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

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submissions@foodstandards.gov.au
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Introduction

We welcome the opportunity to submit to P1024 in relation to amending the novel food provisions of the Food Code.

That said, we are disappointed in most respects with FSANZ's preferred option. It is a deregulatory approach that is complex and uncertain and fails to improve on the current problematic rules. We are particularly concerned at FSANZ's continuing refusal to regulate the use of nanomaterials in food in a scientifically rigorous and justifiable manner.

Preferred Option 3 is proposed, presented and analysed without any discussion of how this option will improve public health. Instead, FSANZ only addresses how this option will benefit industry.

We recommend that Option 3 not proceed and that revision of the Novel Food provisions and definitions occur instead.

Nanomaterials and novel food provisions

The position of FSANZ in relation to nanomaterials in food is completely unacceptable and is based on views that are not supported by the majority of the scientific community.

Currently, FSANZ requires no safety assessment for nanomaterials in food and has no idea of which nanomaterials are in the food chain, in what quantities and what their potential impacts are. Nanomaterials satisfy the requirements for novel foods under the current definitions and the refusal of FSANZ to assess these novel foods and particles informs much of this submission.

FSANZ claims that the safety of nanomaterials can be inferred from the safety of the same material at conventional scale.[i] This is a position not supported by the UK Royal Society[ii], the EU or the German Federal Institute for Risk Assessment– amongst others. The German Federal Institute for Risk Assessment notes that, **"**Despite intensive research over the past 20 years, no generalised conclusions and universally valid risk assessments for nanomaterials are yet possible… All types of nanomaterials, therefore, need to be individually tested and assessed for health impacts."[iii]

Even FSANZ's sister agency the APVMA has concluded that there is a "general consensus that as a result of an increased surface area, altered surface chemistry and increased potential for dissolution, there is a potential for nanoparticles to exhibit a toxicity profile that deviates from that of

conventional materials of the same composition."[iv] It is also interesting to note that NICNAS in its recent proposal to change the regulatory regime for industrial chemicals has indicated that nanomaterials will be placed in the highest hazard band and subjected to safety assessment.[v]

Further the EU is proposing, in its new novel food provisions, to explicitly define all foods containing nanomaterials as novel foods.[vi]

The Principles for Establishing Safety of Products of Nanotechnology (in Supporting Document 2, s 3.1.4) are completely inadequate in light of the refusal of FSANZ to take any steps to date to either ascertain the scale of the presence of nanomaterials in Australian foods or to require the safety assessment of nanomaterials known to be in Australian foods.

FSANZ notes that "Particulate, nanoscale materials that are new to the food supply will be subject to toxicological evaluation as outlined in the Application Handbook." (Supporting document 4). However, requirements in the Handbook are only pertinent if an Application is made for approval. To date, FSANZ has not required manufacturers of nanomaterials in foods to submit applications rendering the Handbook provisions irrelevant. As FoE has demonstrated, engineered nanomaterials are present in foods in Australia and based on test results are likely to be widespread.[vii] The response of FSANZ has been to do nothing. The proposed approach in P1024 is unlikely to change that. This is despite the fact that all engineered nanomaterials are new to the food chain and none have a history of safe use. The lumping of nanomaterials in with the same material at conventional scale is both dishonest and putting the Australian public at risk.

Reprehensibly, FSANZ uses language that suggests that nanomaterials will be assessed when history and a close reading reveals that isn't true. For example, FSANZ states that "The existing application process is the appropriate pathway to market for foods which may represent risk to specific subpopulations and therefore require risk management measures, as well as for particular classes of foods for which risk cannot be predicted without full assessment e.g. particulate, nanoscale novel foods or microorganisms not listed in the Code as eligible foods." (Supporting Document 2, Executive Summary, p. i)

This statement would lead most people to assume that nanomaterials in food will be undergo a safety assessment. However, the use of the term 'nanoscale novel foods' is the key. Not all nanoscale foods are novel according to FSANZ. In fact, only those foods that contain nanomaterials not already in use at a conventional scale will be considered novel.

Further, if such novel foods are deemed not novel by an advisory committee with no regulatory authority, those foods do not even enter the regulatory process. This renders the application provisions and the handbook meaningless. Allowing an untold number of foods to enter the food chain with no regulatory intervention at all, while pretending all novel foods are subject to pre-market safety assessment is deeply dishonest and calls into question the agency's capacity to properly regulate any novel food. Option 3 would potentially improve the current self-regulation by manufacturers by imposing 'basic' data requirements. However, these provisions appear to do nothing to address the uncertainty as to whether self-assessment should occur and to improve the enforceability of the 'safe food' standard that remains in place.

Additionally, little is done to address the manner in which FSANZ has to date exercised its discretion regarding novel foods, or to change the regulatory structure to make it clear that FSANZ is responsible for all decisions as to whether a food is novel or not.

