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Submission to the Food Regulation Standing Committee on Review of FSANZ assessment and approval processes and treatment of confidential commercial information

The New Zealand Institute of Gene Ecology welcomes the opportunity to submit its views for consideration by the Committee on this key area of food safety assurance and regulation. We begin with three overarching observations:

1. A difficulty identified on pp 43-44 of the discussion paper is confusion over the policy/standards interface; specifically, that FSANZ consultation processes elicit submissions on policy, which FSANZ is unable to address. Presumably, this discussion paper *is* an example of a *policy* consultation, and is therefore the appropriate arena for raising broader issues of food policy, priorities, and approach. While food policy is clearly an area of broad public interest, the discussion paper indicates only consultation with "stakeholders". In fact, it appears that (non-transparent) "early consultations" with "some stakeholders" pointed to a "need" to expedite the current process and extend protection of commercial information. We question:

- The transparency and adequacy of the process that led to the identification of this "need" and the prioritising of this "need" above other work that the FRSC, or the food safety system more generally, could be carrying out;
- The limitation of consultation to "stakeholders";
- The compatibility of this alleged need with the three non-negotiable objectives of FSANZ; and
- The adequacy of this consultation process, in terms both of the time allowed and the efforts to involve a wider public.

2. We note that very little has been said about the harms that the current arrangements are alleged to be causing, and that in fact no evidence has been provided supporting the claim that harms are being caused. The paper notes a "backlog" in Group 2 applications assessments. However, whether this backlog constitutes a problem depends on the nature of Group 2 applications, the reasons for the backlog, and, most importantly, whether current arrangements regarding Group 2 applications interfere in any meaningful way with the goals and objectives of the food safety system. This has not been shown. As in the case of increasing numbers of Ministerial review requests (5.25), the numbers are assumed to speak for themselves, when it is the circumstances behind the numbers that must be elucidated. Before making changes that may erode the adequacy and transparency of the assessment process, a genuine need for such changes must be unequivocally demonstrated.

3. While the Ministerial Council "noted that it is important that processes for developing food standards are efficient, and minimise the regulatory burden on the

food industry" and "agreed that there are a number of impediments affecting FSANZ's ability to expedite new or amended Standards, and to protect confidential commercial information" (p.10)[1], it has not indicated that it is properly aware of the impediments affecting the public's ability to express its views and have them addressed. Having been involved in the FSANZ submission process, this organisation can say from experience that the balance between the public interest in safety and a trustworthy regulatory process, on the one hand, and the interests of the private applicant, on the other, is still not correct. In contrast to the discussion document, we do not feel that the balance favours the public. Our own research indicates that considerable time and money must be committed by members of the public to participate in the FSANZ consultation process; and even investment of time and money in a thorough submission does not guarantee that public views will be properly considered. We believe that the compliance cost of consultation is prohibitively high not because there is too much consultation, but because it is not properly supported by either industry or FSANZ. In our view, this is the issue that should receive the Council's priority consideration.

Our overall view is that FSANZ has not yet created the best system for open and effective public consultation. By further reducing the possible flow of information to the public it exacerbates the problem. The best way to expedite proposals for amending the food code is to create a system fully trusted by the public rather than further distancing the public from the process. Addressing the barriers to proper public consultation might make it possible to "streamline" the process while attaining an acceptable standard of "protection of public health and safety" and "transparency and consultation" (p.6).

The following section of the submission mirrors the structure provided in the Discussion Document.

Chapter 5, Part A

The discussion paper suggests that "early bird notification" might be substituted in some (or all?) cases for the Initial Assessment Report. Not enough information has been given as to how this would affect the public's opportunity to assess and respond to applications and proposals. A crucial issue is whether the application materials would be made available to the public at this stage. If not, we strongly oppose this suggestion. While current Initial Assessment Reports produced by FSANZ are so superficial that it is unlikely much would be lost by substituting for them a "2-5 page document", the loss of access to application materials would make it impossible for the public to make a contribution *on the particular application*, as opposed to commenting on general policy issues. (Thus this proposal conflicts with the discussion in chapter 6, part C.) To delay public assessment until the Draft Assessment stage is to significantly reduce the ability of the public to contribute to the process and would prevent FSANZ from taking account of information provided by the public in their risk assessment.

