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Committee Secretary
Senate Standing Committee on Community Affairs
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Canberra ACT 2600

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With the support of:

SAGFIN

FoodWatch

GMFAA

Comments on the Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Bill 2015

Thank you for the opportunity to comment on the Bill.

A. The Bill proposes:

4 Subsection 4(1)
Repeal the following definitions:

i. definition of ***Gene Technology Regulator***;
ii. definition of ***GMO***;
iii. definition of ***GM product***;

The definitions are defined with reference to the Gene Technology Act 2000 so that Section 19 can continue to be effectively implemented in concert with the Gene Technology Regulator's processes. This is essential to facilitating the necessary regulatory relationship between FSANZ, the OGTR and other regulators. Close and formal relationships between our federal regulators are essential to notification, assessment, regulation and monitoring of new industrial processes and their products. Deletion of the definition of GMO and GM product from the Food Standards Act would enable FSANZ to substitute definitions in the

Food Standards Code which are much weaker than those in the Gene Technology Act. The food products of new Genetic Manipulation (GM) techniques now being developed in labs around the world may be automatically excluded from FSANZ regulatory purview as a result of these definitions. But a deregulatory approach may put public health and safety in serious jeopardy, as these products have no history of safe use. Excellent scientific evidence, stringent assessment and epidemiological studies that track the impacts of any of these novel food products that may be commercialized, will be essential.

Recall the L-tryptophan case of 1989 in which the food supplement that Showa Denko synthesised using GM microorganisms caused over 1500 reported cases of a new disease EMS (Eosinophilia Myalgia Syndrome) in the USA, and at least 37 deaths there. US national surveillance found that on average 10% of consumers of Showa Denko's EMS-implicated L-tryptophan were diagnosed with EMS and there was no dose-risk relationship. EMS patients who had taken L-tryptophan supplements had taken them for between 0 and 3,668 days before onset of illness (0 indicating onset of illness on the same day as first taking L-tryptophan supplements), with a median of 127 days and a mean of 275 days.[1]

We therefore recommend retention of these definitions in the FSANZ Act.

B. The Bill proposes:

11 Section 19
Repeal the section.

19 Notices to be given to the Gene Technology Regulator

iv. If a provision of this Act requires the Authority to give a notice concerning an existing or proposed food regulatory measure to the Gene Technology Regulator, the Authority is only required to give the notice if the food regulatory measure relates to food that is or contains a GMO or a GM product.

But FSANZ notice to the OGTR of GM food applications and approvals is essential to the secure and co-ordinated regulation of GMOs and GM food products. The effective and failsafe functioning of the Commonwealth's integrated regulatory system depends on seamless and transparent co-ordination of decisions between various regulators (e.g. the setting of GAPs, MRLs and ADIs between the APVMA and FSANZ).

Co-ordination will be even more critical if the new products of novel GM techniques now being developed in laboratories everywhere, which have no history of safe use in the food supply, begin to be marketed. e.g.

- nuclease-based techniques – Meganucleases; Zinc-finger nucleases ZFNs); Transcription activator-like effector nucleases (TALENs); and Clustered regularly interspersed short palindromic repeats (CRISPR) and associated proteins (Cas); and/or
- Oligonucleotide-directed mutagenesis-based techniques e.g. Single-stranded

[1] http://cot.food.gov.uk/sites/default/files/cot/tryptophanamend200401.pdf

oligo-deoxynucleotides (SSOs or ssODMs); Chimeric RNA-DNA oligonucleotide molecules (RDOs); Small Fragment Homologous Replacement (SFHR); and Triple helix-forming oligonucleotides (TFOs).

We recommend the retention of Section 19. We also ask the committee to recommend that FoFR initiate a full review of the scope of GM techniques to which the present legislation and Food Standards apply. This should be expedited in anticipation that FSANZ may soon receive applications for the licensing of new GMOs, and approval of food products produced using novel GM techniques, that have no history of safe use in the human food supply.

Meanwhile, we also recommend as a precautionary measure that a robust moratorium be placed on commercialisation of all New Breeding Techniques (NBTs) until:

a) peer reviewed, independent whole of life and intergenerational safety experiments on each novel organism are commissioned and completed;
b) our national regulatory system on GMOs and other living organisms is adapted to require notification, assessment, licensing and monitoring of all NBTs; and
c) all potential health and environmental hazards are fully and independently researched, assessed and regulated.