Unless these matters are resolved so that the process and regulations are clear, FoE fears little will change.

It is instructive to note that FSANZ in reviewing the EU regulations (existing and proposed) in Supporting Document 4 fails to mention that all nanomaterials in food will require a pre-market safety assessment. In fact, the definition of novel foods explicitly includes nanomaterials.[viii]

While we have some issues with the proposed EFSA definition of novel foods, we support this approach over FSANZ's proposed approach.

It is predictable that the unsupportable position taken by FSANZ on nanomaterials will only be changed when industry complains – as they did in relation to packaging - that the standards here are so weak that they provide neither utility nor guidance to industry. We should not have to wait for that time – public health and precaution demand that nanomaterials are properly assessed here.

Our experience with FSANZ and nanomaterials has lead FoE to conclude that FSANZ is a regulatory body captured by industry. We have no faith in the ability or inclination of FSANZ to protect public health. Instead, we see an agency devoted to facilitating business while hiding behind industry science and a suite of regulatory loopholes.

Unfortunately, this proposal does nothing to change our view.

- FoE recommends that nanomaterials are explicitly treated as novel foods.
- FoE recommends that this be made retrospective so that nanomaterials FSANZ has already allowed on the market with neither testing nor labelling are subject to safety assessment.

General comments on the existing novel food framework

FSANZ's explanation of the need for this proposal is based on the claim that ambiguity in the legislation is creating market uncertainty (p5).

The subtext here is that the need for this proposal is an industry need, not a public health need. There is certainly a public health need to improve the novel food provisions, but as we have noted, this is clearly not what is driving this proposal.

A deregulatory approach is never designed to improve public health and this proposal is no exception.

FSANZ claims that

> *"The purpose of pre-market assessment approaches is to determine the safety and required mitigation measures prior to food entering the food supply. This is a fundamental principle in*

> *the Australia New Zealand food regulatory framework and ensures that the potential risks posed by certain foods (such as those without a history of safe consumption) are adequately addressed before these foods are sold to consumers"* (s 4.1).

This is simply not true - as demonstrated by FSANZ's failure to explicitly designate nanomaterials as a novel food. The problem is that neither the legislation nor the Act requires that FSANZ make a determination as to whether a new product is a novel food. Instead, we have decisions made by doing nothing. Foods containing nanomaterials have entered the food chain without FSANZ making a decision regarding whether these foods should be assessed or not. FSANZ inevitably responds to this criticism by claiming that manufacturers must not put food on the market that is unsafe (s 1.2). However, the agency admits in P1024 that this is an unenforced and unenforceable standard (see section on Regulatory Authority below). It is not known if manufacturers ever make a finding of safety and on what basis, in part because FSANZ does not require written records from the manufacturer and has to our knowledge never audited this 'standard'. So, the failure of FSANZ to act is not accidental. Nanomaterials in food are allowed on the market by a kind of active neglect. Even worse, there is little public or Parliamentary remedy for this kind of 'decision-making' by FSANZ.

FSANZ notes that it:

> *"has recently conducted a search on food products being offered for sale on the internet containing ingredients considered by the ACNF/NFRG to be novel but for which there has been no application or approval. "The search identified a number of the foods considered novel by the ACNF/NFRG that were present in food products offered for sale in niche markets Australia and New Zealand."* (s3.1)

It is not clear why no one has referred foods containing nanomaterials to the ACNF (including FSANZ itself)? Since nanomaterials haven't been referred despite their potential risks and widespread use, this raises the question of what other novel foods are completely off FSANZ's radar and already on the market.

It appears FSANZ has taken no steps in response to finding novel foods on the market that its own advisory committee has recommended be subject to pre-market safety assessment. This is an extraordinary admission of incompetence.

FSANZ claims that the problem with the Novel Food provisions are uncertainty and ambiguity. However, we would argue that FSANZ's failure to provide guidance, or to use its existing authority to define, clarify, assess and enforce is not primarily a problem of legislation but a problem of regulatory neglect and industry capture.

It does appear – but is by no means certain – that even Option 3 would ensure that this backdoor entrance to the market cannot continue. The requirement that manufacturers must keep written records is welcome, but we say that without faith that FSANZ will actually close this backdoor system of introducing risky foods. It must be said that FSANZ does not even acknowledged a problem with this backdoor, so it remains to be seen whether this loophole persists in legislation. More problematic but equally important is whether FSANZ will do anything to ensure those novel foods that are on the market without assessment will be assessed.

Finally, as the Food intolerance Network has shown, industry 'games' the FSANZ regulatory system. One can attend seminars that instruct industry how to avoid regulations through redefinition, renaming or a variety of other measures.[ix]

Option 3 is not a simple approach to novel foods. It is a complex system with a variety of definitional and interpretive issues that inevitably will be gamed.