Section 5.7 proposes categories of applications that may be subject to a revised "early bird notification" procedure. In our view any such limitations on public access to and

[1] All page numbers are reference to the Discussion Document unless indicated otherwise.

transparency of the process must be clearly and explicitly justified. It is not acceptable to generate such limitations through the creation of arbitrary categories. The diversity of possible categorisations in section 5.7 illustrates this arbitrariness as well as the potential to significantly erode the transparency of the system.

While the entire list is fraught with problems, the final bullet point option in section 5.7 (p.31) is most troubling. Tying the assessment procedure to the outcome of processes in other countries drastically decreases the accountability and transparency of the process and is bound to erode public confidence in the Australia/New Zealand food regulatory system. Not only would the public not have had access to the relevant approval process, but FSANZ could not *a priori* ensure that the foreign processes met minimal standards set by the *Food Standards Australia New Zealand Act 1991* (the Act) and the prescribed objectives of FSANZ.

Chapter 5, Part B

The NZIGE would support, in principle, a change to procedure for a limited range of technical and minor amendments, but it would need to be clearly set out exactly *how they were determined to be minor and technical*. We endorse the statement (5.13) that "it is … difficult for FSANZ to make a judgment on these issues in advance of any consultation." We therefore do not support Options A1 or A2 as they currently stand.

In its discussion of expanding the use of urgency provisions, the paper notes: "It would, however, also be important that the urgency powers remain relatively limited in scope for use in true emergencies (be they public health and safety or trade) rather than for use as a means by which to streamline processes generally." We endorse the spirit of this statement, but we seek clarification on what would constitute a "trade emergency", and in what circumstances such an "emergency" can be permitted to override the three non-negotiable objectives of FSANZ, or the goal of a transparent regulatory system that enjoys the confidence of the public.

In general, NZIGE is not convinced that the case for expanding the emergency powers has been made. We question the need for Option A3 and would find it acceptable only if it can be demonstrated that public access and transparency are not adversely affected. We think this is unlikely.

The suggestion that Ministerial review requests be limited by requiring initiation by more than one jurisdiction seriously compromises the ability of the New Zealand public to protect its own safety and interests within the Australia New Zealand food regulatory system. In addition, as noted above, it has not been demonstrated that the number of Ministerial review requests is in any sense a problem. We therefore question the need for Option A4.

Chapter 6, Part B

An obvious way to relieve FSANZ workload without compromising public access or transparency is to require applicants to include minimum levels and types of information in their applications. NZIGE endorses the following suggestions (in 6.6): "amending the legislation to prescribe certain minimum application requirements (or to enable FSANZ to issue such requirements). … a statutory requirement that an

application be submitted in a prescribed form, and .. minimum requirements for data that must accompany the application. If such minimum requirements are not met the application can be rejected…"

We do not support expanding the role and the confidentiality of pre-application meetings; this option would erode public access and transparency, and the same goal can be accomplished in a way that would not do this (i.e., as described in the previous paragraph).

We thus support Option B1, (i), (ii), and (iii). Regarding identifying a process through which jurisdictions can make proposals (B1.iv), the most important consideration is that the process must be notified and transparent to the public.

Chapter 6, Part C

Option B2(i) seems sensible, and we support it. However, it raises more general issues regarding the process for developing policy guidance.

According to the discussion paper, "there would appear to be a level of confusion amongst stakeholders regarding the policy/regulatory divide and opportunities for input at the policy level. This has meant that a number of stakeholders utilise the FSANZ consultation processes on applications and proposals to address policy issues which are beyond the remit of FSANZ."

We suggest that among the reasons for this is the fact that the FSANZ consultation process, while not particularly accommodating of public input, is still more accessible to the public than the much more obscure policy-related processes occurring in other parts of the food regulatory structure. In other words, the problem is not public misunderstanding, but public access.

For this reason, we oppose the assigning of the function of providing policy guidance to an unaccountable, untransparent "expert body" (re B2(ii)). (The current working of FRSC is also inadequate in this regard.)

