



## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD ADDITIVES

#### Forty-third Session

**Xiamen (Fujian Province), China, 14-18 March 2011**

### DISCUSSION PAPER ON THE REVISION OF SESSION 4 “CARRY-OVER OF FOOD ADDITIVES INTO FOOD” OF THE PREAMBLE TO THE GSFA

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#### **BACKGROUND**

1. At its 42<sup>nd</sup> Session, the Codex Committee on Food Additives (CCFA) noted the decision of the 32<sup>nd</sup> Session of the Codex Alimentarius Commission (CAC)<sup>1</sup> to replace the provisions for the “Carry-over Principle of Food Additives” in Volume 1 of the Codex Alimentarius, which is out of print and not available on the Codex website, with a reference to Section 4 – “Carry-Over of food additives into foods” of the Preamble to the *General Standard for Food Additives* (GSFA). The Committee also considered the request of the Commission to determine whether it was necessary to revise Section 4 of the Preamble to take on board its inconsistencies with Volume 1 of Codex Alimentarius.
2. The CCFA noted that Section 4 of the Preamble to the GSFA did not address the principle in Section 3(d) of the “Carry-over Principle of Food Additives” in Volume 1 of Codex Alimentarius, and that Section 4 superseded the “Carry-over Principle of Food Additives” in Volume 1. As Section 3(d) refers to “*food additive carried over which is present at a level which is non-functional, i.e. at a level significantly less than that normally required to achieve an efficient technological function in its own right*”, it was also pointed out that the inclusion of this principle in the GSFA would result in additional provisions, making its use more restrictive.
3. While noting the differences between the two texts, and in order to make a more informed decision on this matter at its next Session, the Committee agreed to establish an electronic Working Group (eWG), led by Brazil and working in English only, charged to<sup>2</sup>:
  - Review the discussion and relevant decisions of the Committee regarding the elaboration of Section 4 of the Preamble to the GSFA;
  - Analyze the inconsistencies between Section 4 of the Preamble to the GSFA and the “Carry-over principle” in Volume 1; and
  - Consider the need to revise Section 4 of the Preamble to the GSFA including, where appropriate, a proposal for the revision.
4. A comparison between the “Carry-over Principle of Food Additives” in Volume 1 of the Codex Alimentarius and the Section 4 of the Preamble to the GSFA<sup>3</sup>, as well as the specific proposals from the eWG, are presented in Annex 1.

<sup>1</sup> ALINORM 09/32/REP, para. 97

<sup>2</sup> ALINORM 10/33/12, paras. 11-14

<sup>3</sup> CX/FA 10/42/2, Annex 1

**REVIEW**

5. The Preamble to the GSFA provides the scope and the basic principles used in its development. Its first proposed draft was published in 1992 and, since then, it was amended several times.

6. This Section contains a summary of the discussion regarding Section 4 - "Carry-over of food additives into foods" of the Preamble to the GSFA, which was obtained through the examination of the following documents:

- ALINORM 93/12A (25<sup>th</sup> CCFAC)
- ALINORM 95/12 (26<sup>th</sup> CCFAC)
- ALINORM 95/37 (21<sup>st</sup> CAC)
- ALINORM 97/12 (28<sup>th</sup> CCFAC)
- ALINORM 03/12A (35<sup>th</sup> CCFAC)
- ALINORM 05/28/12 (37<sup>th</sup> CCFAC)
- CX/FAC 04/36/6
- CX/FAC 05/37/7

7. In 1993, at the 25<sup>th</sup> Session of the Codex Committee on Food Additives and Contaminants (CCFAC), the Committee has discussed and agreed a number of principles to be reflected in the Preamble to the GSFA. It was stated that it would not be realistic to require compliance with all the provisions with respect to the principles for carry-over of food additives into foods, especially since there was an increasing number of composite foods. Moreover, it was acknowledged that additives present in one of the ingredients of a composite food often had a functional effect in the final product<sup>4</sup>. Hence, the discussion suggested the deletion of paragraph (d) in the referred Section, which was forwarded in square brackets to step 5 for additional comments on the carry-over principle, as follows<sup>5</sup>:

#### **4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS**

*The principle relating to the carry-over of food additives into foods (the "Carry-Over Principle") addresses the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used. The Codex Alimentarius Commission at its 17th Session (1987) adopted a revised statement of the principle as a Codex Advisory Text. The Text is printed in its entirety in Codex Alimentarius, Second Edition, Vol. 1 (General Requirements), pp. 85-88, 1992. The Carry-Over Principle applies to all foods covered by Codex Standards, unless otherwise specified in such standards.*