General Comments on the Proposed and Preferred framework

Generally, the proposed framework is not, as FSANZ claims, innovative. It is a fairly typical example of a deregulatory approach that involves reducing the extent of safety assessment, increasing levels of industry self-regulation and generally reducing the protection of public health. NICNAS has recently taken a very similar approach with its proposed assessment of industrial chemicals and the result will be that 38,000 chemicals currently on the market will continue to be permitted to be sold although they have not been assessed and there will be a 70% reduction in the already low level of assessment of new chemicals.[x]

FSANZ's preferred option will reduce the number of products and foods subject to pre-market assessment and approval (s4.2.3.1), will see an increase in self-regulation (for which there is substantial evidence of limited utility and gaming), and does little to improve the standard of assessment that currently operates or the laissez-faire culture within FSANZ.

It is somewhat incomprehensible that FSANZ can recommend a reduced level of pre-market safety assessment of novel foods when P1024 makes clear that FSANZ doesn't know how many novel foods are on the market with no safety assessment or approval.

FSANZ's draft framework for a graduated risk approach is predicated on the assumption that foods can be graded or grouped according to the extent to which they can be predicted to be of low risk and therefore safe to market. (Supporting document 2, p1). That presumption suffers from the flaw that novel foods, by definition, have a short history in the food chain and a shortage of data relating to their safety. Presumptions of safety based on analogues and similarities to other foods is not supported and is not a scientific approach to food safety.

FoE recommends a far more prescriptive approach to novel food regulation based on the precautionary principle.

The Precautionary Principle

The precautionary principle remains completely absent from P1024 and the broader food regulatory regime in Australia, but is a principle used in Europe and by the US Food and Drug Administration (FDA). For example, the US FDA requires that manufacturers of new foods can demonstrate a "reasonable certainty of no harm."[xi] There is no such legal guidance as to the degree of certainty of safety that is needed for FSANZ or manufacturers.

A precautionary approach to food safety is critical in protecting public health. Essentially, this means ensuring that food is safe before it's released and ensuring that the community knows what's in our food so that we can make informed choices.

The need for precaution is particularly obvious in relation to new technologies and new ingredients or additives, where there is no history of safe use or inadequate data to determine whether a product is safe. This means foods should be determined to be safe as a result of "a comprehensive assessment of the risk to health based on the most reliable scientific data available."[xii]

Unfortunately, FSANZ rejects precaution in favour of supporting the giant food corporations that increasingly control the food chain.[xiii] FSANZ noted in relation to its refusal to label food colourings known to cause hyperactivity in children that the precautionary principle "is generally going to be at odds with a principle of minimum necessary regulation."[xiv]

The lack of a precautionary approach has clear and profound effects on all of us and the food that we eat. At a broad level it has allowed FSANZ to presume the safety of a number of new food products, to ignore evidence of harm and to impose the onus of showing a product is harmful on consumers, who may not even know they are being exposed to these products.

There is substantial work demonstrating how the precautionary principle can and should function within a regulatory regime.[xv] FSANZ's rejection of the precautionary principle is not just academic but has significant implications for those who ultimately bear the risks associated with the production and processing of food.

FoE recommends that a rigorous precautionary approach underpin all FSANZ regulations including the novel food provisions.

Specific framework comments.

Based on our reading of the various P1024 documents, nanomaterials in foods will not be assessed as novel foods unless the material, at whatever scale, has not been previously used in the food chain. It is not clear what other novel foods will be excluded from the novel food provision. FOE is concerned that FSANZ's regulatory provisions are in fact, less important than FSANZ's discretionary powers regarding implementation, auditing and enforcement.

Eligible food criteria

Option 3 proposes to exclude a number of foods from pre-market assessment even though FSANZ acknowledges that the various eligible food criteria designed to identify low risk foods are not free of high or higher risk foods. They therefore cannot be "predicted to be of low risk and therefore safe to market." (Supporting Doc 2, p1).

The proposed exemption for foods from pre-market assessment fails immediately at this point. The first proposed exemption from testing is based on certain classes of food (ECG 2). The basic criteria for being exempt, ie the food is of low risk to public health, is not satisfied by using classes of food as the basis for exemption. FSANZ makes clear that the assumption of safety contains a number of exceptions. As soon as exceptions and exclusions are required the entire system becomes complex and subject to interpretation. In a self-regulatory system this is risky policy and practice.

The basic structure of designating a number of foods 'low risk' and exempting those foods from regulatory pre-market approval is not supported by FoE. This is a standard deregulatory approach and based on FSANZ's current culture and legislation will only create further risks to public health.

In order to have a low risk exemption that works, FSANZ must first have both the definitional and regulatory integrity that would give that concept rigour. That doesn't currently exist. FSANZ's

definition of safe food (which obviously informs risk) is so poor[xvi] that a finding of low risk based even in part on that definition would be disturbing.

