



11 February 2013

Project Officer Application A1055
Food Standards Australia New Zealand
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Dear Sir/Madam

Application A1055 – Short Chain Fructo-oligosaccharides – Call for Submissions

Thank you for the opportunity to comment on this application. The Ministry for Primary Industries (MPI) has the following comments to make.

MPI is not in a position to support option 1 at the present time, as we would like clarification on a number of matters relating to the proposed definition, and the safety studies. These issues are outlined in our submission.

Classification of short chain FOS

The A1055 Call for Submissions report notes that inulin-derived substances are taken not to be nutritive substances. This is correct, in terms of how the Food Standard Code is drafted. However, as noted in the P306 reports, inulin and galacto-oligosaccharides (GOS) were classified as non-nutritive, as FSANZ did not want to pre-empt the outcome of the Ministerial policy development, and the future reviews of the definition of 'nutritive substances' and the infant formula standard. The following extract is from the P306 Final Assessment Report:

*Consistent with section 36, this Proposal adopted a focused approach, by restricting consideration to resolving the current uncertainty surrounding the addition of inulin-derived substances to general foods and inulin-derived substances/FOS and GOS to special purpose foods for infants and young children. Therefore, **the approach taken is considered an interim regulatory response.** FSANZ has taken this interim approach as it plans to consider issues more broadly through a future review of the definition of 'nutritive substance' and its application in the Code, and to a future review of Standard 2.9.1 – Infant Formula Products.*

MPI considers therefore that the Approval Report for A1055 should note that the classification as ‘not nutritive’ was an ‘interim regulatory response that was intended to provide short term regulatory clarity’. A1055 implies that inulin and GOS were assessed to be ‘not nutritive’ substances, when in fact a determination was not made one way or the other.

Terminology

In the A1055 Report, FSANZ uses terminology which is not consistent with that previously used in the P306 reports or in the Food Standards Code. This leads to confusion as to what is currently permitted and what substance is being assessed. Short chain FOS (scFOS) has been defined in application A1055 as mixtures of unbranched polymers of ≤ 9 fructose monomers, in line with the Food Chemicals Codex (2012) definition. Problems arise as scFOS derived from inulin span a larger range of polymerisation (DP 3-9) and many are already clearly included in the current Food Standards Code definition of ‘inulin derived substances’. In the P306 proposal scFOS with a DP 4 -9 derived from inulin were approved for use under the definition of ‘oligofructose’ in the definition of ‘inulin-derived substances’.

Although scFOS derived from sucrose has the same chemical structure as some of those derived from inulin at the lower range of polymerisation, scFOS_{inulin} can have larger range of polymerisation spanning DP greater than 4 and less than 10, and do not always contain a glucose moiety at the terminal end. It is our understanding that this application applies to scFOS_{sucrose} and its equivalence to scFOS_{inulin} with a DP ≤ 4 . It is our interpretation that scFOS_{sucrose} and scFOS_{inulin} with a DP ≤ 4 are essentially identical in chemical structure, except for those scFOS_{inulin} without a terminal glucose moiety. However, many international regulations clearly differentiate between scFOS with a lower range of DP in their regulation, as had FSANZ in the previous proposal P306. FSANZ should clearly identify what is meant by the term “nature identical” as used in the following statement in Supporting Document 1, and how it applies to the scFOS_{inulin} with DP ≥ 4 :

“Hereafter or unless otherwise specified, the term scFOS will be used to cover both scFOS_{inulin} and scFOS_{sucrose} because both are nature identical”

In Supporting Document 1 many studies refer to scFOS but do not characterise the type of scFOS. Some of these studies include prebiotics that contain fructan molecules with a DP greater than 4 derived from inulin that are already permitted in the Food Standard Code. MPI does not consider it appropriate to use scFOS_{inulin} with a higher range of polymerisation as supporting evidence for the approval of scFOS_{sucrose} as sufficient evidence, as their equivalence to all scFOS has not been provided. Where possible FSANZ should be identifying the type of scFOS according to DP to ensure the reader fully comprehends the application.

