Glycom Submission

Consultation Paper for Application 1155 (A1155)
2′-FL and LNnT in infant formula and other products

14 January, 2019

Glycom Submission

A1155: 2′-FL and LNnT in infant formula and other products

This submission is made on behalf of Glycom A/S, Denmark. Glycom A/S is the manufacturer of the oligosaccharide ingredients 2'-fucosyllactose (2'-FL) and lacto-*N*-neotetraose (LNnT) being the subject of application A1155.

These ingredients are highly purified and structure-identical to the same 2'-FL and LNnT molecules of human breastmilk, which are better known by their collective term „human milk oligosaccharides" (HMOs). Glycom A/S manufactures a range of structure-identical human milk oligosaccharides by modern biotechnology and uses the term „human-identical milk oligosaccharides" (HiMOs) to distinguish these manufactured forms from the isolated molecules from the natural source (i.e. human breastmilk). Isolation from natural sources is commercially not feasible due to human breastmilk being the only relevant natural source of 2'-FL and LNnT. Glycom A/S has gained regulatory approval for its structure-identical HiMOs in a growing number of global markets (e.g. EU, US, Singapore, Malaysia, Israel) and wishes to make these innovative ingredients available to the consumers of the common market that is regulated by the Food Standards Australia New Zealand (FSANZ).

Glycom A/S thanks FSANZ for the consultation paper for Application 1155 (A1155), and appreciates the high technical and scientific skills that went into the risk assessment. We welcome the opportunity to consider the preliminary views proposed, and to provide comments to FSANZ relating to the regulation of the voluntary use of 2'-fucosyllactose (2'-FL) alone or in combination with lacto-*N*-neotetraose (LNnT). We thank FSANZ for their consideration of the comments and views raised in this submission.

Comments on the Consultation Paper

Glycom wishes to comment on selected aspects of the 1st Call for Submissions for Application A1155, namely the **Summary of the Assessment** (pages 8ff of 1st CFS).

As general remark we would like to express our agreement to sections that we didn't chose to comment on.

1st selected extract from 1st CFS:

2.2.2 Permitted use

In permitting 2′-FL and LNnT as proposed above, express permission would be provided for both 2′-FL and LNnT to be *used as a nutritive substance* and as *food produced using gene technology* (as discussed in section 1.3.1); noting that no public health and safety concerns have been identified for these substances derived from the applicant's GM production strains. The applicable GM labelling requirements are discussed in section 2.2.5.4 below.

FSANZ's preliminary position is to permit both 2'-FL and LNnT to be *used as a nutritive substance*, and as *food produced using gene technology* derived specifically from GM production strains *E.coli* SCR6 (for 2'-FL) and *E.coli* MP572 (for LNnT), for use in infant formula products and FSFYC.

12

Comment on FSANZ preliminary position

Glycom supports 2'-FL and LNnT to be considered as being *used as a nutritive substance*.

Glycom does not support 2'-FL and LNnT to be considered as *food produced using gene technology*. This would be inconsistent with the approvals received in the EU, US, Singapore, Malaysia and Israel (and a number of forthcoming approvals in additional markets), where 2'-FL and LNnT are regulated as novel foods. The preliminary position may also introduce a barrier to free trade.

It is also Glycom's opinion that this preliminary position is not well-balanced to reflect the scientific data and nature of the ingredients. The ingedients as proposed for addition to foods are highly purified, single molecules and as such virtually indistinguishable from the same molecules from other sources. They are substantially equivalent to the same molecules from different sources. A collection of technical data was presented in the application to support this scientific view.

Secondly, this peliminay position would place 2'-FL and LNnT into the same policy standard that is applied for genetically modified crops and plants, which is highly misleading to the consumer. These ingredients are single-molecule, purified milk oligosaccharides, and not genetically modified plants. In this context, Glycom would also like to comment that vitamins produced with genetically modified microorganisms are not regulated in a similar fashion even though the principles of the manufacturing technology are identical.

2nd selected extract from 1st CFS:

2.2.6 Specifications for 2′-FL and LNnT

Since no specifications currently exist for 2′-FL or LNnT in Schedule 3, FSANZ proposes inserting the specifications provided in the application into the Code. As discussed in SD1, these specifications are approved for use in the EU and US, and relate to the applicant's 2′-FL and LNnT produced by microbial fermentation.

FSANZ's preliminary position is to set specifications for 2'-FL and LNnT using those provided by the applicant.

Comment on FSANZ preliminary position

Glycom supports specifications to be regulated within Schedule 3 (Identity and Purity), but we wish to express that explicit analytical methods should not be linked to the specifications as this would introduce hurdles to adjust quality control in the future to state-of-the-art technological developments which may provide a range of advantages.

Glycom wishes additionally to propose for the strain to be located together with the specification in Schedule 3, and would propose the strain to be prescribed as a derivative of *E. coli* K-12 DH1 MDO. This would help facilitate innovation at a production strain variant level through elimination of current limitations (example: elimination of plasmids, elimination of antibiotic resistance genes, elimination of IPTG use), without any impact whatsoever to the genes being expressed to produce 2'-FL and LNnT. Glycom would be willing to accept a condition for the scope of this application under which no different genes from the ones already assessed can be introduced into potential future improved production strain variants.

3rd selected extract from 1st CFS:

2.2.7 Exclusivity

[…]

The applicant has requested exclusivity for their specific brand of 2′-FL and LNnT[16] on the basis that they, and their business partners, have invested significantly in the technology development and safety studies. FSANZ notes, however, that approval of both 2′-FL and LNnT as food produced using gene technology derived specifically from the applicant's GM production strains, and the proposed specifications discussed above, may provide exclusive permission to the applicant without the need for a specific brand name. FSANZ will further consider this matter in the 2nd Call for Submissions (CFS) when developing the specific drafting.

Comment on FSANZ preliminary position

Glycom wishes to comment that the application has been submitted under the novel food framework and includes a request for exclusive permission for the use of 2'-FL and LNnT as novel foods to allow for Exclusive Capturable Commercial Benefit (ECCB) due to significant investments that Glycom had to make to develop the technology and to support the application. Beyond the investments already made, the corresponding assessment procedure by FSANZ involves a additional significant assessment fee in context of novel foods applications.