pyrophosphate Tetrasodium pyrophosphate Tetrapotassium pyrophosphate
451	Triphosphates Pentasodium triphosphate Pentapotassium triphosphate
452	Polyphosphates Sodium polyphosphate, glassy Potassium polyphosphates
460	Cellulose, microcrystalline and powdered Microcrystalline cellulose Powdered cellulose
461	Methyl cellulose
464	Hydroxypropyl methylcellulose
465	Methyl ethylcellulose
466	Sodium carboxymethylcellulose
470	Aluminium, calcium, sodium magnesium potassium and ammonium salts of fatty acids
471	Mono- and diglycerides of fatty acids
472a	Acetic and fatty acid esters of glycerol
472b	Lactic and fatty acid esters of glycerol
472c	Citric and fatty acid esters of glycerol
472e	Diacetyltartaric and fatty acid esters of glycerol
472f	Tartaric, acetic and fatty acid esters of glycerol (mixed)
473	Sucrose esters of fatty acids
475	Polyglycerol esters of fatty acids
476	Polyglycerol esters of interesterified ricinoleic acids
477	Propylene glycol esters of fatty acids
480	Dioctyl sodium sulphosuccinate
481	Sodium lactylates Sodium stearoyl lactylate Sodium oleyl lactylate
482	Calcium lactylates Calcium stearoyl lactylate Calcium oleyl lactylate
491	Sorbitan monostearate
492	Sorbitan tristearate
500	Sodium carbonates

INS No.	Additive name
	Sodium carbonate Sodium hydrogen carbonate Sodium sesquicarbonate
501	Potassium carbonates Potassium carbonate Potassium hydrogen carbonate
503	Ammonium carbonates Ammonium carbonate Ammonium hydrogen carbonate
504	Magnesium carbonates Magnesium carbonate Magnesium hydrogen carbonate
507	Hydrochloric acid
508	Potassium chloride
509	Calcium chloride
511	Magnesium chloride
512	Stannous chloride
514	Sodium, sulphate
515	Potassium sulphate
516	Calcium sulphate
518	Magnesium sulphate
519	Cupric sulphate
526	Calcium hydroxide
529	Calcium oxide
530	Magnesium oxide
535	Sodium ferrocyanide
536	Potassium ferrocyanide
541	Sodium aluminium phosphate
541	Sodium aluminium phosphate Sodium aluminium phosphate, acidic Sodium aluminium phosphate, basic
542	Bone phosphate
551	Silicon dioxide (amorphous)
552	Calcium silicate
553	Magnesium silicates
	Magnesium silicate
	Magnesium trisilicate
	Talc
554	Sodium aluminosilicate
555	Potassium aluminium silicate
556	Calcium aluminium silicate
557	Zinc silicate
558	Bentonite
559	Aluminium silicate
560	Potassium silicate
570	Stearic acid
575	Glucono delta-lactone
577	Potassium gluconate

INS No.	Additive name
578	Calcium gluconate
579	Ferrous gluconate
620	L -glutamic acid
621	Monosodium glutamate, L-
622	Monopotassium glutamate, L-
623	Calcium glutamate, Di-L-
624	Monoammonium glutamate, L-
625	Magnesium glutamate, Di-L-
627	Disodium guanylate, 5'-
631	Disodium inosinate, 5'-
635	Disodium ribonucleotides, 5'-
636	Maltol
637	Ethyl maltol
900a	Polydimethylsiloxane
901	Beeswax, white & yellow
903	Carnauba wax
904	Shellac
905a	Mineral oil, food grade
905b	Petrolatum (petroleum jelly)
920	L-cysteine monohydrochloride
941	Nitrogen
942	Nitrous oxide
950	Acesulphame potassium
951	Aspartame
952	Cyclamates
952	Cyclohexylsulfamic acid
952	Sodium cyclamate
953	Isomalt
954	Saccharin
955	Sucralose
956	Alitame
957	Thaumatin
965	Maltitol & maltitol syrup
966	Lactitol
967	Xylitol

INS No.	Additive name
1001	Choline salts of acetic, carbonic, hydrochloric, citric, tartaric and lactic acid
1100	Alpha-amylase
1101	Proteases Protease (microbial) Papain Bromelain Ficin
1102	Glucose oxidase
1104	Lipases
1105	Lysozyme
1200	Polydextroses
1201	Polyvinylpyrolidone
1400	Dextrins, white & yellow, roasted starch
1401	Acid treated starch
1402	Alkaline treated starch
1403	Bleached starch
1404	Oxidised starch
1405	Enzyme treated starches
1410	Monostarch phosphate
1412	Distarch phosphate
1413	Phosphated distarch phosphate
1414	Acetylated distarch phosphate
1420	Starch acetate (esterified with acetic anhydride)
1422	Acetylated distarch adipate
1440	Hydroxypropyl starch
1442	Hydroxypropyl distarch phosphate
1450	Starch sodium octenylsuccinate
1505	Triethyl citrate
1518	Triacetin
1520	Propylene glycol
1521	Polyethylene glycol 8000
	4-hexylresorcinol

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APPENDIX 3

DIETARY EXPOSURE ASSESSMENTS OF FOOD ADDITIVES

PROPOSAL P150

ANZ STANDARD FOR FOOD ADDITIVES

The proposed food additive standard (P150) outlines permissions for food additives in four schedules; Schedule 1 lists specific additive permissions; Schedules 2 (miscellaneous additives) and 3 (colours) list additives that are to be considered for use at GMP levels in all processed foods, except where prohibited in Schedule 1; Schedule 4 additives (colours) are permitted in all foods, except where prohibited in Schedule 1, at levels of 290 mg/kg solid food, 70 mg/L liquid processed foods. Some Schedule 2 and 3 additives also have specific permissions in Schedule 1 for additional foods (may be GMP or specified levels of use).

Risk assessment of food additives

The potential risk associated with dietary exposure to a particular food additive is determined by comparing estimates of potential additive dietary exposure to the acceptable daily intake level (ADI) of that additive. The ADI for humans is an amount of food additive that can be ingested daily over a lifetime without any appreciable risk to health. For food additives, the primary source of the food chemical is from the diet.

Food additives can be divided into three classes for the purposes of risk assessment:

- additives with an ADI 'not specified' (205 single additives);
- additives without an ADI (17 single additives); and
- additives with an established or temporary ADI (175 single additives).

There are a total of 397 single additives listed in P150, of these the 175 single additives with an established or temporary ADI were the only ones included in the initial screening process. For the purposes of dietary modelling, additives in the same chemical family and with the same ADI were grouped and treated as one model in the DIAMOND computer program used to estimate dietary exposures. The assumption is made that one form of the additive would be used 'instead of' another form and not 'in addition' to it. Table 1 summarises the numbers of additives in Schedules 1-4 and the additives included in the screening process (175 single additives, equivalent to 69 DIAMOND models).

Additives with an ADI 'not specified', or termed 'acceptable' or 'not limited' (205 single additives) were not included in the screening process because they have a particularly low toxicity and are generally not restricted in their use on the basis of potential human health risk. Their use is controlled by the technological need for the additive. The term 'good manufacturing practice' (GMP) is used in place of a maximum permissible concentration to indicate that no maximum level is specified, but that the additive should be used at a level not higher than necessary to achieve the intended purpose.

Additives without an ADI or 'decision postponed' (17 single additives) were not included in the initial screening process, though may be assessed on an individual basis, as needs arise, or as ADIs are allocated in the future. Determination of

potential risk for such additives is a more subjective process because their current use is based on traditional use in food. While the extensive history of use of such substances in food may be an argument in favour of their having low toxicity, in some instances there may be concerns which would warrant further controls over their use. The absence of overt adverse health effects in humans does not necessarily mean there is an absence of toxic effects at potential dose levels.

Table 1: Summary of Food Additives listed in P150

	Total number of single additives	**Number single additives with an ADI****	**Number single additives without ADI/decision postponed**
Schedule 1: includes additives from schedule 2-4 if permissions given specifically	163 additives	95 single additives (45 DIAMOND models)#	7 single additives
Schedule 2 Misc additives: GMP use in processed foods specified in Schedule 1, except where specified otherwise	196 additives which includes 4 additives (2 groups) for low sodium/low salt foods only and 2 additives subject to clause 4*****	51 single additives (6 DIAMOND models because 12 additives also in Schedule 1)#	4 single additives
Schedule 3 Colours: GMP use in processed foods specified in Schedule 1, except where specified otherwise	25 additives	16 single additives (5 DIAMOND models because 1 additive also in Schedule 1)#	6 single additives
Schedule 4 Colours: permitted to level specified in Schedule 1 (290 mg/kg solid food, 70 mg/L liquids)	13 additives	13 single additives (13 DIAMOND models)#	0 single additives
TOTAL	397 additives	175 additives (69 DIAMOND models)#	17 additives

***** aspartame, sucralose - Clause 4 specifies that intense sweeteners may only be added to food to the extent necessary to replace the sweetness normally provided by sugars in the manufacture of that food

** MTDI for phosphates

# indicates the number of distinct models required in the DIAMOND program for single additives plus additive groups (ie. additives in the same chemical family with the same ADI are grouped and counted as 1 additive model in the DIAMOND program)

Summary of screening process

A total of 397 single additives are listed in the proposed food additive standard P150. Of these, only 5 additives/additive groups (12 single additives) are considered to warrant discussion of risk minimisation options. Of the remaining additives, the 17 single additives with 'no allocated ADI' may need to be considered in the future if more information on reference health standards is made available, 205 single additives were assessed as being of no risk to human health on the basis that the ADI was 'not specified; 40 additives/additive groups with an ADI were assessed as being of no risk assuming the exclusive use of the additive in foods at maximum permitted levels (MPLs) and a further 24 additives with an ADI were assessed as being of no risk assuming actual patterns of use and manufacturers' use levels.