Throughout this submission, MPI will refer to scFOS as that defined by the Food Chemicals Codex (2012) as those fructans with a DP between 3 and 9, and will specify those with a DP less than or equal to 4, and those a with DP greater than 4 but less than or equal to 9.

Short Chain FOS derived from Inulin

The Application states that scFOS_{inulin} is already permitted in the Food Standard Code. In the P306 report scFOS_{inulin} with a DP less than ten but greater than or equal to four is clearly included in the definition of inulin-derived substances. However, the permission of scFOS_{inulin} with a DP ≤ 4 is less clear.

The P306 report states that FSANZ definitions from the Final Assessment Report are the basis of approval, yet none of the definitions refer to a substance that includes scFOS_{inulin} DP ≤ 4 , except the term 'fructo-oligosaccharide'. 'Fructo-oligosaccharides' with a DP ≤ 4 were thought to be typically produced from sucrose and there is no mention of those, that are now recognised in the Food Chemicals Codex, to be derived from inulin. It is questioned whether scFOS_{inulin} DP ≤ 4 were reviewed at the time of the P306 risk assessment as none of the studies referenced appear to include them.

Definitions from P306 Final Assessment Report

The term 'inulin-derived substances' is used to collectively describe inulin, long-chain inulin and oligofructose. This term does not include those fructose polymers derived from sucrose;

the term 'oligofructose' is used to describe those fructans, with β (2 \rightarrow 1) fructosylfructose linkages, where the average DP is less than ten but greater than or equal to four. Oligofructose is derived from inulin. Chicory inulin, for example, contains about 30% oligofructose; and

the term 'fructo-oligosaccharides' is used to describe those fructose polymers with β (2 \rightarrow 1) fructosyl-fructose linkages, where the average DP is less than four and is typically produced from enzymatic condensation of sucrose.

Previously it was MPI's view that the intent of the definition of inulin derived substances was to exclude all scFOS with a DP ≤ 4 from the Food Standards Code based on the statement below in the P306 First Review Report, and on the basis that no studies in the P306 report assessed scFOS_{inulin} with a DP ≤ 4 .

"This decision does not permit the addition of fructo-oligosaccharides (FOS), as defined in the P306 Final Assessment Report, to these foods as there is insufficient evidence to support their addition."

The First Review Report for P306 states that fructo-oligosaccharides, as defined in the Final Assessment Report, are not permitted. The definition of fructo-oligosaccharides as reproduced above, does not exclude those derived from inulin, and only states that fructo-oligosaccharides with a DP ≤ 4 are 'typically' produced from sucrose. MPI would like to seek clarification of where in the P306 report scFOS_{inulin} with a DP ≤ 4 was reviewed and permitted for inclusion.

Current regulation of scFOS as dietary fibre

It would be helpful if the Approval Report for A1055 clarified the current regulatory status of scFOS derived from sucrose, as a source of dietary fibre. In other words, does scFOS_{sucrose} fall within the definition of the already approved oligosaccharides in the definition of dietary fibre in standard 1.2.8 and 1.2.7? Can scFOS_{sucrose} already be added to foods standardised under standards 2.9.2 and 2.9.3, including those in division 4? If scFOS_{sucrose} is already permitted as 'dietary fibre', then A1055 will impose stricter limits.

International regulation

The term scFOS which includes all fructo-oligosaccharides with a DP 3-9 can be quite confusing in relation to assessing international regulations, as in some regulations only certain scFOS are permitted. For example, in the US, GRAS status has only been approved for scFOS with a DP greater than 4 for infant formula, and thus excludes scFOS_{sucrose} and scFOS_{inulin} with a DP ≤ 4 . In the EU, only high molecular weight fructo-oligosaccharides are permitted to be added to infant and follow-on formula, and in a specified ratio to galacto-oligosaccharides.