The use of Eligible Food Criteria to determine if a food is exempt from pre-market safety assessment is clearly problematic. FSANZ gives the example of a food with a history of safe consumption of a food in another country, which could be used to establish an exemption in Australia.

FoE is concerned that the term 'history of safe consumption' has definitional uncertainties. Especially given the current unacceptable definition of safe used by FSANZ and the absence of a surveillance system for sub-lethal and cumulative harms.

FoE does not support the use of EFC. If a food is novel, then by definition the risks are not well known or established, even if there is a claimed history of safe use elsewhere.

FoE recommends that Option 3, including the EFC, not be used to assess novel foods.

If EFC are to be used then FoE recommends:

1. That data justifying a decision that a food satisfies the EFC is publicly available and held or published by FSANZ (not held by the manufacturer)(FoE supports the publication provisions in P1024)
2. That the decision that a food satisfies the to classify a food as EFC is subject to review by the public.
3. That review provisions be substantially amended to be merits based not based on judicial review. Food safety and the public right to be assured of food safety is too critical to leave to judicial review.

FoE recommends that any food containing nanomaterials should not meet the EFC.
FoE recommends that any food produced using synthetic biology should not meet the EFC.

The ACNF

FoE is concerned that there appears to be no systematic approach to novel, or potentially novel foods, by FSANZ's Advisory Committee on Novel Foods (ACNF). Only some foods are assessed and there appears to be no coherent approach to what needs assessing nor even how it is to be assessed by the Committee. In part, P1024 has been proposed because of the failure of the current system, but much of the justification for P1024 sits within the assessments and conclusions drawn by the ACNF.

In light of the fact that nanomaterials in food are recognised as one of the fastest growing areas in food production and that nanomaterials represent unique and generally untested risks, it would seem obvious that FSANZ would refer to the ACNF the question of whether nanomaterials in foods should be considered novel. That has never happened and it is unknown how many novel foods are on the market never having reached the regulatory process or the attention of FSANZ.

Industry has indicated to FSANZ that the current ACNF process is, in their view, a useful avenue for providing clarification on the regulatory status of foods that may potentially be subject to the novel food standard. This is particularly true for foods that the ACNF does not consider to be novel. The expectation is that for foods the ACNF does not consider to be novel, a regulatory pre-market assessment is not required" (p11). This highlights the absurdity of the system – FSANZ accepts that a negative recommendation on novel foods by the ACNF justifies treating a product as non-novel – but because industry doesn't necessarily accept a recommendation of novel as requiring pre-market assessment, FSANZ accepts it has no legal recourse and clearly industry is free to ignore it. No wonder industry likes it.

This process needs clear and legally based decisions to be made by the regulatory authority and those decisions to be subject to review. At present this shadow system of non-regulation works as a one way system. If the advice is favourable to industry they are happy. They take the advice to mean no assessment is required. If not favourable to industry they are free to ignore the advice because it has no legal status and FSANZ is, in any event, unwilling to impose any requirements for testing or to take such matters to court.

This exemplifies so many of the problems with both the Agency and the legislation that it creates and 'administers'.

FoE recommends the disbanding of the ACNF and replacing with an independent expert panel (all subject to strict conflict of interest requirements) to provide advice on what new foods are novel and whether they should be assessed as novel foods (noting again that we do not support Option 3).

Regulatory authority

It seems extraordinary to FoE that FSANZ believes there is any currently ambiguity regarding who decides whether a food should be assessed as a novel food. Regulatory decisions are not the purview of manufacturers, regardless of their view regarding the safety of a product (p9).

Such a view raises concerns that any new novel food provisions will simply founder as FSANZ refuses to exercise its powers and functions. FOE is concerned that under preferred option 3, the industry interpretations of the various ECG and related provisions will see foods exempted. Nothing in these documents demonstrates that FSANZ has addressed this critical shortcoming.

FSANZ notes the risk of being taken to court by a manufacturer if FSANZ requires an assessment and the manufacturer disagrees (p10). FSANZ notes that in such circumstances it has the onus of demonstrating that a food is likely to cause harm. FoE agrees that the current Act not only puts the onus on FSANZ to show a food is unsafe, but the definition of safe food is so limited and porous that FSANZ is unlikely to satisfy that burden of proof.

It should, however, also be noted that FSANZ frequently claims that manufacturers bear the onus of demonstrating the safety of the foods they wish to sell. This is concerning as FSANZ has often referred to this standard in defending its lack of assessment of product such as foods containing nanomaterials[xvii].

New novel food provisions must make clear the right of FSANZ to require an assessment for any novel food based on criteria such as a lack of a history of safe consumption, a lack of relevant data, safety concerns in the scientific literature, etc. The basis for enforcement then becomes whether FSANZ can show, for example, a lack of data or no history of safe consumption.