Due to the large numbers of food additives permitted for use in P150, a screening process with a tiered approach was used to identify additives with an ADI requiring complex dietary exposure assessments (ANZFA 1997, Chapter 3). The DIAMOND computer modelling program, developed by the Authority, was used to estimate dietary exposures from food consumption data and food additive concentration data. The final step in the DIAMOND program for dietary exposure assessments compares estimated dietary exposures with ADI for the specific food additive or food additive group.

Tiered approach to dietary exposure assessments

Stage 1: Screening of additives for further calculations

- budget method (modified budget method and/or reverse budget method); and
- high consumer model.

Stage 2: Dietary exposure estimates

- population surveys, combining individual records of food consumption from national dietary surveys with MPLs of food additives or manufacturers' use levels of additives; and
- surveys of specific additives, combining individual records of food consumption data for food products permitted to contain the additive of interest with manufacturers' use levels by brand name.

Within each stage, a hierarchical and iterative approach to dietary exposure estimations was taken such that the risk assessment process concluded when it was demonstrated that there was no need for further concern.

Budget method screen

Modified budget method (MBM)

The modified budget method (MBM) sets a theoretical maximum level (TML) for use of an additive in a restricted portion of food and beverages in the diet (expressed in mg/kg food), such that the ADI cannot be exceeded when physiological food and fluid requirement are met (ANZFA 1997). The method can only be used for food

additives which have an established or temporary ADI. Based on the 1983 National Dietary Survey, it was assumed that approximately 50% solid food supply by weight may have contained additives (excluding cereals, fresh fruit, vegetables, meat, eggs, fish and nuts/seeds). Although there were no comprehensive data for water consumption in the 1983 survey, a similar figure of 50% beverage supply likely to contain additives was assumed (includes tea and coffee, which may contain flavourings and fruit juice products)[1].

In the screening process, the TML is compared to the technological use level (TUL) of the additive, where known. The TUL is the maximum level of use for an additive or additive group in any food derived from the food additive standard. For additives used at GMP, an approximate manufacturers' (maximum) level is used for that additive.

For additives in Schedule 2-4 where permissions are given for all food categories (except prohibited foods, unless otherwise specified), it was assumed that the additive was used equally in solid food and beverages (ratio 50%:50%), and that 50% food and 50% beverage supply may contain the additive. For Schedule 2-4 additives, a maximum level of use for the budget method calculation was derived from several sources as listed below, starting with sources at the top of the list:

- specific Schedule 1 permissions from the proposed food additive standard;
- permissions in current Food Standards Code;
- information from ANZFA food technologists;
- documented levels of usage from the European Union (EU) or Codex; or
- information on levels of additive use from the food industry.

If known levels of use from the current Code or from food industry information were higher than the listed Schedule 1 permissions, then the higher value was used as the maximum level of technological use in order to obtain a 'worst case' scenario.

Outcome: of the 69 additives/additive groups screened by the budget method, 46 additives/additive groups were identified for further screening because the ratio of TUL: TML was greater than 1, that is, the level of use of the additive to achieve technological function was greater than the theoretical maximum level (summarised in Table 2).

Reverse budget method (RBM)

A reverse budget calculation (RBM) was undertaken for additives identified by the budget method as requiring further screening, but only where the additive had limited use in a single food or food group. The reverse budget method was therefore not used for any additives listed in Schedules 2, 3 or 4. The RBM calculates the amount of food that would need to be consumed in order for the ADI to be met, assuming that the additive is used at the highest MPL in a single food or food group (ANZFA 1997). An assessment was made as to whether consumption of this theoretical amount of food was likely or not on a daily basis, by reference to food consumption data derived from national dietary surveys.

[1] From 1983 survey, solid foods not likely to contain additives comprised 55% total food consumed for males, 58% for females.

Outcome: only 10 Schedule 1 additives/additive groups in the 'requiring further assessment' category had limited uses. A reverse budget method calculation was undertaken for these additives: 5 of the 10 additives/additive groups were designated as being not of public health concern because the limit of food that had to be consumed before the ADI was exceeded was not considered likely to be met on a daily basis. Therefore the second stage of screening (high consumer model) was undertaken for a total of 46 additives/additive groups (summarised in Table 2).

Table 2: Summary of first screening stage using the budget method

	No models	**Further assessment required after MBM (TUL:TML >1)**	**Further assessment required after RBM**	**No further concern**
Additives with specific permissions in Schedule 1	45	35	30	15
Additives with GMP permissions, Schedules 2 (excludes 12 additives also in Schedule 1)	6	3	3	3
Schedule 3 (excludes 1 additive also in Schedule 1)	5	5	5	0
Schedule 4	13	8	8	5
TOTAL	**69**	**51**	**46**	**23**

High consumer model screen (HCM)

46 additives/additive groups from Schedules 1-4 were referred from the budget method screening process, for further screening. The high consumer model (HCM) is based on population data and assumes a person could be a high consumer of two major food groups that contain the additive of interest and a mean consumer of the remaining food groups that contain the additive, where the additive is used at MPLs as proposed in P150 (ANZFA 1997, Chapter 2).

Outcome: 10 additives/additive groups were assessed as being of no risk after the HCM screen, with 36 additives/additive groups referred for detailed dietary exposure assessments.

Dietary exposure assessments

Dietary exposure assessments integrate food consumption data with food additive concentration data (ANZFA 1997, Chapters 2, 3).

For Australia, the best available food consumption data are from national surveys, such as the 1983 and 1985 National Dietary Surveys for adults (25-64 years) and schoolchildren (10-15 years) respectively, and the more recent 1995 National Nutrition Survey for people aged 2 years and over. The 1995 data was not available for use in DIAMOND at the time of full assessment, but will be used to check dietary exposure assessments for food additives identified as being potentially of concern

before inquiry. There are no comprehensive food consumption data based on individual dietary records available from New Zealand. The 1997 NZ National Nutrition Survey data will be released in early 1999 and will be incorporated into DIAMOND next year. In the meantime, it is considered unlikely that a high consumer in New Zealand consumes more of each food item over 24 hours than their Australian counterparts. The DIAMOND program makes best use of the food consumption data that is available by using individual dietary records rather than population statistics. Potential 'at risk' groups can be identified by selecting specific population subgroups defined by age, sex or other demographic characteristics or by food consumption patterns.

Food additive concentration data are derived from P150 (MPLs) or manufacturers' data for the level of use (food additives).The main aim of the tiered approach to dietary exposure assessments for food additives is to identify food additives of potential concern where manufacturers' use level data is required for further modelling, rather than retrieve such data for all additives. The Authority recognised that for these additives, close consultation is required with the food and beverage industry and that it is time consuming for the industry to collate additive use level data.

Detailed dietary exposure assessment (individual records)

A total of 36 additives/additive groups were considered for detailed dietary exposure assessment after the two tier screening process. In this stage of assessment the DIAMOND program calculates food additive exposure levels for each individual in the survey, based on individual dietary records and then derives mean and high consumer additive dietary exposure levels for the survey population (for all respondents and for consumers of foods containing the additive only). Dietary exposure estimates were undertaken for all adults (25-64 years), for adult males, adult females and schoolchildren (10-15 years). In general, the risk of estimated dietary exposures exceeding the ADI was found to be higher for adult males than adult females because of the higher food consumed to body weight ratios in males then females. The risk of estimated dietary exposures exceeding the ADI was also generally higher for schoolchildren than adults for the same reasons.

Outcome: 7 additives/additive groups out of the total of 36 additives/additive groups were not a cause for concern for male or female adults or schoolchildren, including high consumers of the additive, using dietary models that assumed the exclusive use of the additive in foods at MPLs proposed in P150, which is a 'worst case' assumption. The food and beverage industry were consulted about the actual use levels of the remaining 29 additives/additive groups (see Annex 1 for details).

Table 3: Summary of dietary exposure assessments

Additive	Number models	Number requiring further assessment after HCM	Number requiring industry data after detailed assessment	Number requiring development of risk minimisation options	Number with no further concern
Schedule 1	30	21	18	5	13
Schedule 2	3	2	1	0	1

Schedule 3	5	5	2	0	2
Schedule 4	8	8	8	0	8
TOTAL	**46**	**36**	**29**	**5**	**24**

Refined dietary exposure assessment (individual records)

29 additives/additive groups have been identified as being of concern by detailed dietary modelling (individual records), because estimated dietary exposures exceed the ADI. These initial dietary models assume the additive is used at maximum levels in all food classes listed in P150 for that additive. In reality, this will tend to overestimate actual dietary exposure for several reasons:

- manufacturers use lower maximum levels than those proposed in P150;

- the additive may not be used exclusively, other additives with the same technological function may be used in specific food classes;

- the additive may be in conjunction with other additives to achieve a synergistic effect, such that lower amounts of each additive are used than would otherwise be expected or permitted; and/or

- the additive is not used in all the products in one food class.

There are several options for refining the dietary models to take these factors into account. The options chosen depend on whether models are chosen to reflect long term (chronic) exposure by consumers of the additive or consumption patterns for a brand loyal consumer. The Authority has chosen to model for long term exposure patterns because the ADI refers to an 'acceptable level of intake over a life time of exposure'. DIAMOND models give results for the high consumer of the additive (defined as the 95th percentile of additive consumption) as well as the mean consumer. It is considered that the brand loyal consumer is likely be included in this analysis as a potential high consumer. The high additive consumer group will include two categories of high consumers:

- high consumers of single foods; and
- moderate consumers of many foods resulting in a total high consumption of the additive.