##### **4.1 Compliance with the Carry-Over Principle**

*Other than by direct addition, an additive may be present in a food as a result of carry-over from a food ingredient, subject to the following conditions:*

- (a) the additive is permitted in the raw materials or other ingredients (including food additives) according to this General Standard;*
- (b) the amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum amount so permitted.*
- (c) the food into which the additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the ingredients under proper technological conditions or manufacturing practice; and*
- (d) the food additive carried over is present at a level which is nonfunctional, i.e. at a level significantly less than that normally required to achieve an efficient technological function in its own right.*

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<sup>4</sup> ALINORM 93/12A, para. 42

<sup>5</sup> ALINORM 93/12A, Appendix II

#### **4.2 Non-Compliance with the Carry-Over Principle**

*An additive carried over into a particular food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which the additive was used, shall be treated and regarded as an additive to that food, and shall be provided for according to the general principles of this Standard.*

8. In the following year, at the 26<sup>th</sup> Session of the CCFAC, the GSFA Working Group acted to delete from the Preamble both condition (d) and the statement on Non-Compliance with the Carry-over Principle. It was noted that if an additive has no functional effect in a composite food, its presence does not require an authorization; and if it does have an effect, then it must be authorized for use in that food<sup>6</sup>. On this basis, condition (d) was regarded as unnecessary and the Working Group agreed that it should be deleted. Moreover, as a consequence of this deletion, the Working Group recognized that the statement on non-compliance lost its relevance and agreed that it should be deleted as well. Thus, the Committee agreed to delete paragraphs 4.1(d) (Compliance with the Carry-Over Principle) and 4.2 (Non-Compliance with the Carry-Over Principle), “*in order to clarify principles concerning the carry-over of food additives into food*”<sup>7</sup>. The revised draft Preamble to the GSFA was then forwarded to the 21<sup>st</sup> Session of the CAC for adoption at step 8.

9. In 1995, the 21<sup>st</sup> Session of the Commission requested the CCFAC to reconsider and examine those provisions in the Preamble related to the carry-over of additives into foods<sup>8</sup>. Accordingly, in the 28<sup>th</sup> Session of CCFAC, three issues were raised during the deliberations: 1) reverse carry-over, 2) labeling, and 3) the status of condition (d) and the non-compliance statement. It was noted that the definition of carry-over needed further clarification, reverse carry-over should be defined and that additives used in ingredients that had a function in a final composite product should be indicated on the label.

10. Considering the common use of pre-mixes and composite ingredients in the processed food industry, the CCFAC agreed to incorporate the principle of ingredients and raw materials as carriers for additives and to amend the text of the carry-over principle by adding a new paragraph as follows<sup>9</sup>: “*An additive is permitted in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food which is in conformity with the provisions of this standard*”<sup>10</sup>. In this case, the food ingredient into which the additive is introduced is simply a carrier and the additive is intended to be functional in the composite food. Therefore, it should be subject to labeling requirements.

11. The logical extension of the conclusions of the Working Group in 1995 was that a determination had to be made as to whether the additive is unintentionally present in the finished food at a functional level. However, this may not always be practical, since it cannot be expected that a determination of functionality of an additive carried over into the finished food can be made in every case. Therefore, it was decided that guidance on the carry-over of food additives in the Preamble to the GSFA would not include principle 3(d) from Volume 1 of the *Codex Alimentarius*, regarding non-functionality.

12. In 2003, at its 35<sup>th</sup> Session, the CCFAC agreed to set up a Working Group which terms of reference included the revision of the Preamble to the GSFA. The discussions of this Working Group proposed a restriction on the application of the carry-over principle for certain foods in Section 4, especially in foods for infants (item 4.2 of the current version), as well as some other editorial changes<sup>11</sup>. The most recent revision of the Preamble to the GSFA was then forwarded to the CAC for adoption in 2005.

#### **DISCUSSION BY THE EWG**

13. The eWG noted the decision that the GSFA is to be the single reference regarding food additive use within Codex, and agreed that all relevant provisions relating to the carry-over principle of food additives should be described in Section 4 of the Preamble to the GSFA.

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<sup>6</sup> Report of the Working Group, CRD 1, paras. 5 and 6, 26th CCFAC, March 1994

<sup>7</sup> ALINORM 95/12, para. 36

<sup>8</sup> ALINORM 95/37, para. 39

<sup>9</sup> ALINORM 97/12, para. 44

<sup>10</sup> Last sentence of Section 4.1 in the current version of the Preamble to the GSFA

<sup>11</sup> CX/FAC 05/37/7, paras.14 (e) and 25

14. In that regard, the wording of the Preamble to the GSFA was considered more appropriate than the one in Volume 1 of the Codex Alimentarius.