Self-regulation and self assessment

FSANZ notes that "At present, all nutritive substances and novel foods must be assessed and approved by FSANZ before they can be sold. An industry self-assessment pathway may provide industry with greater control over time to market for new foods and timing of the release of proprietary information relevant to establishing safety than is currently afforded by the FSANZ preapproval assessment process."

In light of the current backdoor system that allows foods on the market without assessment and in light of the historical limitations and failings of self–regulation, FoE opposes industry self-assessment. The literature on self-regulation demonstrates that self-regulation rarely accomplishes regulatory objectives unless the interests of industry and the regulatory body are the same or the self-regulation is backed by a strong and enforced regulatory regime. Self-regulation, in those rare cases where it works well, benefits from a small industry with common aims and issues. [xviii] That is not the case here. Industry self-regulation in these circumstances is simply a form of deregulation. The disparate and global nature of the industry makes self-regulation a regulatory nightmare.

FSANZ ignores the likely complexities of such a self-regulatory system in this proposal. Multiple manufacturers of similar ingredients or products produced all over the world will see a host of methodologies, analytical tools, study designs and methods of asserting safety. The lack of any clear way to ensure systematic and consistent assessment is concerning. The differences in foods using the same ingredients (combinations of ingredients and relative quantities or strength) creates significant uncertainties. These measures also need to take into account vertical issues as well. From ingredient to whole food, many issues arise.

It is also well established that relying on industry data to assert a product is safe is not reliable. Industry studies are significantly more likely to be self- serving, inaccurate, or fraudulent.[xix]

FSANZ at least notes this problem: "The inherent risks associated with self assessment need addressing as well" (p14). FSANZ however, does not analyse those risks nor address how they can be avoided in this self-regulatory proposal.

All of this will potentially be further complicated by the Trans Pacific Partnership agreement should it come into force. This would allow the information that forms the basis for a regulatory approval to be excluded from use by other companies, meaning duplication (and confusion) of studies and assessments.[xx]

FoE recommends that all novel foods go through an independent assessment process. This could involve a similar process to environmental impact assessment process. Under the EPBC Act, for example, an initial application is made to either be exempt from assessment or to argue for a particular level of assessment. As long as the criteria are clear and subject to public review, this

allows the case by case evaluation of foods that may present specific difficulties and unique assessment issues or risks. Currently, FSANZ suggests that those who are unsure call FSANZ. This is a profoundly poor and ad hoc process.

The comment by FSANZ regarding the timing for release of proprietary information is irrelevant. If every manufacturer must go through the same regulatory process then the holder of the proprietary information is protected by going first as well as by any applicable IP laws. In addition, the suggestion that the release of proprietary information could wait until release of the food or product means that the public has no right to comment on either the data or conclusions of safety. Once again we point out the pro-industry bias in this proposal.

While FoE opposes self-assessment, we support the view that if self-assessment as outlined in Option 3 occurs related documents should be publicly available.

The question of whole food analysis versus ingredient assessment needs careful consideration. FSANZ has not historically undertaken this kind of assessment but it is what the best available science demands.

Public rights

These proposed provisions do not provide for any public right of review. This is a broader problem relating to FSANZ legislation but it should be rectified in the novel food provisions in the short term. The public's right to seek legal remedies when novel foods aren't assessed should be recognised in law.

Questions (section 3.3)

FoE notes that FSANZ doesn't ask how the current novel food provisions affect the public. These provisions and this proposal appear to be directed at ensuring that industry is happy even if FSANZ can't assure the public that these foods are safe. This is deeply disturbing.

Suggested post-market rather than pre-market assessment

FoE opposes this suggestion – as apparently does FSANZ. FoE does want to comment, however, on this FSANZ comment: "The identification of adverse effects is not likely to be straightforward in a post market environment. Serious acute adverse effects may be identified if they are reported to appropriate authorities. However, the identification of chronic adverse effects is difficult in a post market environment. It is unlikely that chronic adverse effects will be reported to food authorities, as the cause of the chronic effect may not be identified. This highlights the limitations of relying on post-market measures without the support of clear and enforceable pre-market requirements. The potential for foods to cause chronic toxicity can be identified and incorporated into pre-market assessment requirements" (4.1.1)

The unfortunate reality is that post-market reviews, audits, reporting and surveillance systems in Australia are completely inadequate. The pre-market assessments cannot provide for the post-

market surveillance and reporting work that is absolutely critical with novel foods. Reporting should come from the medical community and be based on clear approaches to identifying and tracking chronic effects.

The lack of post-market reporting is a serious shortcoming and dramatically reduces the capacity of FSANZ to provide a safe food system.

