

Model Bills and Regulations Committee Report

October 25-30, 2019 E-Meeting

Committee Recommendation:

The Model Bills and Regulations Committee recommends the following revision be made to the Model Bills and Regulations, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Revise Regulation 4(g) and (h) within the Model Regulations under the Model Bill as indicated in the Attachment

Board Recommendations:

Association Actions:

Committee Report and Minutes:

A concern expressed by Leah Wilkinson, AFIA, at the Louisville MBRC meeting that revisions to Model Regulation 4(g) – Expression of Guarantees for Microorganisms and Enzymes approved by the AAFCO membership during the Louisville Annual Meeting Association Business Session could cause the industry to incur significant relabeling costs.

In response, Chairman Lueders directed the following individuals to further evaluate the issue and report findings to the committee. Emily Bulian Helmes (chair), Jan Campbell, Leah Wilkinson, Angele Thompson, Scott Ziehr, and Padma Pillai.

Emily Bulian Helmes submitted the working group minutes and recommendation on October 16, 2019 (**see Attachment**)

Model Bills and Regulations Committee Chairman Doug Lueders called the E-meeting to order at 11:28 a.m. CDT on October 25, 2019. The single item for discussion was the Microorganisms and Enzymes Expression of Guarantees working group recommendation from October 16, 2019. A motion to accept the working group report and forward their recommendation on to the Board of Directors for their consideration was made by Bob Geiger and seconded by Richard TenEyck. E-voting was commenced at 9:12 p.m. October 25 and results would be tabulated when Chairman Lueders returned to his office the following week.

Results of the votes are; Aye, Bob Geiger, Richard TenEyck, Kristen Green, Darrell Johnson, George Ferguson, Ben Jones and Ken Bowers. Not voting were William Burkholder, Eric Nelson, Mike Davidson, and Austin Therrell. There were no Nay votes. Chairman Lueders did not have to cast a deciding vote. The motion carried by a count of 7 out of 12.

Adjournment

There was no other business. Chairman Lueders adjourned the E-meeting with the announcement of the passing vote count at 8:24 a.m. October 30, 2019.

On behalf of the Model Bills and Regulations Committee, I respectfully submit this report and request acceptance of the report and recommendation by the AAFCO Board of Directors and the Association membership.

Attachment for E-Meeting

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)
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 microorganisms 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 CFU per product unit (e.g., tablets, capsules, liquids) consistent with directions for use and the quantity statement.
- (2) A parenthetical statement following the guarantee shall list each species in order of predominance.

(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 Units of enzymatic activity per product unit (e.g., tablets, capsules) consistent with the directions for use and the quantity statement.
- (2) The source organism for each type of enzymatic activity shall be specified, such as: Protease (*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.