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Dr Howard Dengate
Food Intolerance Network
PO Box 718
WOOLGOOLGA NSW 2456

Dear Dr Dengate,

I am writing in response to a number of issues raised by you on behalf of the Food Intolerance Network (FIN) during communications with FSANZ. While some of these issues arose in relation to *Application A1136 - Glutaminase as Processing Aid*, there are others that were previously raised with FSANZ but were not acknowledged. The purpose of the current correspondence is to provide a consolidated response to these matters, with a view to ongoing engagement with FIN on these and other issues you consider are of public health concern.

Differences in the levels of additives in Australia compared to other countries

FSANZ is often asked to explain differences in food standards compared to other countries, including differences in the types and levels of additives used, and the categories of foods to which additives can be included. Generally, food standards can vary between countries because of differences in legislation, risk analysis (reflecting unique data sets such as dietary consumption data) and food production systems (i.e. use patterns, technology and climate).

It was previously noted that there are differences in the levels of some additives permitted in other countries such as the UK, where levels for sulphites, benzoates and Colour Brown HT (155) are lower than Australia. In addition to a consideration of public health and safety, the maximum permitted levels in the *Australia New Zealand Food Standards Code* (the Code) for these additives are commensurate with the amounts required to perform their technological purpose in foods, which may differ to levels needed in other parts of the world.

From time to time, FSANZ undertakes reviews of food standards to ensure they remain appropriate and continue to be supported by contemporary scientific information and reflect current food production practices. For example, sulphites and benzoates were the subject of *Proposal P298 - Benzoate and Sulphite Permissions*. The outcome of this proposal was the conclusion that there were no public health and safety concern and therefore existing permissions remained appropriate.

Labelling of processing aids

A processing aid is defined as a substance that performs a technological purpose in the course of food processing but does not perform a technological purpose in the food for sale. The Code specifically exempts processing aids from labelling unless they are protein engineered or contain novel DNA or novel protein (through genetic modification), or contain any of the listed food allergens as a result of their production processes or in their final form.

This labelling exemption does not preclude food manufacturers from voluntarily declaring the presence of a processing aid, such as an enzyme.

Not declaring processing aids in the statement of ingredients on product labels is consistent with labelling requirements internationally, including Codex and the European Union (EU) (Attachment 1).

5% labelling threshold for food ingredients

The Code states that when a compound ingredient is less than 5% of the final food, the ingredients that make up the compound ingredient are exempt from labelling unless:
- they are required to be listed in accordance with section 1.2.3—4 (Mandatory declarations of certain foods or substances in food), or
- the ingredient is a substance used as a food additive in the compound ingredient which performs a technological purpose in the food for sale.

The labelling exemption in the Code for food additive ingredients in a compound ingredient is consistent with the Codex General Standard for the Labelling of Pre-packaged Foods (Attachment 1). In the European Union, Article 20 of the EU Regulation No. 1169/2011 exempts food additives from the list of ingredients under similar conditions to the Food Standards Code and Codex (for example, when there is no technological function in the final food). However, the EU Regulation differs from the Food Standards Code and Codex in that it does not set a 5% threshold.

Differences in the approach to the regulation of 'natural alternatives' to propionate bread preservatives and glutamate flavour enhancers

The regulation of substances added to food is based on the purpose of those substances in the food for sale and whether they meet the definitions of those purposes specified in the Code. It is for this reason that some substances are specifically regulated as additives while others are considered ingredients.

For example, Schedule 14 of Standard 1.3.1 Food Additives, lists the technological purposes of food additives including "flavour enhancer" and "flavouring". The current forms of glutamate flavour enhancers prescribed in Schedule 16 fulfil the definition of a food additive and on that basis are explicitly regulated as such. There are six permitted single amino acid salts of glutamate flavour enhancers: L-glutamic acid (620), monosodium glutamate (621), monopotassium glutamate (622), calcium glutamate (623), monoammonium glutamate (624) and magnesium glutamate (625). Outside of these permissions for specific additive forms of glutamate, glutamates that occur naturally in foods or food ingredients are not specifically regulated by the Code

The claims 'No added MSG' and 'MSG free' are not regulated by the Code. These claims are subject to Australian Consumer Law and must not be misleading or deceptive. Claims about MSG should only relate to monosodium glutamate and not other permitted forms of glutamate.

