

CODEX ALIMENTARIUS COMMISSION



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Organization

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Agenda Item 3(a) and 4(b)

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USA comment for Riboflavins in Agenda Item 3a (CX/FA 23/53/3 Add. 1) and consequential effects on alignment (Agenda Item 4b (CX/FA 25/53/6))

The USA supports the inclusion of INS 101(iv) into the group header RIBOFLAVINS in Tables 1 and 2 of the GSFA as described in Annex 2 of CX/FA 23/53/3 Add. 1. Since all riboflavins share a group JECFA ADI “not specified”, there is no safety based reason not to include INS 101(iv) in the group header.

The USA also supports the adoption of separate provisions for each of the four individual riboflavin in Table 3 of the GSFA at CCFA in the context of the specific discussion presented below. A consequential effect of adopting provisions each of the four individual riboflavin in Table 3 is the removal of all Tables 1 and 2 provisions for RIBOFLAVINS from food categories that are not in the Annex to Table 3. This follows the structure of the GSFA, where the use of additives with a JECFA ADI of “not specified” in food categories that are not in the Annex to Table 3 are addressed in Table 3, not Tables 1 and 2. To do so the Committee must first ensure that the Table 3 provisions for each of the four individual riboflavins reflect the status of riboflavins in the commodity standards corresponding to those food categories which have already been aligned. The status of riboflavins in food categories where the corresponding commodity standards have not been aligned does not need to be considered by CCFA53 as that will be addressed via future work of the Alignment Working Group as part of its normal progress to align the GSFA and remaining commodity standards.

Analysis that provisions in Table 3 reflect aligned commodity standards:

- Commodity standards where riboflavins are not allowed: All of the XS notes in the grey highlighted provisions in Annex 2 of CX/FA 23/53/3 Add 1 correspond to food categories that have already been aligned. The exclusion of riboflavins from these commodity standards is already addressed in the “References to commodity standards” section of the Annex to Table 3.
- Commodity standards where riboflavins are allowed: The majority of allowances for riboflavins in commodity standards corresponding to food categories that have been aligned are already addressed in the “References to commodity standards” section of the Annex to Table 3 via general allowances for Table 3 colours and therefore do not require a separate listing in the specific Table 3 provisions for riboflavins. However, there are some specific commodity standards that allow riboflavins that will need to be listed in the Table 3 provisions for riboflavins as they do not allow all Table 3 colours:
 - FC 01.6.2.1:
 - CS 263-1966 (Cheddar) and CS 264-1966 (Danbo)¹ – allowed INS 101(i) only at 300 mg/kg. However, the age of these commodity standards indicate that INS 101(i) was the only Riboflavin available at the time, not that CCMMP specifically excluded riboflavins other than INS 101(i). Other Table 3 additives, including specific colours (chlorophylls) were listed at GMP in these standards.
 - **USA proposal**: list CS 263-1966 and CS 264-1966 in Table 3 provision for each riboflavins at GMP
 - CS 283-1978 (General Standard for Cheese)² – lists specific colours, allowed Riboflavins at GMP.
 - **USA proposal**: list CS 283-1978 in Table 3 provisions for all riboflavins at GMP
 - CS 221-2001 (Unripened Cheese) – lists specific colours, allowed Riboflavins at GMP.
 - **USA proposal**: list CS 221-2001 in Table 3 provisions for all riboflavins at GMP

¹ See related Note 462 in the Tables 1 and 2 provision for RIBOFLAVINS in FC 01.6.2.1

² See related Note 504 in the Tables 1 and 2 provision for RIBOFLAVINS in FC 01.6.2.1

- FC 06.4.3: CS 249-2006 (Instant noodles)³ – allowed INS 101(i) and 101(ii) at 200 mg/kg singly or in combination. However, other Table 3 additives, including specific colours (Beet red and Carmel 1-plain) were listed at GMP in this standard
 - **USA proposal:** list CS 249-2006 in Table 3 provisions for all riboflavins at GMP
- FC 12.5: CS 117-1981 (Bouillons and consommés)⁴ – specifically listed INS 101(i) at 200 mg/kg. However, the standard also had a general reference to all Table 3 colours. CS 117-1981 and the GSFA have already gone through the alignment procedure.
 - **USA proposal:** allow all riboflavins in CS 117-1981 at GMP. Do not list CS 117-1981 in the specific Table 3 provisions as general use of Table 3 colours in this standard are already captured by the “References to commodity standards” section of the Annex to Table 3.

Current alignment work discussed in CX/FA 23/53/6

Several of the commodity standards corresponding to food categories that are not in the Annex to Table 3, and in which there are Tables 1 and 2 provisions for RIBOFLAVINS, are under consideration by the WG on Alignment to CCFA53. CX/FA 23/53/6 makes recommendations for some provisions for RIBOFLAVINS in Tables 1 and 2 as well as generally applicable recommendations for the “References to commodity standards” section of the Annex to Table 3. The decisions of the WG on Alignment pertaining to these commodity standards should be accounted for in the Table 3 provisions for riboflavins and are considered/discussed in the recommendations below:

- FCs 01.1.4 and 01.7: CS 243-2003(Fermented Milks) – allowed INS 101(i) and 101(ii) at 300 mg/kg. However, the standard also had a general reference to all Table 3 colours. CX/FA 23/53/6 recommends provisions for Table 3 additives with numeric use limits in CS 243-2003 have provisions in these food categories in Tables 1 and 2 of the GSFA to reflect the numeric use limit in CS 243-2003.
 - **USA Proposal:** allow all riboflavins in CS 243-2003 at GMP. This is addressed by the proposal on pages 144 and 145 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3.
- FC 01.6.1: CS 262-2006 (Mozzarella) – allowed specific colours, does not list riboflavins.
 - **USA Proposal:** This is addressed by the proposal on page 155 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3. The proposal on pages 109 and 137 of CX/FA 23/53/6 pertaining to adding note XS262 to the provision for Riboflavins in FC 01.6.1 should be discarded by the Alignment WG as that provision will be revoked.
- FC 02.2.2:
CS 253-2006 (Dairy Fat Spreads) – allowed specific colours none of which were Table 3 additives, riboflavins was not listed.
 - **USA Proposal:** This is addressed by the proposal on page 151 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3. The proposals on page 102 and 134 of CX/FA 23/53/6 pertaining to adding note XS253 to the provision for Riboflavins in FC 02.2.2 should be discarded by the Alignment WG as that provision will be revoked.
- CS 256-2007⁵ (Fat Spreads and Blended Spreads) – allowed INS 101(i) and INS 101(ii) at 300 mg/kg. However, the standard also had a general reference to all Table 3 colours. CS 256-2007 and the GSFA, including Table 3, were aligned at CCFA52 (CX/FA 21/52/6).
 - **USA Proposal:** allow all riboflavins in CS 256-2007 at GMP. Do not list CS 256-2007 in the specific Table 3 provisions as general use of Table 3 colours in this standard are already captured by the “References to commodity standards” section of the Annex to Table 3. As a consequence, the Codex Secretariat should remove the specific listing for INS 101(i) and 101(ii) from CS 256-2007 as the use is covered by the general reference to Table 3 colors in CS 256-2007.
- FC 04.1.2.6: CS 160-1987 (Mango Chutney) - does not allow colours.
 - **USA Proposal:** This is addressed by the proposal on page 267 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3. The proposal on page 241

³ See related Note 473 in the Tables 1 and 2 provision for RIBOFLAVINS in FC 06.4.3

⁴ See related Note 344 in the Tables 1 and 2 provision for RIBOFLAVINS in FC 12.5

⁵ CS 256-2007 and the GSFA, including Table 3, were aligned at CCFA52 (CX/FA 21/52/6).

and 256 of CX/FA 25/53/6 pertaining to adding note XS160 to the provision in FC 04.1.2.6 should be discarded as that provision will be revoked.

- FC 12.6: CS 306R-2011 (Chili sauce) – allowed INS 101(i) and INS 101(ii) at 350 mg/kg singly or in combination. However, the standard also had a general reference to all Table 3 colours.
 - **USA Proposal:** allow all riboflavins in CS 306R-2011 at GMP. Do not list CS 306R-2011 in specific Table 3 provisions as the general use of Table 3 colours in this standard is already captured by proposal on page 267 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3. If this recommendation is adopted, CCFA will have to inform CCLAC to remove the specific listing for CS 306R-2011. The proposal on page 241 and 262 of CX/FA 25/53/6 pertaining to adding note E-306 to the provision in FC 12.6 should be discarded as that provision will be revoked.
- FC 13.3: Guideline for ready to use therapeutic foods – this guideline does not allow riboflavins.
 - **USA Proposal:** This is addressed by the proposal on page 338 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3. The proposal on page 317 and 334 of CX/FA 25/53/6 pertaining to adding note A to the provision in FC 13.3 should be discarded as that provision will be revoked.
- FC 13.4: CS 181-1991 and CS 203-1995 – allows additives cleared by JECFA
 - **USA Proposal:** This is addressed by the proposal on page 338 of CX/FA 23/53/6 pertaining to the “References to commodity standards” section of the Annex to Table 3

Summary recommendations as a result of the above discussion:

Recommendation 1

Include INS 101(iv) in the group header RIBOFLAVINS in Tables 1 and 2 of the GSFA as described in Annex 2 of CX/FA 23/53/3 Add. 1.

Recommendation 2

Remove from Tables 1 and 2 provisions for RIBOFLAVINS from food categories that are not in the Annex to Table 3 (presented as grey highlighted provisions in Annex 2 of CX/FA 23/53/3 Add 1).

Recommendation 3

Adopt provisions in Table 3 as per the table below:

INS No.	Additive	INS Functional Class	Step	Year	Acceptable, including foods conforming to the following commodity standards
101(i)	Riboflavin, synthetic	Colour			CS 221-2001, CS 243-2003 CS 249-2006, CS 263-1966, CS 264-1966, CS 283-1978
101(ii)	Riboflavin 5'-phosphate sodium	Colour			CS 221-2001, CS 243-2003 CS 249-2006, CS 263-1966, CS 264-1966, CS 283-1978
101(ii)	Riboflavin from <i>Bacillus subtilis</i>	Colour			CS 221-2001, CS 249-2006, CS 263-1966, CS 264-1966, CS 283-1978
101(iv)	Riboflavin from <i>Ashbya gossypii</i>	Colour			CS 221-2001, CS 249-2006, CS 263-1966, CS 264-1966, CS 283-1978