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SUBMISSIONS IN RESPONSE TO PUBLIC CONSULTATION OF

Proposed Amendments to the Harmful Substances in Food Regulations (Cap. 132AF)

Wyeth (Hong Kong) Holding Company Limited (“Wyeth Nutrition”), a leading nutrition company in Hong Kong supplying quality nutrition products, welcomes the Centre for Food Safety (“CFS”)’s direction in taking extra steps to protect public health which we share the same goal. We agree that the regulatory direction should take reference to international standards or guidelines in other developed markets.

In response to the Public Consultation of Proposed Amendments to the Harmful Substances in Food Regulations (Cap. 132AF) (“Proposed Amendments”) released in December 2020, Wyeth Nutrition would like to put forward our views in this submission for CFS’s consideration.

1. Specification on whether the Maximum Level applies to finished product as sold or as consumed

With reference to the Proposed Amendments, it is found that not all substances are indicated whether the Maximum Level (ML) applies to finished product as sold or as consumed. For clarity purpose, it would be better to specify this for all substances.

2. Applicability and indication of ML

We suggest CFS to consider the nature and form of the foodstuff when establishing the ML, and to indicate the condition in the regulation. Taking the Aflatoxin B₁ ML on dietary foods for special medical purposes intended specifically for infants from the EU regulation ([EC 1881/2006](#)) as an example, the ML refers in the case of milk and milk products, to the products ready for use (marketed as such or reconstituted as instructed by the manufacturer) and in the case of products other than milk and milk products, to the dry matter.

3. Applicability to impose Total Aflatoxins (B₁+B₂+G₁+G₂) ML on infant formula, follow-up formula and dried milk

According to the Proposed Amendments, CFS proposes a ML of 5mcg/kg on any other food (includes infant formula, follow-up formula and dried milk). However, among international regulations and standards, aflatoxins B₁+B₂+G₁+G₂ ML is not commonly applied on infant formula, follow-up formula and dried milk:

- EU ([EC 1881/2006](#)): Aflatoxins B₁+B₂+G₁+G₂ ML is only applied on nuts, dried fruits, cereal products and spices.
- CODEX ([CXS 193-1995](#)): Aflatoxins B₁+B₂+G₁+G₂ ML is only applied on nuts and dried figs

We thus propose not to apply the ML of Total Aflatoxins to infant formula, follow-up formula and dried milk.

4. Applicability to impose Aflatoxin B₁ ML on infant formula and follow-up formula

CFS took reference from the EU ([EC 1881/2006](#)) and proposed a ML of 0.1mcg/kg on any food intended to be consumed principally by persons under the age of 36 months (including infant formula and follow-up formula). As per our understanding, under the EU regulation and foodstuff defined therein, this limit applies to processed cereal-based foods and baby foods for infants and young children, and dietary foods for special medical purposes intended specifically for infants, but does not apply to infant formulae and follow-on formulae, including infant milk and follow-on milk. We thus suggest CFS to consider not to apply ML in these product categories for the prior mentioned substance.

To conclude, we agree the regulatory direction should take reference to international standards or guidelines in other markets. It will be grateful if CFS would take our recommendations into positive consideration.

Wyeth (Hong Kong) Holding Company Limited
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