Annatto (160b)

Schedule 15 of the Code currently permits Annatto extract between 10 and 100 ppm in various food. FSANZ is not aware that Annatto is being increasingly used by food manufacturers or that there has been an increase in complaints regarding reactions, including complaints made directly to FSANZ or via jurisdictions, or medical reports in the scientific literature.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated annatto extracts on a number of occasions (most recently in 2006) and concluded that extracts complying with relevant specifications do not raise safety concerns. The committee concluded that annatto extracts have been associated with occasional reports of hypersensitivity reactions, however when investigated in well-designed studies the incidence of reactions to annatto extract alone is small.

The European Food Safety Authority (EFSA) more recently (2016) concluded that the available data do not indicate a high allergenic potential of the annatto extracts used as food additives. EFSA noted that there is limited evidence of reactions to annatto extract despite widespread use in foods and that the incidence of reactions in double-blind placebo controlled clinical trials was very low. Where reactions were observed it was not always possible to clearly establish whether they were related to annatto extracts because mixtures of additives were used.

FSANZ has seen no evidence to dispute the findings of either JECFA or EFSA; however, if new evidence becomes available that alters these conclusions, FSANZ will review this new information at that time.

Ribonucleotide flavour enhancers

There are three ribonucleotide flavour enhancers permitted in Schedule 16 of the Code: disodium 5'-guanylate (627), disodium 5'-inosinate (631) and disodium 5'-ribonucleotides (635). It has been claimed that these additives were approved without sound scientific evidence and that there have been hundreds of complaints since they were approved. FSANZ is not aware of the details of these complaints, so it is not possible to comment without further scientific or clinical information. Indeed, a search of the peer-reviewed scientific literature using PubMed did not identify any experimental or clinical studies to indicate adverse reactions to these substances. The most recent JECFA evaluation of disodium 5'-guanylate and disodium 5'-inosinate (1993) concluded that dietary exposure to these substances is low relative to the intake of naturally occurring nucleotides.

FSANZ will continue to monitor the scientific literature on these substances and would appreciate being informed of any further experimental or clinical data that FIN becomes aware of.

In addition to the targeted discussion of issues arising in relation to specific applications to amend the Code, FSANZ would like to meet with you on a more regular basis to ensure we are more aware of, and responsive to, your network's concerns.

Yours Sincerely

Glen Neal
General Manager, Risk Management & Intelligence
30 April 2018

ATTACHMENT 1

Codex exemption for declaration of processing aids and some food additives

Codex General Standard for the Labelling of Pre-packaged Foods
Section 4.2 (List of ingredients)
Section 4.2.1.3

'Where an ingredient is itself the product of two or more ingredients, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion (m/m). Where a compound ingredient (for which a name has been established in a Codex standard or in national legislation) constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared.'

Section 4.2.4 (Processing aids and carry-over of food additives)
Section 4.2.4.2

A food additive carried over into foods at a level less than that required to achieve a technological function, and processing aids, are exempted from declaration in the list of ingredients. The exemption does not apply to food additives and processing aids listed in section 4.2.1.4.

Section 4.2.1.4 refers to allergens.

A. EU exemption for declaration of processing aids and some food additives

EU Regulation (EU) No. 1169/2011 on the provision of food information to consumers
Article 20 (Omission of constituents of food from the list of ingredients) exempts from the list of ingredients:

(b) Food additives and food enzymes:

- *(i) Whose presence in any given food is solely due to the fact that they were contained in one or more ingredients of that food, in accordance with the carry-over principle referred to in points (a) and (b) of Article 18(1) of Regulation (EC) No 1333/2008, provided that they serve no technological function in the finished product; or*
- *(ii) Which are used a processing aids*

(d) substances which are not food additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even in an altered form.

Regulation (EC) No 1333/2008 on Food Additives
Article 18 (Carry-over principle) states:

1. The presence of a food additive shall be permitted:

- *(a) in a compound food other than as referred to in Annex II, where the food additive is permitted in one of the ingredients of the compound food;*
- *(b) in a food to which a food additive, food enzyme or food flavouring has been added, where the food additive:*
  - *(i) is permitted in the food additive, food enzyme or food flavouring in accordance with this Regulation; and*
  - *(ii) has been carried over to the food via the food additive, food enzyme or food flavouring; and*
  - *(iii) has no technological function in the final food*

Yours sincerely

STAFF NAME
POSITION

Date 2011