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Response to the 2nd Call for submissions – Application A1155:

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BASF welcomes the opportunity to comment on the 2nd call for submission regarding Application A1155 permitting the voluntary addition of 2'-O-Fucosyllactose (2'-FL) alone or in combination with Lacto-N-neotetraose (LNnT), produced by microbial fermentation, in infant formula products and formulated supplementary foods for young children in Australia and New Zealand.

BASF supports the FSANZ's view regarding that the proposed permission that it would also supports international consistency and a competitive food industry (high order policy principles 2(b) and (c)), providing trade opportunities, by also providing alternative options to existing inulin-type fructans (ITF) and galacto-oligosaccharides (GOS) as permitting alternative options to these oligosaccharides provides industry with innovation opportunities.

Furthermore, BASF supports FSANZ's conclusion that 2'--FL is binding to invasive *C. jejuni* strains and subsequently inhibiting their attachment and growth, is biologically and mechanistically plausible and thereby has an anti-infective effect and also that the evidence would also support the biological and mechanistic plausibility of a bifidogenic effect from the proposed use of 2'-FL'- alone or with LNnT, if the bifidobacterium strains which metabolise these oligosaccharides are present.

Furthermore, we support FSANZ's approach to set specifications for 2′-FL and LNnT in the Code without specifying the methods of analysis.

Following now the BASF comments to the 2nd call for submission***:***

> ***FSANZ's approach is to provide 15 months exclusivity from the date of gazettal for the applicant's brand of 2'-FL and LNnT.*** *(Point 2.2.7 of the CFS report).*

BASF appreciate FSANZ's approach to link permission to the gene-gene-donor information and not to the productions strain as the latter approach would provide exclusive permission to the applicant, without the need for a specific brand name. However, we want to point out that an efficient internationally competitive food industry is not supported by permission of specific gene-gene donor combinations, that are restricting market access for safe products. Instead, generic approvals for products meeting the specifications are supporting an efficient, internationally competitive food industry. The current manufacturers of 2'-FL have equivalent products and the developed strains are all suitable for the same purpose. There is no convincing reason to limit the permission to a specific proprietary production route. Furthermore, it would exclude other 2'-FL manufacturers to supply this important nutrient to the Australian and New Zealand infant food industry. Since 2'-FL is still a new ingredient in food supply the global capacities are still limited to cover the global needs. Excluding other suppliers from the Australian and New Zealand market by a company-

specific authorization would limit the access of Australian and New Zealand companies to these new ingredients and therefore, limit the access of parents that need to also rely on infant formula for the best available infant formula ingredients.

Therefore, we are strongly in favor of a generic approval / authorization instead of providing a 15 months exclusivity for the applicant's brand of 2'-FL and LNnT for the following reasons:

1. 2'-FL and LNnT are nutritive substances which are important ingredients for infant nutrition and is a significant improvement that narrows the nutritional gap between infant nutrition and human milk and can provide benefits for many infants that cannot be breastfed. Therefore, sufficient availability on the Australian and New Zealand market is the prerequisite for offering these benefits. An applicant-specific exclusive approval would exclude competition in the Australian and New Zealand market with the additional risk of a possible insufficient supply by only one permission holder considering also the worldwide requirement for these important ingredients. This could be avoided if FSANZ would decide to base the novel food specification on a generic product authorization instead of providing exclusive permission to the applicant.

2. If the current intention of FSANZ were followed to adopt the application of 2′-FL and LNnT as food produced using gene technology derived specifically from the applicant's specific gene-gene donor combinations , and if FSANZ would adopt the specifications as proposed by the applicant naming the brand name, FSANZ would provide exclusive permission to that applicant for a period of 15 months and thereby limit the access of this important ingredient for other infant formula companies during that time.

3. 2'-FL is manufactured by different companies with similar specification and is already available in different markets and cannot be considered a "novel" ingredient. The applied technologies for the production of the HMO products are common technological standard, as based on the same process principles and resulting in the same high-quality product which ensures all safety aspects as needed in particular when intended to be used in infant nutrition.

4. Authorization in the European Union is generic, and the Union list serves as a reference for economic operators who wish to place in the market an authorized novel food. No subtypes of the strain or any specific gene-gene donor combinations, which might be used by different companies, are mentioned in the specification of the European Union list indicating the equivalence of the products and the production methods and aiming to support an efficient and internationally competitive food industry as well as provision of the market with important and beneficial human milk identical ingredients.

5. 2'-FL and LNnT were granted generic authorizations in Singapore by the Singapore Food Agency for the use as ingredients in infant formula including follow up formula and growing up milk independent of the way of manufacture (by fermentation or synthetically).

6. 2'-FL was also recently granted a generic authorization in Malaysia as a permitted added nutrient by the Ministry of Health, Malaysia. This nutrient can now be added to general food, infant formula, follow up formula and formulated milk powder for children.

In conclusion:
Given the above reasons, we strongly proposed that 2‘-FL and LNnT be granted a generic authorization instead of providing exclusivity to allow better access of this important nutritive ingredient for the overall benefit of the infant population in Australia and New Zealand.
We understand the intention of the FSANZ NOVEL FOOD STANDARD for granting an exclusivity with regard to the importance of data protection and/or first to market advantage to ensure commercial advantage for the first applicant.
It shall be pointed out that in particular the product 2’-FL is manufactured by different companies with the same resp. highly similar specification and is already available in different markets and cannot be considered a “novel” ingredient anymore. The applied technologies for the production of the HMO products are common technological standard, as based on the same process principles and resulting in the same high-quality product which ensures all safety aspects as needed in particular when intended to be used in infant nutrition.