SUBMISSION FROM SA HEALTH

24 March 2016

Proposal P1024 - Revision of the Regulation of Nutritive Substances & Novel Foods

The purpose of this Proposal is to develop an improved framework for the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (the Code). The following comments are split into two sections: a response to the questions contained in the paper relating to regulatory issues, and a proposed alternative option.

SA Health Response re: Regulator Interpretation, Implementation, Compliance and Enforcement View

Section 3.3

Currently the effect on SA Health is minimal as most relevant businesses are located in other states or territories. The spread of businesses in SA are mostly small-medium enterprises (SMEs) and the majority are in the food service category, not manufacturer or importer/distributor category. Despite this, the current definitions are vague as elements of the definition are can have a range of interpretations and thus the current provisions do not allow the ability to have a clear compliance strategy.

Section 4.2.1

The permitted list in is useful however is not extensive enough possibly due to a limited number of applications that have been sent to FSANZ. This could be due to the ambiguous definitions.

Section 4.2.2

As a complete option, amending the definitions is not sufficient to solving the ambiguity issue however support combining the definitions or eradicating the novel food definitions.

Section 4.2.3.1

The eligible food criteria (EFC) proposed appears to be appropriate. (FSANZ may wish to consider the possibility of including medium risk foods with limits or conditions similar to other aspects of the Code e.g. maximum residue limits.) Information such as a dossier held by a business to support the safety of eligible foods is useful however approval through FSANZ is a better option as not all businesses have the skills and knowledge appropriate for understanding the requirements of a dossier – whether that be a systematic review, or a safety assessment on traditional use.

The exclusions to the EFC are appropriate – those requiring pre-market assessment to establish safety e.g. weight loss or pharmacological properties would come under

therapeutic goods legislation; those that are prone to misuse by certain suppliers would generally come under legislation in the jurisdiction of the police; and, foods that have potential for adverse effects in non-target populations should undergo an assessment.

Section 4.2.3.3

The EFC and FSANZ assessment aspects of the draft framework presented in Option 3 is viable.

SA Health is of the view that the industry self-assessment aspect however is not viable as it is too complicated. The further option proposed reflects a more viable and less complicated alternative. This aspect may suit larger businesses that have the ability, capacity and resources to invest into such safety assessments however most SMEs will not have the ability, capacity or resources to be able to meet this requirement. There are also complications for regulators in assessing dossiers in relation to ability, capacity and resources – this has been highlighted through the opportunity for industry to hold dossiers for self-substantiated general level health claims in Standard 1.2.7. There are currently regulator work groups completing projects to assess the impacts on ability, capacity and resources which are potentially complicated. Whilst the process of industry self-assessment is for a different outcome in this proposal, it is anticipated that similar impacts would apply.

Notification and publication of dossiers may not necessarily provide enough regulatory oversight and consumer confidence. Assuming that it would assumes that the dossiers published are accurate in their assessment, that regulators have had the resources to assess them and that consumers have the ability to interpret them.

Section 4.3.1

No, agree that these foods are generally added for a similar purpose so can be combined. The end outcome is about the safety of the food/ingredient and novel food definition had been created with the purpose of establishing safety (so could be considered redundant as Food Acts require food to be safe).

Section 6.2

Yes, support retaining exclusive permissions in the Code for foods approved by FSANZ. Given FSANZ's remit, there is confidence in the risk assessments performed by FSANZ. Exclusive permissions in the Code also allow for clarity in interpretation and thus ease of communication, implementation and establishing compliance strategies.

Further regulatory option for consideration

It is proposed that FSANZ considers in addition to the regulatory options provided in P1024 Consultation paper a further option. The option would -

1. Amend the technological purposes listed in Schedule 14 to include “achieve a nutritional purpose”.

2. Remove *Standard 1.5.1 - Novel foods*

3. Amend *Standard 1.4.4 – Prohibited and restricted plants and fungi* to be an expanded list of prohibited substances that cannot be added to food

<u>The proposed regulatory changes may have the following effects:</u>

1. Nutritive substances would be considered food additives if used for a nutritional purpose. This would mean that nutritive substances would require a risk analysis before being placed on the positive list of approved substances Risk analysis can lead to effective regulatory decisions, even when available information is limited. FSANZ is the most appropriate body to conduct the risk analysis. FSANZ is open and transparent about its risk analysis processes in order to increase community understanding about the decision-making process and to encourage an informed debate about the potential safety risks associated with food.

   The provisions in Standard 1.3.2 Vitamins and Minerals could also be moved into the Food additives standard since vitamins and minerals are considered a nutritive substance (or vice-versa i.e. Standard 1.3.2 could become ‘Nutritive Substances if there are concerns in relation to keeping this standard.

   Novel Foods would no longer be regulated by a novel food standard. The concept of novel foods is flawed. A novel food is a food that has the potential for adverse effects in humans. Until a risk analysis is performed it is not possible to distinguish a novel food from any other food since the potential for adverse effects has not been established.

   The removal of the novel food standard would mean that food that is not safe and suitable will continue to be prohibited from sale because of the requirements of the Food Acts.

   The decision of whether a novel food (like any other food) is safe and suitable is made by the food business, enforced by the States and Territories and decided by the courts if in dispute. It is currently the responsibility of the food business to provide information to support their decision that the food offered for sale is safe and suitable.

   2. A risk analysis determines the approved use of a nutritive substance.
      a. If the risk analysis of a nutritive substance determines that it is unsafe, then it could be added to a listed of prohibited substances in a Standard such as Standard 1.4.4.
      b. If the risk analysis of a nutritive substance determines that it is safe, then it could be added to a listed of approved additives in Standard 1.3.1.

c. If the risk analysis determines that it is safe with limited use, then the limits and restrictions of foods that is may be used in can be placed in Schedule 15.

Scenario

1. *A nutritive substance is offered for sale.*

The food business will decide if there is permission for the particular nutritive substance by consulting the Food Standards Code.

- They would consult the additives standards to see if there is a listing providing permission for the substance being used for a nutritive purpose.
- They would also consult the prohibited substances list to see if they were not allowed to use it.

If the substance is not listed in the Code, the food business would need to make a decision about whether the substance is just a safe and suitable food rather than a nutritive substance.

- If the food business intends to use the substance for a nutritive purpose they would not be allowed to use it without applying to amend the Code by an application to FSANZ. FSANZ would conduct a risk analysis and if found safe, a permission could be provided. If determined unsafe, then either regulatory requirements would limit its use or it would be placed on the negative list of prohibited substances and not allowed to be used.
- If the food business intends to use the substance as a food and not with the technological function as a nutritive substance then they would be allowed to do so, but it would remain their responsibility to offer for sale a food that is safe and suitable. This is currently the case with food which may be a used as a food or a food additive depending on the purpose. It would remain the food businesses responsibility to be able to defend their decision in court.

2. *A novel food is offered for sale.*

The food business would decide if the food is being sold as a food or whether it is to be used to achieve a nutritional purpose which is a technological function that would make it a food additive.

1. If offered for sale as a food the food business will decide if the food is safe and suitable. They would also consult the prohibited substances list to see if they were not allowed to use it.
2. If offered for sale as a food additive with the technological function of nutritional purpose it would require permission in the Food Standards Code, Standard 1.3.1. If no permission within the food standards code, then an application to amend the Code would be made to FSANZ and a risk analysis conducted.

In relation to SD5 and the potential to mislead consumers, SA would like to see further exploration about how the proposed new approach (or any alternative) to regulation of nutritive substances and novel foods interfaces with Standard 1.2.7 Nutrition, health and related claims.