15. Most participants were of the view that the scope and the application of the carry-over provisions are well defined in the current text of Section 4.1 of the Preamble to the GSFA, and Section 3(d) from Volume 1 should not be included, due to the following reasons:

- It may be misinterpreted as requiring that any carry-over of an additive must not be functional in the final food.
- Carry-over of food additives should not be permitted just because an additive is present at a level which is non-functional.
- There are specific labeling requirements for food additives that are carried over into and are functional in the final food<sup>12</sup>.

16. The eWG noted that the term "carry-over of food additives" literally describes the transfer of food additives from ingredients or raw materials to the final product, and it should include food additives carried over to the final product which do or do not have a technological effect.

17. Hence, the eWG agreed that the conditions applying to the carry-over of food additives are well provided in Section 4.1 of the Preamble to the GSFA, and no further definition would be necessary.

18. The discussion by the eWG also included proposals for labeling guidance within the Preamble to the GSFA, due to the current text in Section 4.1 that describes the use of ingredients as "carriers" of food additives in composite foods: "*An additive may be used in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard*". Nevertheless, the eWG considered that it was not appropriate to include text regarding labeling in Section 4 of the Preamble to the GSFA, as it is beyond the scope of the GSFA and the CCFA. Proposed amendments to this sentence are presented in Annex 1.

19. Regarding the conditions applying to carry-over of food additives in Section 4.1 (a)-(c) of the Preamble, the eWG noted that the current text makes reference to the provisions in the GSFA, but not to other provisions included in commodity standards. Discussion by the eWG suggested that the CCFA could address this issue by:

- i. Making an appropriate amendment to the end of each condition in the Preamble, as recommended in Annex 1;
- ii. Including the carry-over principle in commodity standards;
- iii. Amending the relevant commodity standards provisions to refer to the GSFA; and/or
- iv. Amending the Section dedicated to the "Format for Codex Commodity Standards" in the Procedural Manual.

20. The eWG noted that Section 1.2 of the Preamble to the GSFA "*sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex... The General Standard for Food Additives (GSFA) should be the single authoritative reference point for food additives*"<sup>13</sup>. If the current wording of the Preamble was established with the understanding that all food additive provisions, including those in commodity standards, would (eventually) be captured in the GSFA, then the Preamble would not need to refer to carry-over of food additives in commodity standards if the GSFA contained all the food additive provisions included in such standards. Since the Committee continues to work towards completion of the GSFA, paragraphs (a)-(c) of Section 4.1 of the Preamble may not need to be revised to refer to commodity standards, because at such time as the GSFA is complete in this regard, the Preamble would need to refer to the GSFA only, as it currently does.

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<sup>12</sup> Section 4.2.4, CODEX STAN 1-1985

<sup>13</sup> Section 1.2, CODEX STAN 192-1995

21. The eWG agreed with the need to correct inconsistencies regarding the statement of carry-over in the current Section 4.2 of the Preamble to the GSFA (Foods for Which the Carry-Over of Food Additives is Unacceptable) and in the commodity standards included under food categories 13.1 (Infant formulae, follow-up formulae, and formulae for special medical purposes for infants) and 13.2 (Complementary foods for infants and young children).

22. The current text in Section 4.2 of the Preamble to the GSFA states that carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to categories 13.1 and 13.2.

23. However, the food additive sections of CODEX STAN 73-1981 (*Codex Standard for Canned Baby Foods*) and CODEX STAN 156-1987 (*Codex Standard for Follow-up Formula*) contain a statement on carry-over that references Section 3 of Volume 1<sup>14</sup>. Moreover, the food additive sections of CODEX STAN 72-1981 (*Codex Standard for Infant Formula and Formula for Special Dietary Purposes Intended for Infants*) and 74-1981 (*Codex Standard for Processed Cereal-based Foods for Infants and Young Children*) contain explicit text regarding carry-over that references the text in the Preamble to the GSFA<sup>15</sup>. The text in these Standards therefore allows the carry-over of food additives, whereas Section 4.2 of the Preamble to the GSFA does not.

24. It was also suggested to revise Section 5 – FOOD CATEGORY SYSTEM, item (c) of the Preamble to the GSFA, which is out of the scope of the eWG, in order to include in its list of examples other composite foods captured throughout the food category system.