If it is assumed the aim is to construct a realistic dietary model for chronic exposure to be able to compare estimated dietary exposures to the ADI, then it could be assumed that people over a life time choose a variety of brands within one food class. In this case, we could use one of two additive levels for each food class in the model:

- arithmetic mean (average of all known manufactures' use levels)
- weighted mean (manufactures' use levels weighted according to market share within a food class)

In general, the Authority assumed an arithmetic mean, unless one manufacturer was known to have a major share of the market (>50%), in which case a weighted mean

was used or where market share information was not available, the level of use of the major manufacturer was substituted in the model.

In some cases, data were available from the food and beverage industry on the proportional use of different additives that achieve the same function in the specified food class. Where relevant, such data were incorporated into dietary models when it could be established that this pattern of use was always the case.

Further information from the food and beverage industry on the use of the additive within a food class and restriction to certain food products was also considered when interpreting the final dietary exposure assessments.

Outcome: following dietary exposure assessment of 29 additives/additive groups using refined models, a further 2 additives/additive groups were assessed as being of no risk, assuming manufacturers' levels of use in Australia or New Zealand (summarised in Annex 2). These dietary models still assume that all the product within any one class assigned an additive level contains the additive. For some additives this does not reflect actual patterns of use and will overestimate additive dietary exposures.

For the 27 additives/additive groups remaining, 22 additives/additive groups were considered not likely to be of real concern after further information was sought on their actual patterns of use within specified food classes from the food and beverage industry (summarised in Annex 2).

Interpretation of results

Interpretation of dietary exposure assessments is difficult for several reasons. First, the estimate is a combination of two data sets, namely food consumption and food additive concentration data, each with a (usually) unquantified margin of error. Second, in nearly all cases, the dietary exposure estimate for a food additive will be overestimated because of the 'worst case' assumptions made in constructing the dietary model, though the extent of the overestimation may be unknown. This would still be the case in refined dietary models because models still assume that the whole of the food class contains the additive at the estimated manufacturers' use level.

There may be cause for public health concern where estimated dietary exposures to a food additive exceed the ADI. However, it is recognised that occasional excursions of dietary exposure over the ADI are not a risk to health, though continual excursions over a period of time may be, the extent of the risk depending on the toxicological basis on which the ADI was established. Unfortunately, the use of 24-hour recall food consumption data does not allow the identification of the extent and duration of such potential excursions over the ADI (ANZFA 1997, Chapter 2). Future research may enable the use of other types of dietary surveys, such as food frequency data, to be incorporated into dietary models to account for long term patterns of food consumption. In view of the uncertainty and potential errors in dietary exposure assessments, all the 29 additives/additive groups identified as having the potential

for dietary exposure estimates to exceed the ADI, based on individual dietary records, were considered to be of concern and further information sought from the food and beverage industry on their actual use.

Risk management options

The additive groups sulphites, nitrites, cyclamates, saccharin and propylene glycol, have been identified as cause for concern because actual dietary exposures have the potential to exceed the ADI for either adults or schoolchildren. Risk minimisation options for these additives have been considered by the Authority.

For sulphites, the food industry is encouraged to use GMP levels at all times. Where suitable alternative methods of preservation exist, the industry is encouraged to replace sulphur dioxide and sulphites. Appropriate labelling would help to alert individuals, who cannot tolerate sulphites, of their use in specific food products (refer to P161 Specific Labelling Statements for labelling provisions).

For nitrites, draft P150 permissions have been restricted to specific processed meats.

For cyclamates, draft P150 permissions have been lowered for soft drinks and fruit juice products, deleted for tabletop sweeteners and will not be extended to spoon-for-spoon products. The food and beverage industry should be encouraged to phase out extensive use of this additive in the future, particularly in cordials, soft drinks and fruit juice drinks.

For saccharin, P150 permissions will not be extended to spoon-for-spoon products. One option to reduce the potential risk of exceeding the ADI from excessive consumption of tabletop saccharin sweeteners is the use of voluntary warning on labels about the potential risks associated with excess consumption.

For propylene glycol, permission for use on fruits and vegetables has been restricted to 4.1.3 Fruit salad only, and deleted for 4.1.2 Surface treated fruits and vegetables.

Annex 1

Additives identified for detailed dietary exposure assessments by two tier screening process

Schedule 1 (18 additives):

160b	Annatto extracts
210-213	Benzoates *
220, 221-225, 228	Sulphites
234	Nisin *
249, 250	Nitrites
262ii	Sodium diacetate *
338-341, 450-452, 542	Phosphates
355, 357	Adipates
473	Sucrose esters of fatty acids
475	Polyglycerol esters of fatty acids *
476	Polyglycerol esters of interesterified ricinoleic acids
480	Dioctyl sodium sulphosuccinate *
541	Sodium aluminium phosphate
950	Acesulphame potassium *
952	Cyclamate
954	Saccharin *
956	Alitame *
1520	Propylene glycol

Schedule 2 (1 additive):

365	Sodium fumarate

Schedule 3 (2 additives)

101	Riboflavin
172	Iron oxide

Schedule 4 (8 additives):

110	Sunset yellow *
122	Azorubine *
123	Amaranth
124	Ponceau *
132	Indigotine *
142	Green S *
151	Brilliant black
155	Brown HT *

* estimated dietary exposure exceeds the ADI for only high consumers (95th percentile of additive exposures), males and/or for schoolchildren.

Annex 2

Explanatory notes on additives identified for further investigation

Schedule 1 (18 additives):

1. Annatto extracts (160b)

Annatto is a yellow colouring, permitted in a wide variety of foods and beverages. The permission for annatto in P150 is actually for norbixin, the active compound, which is assumed to be present at a maximum of 3% total annatto content. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (modified fermented milks 33 mg/kg, unripened cheese 0 mg/kg, margarines 5 mg/kg , fat emulsions <80% oil 5 mg/kg, ice-creams, biscuits, cakes and pastries, wine based drinks, and mixed foods).

Results indicate that estimated dietary exposures exceed the ADI for norbixin of 0.07 mg/kg bw for all adult and child respondents (150% ADI, 345% ADI for mean level consumers respectively).

The main contributor to annatto dietary exposure for adults from the dietary model was processed cheese (33% total exposure), mainly because of its high proposed level of use (600 mg/kg) compared with other food products. For schoolchildren, ice cream and ice confections were also important contributors due to higher consumption levels of this food class than adults (30% total exposure for processed cheese, 24% for ice creams & ice confections).

However, the dietary model assumes that annatto is used exclusively in all the products in each food class for which permission is give. As annatto is a colouring, its actual use will be restricted within each food class to those products requiring a yellow colour and dietary exposures will consequently be much lower than estimated. In addition, not all products use annatto at 3% norbixin, many will use it as a colouring with a lower (and cheaper) norbixin level. There are also alternative yellow colours that may be used in these products.

Outcome: In reality, it is considered that annatto dietary exposures are not likely to exceed the ADI, given current patterns of use.

2. Benzoates (210-213)

Benzoic acid, sodium, potassium and calcium benzoates are preservatives with a wide range of permissions in foods and beverages. The refined dietary model substitutes mean industry use levels for some food classes using data provided by the food and beverage industry (ice confection 200 mg/kg, fruit & veg spreads 275 mg/kg, confectionery products 482 mg/kg, fruit & veg juices 200 mg/kg, soft drinks except kola type drinks 400 mg/kg, fat based dips 376 mg/kg dressings, mayonnaise 292 mg/kg mg/kg and fat emulsions, icings & frostings, semi-preserved fish products, kola type drinks and sauces 0 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI of 5 mg/kg bw for adults (26% ADI adult mean consumer, 87% ADI adult high

consumers) or child mean consumers (47% ADI) but may exceed the ADI for child high consumers (144% ADI).

The main contributors to benzoates dietary exposures from the dietary model were fruit & vegetable juices and soft drinks (except kola type drinks) for adults (22%, 58% total exposure respectively) and for schoolchildren (22%, 57% total exposure respectively).

The dietary model assumes that benzoates are used exclusively in all the products in each food class for which the permission is given. In reality, this is not likely as many beverage products are preservative free (for example, kola drinks, lemonades, sports drinks, tetra-pak juices and fruit juice drinks), with the possible exceptions of some minor brands. The dietary model did account for no preservatives in kola type drinks but assumed all other soft drinks, juices and juice drinks contained benzoates. Market data (Annual Report of the Retail World, December 1997) indicate that kola type drinks and lemonade make up 63% soft drink market (53% kola drinks, 10% lemonade). The proportion of fruit juice products packed in vacuum or tetra-paks that contain no preservatives is also high, with cordials being the major product containing preservatives.

In addition to market share considerations, alternative preservatives, such as sulphites, may be used instead of benzoates in soft drinks or as a mixture in cordials. Likewise in food products, a mixture of preservatives or alternatives are also used. Consequently benzoate dietary exposures will be much lower than estimated.

Outcome: in reality, it is considered that benzoates dietary exposures are not likely to exceed the ADI, given current patterns of use.

3. Sulphites (220, 221-225, 228)

Sulphur dioxide, sodium and potassium sulphite, bisulphite and metabisulphite are preservatives with a wide range of permissions in foods and beverages, used mainly to inhibit browning of foods and drinks. Sodium metabisulphite is also used as a flour treatment agent. The refined dietary model substitutes mean industry use levels for some food classes using data provided by the food and beverage industry (ice confection, peeled fruits & veg 0 mg/kg, apples for manufacturing purposes 50 mg/kg, fruit & veg spreads 50 mg/kg, candied fruit & veg 280 mg/kg, fruit & veg prep incl pulp 67 mg/kg, dried mashed potato 400 mg/kg, confectionery products, icings & frostings 2 mg/kg, flour products mg/kg, animal products 300 mg/kg, sugars & syrups 300 mg/kg, vegetable protein products 200 mg/kg, fruit & veg juices 155 mg/kg, soft drinks except kola type drinks 230 mg/kg, fruit wines 117 mg/kg, dressings, mayonnaise and sauces 0 mg/kg mg/kg).