These post-market systems can and should be put in place, but it is absurd for FSANZ to pretend that this can be accomplished at the pre-market stage.

A fourth option

FoE recommends that a fourth option for the regulation of novel foods and nutritive substance be considered based on a precautionary approach to novel foods. This is justified by the nature of the risks and uncertainties inherent in novel foods. A precautionary approach should apply to definitions; what foods are captured; the nature, scope, independence and requirements for pre-market safety assessment; auditing requirements; surveillance requirements; and enforcement.

Alternatively, FoE supports a tightening of the novel food provisions and improving the definition of novel foods, more closely aligned with the EU.

Miscellaneous comments

FSANZ suggests that foods having the potential for adverse effects if consumed by non-target population subgroups (e.g. children, pregnant and lactating women, elderly, immunocompromised), and/or will not satisfy the EFC. FoE supports this in principle but wonders how this can be reconciled with FSANZ's current draft definition of safe food, which specifically excludes adverse effects on population subgroups that comprise less than 50% of the population. Additionally, the specific criteria for adverse effects needs clear elaboration.

FoE supports the combining of the provisions for nutritive substances and novel foods in principle, provided that it captures the full range of products that currently exist and may be developed. If the definition identifies foods produced using new technologies or techniques – being technologies or techniques that do not have a history of use in the food industry, most of the new foods likely to be developed will be captured.

The most obvious pitfall of combining the definitions is that if the definitions are not sufficiently specific or clear, we will have some of the same problems we have now.

FoE opposes exclusive use provisions. This is a form of extra-legal intellectual property not part of any current IP system. An 'innovative' combination of ingredients would not and should not be subject to this form of commercial exclusivity and nor should other 'innovations' unless they can satisfy existing IP requirements.

Post market surveillance is already a critical issue. It is largely absent from the current regime and it shows. It is not clear what kind nor what level of post-market surveillance will occur under the current proposal.

While we support the publication of industry safety data for exempt foods should this option proceed, this data needs to be audited. The legislation should provide both the authority to audit this data as well as to set out minimum standards, scale and frequency of audits as well as regular audit reports.

Proposal P1024, p17

The proposed changes to the novel food provisions would not be applied retrospectively to foods that were marketed under the existing Code requirements for nutritive substances and novel foods." This is unacceptable given the way the use of nanomaterials in food has been ignored. These provisions should provide that if a food is on the market without having been assessed as a novel food and is deemed novel under the new provisions, it should be subject to safety assessment. While this may impose burdens on industry, public health must become the agency's priority.

Proposal P1024, p20

FoE supports the public release of safety data and records held by manufacturers should Option 3 proceed. However, accountability as well as transparency is required. Public rights to seek a recall of the product should the safety materials held by the manufacturer not rise to the required level of rigour should be instituted.

Summary of option 3

While FSANZ calls this an innovative approach, it is a classic deregulatory model. Allowing certain foods to be exempt is an improvement on the current system, where novel foods can be on the market with no testing or approval and not even the awareness of FSANZ, but it is not adequate.

The reality is that once a category of exemption exists, manufacturers will seek ways to ensure their foods are in that category. Self-assessment will result in most – and perhaps every - novel food being assessed as safe. Industry self-assessment is far from best practice and far from reliable.

A proportionate risk approach suffers a fairly clear fault – it presumes to be able to determine the level of risk prior to assessment. This makes little sense, unless the parameters of risk are so narrow that they are inadequate. This is the norm now in food assessment and it is important that FSANZ actually develop a scientifically justifiable standard of assessment that considers the long term, synergistic, compound and cumulative risks of a suite of exposures and exposure pathways.

Transitional Provisions

FoE remains concerned that the failure of the current system to capture nanomaterials and other unassessed novel foods will be validated in any transition provisions. FoE recommends specific provisions that ensure that there is assessment of novel foods captured under the new act but not presented for assessment under the current act.

Pro-industry bias

This entire proposal and many of its elements betray the deep pro-industry bias that FSANZ brings to its regulatory role. In addition to those already noted, we point out a few more here.

Questions 3.3 asks, **"**How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?"

This question assumes that the only stakeholders affected by definitional changes are government agencies and industry. It fails to consider that there may in fact be other stakeholders – e.g. the public and public interest organisations affected by these definitions.

Fewer assessments, reliance on self-regulation, lack of clarity regarding self-assessment and EFC are examples of industry bias at work.

While FSANZ often repeats that its primary objective is protecting public health and safety P1024 does not argue or substantiate any public health benefit.

Specific Comments on the EFC – Supporting document 3

It is not possible to establish that a food is likely to be safe when there is little supporting information available (for example, compositional data) and the food does not have a significant history of safe consumption as a food in Australia, New Zealand or other countries." (p6) However, FSANZ also indicates that one of the criteria used by the ACNF was that 'no safety concerns were identified'(p2). With new foods safety concerns are unlikely to be identified, given the lack of surveillance and reporting for sub-lethal and chronic impacts. This is not a basis for declaring a food is not novel.

