



Enquiries to: Food Safety Standards and
Regulation,
Health Protection Branch
Department of Health
Telephone: (07) 3328 9310
Facsimile: (07) 3328 9354
Email: foodsafety@health.qld.gov.au
File Ref:

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Standards Management Officer
Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610

Dear Sir / Madam

Submission – Proposal P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods

Thank you for the opportunity to provide a submission on the Call for Submissions paper for Proposal P1024.

This submission provides technical advice and comments related to this issue. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government when notification is made by the FSANZ Board to the Australia and New Zealand Ministerial Forum on Food Regulation.

In this submission, references to novel foods also include substances and components of foods that are added other foods.

It is noted that in Table 1 of the consultation paper, a number of options for self-assessment pathways and alternative models were proposed, which may be outside the currently limits to the scope of FSANZ's remit under the FSANZ Act. However, if there are better models for the regulation of nutritive substance and novels foods that are currently possible under the current regulatory scheme, these should ideally be explored and considered, perhaps through dialogue with the Food Regulation Standing Committee and the Australia and New Zealand Ministerial Forum on Food Regulation.

Novel foods and nutritive substances are traded internationally and may be found in foods imported into Australia. There is likely to be an international need to assess the safety of higher risk nutritive and novel foods, or at least share assessments. Furthermore, businesses selling these substances will often wish to make associated health claims, which may require assessment. Consideration should be given to exploring options for an appropriate international body to assess novel foods and nutritive substances, particularly chemical substances and extracts, perhaps similar to the Joint FAO/WHO Expert Committee on Food Additives.

Office
Health Protection Branch
Queensland Health
Level 3, 15 Butterfield Street
Herston QLD 4006

Postal
PO Box 2368
Fortitude Valley BC QLD
4006

Phone
(07) 3328 9310

Fax
(07) 3328 9354

Some novel foods, if sufficiently poisonous, could potentially be regulated under Standard 1.4.4 Prohibited and restricted plants and fungi. Or, they may be already captured by Standard 1.4.4 but under certain conditions be acceptable for sale as novel food. As such, the framework proposed in the next round of consultation may need to incorporate the use of Standard 1.4.4 in some instances.

If the proposed modified framework is adopted, there may be instances where there is disagreement about whether a food/substance is an eligible food. A mechanism may be needed to obtain a ruling or for jurisdictions to agree on whether the food meets the criteria for an eligible food.

There may be cases where there is serious doubt as to whether a particular eligible food is safe. The framework should incorporate a suitable mechanism for the safety of such a food to be reviewed. Food regulators should ideally be able to trigger an assessment where there is some evidence a novel food or substance is unsafe (e.g. FSANZ rapid risk assessment). Furthermore the eligible food criteria must not override or conflict with the offence provisions in State and Territory Food Acts for the sale of unsafe and unsuitable food.

It could be helpful to industry (e.g. importers of dietary supplements) and food enforcement agencies for a list of novel foods and substances that have been assessed as not being eligible foods. Similarly it would be helpful for a 'not permitted list' to be published, such as novel foods and substances that have been rejected by FSANZ as permitted novel foods or substances. Consideration would need to be given as to whether it may be more appropriate for such lists to be published on the internet, such as on the FSANZ website, rather than within the Food Standards Code.

The framework for regulation of novel foods and nutritive substances needs to effectively deal with substances added to foods for their physiological effects in the human body, whether actual or perceived.

The framework more suited to novel foods where there is a manufacturer or importer of the individual novel food in Australia. It does not appear to as effectively deal with products such as dietary supplements that contain mixtures of different foods and substances. Many dietary supplement type products are imported. The same products may be imported by multiple importers. Since these substances are just components of a various products, the importers of these products may not hold the necessary data to support safety of eligible food. It would be helpful for businesses and food enforcement officers if lists were available for foods that have been determined to be or not be eligible foods.

Consideration could be given to including in the overall regulatory framework a way of monitoring adverse reactions to novel foods. Since many of these types of substances may also be sold in complementary medicines, it would be more effective if these were considered with adverse reactions reported to the Therapeutic Goods Administration.

Serious concerns are raised about the proposed grandfathering arrangements. There are likely to be novel foods and nutritive substances currently available in Australia, which may not comply with current requirements and which may be potentially unsafe. It would be undesirable to legally legitimise these foods or substances and hinder the ability of enforcement agencies to take action in relation to them in the future. Furthermore, such grandfathering may bring the Food Standards Code into conflict with the general offences for the sale of unsafe and unsuitable food in State and Territory Food Acts. There would also be the potential for novel foods and substances to be introduced into Australia ahead of the implementation of any new regulatory measure so they are permitted under the new arrangements.

A preferred approach would be for a delayed implementation period to allow businesses to comply with the new requirements and no grandfathering (other than novel foods currently listed in the novel food standard). That is, existing products should comply with the new requirements.

Grandfathering of microorganisms may be problematic because many will not have been well characterised. Grandfathering could also bring the Food Standards Code into conflict with the safety and suitable offences in State and Territory Food Acts where these microorganisms or foods that contain them are found to be unsafe.

In relation to the exclusive permissions, Queensland Health as an enforcement agency is not likely to prioritise resources being put into enforcing a breach of exclusive provisions. It may be more appropriate for enforcement of intellectual property to be managed as per other types of intellectual property rather than by food enforcement agencies.

Should you require further information in relation to this matter, please contact Food Safety Standards and Regulation, Health Protection Branch, Queensland Health on (07) 3328 9310 or at foodsafety@health.qld.gov.au

Food Safety Standards and Regulation Unit
Health Protection Branch
Department of Health
Queensland Government