*c) The food category system takes into consideration the carry-over principle. By doing so, the food category system does not need to specifically mention compound foodstuffs (e.g., prepared meals, such as pizza, because they may contain, pro rata, all the additives endorsed for use in their components), unless the compound foodstuff needs an additive that is not endorsed for use in any of its components.*

#### **RECOMMENDATIONS OF THE EWG**

25. Based on the contributions sent by the participants and the considerations raised above, the CCFA may wish to consider the following recommendations of the eWG:

##### **RECOMMENDATION I**

To analyze the proposed amendments presented in Annex 1, as underlined and **bold** text, and forward to the Commission for adoption those agreed to by the Committee.

##### **RECOMMENDATION II**

To request the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) to comment as to whether carry-over of food additives from ingredients is inappropriate for the foods included in the standards falling under food categories 13.1 (Infant formulae, follow-up formulae, and formulae for special medical purposes for infants) and 13.2 (Complementary foods for infants and young children). This recommendation is due to the observed inconsistencies between the provisions in Section 4.2 to the Preamble to the GSFA, which prohibits carry-over of food additives in food categories 13.1 and 13.2, and the carry-over provisions in standards for foods in categories 13.1 and 13.2.

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<sup>14</sup> 4.6. Carry-Over Principle: Section 3 of the “Principle Relating to the Carry-Over of Food Additives into Foods” as set forth in Codex Alimentarius Volume 1 shall apply.

<sup>15</sup> Section 4. Food Additives: *Only the food additives listed in this Section or in the Codex Advisory List of Mineral Salts and Vitamin Compounds for Use in Foods for Infants and Children (CAC/GL 10-1979) may be present in the foods described in Section 2.1 of this Standard, as a result of carry-over from raw material or other ingredient (including food additive) used to produce the food, subject to the following conditions:*

*The amount of the food additive in the raw materials or other ingredients (including food additives) does not exceed the maximum level specified; and The food into which the food additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the raw materials or ingredients under good manufacturing practice, consistent with the provisions on carry-over in the Preamble of the General Standard for Food Additives (CODEX STAN 192-1995).*

**RECOMMENDATION III**

To request other Codex Committees, as appropriate, to inform whether there are other food categories, or specific foods that are included under Codex commodity standards that should be specifically listed under Section 4.2 of the Preamble to the GSFA. This recommendation considers the possibility of additional food categories or specific foods subject to commodity standards where carry-over of food additives is unacceptable.

The Codex Secretariat could facilitate this consultation by preparing a list of amendments to commodity standards where inconsistencies exist in order to correct them.

The eWG also recommends that, until Recommendations II and III can be implemented, the current text in Section 4.2 of the Preamble to the GSFA should be maintained.

**RECOMMENDATION IV**

To delete all references to “The Principles Relating to the Carry-over of Food Additives into Foods” in Volume 1 from Codex standards.

**ANNEX 1**

| <p><b>THE PRINCIPLE RELATING TO THE CARRY-OVER OF FOOD ADDITIVES INTO FOODS (VOLUME 1)</b></p>   | <p><b>GSFA - PREAMBLE<br/>4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS</b></p>   | <p><b><u>RECOMMENDATION OF THE eWG</u><br/>4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS</b></p>  |
|--|--|--|
| <p><b>1. SCOPE</b><br/>For the purposes of the Codex Alimentarius, the Principle relating to the Carry-Over of Food Additives into Foods (the “Carry-Over Principle”) applies to the presence of additives in food as a result of the use of raw materials or other ingredients in which these additives are used.</p> |  |  |
| <p><b>2. APPLICATION</b><br/>The Carry-Over Principle applies to all foods covered by Codex Standards, unless otherwise specified in such standards (see Section 4).</p>   |  |  |
| <p><b>3. CONDITIONS UNDER WHICH THE CARRY-OVER PRINCIPLE APPLIES</b><br/>The presence of an additive in food, through the application of the Carry-Over Principle, is generally permitted if:</p>  | <p><b>4.1 CONDITIONS APPLYING TO CARRY-OVER OF FOOD ADDITIVES</b><br/>Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:</p> | <p><b>4.1 CONDITIONS APPLYING TO CARRY-OVER OF FOOD ADDITIVES <u>[FROM INGREDIENTS AND RAW MATERIALS INTO FOOD]</u></b><br/>Other than by direct addition, an additive may be present in a food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:</p>                               |
| <p>a. the additive is permitted in the raw materials or other ingredients (including food additives) by an applicable Codex Standard or under any other acceptable provision which takes into account the safety aspects of food additives;</p>  | <p>a. The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard;</p>  | <p>a. The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Standard <b><u>[and/or any other adopted provision included in the Commodity Standards] OR [or applicable Commodity Standard] OR [existing Codex Standards];</u></b></p>                               |
| <p>b. the amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum amount so permitted;</p>   | <p>b. The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard;</p>  | <p>b. The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Standard <b><u>[and/or any other adopted provision included in the Commodity Standards] OR [or applicable Commodity Standard] OR [existing Codex Standards];</u></b></p> |

