

Memorandum

Date: 16 October 2019

To: Doug Lueders, Chair Model Bill and Regulations Committee (MBRC), AAFCO

From: Emily Bulian Helmes, MBRC Work Group (WG) Leader (ETA) *EBH*

Cc: Padma Pillai (FDA); Jan Campbell (NGFA); Leah Wilkinson (AFIA); Angele Thompson (PFI)

Subject: Regulation 4 Expression of guarantees regarding (g) Microorganisms and (h) Enzymes

The MBRC WG met on October 8 to discuss the editorial changes needed to Regulation 4, Expression of Guarantees (g) and (h). The outcomes of this meeting were:

1. The WG was aligned on the modified language for Model Regulation 4 – Expression of Guarantees for Microorganisms and Enzymes (see below version), subject to concurrence from ETA and AFIA members, which was received on October 16.
2. The WG agreed on the following path forward regarding resolution of the Industry-expressed concern over potentially misleading language approved by the AAFCO Membership in August 2019 regarding Expression of Guarantees for Direct-Fed Microorganism products:
 - a. Contact Doug Lueders to find out whether or not the AAFCO By-Laws would permit the below MBRC WG recommended Regulation 4 Editorial Changes to be moved forward for consideration by the AAFCO Board without a vote by the MBRC.
 - b. In the event that the AAFCO MBRC must vote and approve of this Editorial Change, the WG recommends:
 - i. Requesting that Chair Lueders request that MBRC members be contacted and that an electronic vote be made by Nov 15 to approve this Editorial Change to Regulation 4 Expression of Guarantees. This would enable the editorial change to be voted on by the AAFCO Membership at the Jan 2020 AAFCO Board Meeting. By so doing, the electronic OP would be updated early in 2020 to reflect the corrected language, even though the 2020 AAFCO OP in print would include the potentially misleading language.
 - ii. Request Chair Lueders ask the AAFCO Board for help to encourage AAFCO Members to use regulatory discretion as regards the language in the print version of the 2020 AAFCO OP. FDA permits guarantees of microorganism content be labeled based on total microorganism CFU/g (or CFU/lb) and does not require guarantees by each species, as may be inferred from the approved language. In the edited language (below), both approaches to guaranteeing microorganism content are permitted.

10/16/2019 MBRC WG Recommended Editorial Changes to AAFCO Model Regulation 4 Expression of guarantees regarding (g) Microorganisms and (h) Enzymes

Regulation 4. Expression of guarantees

.....
.....

(g) Guarantees for ~~viable~~ microorganisms ~~shall list each genus and species in order of predominance, and~~ shall be stated and conform to the following:

(1) Colony forming units per gram (CFU/g) or per pound (CFU/lb) consistent with the directions for use~~;~~ or

~~(2) CFU per product unit (e.g., tablets, capsules, granules, or liquids) consistent with directions for use and the quantity statement or weight equivalent (e.g., 1 fl oz = 28 grams) for liquid products.~~

~~(3) A parenthetical statement following the guarantee shall list each genus and species of microorganism in order of pre2- dominance.~~

(h) Guarantees for enzymes shall be stated and conform to the following:

(1) Units of enzymatic activity per unit weight or volume consistent with the directions for use~~;~~ or

~~(2) Units of enzymatic activity per product unit (e.g., tablets, capsules, granules, or liquids) consistent with the directions for use and the quantity statement or weight equivalent (e.g., 1 fl oz = 28 grams) for liquid products.~~

~~(3) The source organism for each type of enzymatic activity shall be specified, such as: pProtease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.~~