Results indicate that estimated dietary exposures exceed the ADI of 0.7 mg/kg bw for all adults and schoolchildren (162% ADI adult mean consumer, 518% ADI adult high consumers), 270% ADI child mean consumer, 1019% ADI child high consumer).

The main contributors to sulphites dietary exposures from the dietary model were dried fruit & vegetables and soft drinks for adults (35%, 18% total exposure respectively) and for schoolchildren dried fruit & vegetables, fruit and vegetable juices and soft drinks (21%, 17% 38% total exposure respectively).

Sulphites are in some ways unique additives, in that the level of use typically does not reflect the level remaining in the foods at the time of ingestion, due to losses during processing and storage of treated foods. For example, dried vegetables may contain up to 3000 mg/kg sulphites but if rehydrated and cooked prior to ingestion the actual level of sulphite consumed will be much lower. Consequently dietary exposure estimates do not reflect the residual level of sulphites in foods 'as consumed' and will overestimate actual dietary exposures. For some sensitive individuals, acute effects of sulphites from a single meal may also be of concern. The adverse effects of sulphites (idiosyncratic intolerance) appear to be related to 'dose', that is, the amount of sulphites ingested at any point in time. The issue of sensitive individuals has not been considered in dietary modelling for chronic exposures to sulphites. The twenty-seventh meeting of JECFA expressed a view that appropriate labelling is the only means of protecting individuals who cannot tolerate certain food additives.

The dietary model assumes that sulphites are used exclusively in all the products in each food class for which the permission is given. In reality, this is not likely as many beverage products are preservative free (for example, kola drinks, lemonades, sports drinks, tetra-pak juices and fruit juice drinks), with the possible exceptions of some minor brands. The dietary model did account for no preservatives in kola type drinks but assumed all other soft drinks, juices and juice drinks contained sulphites. Market data (Annual Report of the Retail World, December 1997) indicate that kola type drinks and lemonade make up 63% soft drink market (53% kola drinks, 10% lemonade). The proportion of fruit juice products packed in vacuum- packed or tetra-paks that contain no preservatives is also high, with cordials being the major product containing preservatives. The assignment of a sulphite value to all fruit and vegetable juice and juice products will therefore result in an overestimate of dietary exposure

In addition to market share considerations, alternative preservatives, such as benzoates, may be used instead of sulphites in soft drinks or as a mixture in cordials. Likewise in food products, a mixture of preservatives or alternatives are also used. Consequently, assumptions in the dietary model tend to overestimate sulphite dietary exposures and because losses during processing and preparation are not accounted for estimated dietary exposures are considerably higher than actual exposures.

Outcome: in reality, it is considered that sulphite dietary exposures may not exceed the ADI, but in view of the higher potential risk for schoolchildren and high consumers of the additive, industry should be encouraged to use GMP levels at all times. Where suitable alternative methods of preservation exist, sulphur dioxide and sulphites should be replaced. Appropriate labelling would help to alert individuals who cannot tolerate sulphites of their use in specific food products.

4. Nisin (234)

Nisin is a preservative permitted in a limited range of foods at GMP, with specific permissions for modified cream products and hotplate products given in P150. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (processed cheese 12.5 mg/kg, hotplate products 2.5 mg/kg, beer 0 mg/kg and an EU level for fat based dips of 3 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI of 0.05 mg/kg bw for adults or child respondents or high consumers of the additive (8% ADI adult mean consumer, 25% ADI adult high consumers; 12% ADI child mean consumer, 36% ADI child high consumer).

The main contributors to nisin dietary exposures from the dietary model were modified cream products and processed cheese for adults (53%, 42% total exposure respectively) and modified cream products, processed cheese and hotplate products for schoolchildren (18%, 74%, 8% total exposure respectively).

Outcome: nisin is considered to be of no further concern, given current patterns of use. It should be noted that there are two very different ADIs published for nisin. The US FDA use an ADI for nisin of 0.05 mg/kg bw which is much lower than the JECFA ADI of 0.825 mg/kg bw for nisin, set in 1968. The ANZFA evaluations have used the lower, more conservative ADI which therefore provides a large margin of safety.

5. Nitrites (249, 250)

Nitrites are preservatives and colour fixatives, permitted in a limited number of processed meat products. The refined dietary model substitutes industry use levels for these food classes using data provided by the food industry (processed meat, whole cuts 50 mg/kg, fresh sausages 0 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for nitrites of 0.06 mg/kg bw for all adult mean consumers of the additive (94% ADI) but do exceed the ADI for high consumers (354% ADI). The ADI is exceeded by schoolchildren at a mean and high consumer level (106% ADI, 385% ADI respectively).

The main contributor to nitrite dietary exposure from the dietary model was processed comminuted meat & products for both adults and schoolchildren (69%, 75% total exposure respectively).

However, the dietary model assumes that nitrite is used exclusively in all the products in each food class for which the permission is given (except fresh sausages). In reality, this is not likely as some products are preservative free and consequently dietary exposures will be lower than estimated.

Outcome: In reality, it is considered that nitrite dietary exposures may not exceed the ADI, but in view of the higher potential risk for schoolchildren and high consumers of the additive, risk minimisation options have been considered. It is proposed to restrict the permission for nitrite use to very specific processed meat products (see proposed draft P150).

6. Sodium diacetate (262ii)

Sodium diacetate is a food acid permitted specifically in fresh poultry at 5000 mg/kg and also in a wide variety of foods and beverages at GMP according to Schedule 2 permissions. The refined dietary model substitutes industry use levels for these food classes using data provided by the food industry. Market share data for fresh poultry

has also been considered in the refined model. (Sodium diacetate is assumed to be used at 0 mg/kg beverages, 5000 mg/kg in hotplate products, 12000 mg/kg fancy breads, and 5000 mg/kg in fresh poultry. The dietary model accounted for the use of the additive in a maximum of 5% of all fresh poultry).

Results indicate that estimated dietary exposures do not exceed the ADI for sodium diacetate of 15 mg/kg bw for mean adult consumers (27% ADI), but does exceed the ADI for high consumers (128% ADI). For schoolchildren estimated dietary exposures are lower than the ADI for mean consumers but exceed the ADI for high consumers (50% ADI and 200% ADI respectively).

The major contributor to dietary exposure for sodium diacetate exposure from the dietary model was fancy breads for adults and schoolchildren (80% and 78% total exposure respectively).

However, the dietary model assumes that sodium diacetate is used exclusively in all the products in each food class for which the permission is given, however this known not to be the case. The permission for hotplate products relates only to crumpets which is a small proportion of the whole category. Likewise for fancy breads the permission is related to muffins only. Sodium diacetate may be used in plain bread at very low levels, but use level data were not provided by the food industry. There is also a wide range of food acids apart from sodium diacetate that are used to achieve the same technological function in these product categories. Consequently dietary exposure assessments will overestimate actual dietary exposure because models assume exclusive use of the additive in all product categories.

Outcome: n reality, it is considered that sodium diacetate dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

7. Phosphates (338-341, 450-452, 542)

The phosphates have been treated as one group for the purposes of dietary modelling, combining specific permissions for different forms of phosphates. In all cases the highest permission or level of use in any one product category was selected in the dietary model as a 'worst case scenario'. Phosphoric acid is a food acid; sodium, potassium, calcium, ammonium and magnesium phosphates, sodium and potassium pyrophosphates, triphosphates, metaphosphates, polymeta-phosphates and polyphosphates are mineral salts; and bone phosphate is used as an anti-caking agent. Phosphates are permitted in a wide variety of foods and beverages.

The refined dietary model substitutes mean industry use levels for some food classes using data provided by the food industry (phosphates are assumed to be used in flavoured milks at 500 mg/kg beverages, cream products 6000 mg/kg, processed cheese 30000 mg/kg, hotplate products 6000 mg/kg biscuits, cakes & pastries 3000 mg/kg, fresh fish & products 1300 mg/kg, processed fish & products, fully preserved fish & products 2200 mg/kg, salt & salt substitutes 20000 mg/kg, fruit & veg juices 880 mg/kg, soft drinks 0 mg/kg except kola type drinks at 570 mg/kg, wines 400 mg/kg and fat based dips 20000 mg/kg).

Results indicate that estimated dietary exposures do not exceed the MTDI for phosphates of 70 mg/kg bw for any consumer (10% MTDI adult mean consumers,

30% MTDI adult high consumers, 10% MTDI child mean consumers, 31% MTDI child high consumer).

The major contributor to dietary exposure for phosphates exposure from the dietary model for adults were processed cheese, biscuits, cakes & pastries and fruit & vegetable juices & products (29%, 32% and 13% respectively) and the same for schoolchildren (34%, 23% and 27% total exposure respectively).

The dietary model indicates that dietary exposure to phosphates do not exceed the MTDI, in fact actual dietary exposures will be lower than this estimate. The dietary model assumes that phosphates are used exclusively in all the products in each food class for which the permission is given, however this is not likely. There are also a wide range of mineral salts and anti-caking agents apart from phosphates that are used to achieve the same technological function in these product categories.

Outcome: in reality, it is considered that phosphates dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

8. Adipates (355, 357)

Adipates are food acids permitted specifically in salt and salt substitutes at GMP, and also in a wide variety of foods and beverages at GMP according to Schedule 2 permissions. For refined modelling, information was obtained from the food industry to the effect that adipates are not widely used (apart from salt and salt substitutes and desserts 2000 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for adipates of 5 mg/kg bw for adult mean consumers (76% ADI), but do exceed the ADI for high consumers (172% ADI). For schoolchildren the ADI is exceeded by both mean and high consumers (166% ADI, 446% ADI respectively).