| <p><b>THE PRINCIPLE RELATING TO THE CARRY-OVER OF FOOD ADDITIVES INTO FOODS (VOLUME 1)</b></p>   | <p><b>GSFA - PREAMBLE</b><br/><b>4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS</b></p>   | <p><b><u>RECOMMENDATION OF THE eWG</u></b><br/><b>4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS</b></p>  |
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| <p>c. the food into which the additive is carried over does not contain the food additive in greater quantity than would be introduced by the use of the ingredients under proper technological conditions or manufacturing practice, and</p>  | <p>c. The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard.</p> | <p>c. The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with the provisions of this standard <b><u>[and/or any other adopted provision included in the Commodity Standards] OR [or applicable Commodity Standard] OR [existing Codex Standards].</u></b></p>  |
| <p>d. the food additive carried over is present at a level which is non-functional, i.e., at a level significantly less than that normally required to achieve an efficient technological function in its own right in the food.</p>   |   |   |
| <p><b>4. SPECIAL CONDITIONS</b></p> <p>4.1 An additive carried over into a particular food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which this additive was used, shall be treated and regarded as an additive to that food, and shall be provided for in the Section on Food Additives of the applicable Codex Standard.</p> | <p>An additive may be used in a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with the provisions of this standard.</p>   | <p><b><u>[4.2 SPECIAL CONDITIONS APPLYING TO THE USE OF FOOD ADDITIVES NOT DIRECTLY AUTHORISED IN FOOD INGREDIENTS AND RAW MATERIALS]</u></b></p> <p>An additive may be used in <b><u>[or added to]</u></b> a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a <b><u>[finished]</u></b> food <b><u>[(e.g. composite food)]</u></b> that is in conformity with the provisions of this standard, <b><u>[including any maximum level applying to the food is not exceeded]. [This corresponds to “direct addition additives”].</u></b></p> <p>OR</p> <p><b><u>[An additive carried over into a particular food in a significant quantity or in an amount sufficient to perform a technological function in that food as a result of the use of raw materials or other ingredients in which this additive was used, shall be treated and regarded as an additive to that food, and shall be provided for in this Standard or in the Food Additives provision of the applicable Commodity Standard].</u></b></p> |



| <p><b>THE PRINCIPLE RELATING TO THE CARRY-OVER OF FOOD ADDITIVES INTO FOODS (VOLUME 1)</b></p>   | <p><b>GSFA - PREAMBLE</b></p> <p><b>4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS</b></p>  | <p><b><u>RECOMMENDATION OF THE eWG</u></b></p> <p><b>4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS</b></p>   |
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|  | <p><b>4.2 FOODS FOR WHICH THE CARRY-OVER OF FOOD ADDITIVES IS UNACCEPTABLE</b></p> <p>Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.</p> <ul style="list-style-type: none"> <li>a. 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.</li> <li>b. 13.2 - Complementary foods for infants and young children.</li> </ul> | <p><b>[4.3] FOODS FOR WHICH THE CARRY-OVER OF FOOD ADDITIVES IS UNACCEPTABLE</b></p> <p>Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories, unless a food additive provision in the specified category is listed in Tables 1 and 2 of this standard.</p> <ul style="list-style-type: none"> <li>a. 13.1 - Infant formulae, follow-up formulae, and formulae for special medical purposes for infants.</li> <li>b. 13.2 - Complementary foods for infants and young children.</li> </ul> |
| <p><b>5. STATEMENTS IN CODEX STANDARDS REGARDING CARRIED OVER ADDITIVES</b></p>  |   |   |
| <p>5.1 Where the Carry-Over Principle does not apply to a food, i.e., where the presence of additives carried over is not permitted in the food, this should be clearly stated in the relevant Codex standard using the following statement:</p> <p><i>“no food additives shall be present as a result of Carry-Over from raw materials or other ingredients”.</i></p> |   |   |
| <p>5.2 Where reference to the applicability of the Carry-Over Principle is specifically made in a Codex Standard, the following statement should be used:</p> <p><i>“Section 3 of the Principle relating to the Carry-Over of Additives into Foods shall apply”</i></p>  |   |   |