

## Item D6 Talking Points – A1039 Low THC Hemp as a Food

### Introduction

- FSANZ is currently preparing the final report for this Application.
- The Ministerial Council asked that this application be presented for discussion at a face-to-face meeting. To meet this timeline, the final report will be considered by the Board at the April Board teleconference. The Forum on Food Regulation will consider it in June 2012.
- We are providing an update today to keep the Board up to date on the issues that we are addressing in our assessment.
- At Assessment FSANZ's preferred option was to approve the sale of hemp seed products, including de-hulled hemp seeds, oil, beverages and flour, subject to maximum levels of THC. The preferred option also included a requirement that whole hemp seeds not be permitted to be sold as food and that hemp seed products only contain hemp seeds that are non-viable.
- We received just over 50 submissions. Most submitters were in favour of approving hemp foods. However, government and Police submitters were generally not in favour of approval.
- We received whole of government responses from NSW, Queensland and New Zealand, in addition to submissions from South Australia Health, Western Australia Health and the Australian Department of Agriculture, Fisheries and Forestry. Western Australia Police and Tasmania Police also provided submissions. The Department of Health and Ageing also provided submission that was received after the submission cut-off date. We cannot formally accept this as a submission, but have noted their issues.
- DoHA, NSW and SA stated they did not support the approval of hemp foods. Qld, WA Health and New Zealand did not state their positions, but did raise a number of

issues that they consider would require consideration by FSANZ and the tone of these submissions was not positive in terms of approving hemp foods. The Police agencies identified issues that they consider would require addressing before hemp foods could be approved. DAFF was supportive of FSANZ's preferred option at Assessment.

- Some of the issues from submissions are readily addressed or have been addressed in our assessment to date. However, there are some issues that we are investigating further in preparation of the final report. Some of the issues raised are outside of the scope of what we can consider in making a decision to amend the Code.

### **Issues of importance for final report**

- It is important for FSANZ to clearly distinguish the issues we can address in making a decision on a food regulatory measure and those issues that may influence the decision to be made by Ministers.

### **Issues – in scope**

- There are two main issues of concern for Police and government agencies. Firstly, police agencies in particular have raised concerns that the consumption of hemp foods will interfere with the results of roadside or workplace saliva testing methodologies. Police are concerned that consumption of hemp foods will result in a greater number of positive saliva screen test results which will require confirmatory blood tests (which would have cost and time implications for Police and individuals). To address this FSANZ is refining our estimates of whether this risk is likely to occur, based on metabolism of cannabis after consumption and the methodologies employed in saliva swab testing.
- Secondly, Government submitters questioned whether the maximum levels for THC proposed at Assessment could be lowered, or even reduced to zero (DoHA

noted that only zero levels of THC could be considered before they could support approval). FSANZ is investigating whether we can obtain any further information from industry on the achievability of lower levels of THC in hemp food products. There is no safety concern to warrant lowering maximum levels, however if lower levels are achievable, this may assist in alleviating some concerns from government and Police stakeholders.

### **Other issues in scope**

- Submitters also noted other issues that FSANZ will address in the final report.
  - Firstly, we are investigating the need to include additional clarification in the drafting in relation to the use of viable seeds in production of foods and whether we need to specifically refer to 'low THC hemp'.
  - Secondly we will provide additional comment on the availability of suitable methods and systems for assessing compliance that hemp seeds are non-viable (and hulled) and for testing of THC levels in hemp food matrices.
- Thirdly there have been additional requests for labelling statements or prohibition of certain statements which we will consider further before finalizing the approval report.
- And fourthly there was some concern over the presence of other cannabinoids which we are addressing.

### **Outside of scope**

A number of submitters again noted issues which are outside our scope to consider. These issues have previously been considered by the Board. FSANZ will make it clear that these are issues that we cannot take into consideration in our decision. Inclusion of these issues in the final report may offer assistance for Ministers in their decision making.

They include:

1. Impact of other legislation: Legislation relating to the control of drugs and controlled substances, including poisons, may need to subsequently be amended before hemp foods could legally be sold and consumed in Australia and New Zealand.
2. UN Conventions on narcotics: Differing views have been expressed with respect to whether hemp foods should be subject to the UN Conventions and DoHA again noted that they consider the approval of hemp foods, with any levels of THC, would contravene the UN Convention.
3. Acceptance of illicit Cannabis: This relates to the potential for hemp foods sending a confused message to consumers about the acceptability and safety of illicit Cannabis. This concern is held by some stakeholders (particularly drug strategy agencies). However, FSANZ has noted that hemp seed oil is permitted for sale as a food in New Zealand and a variety of hemp products are available for sale in Australia and New Zealand. These permitted uses of hemp are also subject to this issue, and appear to have been managed. The responses received by FSANZ from international agencies noted that this did not appear to be an issue in those countries where hemp foods are permitted.

### **Preferred regulatory option**

Melanie Fisher will provide information on the benefit cost analysis next. However a key uncertainty in this assessment is the lack of data available on which to base the benefit cost analysis. This makes it difficult to use this as a decisive factor in determining the preferred option. However on the basis of the lack of risk, effects on industry and trade, our evaluation of international experience with hemp foods, the benefits for consumers, potential gains for industry and relative impacts on law enforcement FSANZ proposes to retain option 2B as the preferred option at this stage. That is, to approve the sale of low THC processed hemp seed products, excluding viable hemp seed.

We are asking the Board to provide comment on this approach, noting that we have performed a thorough analysis of the application within the scope of our Act, whilst providing enough information on those areas outside our responsibility to assist the Ministerial forum to make their decision. Our communication material will address our areas of responsibility to protect our reputation as an impartial decision maker.

## Background

Four potential regulatory options have been developed:

Option 1: Reject the Application, thus **not approving the use of low THC foods**

Option 2A: Prepare draft variations to permit the use of **low THC hemp seed oil products only** as food with maximum limits in the Code

Option 2B: Prepare draft variations to permit the use of **low THC processed hemp seed products** (which includes hulled seed but **excludes viable hempseed**) as a food with maximum limits in the Code

Option 2C: Prepare draft variations to permit the use of **low THC whole hemp seeds and hemp seed products** as food with maximum limits in the Code.

- Option 1 (status quo) is not supported by the risk assessment.
- Option 2A (hemp oil only) would provide only a limited market for food producers and limit the potential market for hemp producers. However, it would also result in hemp seed oil being permitted in both Australia and New Zealand, removing the current disparate situation between the countries. The effect on enforcement is not likely to be significant, particularly as the concern relating to distinguishing between different seeds will not be realised.
- Option 2C (all foods, including seeds) would provide the greatest market potential for hemp and food producers and the greatest variety in hemp food products for consumers. However, the ability to distinguish between hemp seeds and high THC Cannabis seeds would be a significant concern for law enforcement agencies under

this option.

- Option 2B (processed products, such as flour, oil, milk, protein powder and including hulled seeds) would provide significantly more potential than option 2A. In comparison to Option 2C it may limit the potential market for hemp and food producers. However, this option lessens the concern for law enforcement agencies relating to distinguishing between different types of Cannabis seeds, due to only processed and observably non-viable hemp seeds being permitted for retail sale.