The contributors to dietary exposure for adipates exposure from the dietary model for adults were desserts, non-dairy (66%) and dairy (34%). A reverse pattern was found for schoolchildren (non-dairy desserts 34%, dairy dessert 66%). As there are no food consumption data for salt or salt substitutes, and the use of adipates is very limited, a reverse budget method model was used to calculate how much salt or salt substitute alone could be consumed before the ADI was exceeded. The calculated limit was 13 g/day for males, 10 g/day for females and 8 g/day for a child (10-15 years old). It is considered unlikely that this limit would be exceeded by consumers of added salt or salt substitutes on a daily basis over a lifetime.

The dietary model assumes that adipates are used exclusively in all the products in each food class for which the permission is given. In reality, it is recognised that there are a wide range of food acids apart from adipates that achieve the same technological function that may be used as alternatives in both salt/salt substitutes and desserts. Adipates are expensive and is used in a limited number of desserts as an alternative to fumaric acid only where a low acidity is required. The list of desserts used in the dietary model was extensive, whereas adipates are used in some jelly and dessert mixes only. Dietary exposures will therefore be considerably lower than estimated.

Outcome: in reality, it is considered that adipates dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use. However, if the

range of use was extended to other foods in the future, risk management options may need to be reviewed.

9. Sucrose esters of fatty acids (473)

Sucrose esters of fatty acids are emulsifiers permitted in a wide range of foods and beverages. The refined dietary model substitutes industry use levels for several food classes using data provided by the food and beverage industry (margarine & fat emulsions 10000 mg/kg, chewing gum, biscuits, cakes and pastries 10000 mg/kg, flavoured milk & products, sugar based confectionery, processed meats, dietetic foods, wine based drinks, spirits & liqueurs, dairy & non-dairy desserts 5000 mg/kg, coffee, tea & substitutes 1000 mg/kg, fat based dips 20000 mg/kg, sauces 10000 mg/kg and soups 2000 mg/kg).

Results indicate that estimated dietary exposures exceed the ADI of 30 mg/kg bw for adults (101% ADI adult mean consumer, 208% ADI adult high consumers), and schoolchildren (111% ADI child mean consumer, 290% ADI child high consumer).

The main contributors to polyglycerol esters of fatty acids dietary exposures from the dietary model were biscuits, cakes & pastries and coffee, tea beverages for adults (22%, 46% total exposure respectively) and flavoured milks, ice cream & edible ices and biscuits, cakes & pastries, for schoolchildren (13%, 13%, 29% total exposure respectively).

However, the dietary model assumes that sucrose esters of fatty acids are used exclusively in all the products in each food class for which permission is given. The dietary model includes a wide range of foods and beverages, not all of which will use sucrose esters of fatty acids because there are many other emulsifiers that achieve the same technological function. In addition, only some of the products in each food class will contain emulsifiers. Dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that sucrose esters of fatty acids dietary exposures are not likely to exceed the ADI, given current patterns of use.

10. Polyglycerol esters of fatty acids (475)

Polyglycerol esters of fatty acids are emulsifiers permitted in a limited number of fat-based products. The refined dietary model substitutes industry use levels for one food class using data provided by the food and beverage industry (biscuits, cakes and pastries 2000 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI of 25 mg/kg bw for adult respondents or high consumers of the additive (24% ADI adult mean consumer, 78% ADI adult high consumers), but estimated dietary exposures do exceed the ADI for schoolchildren (106% ADI child mean consumer, 196% ADI child high consumer).

The main contributors to polyglycerol esters of fatty acids dietary exposures from the dietary model were biscuits, cakes & pastries and sauces for adults (25%, 29% total exposure respectively) and confectionery, biscuits, cakes & pastries, and sauces for schoolchildren (18%, 17%, 45% total exposure respectively).

However, the dietary model assumes that polyglycerol esters of fatty acids are used exclusively in all the products in each food class for which permission is given. In

reality, this will not be the case as there are many other emulsifiers that achieve the same technological function. In addition, not all products in each food class will contain emulsifiers. Dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that polyglycerol esters of fatty acids dietary exposures are not likely to exceed the ADI, given current patterns of use.

11. Polyglycerol esters of interesterified ricinoleic acids (476)

Polyglycerol esters of interesterified ricinoleic acids are emulsifiers permitted in a limited number of fat-based products. The refined dietary model substitutes industry use levels for one food class using data provided by the food and beverage industry (cocoa and chocolate products 3600 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI of 7.5 mg/kg bw for adult respondents or high consumers of the additive (30% ADI adult mean consumer, 87% ADI adult high consumers). Estimated dietary exposures are lower than the ADI for schoolchildren who are mean consumers but just exceed the ADI for schoolchildren who are high consumers (41% ADI child mean consumer, 104% ADI child high consumer).

The main contributor to polyglycerol esters of interesterified ricinoleic acids dietary exposures from the dietary model was margarines (50% total exposure for adults, 54% total exposure for schoolchildren).

However, the dietary model assumes that polyglycerol esters of interesterified ricinoleic acids are used exclusively in all the products in each food class for which permission is given. In reality, this will not be the case as there are many other emulsifiers that achieve the same technological function. Dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that polyglycerol esters of interesterified ricinoleic acids dietary exposures are not likely to exceed the ADI and the additive is of no further concern, given current patterns of use.

12. Dioctyl sodium sulphosuccinate (480)

Dioctyl sodium sulphosuccinate is an emulsifier, permitted in a limited number of non-alcoholic beverages. The refined dietary model substitutes industry use levels for one food class using data provided by the food and beverage industry (water based flavoured drinks 5 mg/kg). In addition, the dietary model takes into account the fact that dioctyl sodium sulphosuccinate use is restricted to cloudy beverages such as orange and lemon flavours (assumed maximum 30% market).

Results indicate that estimated dietary exposures do not exceed the ADI of 0.1 mg/kg bw for adult respondents or high consumers of the additive (17% ADI adult mean consumer, 58% ADI adult high consumers). Estimated dietary exposures are lower than the ADI for schoolchildren who are mean consumers but exceed the ADI for schoolchildren who are high consumers (43% ADI child mean consumer, 136% ADI child high consumer).

The main contributor to dioctyl sodium sulphosuccinate dietary exposure from the dietary model was fruit & vegetable juice products (64% total exposure for adults, 75% total exposure for schoolchildren).

However, the dietary model assumes that dioctyl sodium sulphosuccinate is used exclusively in all the products in each food class for which permission is given. In reality, this will not be the case as emulsifiers may not be used in all products and sucrose acetate isobutrate (emulsifier) may be used instead of dioctyl sodium sulphosuccinate in non-alcoholic beverages. Dietary exposures will consequently be lower than estimated.

Outcome: In reality, it is considered that dioctyl sodium sulphosuccinate dietary exposure is not likely to exceed the ADI and the additive is of no further concern, given current patterns of use.

13. Sodium aluminium phosphate (541)

Sodium aluminium phosphate is an acidity regulator and emulsifier, permitted specifically in baking compounds where it acts as a raising agent. The additive is used in conjunction with other raising agents, providing a raising effect at the end of the baking period. Sodium aluminium phosphate may be added to baking powders and some self-raising flours. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (hotplate products 6000 mg/kg, biscuits, cakes and pastries 3000 mg/kg). The model accounted for the fact that the additive is mainly used in cakes and not biscuits or pastries (47% product category).

Results indicate that estimated dietary exposures do not exceed the ADI[1] for sodium aluminium phosphate of 6 mg/kg bw for either adult mean or high consumers (28% ADI and 85% ADI respectively). For school children the ADI is only exceeded by high consumers (48% ADI mean consumers and 157% ADI high consumers).

The main contributor to sodium aluminium phosphate dietary exposure from the dietary model was biscuits, cakes & pastries (83% total exposure). For school children the major contributor was also biscuits, cakes & pastries (75% total exposure). However, the dietary model assumes that all the additive used as a raw ingredients will remain in the final product, as assumption that is not true for a raising agent. By definition, the additive is broken down during baking and reacts with soda to produce carbon dioxide which serves to raise the product. Providing the correct amount of sodium aluminium phosphate is used in the recipe, there will be no residual additive in the final product. In most cases, recipes are developed such that there is an excess of sodium bicarbonate in the final product, not the raising agent.

In addition, the additive will not be used in all products in the categories included in the dietary model. For example, the permission used for hotplate products is specifically for crumpets only, and not other products in this category such as pancakes and pikelets. Homemade produce may not contain sodium aluminium phosphate even as a raw ingredient. Dietary exposures will consequently be considerably lower than estimated.

Outcome: in reality, it is considered that sodium aluminium phosphate dietary exposures are not likely to exceed the ADI, given current patterns of use.

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[1] The ADI for sodium aluminium phospate is temporary (JECFA 1982) and is based on feeding studies in dogs and humans. In fact, no observable toxic level was observed in these studies; the ADI is derived from applying a safety factor of 200 to the highest feeding amount used in the dog studies (3% sodium aluminium phosphate in the diet).

14. Acesulphame potassium (950)

Acesulphame-K is an intense sweetener, permitted in a wide range of food and beverages at specified levels. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (maximum usage levels; flavoured liquid milk 310 mg/kg, modified fermented milk 300 mg/kg, confectionary 1200 mg/kg, table top sweeteners 5000 mg/kg, water based flavoured drinks 86 mg/kg, soft drinks 330 mg/kg, kola type drinks 50 mg/kg, electrolyte drinks 79 mg/kg, dairy desserts 800 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for acesulphame-K of 15 mg/kg bw for mean consuming adults (91% ADI), but do exceed the ADI for high consuming adults (214% ADI). For school children the ADI is met for the mean consumers (100% ADI), but exceeds the ADI for high consumers (312% ADI).

The main contributors to acesulphame-K dietary exposure from the dietary model for adults were coffee/coffee substitutes/tea and soup (51% and 18% total exposure respectively). The major contributors for school children were fruit & vegetable juice products and soup (37% and 16% total exposure respectively).

