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FSANZ: Applications and Submissions - Submission

Tuesday, 15 March, 2011

1. Assessment Report Number: A1034

2. Assessment Report Title: Advantame as a High Intensity Sweetener

3. Organisation Name: Department of Health, Victoria

4. Organisation Type: Government Agency

5. Representing: Department of Health, Victoria

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12. Submission Text: Application A1034 - Advantame as a High Intensity Sweetener. Second Assessment Report submission: This response is provided on behalf of the Department of Health (DH), Victoria. The DH supports Option 2A: to approve the use of Advantame as an intense (non-nutritive) sweetener in schedule 1 of Standard 1.3.1 at restricted maximum levels in table top sweeteners (powdered only) and a range of powdered beverages including including fruit flavoured drinks, milks and flavoured milk drinks, instant tea and coffee, milk and non-milk based meal replacements, and protein drinks; as requested by the applicant. The DH is satisfied that the applicant has met its obligations under the FSANZ Act and the FSANZ Application Handbook in that it has provided information: • to show that the use of Advantame is technologically justified • to demonstrate the technological function of Advantame in the products for which approval is sought • to enable FSANZ to conduct dietary exposure modelling and an assessment of the safety of Advantame and • describing a suitably robust analytical method to detect and quantify Advantame in the products for which approval is sought. In supporting Option 2A, the DH agrees with the conclusions drawn by FSANZ in its assessment of the above issues and notes that the dietary exposure modelling also included products in the same food group as the foods specified by the applicant, resulting in a more conservative estimate. The DH considers that the amendment to the Code under Option 2A is justified

and is enforceable because there is a robust analytical method to detect and quantify Advantame in the products for which approval is sought. The DH notes that Option 2B would result in a wider range of foods being permitted to contain Advantame than for Option 2A, with no restricted maximum levels. The corollary of the obligation on the Applicant to provide certain information is that, logically, any proponent of Option 2B should be required to provide the same kind of information as it applies to the extended range of foods. The information provided suggests that this obligation has not been met in relation to Option 2B. The FSANZ Regulations 1994 under Schedule 4 Clause 1, 1.2 gives the example of a General procedure level 1 as: 'an application for the variation or development of a food regulatory measure involving extending permission for use of a food additive'. The assessment report does not provide information for the extended range of foods proposed under Option 2B: • demonstrating the technological function of Advantame. Foods with varying moisture, pH and levels of processing have not been considered. • including these foods in dietary exposure modelling; and • describing a suitably robust analytical method to detect and quantify Advantame. In particular, the provision of methods of analysis that can be applied to the extended range of foods is critical to the enforceability of the standard by State and Territory food regulators (including local governments). Advantame is a new substance and no analytical method development has been undertaken for the wide range of foods contemplated by Option2B. As a result, the Standard would be unenforceable. Food standards are laws which must be capable of being enforced using the range of regulatory tools that are currently available under each State and Territory's Food Act. It is not appropriate to make unenforceable laws as this approach risks bringing the entire food regulatory system into disrepute. Any prosecutions for offences of the Food Standards Code must be proved beyond reasonable doubt. In the case of a standard relating to the authorised uses of a food additive, compliance can only be demonstrated by an approved analyst certifying whether or not the particular food in question is compliant with the standard according to a robust analytical method which would be accepted by a court of law. It is not appropriate to propose a standard on the assumption that a method of analysis may potentially be developed to enable its implementation after the law is made. Robust policy development requires implementation issues to be factored into the design of laws so that laws can be applied and enforced as intended. In this context, dry mixed powders present a relatively straight forward matrix for analysis compared with the complexities of high moisture processed foods where each food may require a different approach. DH also has some concerns about the lack of proposed maximum levels for a substance which has an established acceptable daily intake (ADI). DH recommends that option 2A be implemented. Option 2B should not be pursued but can be considered in a subsequent process when the proponent can demonstrate that all the issues associated with Option 2B outlined above have been satisfactorily resolved. If option 2B is proposed to be pursued at this time, the DH would like a clear response to the points made above. Finally DH also recommends that FSANZ considers reviewing its approach to toxicological assessments, in particular, the external peer review process in seeking expert scientific opinion. We suggest a panel review process be adopted, which is consistent with the approach undertaken by the European Food Safety Authority (EFSA).