In the document FSANZ states that it "does not propose to regulate new processes under the framework of a potential alternative approach to regulating nutritive substances and novel foods."(p. 3). This appears to suggest that the EFC are based solely on the food not the process by which it is produced. No reason is given for this position and the view of FoE is that new processes can have substantial effects on the safety of food. FSANZ's statement is somewhat confusing in light of the EFC being based in good part on processing method (see e.g. Table 2, p. 8).

While FoE is not intending to comment generally on the proposed regulation of microorganisms, we are concerned at the proposed use of broad taxonomic similarities as a basis, at least in part, for asserting safety (p.4).

2.2.1 EFC 2:Whole Foods

FSANZ is proposing to presume whole foods as a class satisfy EFC 2 and are exempt from pre-market safety testing requirements, despite acknowledging that 'some' whole foods may not be safe. FSANZ's claim that the approach in Option 3 will remove ambiguity fails at this first hurdle. Whole foods are deemed to satisfy EFC, even though they may not be safe, in which case the manufacturer

must mitigate. The mitigation measures are apparently up to the manufacturer as long as they make the food safe.

The process gets worse. FSANZ then adds to the EFC a requirement that "a history of safe consumption in countries other than Australia and New Zealand should also be held" (p6). This is the first time this requirement, apparently superimposed on the EFC standard, has been raised.

No criteria are provided for determining a history of safe consumption in other countries, only adding to the uncertainty of these provisons.

FSANZ notes that "If a food business cannot satisfactorily show that their eligible food is safe, based on these basic information requirements, the food should not be sold as an eligible food." (p6) This reverts to the current requirement that manufacturers make decisions as to whether a food is safe – a situation that FSANZ recognises in P1024 as untenable.

The complexity increases in the discussion of biofortification (p6). FSANZ "considers biofortified whole foods should be considered eligible foods in keeping with the eligible food criterion for animal and plant commodities," despite no history of safe use, limited commercial presence and presumably little data that would support a finding of safety.

This is deeply disturbing. The entire concept of having EFC is that foods known to be low risk are exempt from pre-market assessment, but as the EFC are elucidated it becomes clear that's not the system at all. There may not, in fact, be any system, except a determination to limit assessments for the benefit of industry.

FSANZ claims that food classes will be defined in ways that ensure that foods that do not have a history of safe consumption are not eligible (p7), yet no proposed definitions are provided. Even a cursory analysis of 'history of safe consumption' – if that is to be the basic standard – shows it's not a simple proposition. What history is required? Is an oral history of use sufficient? How is 'safe' consumption shown in the absence of any kind of surveillance of the population that has traditionally consumed the food? Is 'safe' going to rely on the current FSANZ definition?

The proposed criteria require manufacturers to hold information regarding safety, but that presumes that such data exists or that a finding of safety can be made even in the absence of adequate information. Recently, the APVMA made the argument that its role as regulator was to make regulatory decisions based on the available evidence, rather than requiring a filling of data gaps.[xxi] FOE is concerned that this may be FSANZ's position as well. If so, there are no legitimate criteria that FSANZ can set out unless it is prepared to refuse approval in the event those criteria aren't met.

It's not clear why FSANZ bothers with a problematic food classes approach when the issue is whether there is a history of safe consumption. The fact that the agency has already carved out (p. 8) an exception for algae and fungi and admits that other classes of whole foods contain foods that don't satisfy EFC shows that using food classes won't address the issue of history of safe consumption nor demonstrate that classes of food are inherently safe.

Regarding Extracts, p. 11

It appears that it will fall on manufacturers to make a determination of 'natural levels' in the absence of clear guidance from FSANZ regarding how to make that determination in light of historical and global variations.

In some cases safety will depend on the method of preparation of the food. It is not clear how this will be addressed via self-regulation.

EFC 4.

The issue of insufficient safety information, which is raised in the context of ACNF considerations of substances, is a critical issue with novel foods but isn't directly addressed in any criteria. It is only partially and indirectly addressed in a 'history of safe use' approach.

If the substance is a newly synthesised substance that does not have a history of human then it is proposed not to be eligible for EFC 4. However, FSANZ has noted elsewhere that processes will not form a basis for such a determination. We note our support for process based criteria, but FSANZ needs to clarify its position on this issue.

FoE agrees that "Natural range" needs definition, but we once again express concern at the industry focus in considering what natural range might mean. We also note again the increasing complexity and inherent uncertainty that is emerging in this framework.