The A1055 Call for Submissions reports states that scFOS is permitted in the US and EU, however it needs to be clear that it is only the higher range of polymerization permitted for infant formula.. Amending the Code to include scFOS with a DP ≤ 4 , or scFOS_{sucrose}, would align with Japanese regulations, and those countries where FOS has not been explicitly characterised and defined.

Physiological benefits

Of the studies reported in Section 4 of Supporting Document 1 as having a beneficial physiological effect, only one of the studies has characterised the scFOS as a fructo-oligosaccharide with a DP ≤ 4 (Pickering 1993). In this study a very small beneficial effect was only seen at one point in time (day 28), at all other time points there was no difference between those infants that were breastfed, or fed formula with or without scFOS DP ≤ 4 . The remaining studies listed as having a beneficial effect either did not characterise the scFOS and were assessed in older infants (O’Ryan 1996), or contained Raftilose95 (Euler 2005, Bettler and Euler 2006) which was previously assessed in the P306 proposal and was defined as an oligofructose derived from inulin with a DP < 10 but ≥ 4 .

One study in infants which identified that scFOS DP ≤ 4 was used as the intervention, reported no significant effect on stool consistency (Malacaman 1993). A second study identified as using scFOS DP ≤ 4 intervention in toddlers with a history of constipation found an improvement in stool consistency at one dosage out of four (0.6g/kg body weight) when provided for two days (Pollack 2001).

If the two studies that use Raftilose95 are excluded from the assessment of beneficial effects of scFOS derived from sucrose, or scFOS with a DP ≤ 4 , there is only very weak evidence to suggest that scFOS derived from sucrose has any beneficial effect on stool consistency in infancy. It is questionable as to whether this meets policy principle (j) that states “substances subject to pre-market assessment for use in infant formula and follow on formula should have a substantiated beneficial role in the normal growth and development of infants and children’.

Sweetness of short chain FOS

We note the conclusion in the A1055 Call for Submissions report that any increase in sweetness contributed by short chain FOS is expected to be minimal. However it is known that fructo-oligosaccharides with a lower DP have a higher level of sweetness. Therefore, if manufacturers choose to add only scFOS with a DP ≤ 4

instead of combinations with longer chain fructans, the product will be sweeter. The degree of increase in sweetness could easily be measured in experiments; MPI considers that this point needs fuller analysis at the Approval Report stage, particularly for infant formula and follow on formula.

Processing aid - Invertase from *Aspergillus niger*

If the outcome of A1055 is to permit scFOS derived from sucrose, MPI supports the amendment to Standard 1.3.3 to permit the inclusion of invertase (EC 3.2.1.26) from *Aspergillus niger*. MPI supports the amendment on the basis that there are no identified public health and safety issues, and that an acceptable daily intake “not specified” is considered appropriate. FSANZ may consider updating the name ‘invertase’ to β -Fructofuranosidase in line with the Codex Inventory of Processing Aids.

Proposed Definition for inulin-type fructans

MPI would like to seek clarification on the term ‘predominantly’ in the proposed definition of ‘inulin-type fructans’. Is it the intention to include those fructans which also contain the $\beta(2\rightarrow6)$ linkages as noted in the report as levan type fructans? We are aware of highly branched inulin-type fructans from the agave plant which contain a high proportion of $\beta(2\rightarrow6)$ linkages and would like to ensure that the proposed definition captures the appropriate types of fructans. Alternatively it could be considered that a list of permitted plants that can be used as the source of inulin for food products is considered. Most commercial sources of inulin will have been characterised already and could be included.

The term ‘inulin-type’ is vague as it is not clear how close to inulin it has to be, to be the type.

MPI suggests that internationally accepted definitions are used in the Food Standards Code, and that the permissions are listed out separately. Combining all proposed substances into one sentence is not providing Code users with certainty over what is permitted.

We look forward to further information provided in the Approval Report.

Yours sincerely