



## **Nestlé Australia Ltd Submission**

Consultation paper – Proposed clarification that goods are therapeutic goods – goods containing folate substances in certain circumstances.

Response – 17<sup>th</sup> September 2019

## **Nestlé Submission**

### **Consultation paper – Proposed clarification that goods are therapeutic goods – goods containing folate substances in certain circumstances.**

Nestlé welcomes the opportunity to provide comments in response to TGA's proposal to declare certain goods containing folate substances to be therapeutic goods when used, advertised, or presented for supply in a certain way.

Food standard 2.9.5 "Food for special medical purposes" is a standard under the foods standards code that permits a food to be specially formulated for people who have special medically determined nutrient requirements.

Foods for special medical purposes ('FSMP') can be represented as being for the dietary management of a disease, disorder or medical condition.

FSMP must not

- (a) Refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition: OR
- (b) Be compared with a good that is:
  - (i) Represented in any way to be for therapeutic use; or
  - (ii) Likely to be taken to be for therapeutic use.

It is already therefore not permitted for a food presented as being for a Food for Special Medical Purposes to make therapeutic claims.

Therefore it should not be necessary for TGA to make this order as these types of goods are not permitted to make therapeutic claims. If these type of goods are making therapeutic claims that would already make them therapeutic goods as defined by the Therapeutic Goods Act.

### **Issues with the requirements of column 3 of schedule 2.**

The presentation inclusions of Column 3 mean that if a FSMP product which complies with the Food standards code and contains folate is used, advertised or presented for supply, for therapeutic use, or in a way that is likely to be taken to be for therapeutic use then TGA has declared that the product is a therapeutic good.

This definition may cause unintended problems for manufacturers / suppliers of FSMP products that comply with the food standards code.

- (1) Manufacturers / suppliers of FSMP products cannot control every usage of their product. If an FSMP product is used by someone for therapeutic use, when the goods are not advertised or presented for that use by the manufacturer or supplier then this should not make the products therapeutic goods.
- (2) Manufacturers / suppliers of FSMP products may not be responsible for all the advertising or presentation for supply of their products. If a manufacturer / supplier of an FSMP product is fully complying with the food standards code for their product and if, unknown by or unrelated to the to the product manufacturer / supplier, some third party advertises or presents the FSMP product for therapeutic use that should not make the FSMP product a therapeutic good. In this case the issue is not with the FSMP product, the issue is with the advertisement making illegal therapeutic claims and the person making the advertisement would be responsible.

## **Other**

As this proposed order is limited to therapeutic use related to a folate substance, schedule 2 Column 3 (d) should be amended to “curing or alleviating an inborn error of **folate** metabolism;” This is consistent with the wording of point (e) which specifies folate deficiency and would help provide clarity and oval consistency.

## **Conclusion**

It should not be necessary to make this order. The food standards code already prohibits FSMP products from making therapeutic claims. The definition of therapeutic goods and therapeutic use is already included in the Therapeutic Goods Act.

If a product on the market purports to be a Foods for Special Medical Purposes product but is making therapeutic claims it is not complying with the Food Standards Code and is already defined as a therapeutic goods by the Therapeutic Goods Act.

This order does nothing to clarify or enhance the definition of therapeutic goods found in the Therapeutic Goods Act.

Therapeutic Goods under the Act means goods that are represented in any way to be, or that are, whether by the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use.

Rather than providing clarity about the regulation of therapeutic goods this order by further defining certain goods as therapeutic goods by how the goods are used or advertised could cause unintended consequences for manufacturers and suppliers of Foods for Special Medical Purposes products. This is because manufacturers cannot control how their products are used and people other than the manufacturer may advertise a Foods for Special Medical Purposes product without the knowledge of the product manufacturer / supplier.