However, the dietary model assumes that acesulphame-K is used at a maximum level exclusively in all the products in each food class for which permission is given, including an assumption that all added sugar is replaced with a spoon-for-spoon sweetener at equivalent sweetness to sugar (5000 mg/kg). In reality, this is not the case as intense sweeteners are not used in all products in each category. For example, only 25% soft drink products were reported in 1994 to be consumed as low joule products, as were 11% cordial drinks, 7% flavoured milks, 38% flavoured yoghurts, 6% jams, 26% jelly and 51% chewing gum (ANZFA 1995). Fruit and vegetable juice products were not included in the 1994 survey, but again only a small proportion of these products contain intense sweeteners. There are also several alternative intense sweeteners used in low joule products. Acesulphame-K is currently used in very few products in the Australian and New Zealand markets and is often used in combination with another intense sweeteners to achieve a synergistic effect. Dietary exposures will consequently be very much lower than estimated.

The 1994 Authority survey of intense sweetener consumption, using information based on brand and flavour of low joule products, indicated that actual dietary exposure to acesulphame-K was very low (1% ADI mean consumer, 3% ADI 90th percentile consumer).

Outcome: in reality, it is considered that acesulphame-K dietary exposures are not likely to exceed the ADI, given current patterns of use. However, if the range of use is extended to other foods in the future, risk management options may need to be reviewed.

15. Cyclamate (952)

Cyclamate is an intense sweetener, permitted in a restricted range of food and beverages at specified levels. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (mean levels; sterile fruits & vegetables in sealed containers 500 mg/kg, confectionary < 50 % sugar incl toppings 3390 mg/kg, spoon for spoon and table top

sweeteners 0 mg/kg, water based flavoured drinks 706 mg/kg, soft drinks 833 mg/kg, kola type drinks 733 mg/kg, desserts, non-dairy incl jelly 507 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for cyclamate of 11 mg/kg bw for mean or high consuming adults (24% ADI, 85% ADI respectively), or for child mean consumers (58% ADI) but do exceed the ADI for high consuming children (168% ADI).

The main contributors to cyclamate dietary exposure for adults from the dietary model were soft drinks and soup (29% and 33% total exposure respectively). The major contributors for school children were soft drinks, kola type drinks and soup (43% and 12%, 13 % total exposure respectively).

The dietary model assumes that cyclamates are used exclusively in all the products in each food class for which permission is given. In reality this is not true for all product categories. For example, only 25% soft drink products were reported in 1994 to be consumed as low joule products, as were 11% cordial drinks, 7% flavoured milks, 38% flavoured yoghurts, 6% jams, 26% jelly and 51% chewing gum (ANZFA 1995). However, cyclamates may always be used in some low joule product categories, for example in cordials and jelly. Although proposed for use in soup, spoon for spoon and table top sweeteners, cyclamate is not currently used in these product categories. In the soft drink category, cyclamate and saccharin are rarely used, especially by the major brands. Cyclamate is normally used in combination with saccharin in cordials and soft drinks to achieve a synergistic effect, which has been taken into account in the additive levels used in the dietary models.

The 1994 Authority survey of intense sweetener consumption, using information based on brand and flavour of low joule products, indicated that actual dietary exposure to cyclamate was below the ADI for mean consumers but exceeded the ADI for high consumers (23% ADI mean consumer, 107% ADI 90th percentile consumer). In this survey, cordial was the main contributor to cyclamate dietary exposures. Results show that it is possible for high consumers of a cordial, containing 830 mg/kg cyclamate, to exceed the ADI for cyclamate. For example Aboriginal and Torres Strait Islander consumers reported mean daily consumption of cordial of 1275 mL/day, resulting in the ADI for cyclamate being exceeded from this product alone.

It is proposed in P150 to restrict permitted levels of cyclamate in all non-alcoholic beverages; the lower levels proposed means that cyclamate will have to be used in conjunction with other sweeteners to achieve desired sweetness levels. Revised dietary models using the proposed levels rather than current levels of use combined with no use assumed in soup or table top sweeteners, indicate that the ADI would not be exceeded by any adult consumers (mean consumers 12% ADI, high consumers 45% ADI) or child mean consumer (36% ADI) but may be by a child high consumer (102% ADI).

Outcome: in reality, it is considered that cyclamate dietary exposures may exceed the ADI for high consumers of specified products, given current patterns of use and current permissions. However, if cyclamate use was restricted to the proposed categories of use, with the permissions for soup, spoon-for-spoon and other table-top sweeteners deleted, then there would be less cause for concern. The food and beverage industry should be encouraged to phase out extensive use of this sweetener in the future, particularly in cordials, soft drinks and fruit juice drinks.

16. Saccharin (954)

Saccharin is an intense sweetener, permitted in a restricted range of food and beverages at specified levels. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (mean levels; sterile fruits & vegetables in sealed containers 40 mg/kg, fruit & veg spreads 285 mg/kg, confectionary < 50 % sugar incl toppings 231 mg/kg, spoon for spoon 0 mg/kg, pure saccharin table top sweeteners 348000 mg/kg, water based flavoured drinks 51 mg/kg, soft drinks 95 mg/kg, kola type drinks 80 mg/kg, desserts, non-dairy incl jelly 37 mg/kg, sauces 270 mg/kg, soup 167 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for saccharin of 5 mg/kg bw for adult mean consumers (38% ADI) but do just exceed the ADI for adult high consumers (104% ADI respectively). Dietary exposures for all children are below the ADI (child mean consumers 20% ADI, high consumers 52% ADI). Differences in dietary exposures between adults and schoolchildren are explained by the higher consumption of tabletop sweeteners by adults.

The main contributors to saccharin dietary exposure for adults from the dietary model were table top sweeteners, soup and soft drinks (80%, 7% and 5% total exposure respectively). The major contributors for school children were soft drinks, kola type drinks, tabletop sweeteners and soup (31%, 8%, 14% and 14% total exposure respectively).

The dietary model assumes that saccharin is used exclusively in all the products in each food class for which permission is given. In reality this is not true for all product categories. For example, only 25% soft drink products were reported in 1994 to be consumed as low joule products, as were 11% cordial drinks, 7% flavoured milks, 38% flavoured yoghurts, 6% jams, 26% jelly and 51% chewing gum (ANZFA 1995).

However, saccharin may always be the sweetener used in some low joule product categories, for example in cordials, jelly and soup. Although proposed for use in spoon for spoon sweeteners, saccharin is not currently used in this product categories. In the soft drink category, cyclamate and saccharin are rarely used, especially by the major brands. Saccharin is normally used in combination with cyclamate in cordials and soft drinks to achieve a synergistic effect, which has been taken into account in the additive levels used in the dietary models.

The 1994 Authority survey of intense sweetener consumption, using information based on brand and flavour of low joule products, indicated that actual dietary exposure to saccharin was below the ADI for all consumers (9% ADI mean consumer, 56% ADI 90th percentile consumer). In this survey, table top sweeteners and cordial was the main contributors to saccharin dietary exposures. Results show that it is not likely that high consumers of either product category alone will exceed the ADI for saccharin from consumption of these products alone; for example over 30 pure saccharin tabletop tablets or over 5 litres of cordial would need to be consumed by a 71 kg adult to exceed the ADI (equivalent of over 20 pure saccharin tablets or 3.3 litres cordial per day for a 46 kg child).

Dietary models that assume saccharin can also be used in spoon-for-spoon sweeteners as a replacement for added sugars (3333 mg/kg saccharin) indicate that many more adults would have dietary exposures to saccharin that potentially exceed the ADI (adult mean consumer 59% ADI, adult high consumers 164% ADI) though

predicted dietary exposures for children would still be below the ADI (child mean consumer 38% ADI, child high consumer 94% ADI).

Outcome: in reality, it is considered that saccharin dietary exposures are not likely to exceed the ADI, with the exception of very high consumers of tabletop saccharin based sweeteners. However, if saccharin use was extended to spoon-for-spoon, then there would be cause for concern. A potential option for reducing the risk for consumers of tabletop sweeteners of exceeding the ADI is the voluntary labelling of these products to the effect that excess consumption is not desirable. This option has been followed in the UK, with wide use of the voluntary warning statement on saccharin based tabletop sweeteners.

17. Alitame (956)

Alitame is an intense sweetener, permitted in a wide range of food and beverages at specified levels. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (maximum usage levels; chewing gum 250 mg/kg, tabletop sweeteners 500 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for alitame of 1 mg/kg bw for mean consuming adults (53% ADI), but do exceed the ADI for high consuming adults (135% ADI). For school children the ADI is exceeded for both the mean and high consumers (105% ADI and 235% ADI respectively).

The main contributor to alitame dietary exposure from the dietary model for adults were biscuits, cakes & pastries (26% total exposure). The major contributors for school children were biscuits, cakes & pastries, soft drinks and confectionary (19%, 12% and 11% total exposure respectively).

However, the dietary model assumes that alitame is used at a maximum level exclusively in all the products in each food class for which permission is given (sweetener at equivalent sweetness to sugar of 500 mg/kg). In reality, this is not the case as intense sweeteners are not used in all products in each category. For example, only 25% soft drink products were reported in 1994 to be consumed as low joule products, as were 11% cordial drinks, 7% flavoured milks, 38% flavoured yoghurts, 6% jams, 26% jelly and 51% chewing gum (ANZFA 1995). There are also several alternative intense sweeteners used in low joule products. Alitame is currently used in only one or two products in the Australian and New Zealand markets and is often used in combination with another intense sweeteners to achieve a synergistic effect. Dietary exposures will consequently be very much lower than estimated.

The 1994 Authority survey of intense sweetener consumption, using information based on the brand and flavour of low joule products, indicated that alitame was not consumed by any person in the survey.

Outcome: in reality, it is considered that alitame dietary exposures are not likely to exceed the ADI, given current patterns of use. However, if the range of use was extended to other foods in the future, risk management options may need to be reviewed.