We also warn that the division between policy and standards is not necessarily self-evident. We therefore cannot support any move to allow FSANZ to rule out submissions *a priori* on the grounds that they do not address the particular application/standard unless the grounds for that move are made transparent and the submitter is directed to an appropriate party to receive the concerns expressed in the submission. (We note that in fact FSANZ currently fails to respond to most of the submissions it receives, except by summarising them; a good recent example of this is A525. We therefore doubt much time can be saved by making official a current practice.)

We endorse any move (B2(iii)) toward expanding public access to processes through which policy is developed, but we note that the opportunities to contribute policy development must be real as well as clearly laid out, that the public needs to be properly supported in their involvement in these activities, and that the effectiveness of the support should be evaluated from time-to-time.

The difficulty of clearly distinguishing standards from policy is well illustrated by the discussion of Standards Development Committees. If the development of standards were simply a matter of implementing the policy guidelines produced by ANZFRMC, such committees would not be necessary. The fact that such committees exist and are themselves confused about their role in relation to advice on policy issues highlights the artificiality of the policy/standards divide. The idea that this problem can be "solved" by removing the representative aspect of the committees and turning them into "expert bodies" (6.43) is therefore alarming. This would not remove the policy aspects from their work; it would simply make this policy work even more inaccessible to the public. We therefore cannot support Option B3.

Chapter 6, Part C

Apart from the issue of applications lacking adequate supporting information, the case has not been made that "clock-stops" either are being used inappropriately or are causing harm. We therefore see no case for further restricting the use of "clock-stops". With the adoption of Options B1 (i), (ii), and (iii), there should be no need for further restrictions. It is doubtful that further restrictions can be adopted without adversely impacting upon the core objectives of FSANZ.

Chapter 7, Part A

No evidence has been presented that harms are being caused by current practices of public notification. It is easy to make claims that innovation is restricted. Where is the evidence for this? And where is the evidence that the public interest in this innovation would outweigh public interest in transparency? Before restrictions on public knowledge and access are considered, harms must be demonstrated.

The transparency of the FSANZ system and the public's right to know may have costs to the industry, but these costs are appropriate. The industry benefits from public research investment, infrastructure and consultation. Society even subsidises the costs for regulating the industry. These are services and products that we believe dwarf the costs of hypothetical lost market opportunities.

Before any move is suggested to streamline the review process or decrease the flow of information about food and food products, independent research on the actual costs to industry are required. These costs should be evaluated in the context of the many ways industry benefits from other public processes. Complaints from industrial stakeholders that the procedures cost too much money are inadequate evidence.

Any effort to eliminate or reduce the perceived disadvantages to industry with regard to FSANZ's current practices for notifying applications must not further compromise the transparency of the regulatory process, which we contend is a significant advantage to the food and biotechnology industries in the longer term, and must not further undermine the public's right to know about its food. On these grounds we strongly object to Options C2, C4 and C5.

With regard to C3, we note that a situation in which CCI protection remains in perpetuity and cannot be revisited is clearly unacceptable. Our concern is with the

relative ease with which CCI status is acquired, as this directly compromises the ability of the public to assess applications and provide relevant information to FSANZ.

Of the options discussed, the only way to address the alleged problem without undermining the objectives and goals of the FSANZ Act would be to utilise aspects of C1 and C6. We support a modified version of Option C6. To minimise the "'free-rider' effect" and restore the "first market advantage" to the innovating manufacturer, the Act could be modified to make any revised standard applicable exclusively to the successful applicant or exclusive for a defined period of time, in the way of copyrights and patents (such as discussed on p.49-50). Unlike patent protection, however, other manufacturers wishing to produce foods of that type could still apply for, and presumably attain, a modification of the standard for their food provided that they at least met the same level of reporting. This modification allows for the continued release of information to the public, a release essential for their right to be informed during the consultation process, while protecting the legitimate investment in the applicants' intellectual property. We would not support a provision combining either Options C1 or C6 with further restrictions on access to information.

The most significant barrier to the effective assessment of applications to FSANZ is that the public is not sufficiently supported in their role as consultants. A more appropriate focus for policy development is how to use the food regulatory system to raise the capacity of the public to assess applications, especially those of intense public interest.

Yours sincerely,

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