C. **FSANZ is justified** in preferring to give notice of its regulatory activities on its website, rather than in the print media. However, we are not satisfied that FSANZ is sufficiently proactive in drawing attention to this information by notifying all relevant people in the food industry or the interested public of new proposals and decisions to amend or vary food standards and codes of practice. Relying solely on email to issue notices, newsletters, media releases and the like is insufficient to ensure that those who should be aware of proposed changes are fully apprised of FSANZ' activities.

We therefore recommend that FSANZ be required to also communicate its activities to its constituents not only by email but also by other electronic means, such as SMS texts, Facebook, and other cyber systems, etc.

D. **We disagree** with the following proposals to amend the Act:

32 Paragraph 63(3)(i) 4
Repeal the paragraph, substitute: 5
if applicable—a Regulation Impact Statement.

87 Paragraph 101(4)(g) 24
Repeal the paragraph, substitute: 25

i. (g) if applicable—a Regulation Impact Statement in relation to 26 the standard or variation.

The addition of 'if applicable' is unacceptable as:

- It is unclear who may be empowered to decide what is or is not applicable;
- No criteria of applicability appear to be set;
- A Regulation Impact Statement is an essential component of public accountability.

We recommend that the existing Paragraphs be retained, without amendment.

E. **We are substantially in agreement** with the following sections, as amended, to integrate the new name of the Forum on Food Regulation into the Act.

36 Subsection 64(2)
Repeal the subsection, substitute: 24
(2) If the Authority has notified the Forum on Food Regulation under 25 subsection (1), the Forum may direct the Authority to give the 26 Forum such information as the Forum **reasonably** requires for the 27 purpose of assisting the Forum to make a decision about the draft 28 under Division 3.

40 Subsection 69(5)
Repeal the subsection, substitute: 18

i. (5) If the Authority has notified the Forum on Food Regulation under 19 subsection (4), the Forum may direct the Authority to give the 20 Forum such information as the Forum **reasonably** requires for the 21 purpose of assisting the Forum to make a decision about the draft 22 under Division 3.

88 Subsection 101(5)
Repeal the subsection, substitute: 2

ii. (5) If the Authority notifies the Forum on Food Regulation that the 3 Authority has re-affirmed a standard or variation of a standard, the 4 Forum may direct the Authority to give the Forum such 5 information as the Forum **reasonably** requires for the purpose of 6 assisting the Forum to make a decision about the standard or 7 variation under section 102.

However, we recommend that the word 'reasonably' be deleted from all these Subsections. Who is empowered to exercise this discretion and what is reasonable in such circumstances are undefined. Removing the word 'reasonable' would ensure that the Forum has unfettered and unlimited access to the evidence it needs to make fully informed decisions, particularly when it decides to review, and perhaps reject or modify, FSANZ's recommendations and decisions.

F. **We concur with** the deletion of Subsection 92 (c). **However, we recommend** that Subsection 92 (d) be retained and rebadged as:

92 (c) the Authority must publish on the Authority's website a copy of:
1. the notice; and
2. the text of the draft or the amended draft.

G. **We strongly reject the proposal** to repeal Subsections 116(1) to (2) and to substitute:

Constitution of the Board
(1) The Board consists of:
(a) the Chief Executive Officer; and
(b) 11 members the Minister appoints under section 116A.

This proposal, together with the proposed repeal of Subsections 116 (2B) to (5) would give the Minister for Health unfettered powers to appoint FSANZ Board members without the:

- guidance or recommendations that sectoral or public nomination, or consultation, processes would provide;
- imprimatur of the Forum on Food Regulation being required; and
- consultation with the Forum on Food Regulation.

Vesting the power to appoint the FSANZ Board in a single Minister would politicise the appointment process and disenfranchise all other members of the Forum on Food Regulation, plus their constituents. It would repeal those provisions in the present Act which help to ensure that the Board is broadly representative and diverse in its composition, expertise and views, as it should be. Giving a Minister sole power to appoint would be an invitation for the most numerous and powerful sectoral interests on the Board to be over-represented and too influential. This would be undemocratic and not in the public interest.

We therefore recommend that Subsections 116 (1) (1A) (1B) and (2) be retained in the Act unamended.

Conclusion

Thank you for reading and favourably considering our comments. Please adopt our recommendations and, accordingly, make the proposed amendments to the Bill.

Yours sincerely,

Bob Phelps
Executive Director