18. Propylene glycol (1520)

Propylene glycol is a humectant, permitted specifically in surface treated fruits and vegetables and desiccated coconut at levels specified in P150. It is also allowed in a wide variety of foods and beverages at GMP according to Schedule 2 permissions. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (0 mg/kg surface treated fruit and vegetables but 30000 mg/kg fruit salads, 400 mg/kg ice confection, 4000 mg/kg beverage whitener).

Results from dietary models that assume the additive is used on all surface treated fruit and vegetables indicate that estimated dietary exposures exceed the ADI for propylene glycol of 25 mg/kg for both mean and high consuming adults (389% ADI and 1125% ADI respectively). For school children, the ADI is also exceeded for mean and high consumers (406% ADI and 1096% ADI respectively). However, it is considered unlikely that propylene glycol is used on surface treated fruits and vegetables (apples, pears, citrus, walnuts), it's major use being on packed (not home prepared) fruit salads, or desiccated coconut (mainly imported products). Dietary models that take this limited use in fruit and vegetables into account result in much lower dietary exposures for adults and children (<6% ADI all consumers).

The main contributor to propylene glycol dietary exposure from the revised dietary model for adults and schoolchildren was fruit salad (91%, 84% of total exposure respectively).

The dietary model assumes that propylene glycol is used exclusively in all the products in each food class for which permission is given. In reality, this will not be the case, and there are many other humectants that may be used that achieve the same technological function. However, propylene glycol is allowed in a wide range of foods and beverages, but residual amounts in the final food are negligible. It is used in the oil refining business (eg. in shortening) as a reagent to produce propylene glycol fatty acid esters, however, there is no propylene glycol remaining in the final product. It is also used extensively in the flavour industry, which may result in carry over to many food and beverage products, as is the case for the ice confection, though in these cases, the resultant amount of additive carried over will be very low. Dietary models for propylene glycol will therefore tend to overestimate potential exposure.

Outcome: dietary models that assume that propylene glycol is used on surface treated fruits and vegetables result in estimated dietary exposures that exceed that ADI for all consumers. In reality, it is considered that propylene glycol dietary exposures may not exceed the ADI, but in view of the higher potential risk for schoolchildren and high consumers of the additive, risk minimisation options should be considered. Restriction of permissions for fruit and vegetables to 4.1.3 fruit salads only would considerably lower the potential risk of exceeding the ADI.

Schedule 2 (1 additive):

19. Fumarates (365-368)

Sodium, potassium, calcium and ammonium fumarates are food acids, permitted in a wide range of foods and beverages. The refined dietary model substitutes industry

use levels for some food classes using data provided by the food and beverage industry, along with values from the current Australian Food Standards Code and the EU (not used in confectionery, chewing gum; 1500 mg/kg dairy desserts). Account was also taken of the fact that fumarates are only used in grape/cherry water based flavoured drinks (1% market) and in coffee substitutes (1% tea & coffee market). Results indicate that estimated dietary exposures do not exceed the ADI for fumarates of 6 mg/kg bw for adults mean consumers (36% ADI) but do exceed the ADI for high consumers (128% ADI). A similar pattern was found for school children (mean consumers 35% ADI, high consumers 290% ADI).

The main contributors to fumarates dietary exposure from the dietary model for adults were biscuits, cakes & pastries, and dairy desserts (78% and 9% of total dietary exposure respectively). For schoolchildren, the main contributors to dietary exposure were the same food categories but in different proportions (biscuits, cakes & pastries 59%, dairy desserts 33% of total exposure).

However, the dietary model assumes that fumarates are used exclusively in all the products in each food class for which permission is given. In reality, this will not be the case as food acids may not always be used in all products and alternative food acids may be used instead of fumarates in many foods. Dietary exposures will consequently be much lower than estimated.

Outcome:: in reality, it is considered that fumarates dietary exposure is not likely to exceed the ADI and the additive is of no further concern, given current patterns of use.

Schedule 3 (2 additives):

20. Riboflavin (101)

Riboflavin is a yellow colouring, permitted in a wide variety of foods and beverages and a vitamin, that may also be added to foods specified in Standard A9 Vitamins and Minerals. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry, along with values from the current Australian Food Standards Code. (Riboflavin is not used in sugar based confectionary, processed, semi preserved and fully preserved fish, and water based flavoured drinks; dried milk 2 mg/kg, processed fruit & vegetables 2.6 mg/kg, flour 11.4 mg/kg, processed cereals including breakfast cereals 11.4 mg/kg, flour & flour products from 11.4-20 mg/kg, breads 8 mg/kg, biscuits, cakes & pastries 42.5 mg/kg yeast & yeast products 86 mg/kg, mixed foods 50 mg/kg).

Results (when the higher level of 20 mg/kg for flour products is used in the model, in order to assume a worst case scenario) indicate that estimated dietary exposures do not exceed the ADI for riboflavin of 0.5 mg/kg bw for all adults both mean and high consumers (24% ADI and 79% ADI respectively). For school children estimated dietary exposures are lower than the ADI for mean consumers (43% ADI) but exceed the ADI for high consumers (128% ADI). The difference between the two levels modelled for flour products only changed estimated dietary exposures by <1% ADI.

The main contributors to riboflavin dietary exposure from the dietary model for adults were mixed foods, biscuits, cakes & pastries, and breads and related products (60%, 24% and 10% of total dietary exposure respectively). For schoolchildren, the main

contributors to dietary exposure were the same as for adults, at 64%, 19% and 8% of total exposure.
However, the dietary model assumes that riboflavin is used exclusively in all the products in each food class for which permission is given. Where riboflavin is used as a colouring, its actual use will be restricted within each food class to those products requiring a yellow colour. Riboflavin is an expensive additive, therefore its use as yellow colour is likely to be limited, particularly when alternative cheaper food additives could be used to achieve the same result. Due to these reasons, dietary exposures will consequently be much lower than estimated. The above results do not take into consideration that riboflavin may potentially be used in a wide range of other foods and beverages at GMP. However, the food industry provided data for all known major uses of riboflavin in the current market.

Riboflavin is also present naturally in a range of foods, major food sources of riboflavin reported in the 1983 National Dietary Survey (NDS) were milk and milk products, meat, cereals and cereal products. Reported mean dietary exposures to riboflavin in the NDS were 2.27 mg/day for males (0.029 mg/kg bw/day) and 1.77 mg/day for females (0.027 mg/kg bw/day). Dietary models already account for riboflavin in cereal products. The addition of riboflavin from natural sources to total dietary exposures increases the estimated mean dietary exposure for all adults by a small amount (24% ADI to approximately 29% ADI).

Outcome: In reality, it is considered that riboflavin dietary exposure is not likely to exceed the ADI and the additive is of no further concern, given current patterns of use.

21. Iron oxides (172)

Iron oxides are colours, red, black and yellow, which are permitted in a wide variety of food and beverages at GMP, as specified in Schedule 3 (ADI 0.5 mg/kg bw). Dietary modelling could not be undertaken for this additive because no actual levels of use were obtained from the food industry. It is not currently permitted in Australia, and although it is permitted in New Zealand, no levels of usage were obtained from New Zealand manufacturers to allow for further modelling. However, as for all the colours, iron oxides will not be used in all products but only those requiring specific colours. As it is an expensive additive, its use as a red, black or yellow colour is also likely to be limited, with alternative cheaper food additives being used in preference.

Outcome: it is considered unlikely that actual dietary exposures of iron oxides will exceed the ADI for any consumer, given current patterns of use.

Schedule 4 (8 additives):

22. Sunset yellow (110)

Sunset yellow is a yellow colouring, permitted in a wide variety of foods and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (not used in modified fermented milks, dried milks, margarines or fat emulsions <80% oil, processed meats, table top sweeteners, yeast & yeast products, kola type drinks; ice-cream 5 mg/kg, ice confection 150 mg/kg, all confectionery 90 mg/kg, biscuits, cakes and pastries 20 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for sunset yellow of 2.5 mg/kg bw for adult mean consumers (45% ADI) but does just exceed the ADI for male high consumers (112% ADI). For schoolchildren the ADI is exceeded for mean consumers and high consumers respondents (103% ADI, 227% ADI respectively).
The main contributor to sunset yellow dietary exposure from the dietary model for adults were mixed foods and processed fruits & vegetables (48%, 17% total exposure respectively). For schoolchildren, water based flavoured drinks were also important contributors due to higher consumption levels of this food class than adults (57% total exposure for mixed foods, 8% for water based flavoured drinks except kola type, 7% processed fruits & vegetables).

However, the dietary model assumes that sunset yellow is used exclusively in all the products in each food class for which permission is given. As sunset yellow is a colouring, its actual use will be restricted within each food class to those products requiring a yellow colour and dietary exposures will consequently be much lower than estimated. There are also alternative yellow colours that may be used in these products.

Outcome: In reality, it is considered that sunset yellow dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

23. Azorubine (122)

Azorubine is a red colouring, permitted in a wide variety of food and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (not used in modified fermented milks, dried milks, margarines and fat emulsions <80% oil, processed meats, table top sweeteners, yeast and yeast products, kola type beverages; ice confection 80 mg/kg, biscuits, cakes and pastries 20 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for azorubine of 4 mg/kg bw for all adult mean and high consumers (27% ADI, 68% ADI respectively). For school children estimated dietary exposures are lower than the ADI for mean consumers (70% ADI) but exceed the ADI for high consumers (152% ADI).

The main contributors to azorubine dietary exposures from the dietary model for adults were mixed foods and processed fruits and vegetables (36% and 16% total exposure respectively). For schoolchildren, mixed foods and soft drinks were major contributors (57% total exposure for mixed foods, 8% for soft drinks).