"FSANZ recognises that some substances naturally present in foods can also be produced synthetically. However, FSANZ believes this issue requires further consideration before synthetic analogues could be included in the eligible food criterion." (p15). FoE supports this position. Once again, we note that issues of how foods/substances/ingredients are processed keeps arising and needs specific consideration.

Exclusions from EFC – pharmacological effects

FoE supports the exclusion of foods that have pharmacological effects from the EFC.

In addition to the difficulties in defining 'pharmacological' the meaning of 'intended levels of consumption' also needs clarification as most foods do not identify an intended level of consumption.

FSANZ notes that "Because the word 'potential' can refer to any level of chance, the intent here is that the potential for adverse effects should be based on evidence that raises a reasonable level of concern, rather than being a theoretical potential only." This 'clarification' of 'potential' creates obvious uncertainties and ambiguities. What onus does the manufacture bear to determine such potential? In the absence of data, what expectations does FSANZ have that the needed information will be secured?

While FSANZ suggests that the food industry dislikes ambiguity, it is equally true that ambiguity can be a shield behind which industry decides not to investigate or act.

FoE supports exclusion 2 regarding weight loss properties.

[i] Senate Estimates questons on notice SQ15-000822, SQ15-000778, October 2015

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[iii] Chemical Watch (2015) Bfr announces nanomaterial categorisation project. https://chemicalwatch.com/44630/bfr-announces-nanomaterial-categorisation-project. Link to Bfr media release in German: http://www.bfr.bund.de/de/presseinformation/2016/03/gesundheitliche_bewertung_von_industriell_genutzten_nanomaterialien_soll_einfacher_werden-196219.html

[iv] APVMA (2015). Nanotechnologies for pesticides and veterinary medicines: regulatory considerations. http://apvma.gov.au/sites/default/files/publication/15626-nanotechnologies-pesticides-veterinary-medicines_regulatory-considerations_july2015.pdf

[v] NICNAS (2016). Implementing reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Consultation paper 2. https://www.nicnas.gov.au/__data/assets/pdf_file/0014/21731/NICNAS-Reforms-Consultation-Paper-2.pdf

[vi] European Food Safety Agency (EFSA) (2016). Draft guidance on the preparation and presentation of 2 an application for authorisation of a Novel Food.

[vii] Friends of the Earth (2015). Independent testing finds potentially harmful nanoparticles in common food products. http://emergingtech.foe.org.au/independent-testing-finds-potentially-harmful-nanoparticles-in-common-food-products/

[viii] European Food Safety Agency (EFSA) (2016). Draft guidance on the preparation and presentation of 2 an application for authorisation of a Novel Food. http://www.efsa.europa.eu/sites/default/files/consultation/160218.pdf

[ix] Food Intolerance Network (2015) References for articles about FSANZ (2015), http://fedup.com.au/information/information/references-for-articles-about-fsanz-2015

[x] NICNAS (2016). Implementing reforms to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), Consultation paper 2.

[xi] Druker, S. (2015). Altered Genes, Twisted Truth. Clear River Press. p. 161.

[xii] *Commission v. Kingdom of Denmark (*2003) Case C-192/01 *,* *http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d2dc30dd84ebe8a44a174b0dba0beb3a3af8edb3.e34KaxiLc3qMb40Rch0SaxuSax10?text=&docid=48614&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=1268117*, paragraph 51

[xiii] Food Standards Australia New Zealand, undated. Inquiry Report: A338 – Food Derived from Glyphosate-Tolerant Soybeans

[xiv] FSANZ (2010). Final assessment report, Application A603, Red 3 Eryrhrosine Colouring Preparations, p22. https://www.foodstandards.gov.au/code/applications/documents/A603%20Erythrosine%20FAR%20FINAL.pdf

[xv] Stirling, A. (2002). Science, Precaution and Practice. Public Health Reports, **117**:521-533.

[xvi] See FoE (2015). Submission to FSANZ review of Safe Food Australia.

[xvii] Senate Estimates response to question on notice (2015). SQ15-000778, question 10.

[xviii] King, L. *et al.* (2010). Industry self regulation of television food advertising: Responsible or responsive. Intl. J. Pediatric Obesity. Vol 3, Supplement 3; Chambers, SA. et al. (2015). Reducing the volume, exposure and negative impacts of advertising for foods high in fat, sugar and salt to children: A systematic review of the evidence from statutory and self-regulatory actions and educational measures.

[xix] See e.g. Lesser *et al. (2007*) Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles. *PLoS Med* **4(1**); Washburn, J. (2007). Science's Worst Enemy: Corporate funding. Discover Magazine. http://discovermagazine.com/2007/oct/sciences-worst-enemy-private-funding

[xx] Trans Pacific Partnership Agreement (2016). Articles 18.47, 18.50

[xxi] Friends of the Earth (2016). *A new branch of science is born*. http://emergingtech.foe.org.au/a-new-branch-of-science-is-born/