However, the dietary model assumes that azorubine is used in all the products in each food class for which a permission is given. As azorubine is a colouring, its actual use will be restricted within each food class to those products requiring a red colour. Also, either azorubine or amaranth are used in a product, or occasionally as a mixture. Azorubine is used by major manufacturers, however makes up 50% of the foods azorubine or amaranth is used in. The above modelling results do not take this into consideration. Consequently dietary exposure to azorubine will be much lower than estimated.

Outcome: In reality, it is considered that azorubine dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

24. Amaranth (123)

Amaranth is a red colouring, permitted in a wide variety of food and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry. Market share data for some of the food products has also been considered in the refined model. For example, for the category of roe, amaranth will only be used in red roe which is assumed to be 50% of the roe market. Therefore, the permission level for roe was halved to incorporate this market share. (Amaranth is not used in dried milks, margarines and fat emulsions <80% oil, fresh roe, table top sweeteners, kola type beverages; 15 mg/kg for raspberry coloured confectionary, 145 mg/kg canned roe, 35 mg/kg for fruit and vegetable juice products, non-kola water based flavoured drinks, and spirits and liqueurs.)

Results indicate that estimated dietary exposures when using industry use levels and market share data exceed the ADI for amaranth of 0.5 mg/kg bw for all adult and child respondents (260% ADI, 592% ADI for mean level consumers respectively).

The main contributors to amaranth dietary exposures from the dietary model for adults were mixed foods, processed fruits and vegetables and biscuits, cakes and pastries (43%, 13% and 9% respectively). For schoolchildren, the major contributors to amaranth dietary exposure were mixed foods (53% total exposure) and ice cream and edible ices (8% of total exposure).

However, the dietary model assumes that amaranth is used in all the products in each food class for which a permission is given. As amaranth is a colouring, its actual use will be restricted within each food class to those products requiring a red colour. Amaranth is really only used for raspberry coloured foodstuffs, which constitute a very small proportion of total foods consumed. Even in these cases, either amaranth or azorubine are used, or a 50:50 mixture. Smaller manufacturers may use amaranth in preference to azorubine as it is more stable and easier to handle during processing. The above modelling results do not take these restricted uses into consideration, consequently dietary exposure to amaranth will be considerably lower than estimated.
Australian manufacturers also noted that they are decreasing their use of amaranth in foods as some export countries did not permit its use.

Outcome: in reality, it is considered that amaranth dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

25. Ponceau 4R (124)

Ponceau is a red colouring, permitted in a wide variety of food and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (not used in modified fermented milks, dried milks, margarines or fat emulsions <80% oil, processed meats, table top sweeteners, yeast & yeast products; 80 mg/kg ice confection, 20 mg/kg sugar based confectionary and biscuits cakes and pastries).

Results indicate that estimated dietary exposures do not exceed the ADI for ponceau of 4 mg/kg bw for all adult mean and high consumers (27% ADI and 68% ADI respectively). For schoolchildren estimated dietary exposures are lower than the ADI for mean consumers but exceed the ADI for high consumers respondents (68% ADI, 150% ADI respectively).

The main contributors to ponceau dietary exposures from the dietary model for adults were mixed foods and processed fruits and vegetables (52% and 16% of total dietary exposure respectively). For schoolchildren, the major contributors were mixed foods (58% exposure), soft drinks (non-kola) (8% exposure) and ice cream and edible ices (7% exposure).

However, the dietary model assumes that ponceau is used in all the products in each food class for which a permission is given. As ponceau is a colouring, its actual use will be restricted within each food class to those products requiring a red colour. Ponceau is not commonly used by industry but only in limited items when a bright red colour is required. There are alternative red colours that may be used in these products. Therefore, dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that ponceau dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

26. Indigotine (132)

Indigotine is a blue colouring, permitted in a wide variety of foods and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (not used in flavoured milks, modified fermented milks, dried milks, margarines or fat emulsions <80% oil, biscuits, cakes & pastries, processed meats, edible casings, tabletop sweeteners, yeast and yeast products, soft drinks and kola type drinks; ice confection at 80 mg/kg, and 5 mg/kg for sugar based confectionary).

Results indicate that estimated dietary exposures do not exceed the ADI for indigotine of 5 mg/kg bw for adult mean or high consumers (20% ADI, 52% ADI respectively). For schoolchildren estimated dietary exposures are lower than the ADI for mean consumers but exceed the ADI slightly for high consumers respondents (49% ADI, 110% ADI respectively).

In theory, the main contributor to indigotine dietary exposure from the dietary model for adults were mixed foods and processed fruits & vegetables (55% and 17% total exposure respectively). For school children the major contributors were mixed foods (65% total exposure), ice cream and edible ices (8%) and processed fruits & vegetables and processed cereal and meal products (both 7% of total exposure).

However, the dietary model assumes that indigotine is used in all the products in each food class for which a permission is given. As indigotine is a colouring, its actual use will be restricted within each food class to those products requiring a blue colour. In reality, indigotine is not commonly used by industry. In addition to this, there are few blue foods available, apart from some confectionary, ice cream and water based flavoured drinks. There are also alternative blue colours that may be used in these products. Therefore, dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that indigotine dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

27. Green S (142)

Green S is a colouring, permitted in a wide variety of foods and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (not used in flavoured milks, modified fermented milks, dried milks, margarines or fat emulsions <80% oil, fruit & vegetable spreads, flour products, biscuits, cakes & pastries, processed meats, processed & semi-& fully preserved fish, table top sweeteners, yeast & yeast products, kola type drinks; ice confection 80 mg/kg).

Results indicate that estimated dietary exposures do not exceed the ADI for green S of 5 mg/kg bw for adult mean or high consumers (20% ADI, 52% ADI respectively). For schoolchildren estimated dietary exposures are lower than the ADI for mean consumers but exceed the ADI for high consumers (52% ADI, 116% ADI respectively).

In theory, the main contributor to green S dietary exposure from the dietary model for adults were mixed foods and processed fruits & vegetables (48%, 15% total exposure respectively). For schoolchildren, water based flavoured drinks were also important contributors due to higher consumption levels of this food class than adults (56% total exposure for mixed foods, 8% for water based flavoured drinks except kola type, 7% ice cream).

However, the dietary model assumes that green S is used exclusively in all the products in each food class for which permission is give. In fact green S is used rarely as it is cheaper to use a mixture of blue and yellow colours. Is actual use is restricted to ice confection and confectionery food classes and to specific products within these classes requiring a bright green colour (eg coloured coatings to chocolate sweets). Even in these confectionery products, the proportion of green coated chocolates is small. Dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that green S dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

28. Brilliant black (151)

Brilliant black is a colouring, permitted in a wide variety of foods and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry. Market share data for one food product has also been considered in the refined model. This being for the category of roe, brilliant black will only be used in black roe which is assumed to be 50% of the roe market. Therefore, the permission level for roe was halved to incorporate this market share. (Brilliant black in not used in flavoured milks, modified fermented milk, dried milk, cheese and cheese products, margarines or fat emulsions <80% oil, ice confection, processed fruits and vegetables, processed meats, edible casings, fresh roe, tabletop sweeteners, yeast and yeast products and kola type drinks; 20 mg/kg in biscuits, cakes & pastries, 200 mg/kg canned roe.)

Results indicate that estimated dietary exposures when using industry use levels and market share data do not exceed the ADI for brilliant black of 1 mg/kg bw for adult mean consumers (85% ADI) but does exceed the ADI for high consumers (238% ADI). For schoolchildren the ADI is exceeded for both mean and high consumers (247% ADI and 560% ADI respectively).

The main contributors to dietary exposure to brilliant black from the dietary model for adults were mixed foods (66% total exposure) and ice cream & edible ices and soft drinks (non-kola) (both 7% total exposure). For schoolchildren the major contributors to dietary exposure were mixed foods, ice cream & edible ices and processed cereal and meal products (64%, 8% and 7% of total exposure respectively).

However, the dietary model assumes that brilliant black is used in all the products in each food class for which a permission is given. As brilliant black is a colouring, its actual use will be restricted within each food class to those products requiring a black or dark colour. In reality, there are few black foods available, though the colour may be used in low amounts to make a 'chocolate/brown' colour in cocoa and chocolate products and possibly ice creams and confection. Dietary exposures will consequently be much lower than estimated.

Outcome: in reality, it is considered that brilliant black dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.

29. Brown HT (155)

Brown HT is a colouring, permitted in a wide variety of foods and beverages. The refined dietary model substitutes industry use levels for some food classes using data provided by the food and beverage industry (not used in modified fermented milk, dried milk, margarines or fat emulsions <80% oil, processed fruits and vegetables, processed meats, tabletop sweeteners, yeast & yeast products and kola drinks; 100 mg/kg biscuits, cakes and pastries).
Results indicate that estimated dietary exposures do not exceed the ADI for brown HT of 1.5 mg/kg bw for adult mean consumers (60% ADI) but does exceed the ADI for high consumers (160% ADI). For schoolchildren the ADI is exceeded for both mean and high consumers (165% ADI and 365% ADI respectively).

The main contributors to dietary exposure to brown HT from the dietary model for adults were mixed foods, cheese & cheese products and soft drinks (non-kola) (62%, 8% and 6% total exposure respectively). For schoolchildren, the major contributors were mixed foods (64% total exposure), soft drinks (non-kola) (9% exposure) and processed cereal and meal products (6% total exposure).

However, the dietary model assumes that brown HT is used in all the products in each food class for which a permission is given. As brown HT is a colouring, its actual use will be restricted within each food class to those products requiring a brown or dark colour. There are also alternative brown colours which may be used by industry, such as caramel for example. Brown HT is known to be used in chocolate topping and flavoured milks. Dietary exposures will consequently be much lower than estimated.

Outcome: In reality, it is considered that brown HT dietary exposures are not likely to exceed the ADI for any consumer, given current patterns of use.