



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON CONTAMINANTS IN FOODS**

**9<sup>th</sup> Session**

**New Delhi, India, 16 – 20 March 2015**

**DISCUSSION PAPER ON APPROACHES FOR PHASING IN OF LOWER MAXIMUM LEVELS FOR  
CONTAMINANTS**

**(Prepared by FAO, WHO and the Codex Secretariat)**

**Background**

1. Agreement on MLs<sup>1</sup> that are fully health protective and do not disrupt trade in terms of availability of food may be difficult to reach especially when the concerned commodity is widely traded and is a staple food in some countries or regions. In this regard, divergent views can be held on the MLs themselves, the way the commodities are grouped, to what form of the commodity the ML should apply (e.g. raw/unprocessed and/or processed commodities), etc.

2. Some of the most common arguments in the CCCF<sup>2</sup> that may delay decision on the establishment of such MLs relate to the lack of representative data from all or most of the regions concerned and therefore the need for new/additional data (e.g. occurrence data, consumption data, etc.); availability of internationally validated analytical methods to either generate data and/or enforce the ML (the latter including methods of analysis readily available for routine analysis that will not create further burden on developing countries); different dietary patterns amongst countries / regions that may deserve higher or lower MLs; different levels of contamination of the commodity and the availability of GAPs<sup>3</sup>, GMPs<sup>4</sup>, and other mitigation measures that can be applied worldwide on a large scale including by small and medium-size enterprises which would allow lower MLs.

3. Moreover, withdrawal of PTWIs<sup>5</sup> by JECFA<sup>6</sup> (especially when it relates to highly toxic contaminants such as some heavy metals and mycotoxins) further require the application of the ALARA<sup>7</sup> principle. The application of this principle has led to extensive discussions as to whether further reduction of the MLs would lead to a measurable reduction in health risk without having a negative impact on trade flow and limiting availability of food, in particular when the commodity is a staple food.

4. The above has been evidenced in the past years with the establishment of MLs for inorganic arsenic in polished (completed) and husked rice (ongoing), the establishment of MLs for fumonisins in maize and maize products (completed), and the establishment of MLs for DON<sup>8</sup> in cereals and cereals-based products (ongoing).

5. The way the Committee has dealt with the establishment of lower MLs in particular for situations where food safety and food security need to be considered, is the development of COPs<sup>9</sup> either with or without corresponding MLs. In cases where both COPs and MLs are established, they may be accompanied by a request to collect / generate additional data to further reduce the MLs in future or within a limited time interval.

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<sup>1</sup> Maximum level

<sup>2</sup> Codex Committee on Contaminants in Foods

<sup>3</sup> Good agricultural practices

<sup>4</sup> Good manufacturing practices

<sup>5</sup> Provisional tolerable weekly intake

<sup>6</sup> Joint FAO/WHO Committee on Food Additives

<sup>7</sup> As low as reasonable achievable

<sup>8</sup> Deoxynivalenol

<sup>9</sup> Code of practice

6. In the discussion on MLs for fumonisins in maize and maize products some delegations, representing countries with high consumption of maize, raised concern that the proposed levels may not be sufficiently health protective for all populations. However, recognizing the need for an ML that would not lead to too high rejection rates and thereby disrupting the food supply and impacting on food security, these delegations supported the proposed ML, with the understanding that measures should be undertaken to reduce contamination in parallel with implementing the ML, and that based on new data, exposure and impact assessments should be undertaken by JECFA within three years to reconsider the ML.<sup>10</sup>

7. At the 8<sup>th</sup> Session of CCCF, in light of the discussion of fumonisins and DON, the WHO<sup>11</sup> Representative suggested that there might be a need to explore additional ways of developing MLs, such as phasing in of MLs over a defined period of time. The Representative suggested that FAO<sup>12</sup> and WHO together with the Codex Secretariat prepare a discussion paper for consideration at the next session of the Committee laying out a process for such an approach, which might then help to find agreement on MLs for several contaminants. Consideration would be given to implications of such an approach under the WTO-SPS Agreement<sup>13</sup>, COPs, Codex rules and procedures and other relevant aspects.<sup>14</sup>

8. The proposed approach does not imply any new procedure for the development of MLs, but rather evidences the practices that the Committee have put in place to facilitate the establishment of MLs in specific situations when consensus is difficult to reach, but a decision must be made to address public health concerns, particularly in situations where food safety and food security aspects should be taken into account. Such situation is described in paragraph 9 and the key features proposed are basically a recollection of what the Committee has already put in place, but with a more structured and consistent approach as well as a clear commitment on a target ML and a time-frame.

### **Proposed approach**

9. Where agreement cannot be reached on ML, a slightly higher ML be implemented, with the commitment to review this ML after a defined period of time, aiming towards a lower defined target ML. This approach will only be applied in cases where setting MLs that are low enough to cover all possible exposure scenarios, may at the same time significantly impact on availability of staple food commodities, and as such consensus cannot be reached. This approach is not intended for scenarios where MLs could be defined that are both protective in all possible exposure scenarios and do not impact on food security.

10. Some key features of the proposed approach are the following:

- The (slightly) higher ML being implemented would still need to be health-protective for the global population
- This ML can be implemented without significantly impacting on food security (i.e. impact on availability of the commodity).
- Such ML should be accompanied by a Code of Practice or other recommendation for risk mitigation measures to decrease contamination over time.
- The decision should be accompanied with a clear commitment to implement risk mitigation measures to aim at a lower ML, and a target ML should be defined.
- The timeframe after which the ML is expected to be reviewed will have to be defined on a case by case basis depending on the contaminant/commodity combinations and the feasibility to implement measures to reduce contamination e.g. 3-5 years.
- Sufficient occurrence data and any other relevant data identified by CCCF for the particular contaminant/commodity situation need to be generated after implementation of measures to reduce exposure that allow for a review and refinement of the ML.

### **Codex Rules and Procedures**

11. The usual Codex rules and procedures for setting MLs will apply also in this case. The only difference to the current process is that the ML will be set with the explicit recognition that a lower ML is the target to be reached within an agreed timeframe.

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<sup>10</sup> REP14/CF, paras 71-72.

<sup>11</sup> World Health Organization

<sup>12</sup> Food and Agriculture Organization

<sup>13</sup> Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization

<sup>14</sup> REP14/CF, para 57

12. After reaching the timeframe, and based on availability of relevant data, the CCCF should decide on whether to revoke the ML or to extend the timeframe to collect more data and if so to specify the new time frame and data needed.

13. Furthermore, in line with the Working Principles for Risk for Application in the Framework of the Codex Alimentarius, risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decision. Food standards and related texts should be reviewed regularly and updated as necessary to reflect new scientific knowledge and other information relevant to risk analysis.

14. In addition, the General Principles of the Codex Alimentarius states that the CAC<sup>15</sup> and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related texts shall be revised or removed in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts. Each member of the Commission is responsible for identifying, and presenting to the appropriate committee any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts.

15. For what concerns the WTO-SPS Agreement, no specific consideration will be applicable in this case as those MLs while in force would be considered as full Codex Standard.

### **Recommendation**

16. The Committee is requested to consider the approach described in paragraph 10 with the understanding that the approach will be applied for situations described in paragraph 9.

17. If the approach is found agreeable, the Committee is invited to consider to apply this approach on a pilot basis for an ML / MLs for DON.

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<sup>15</sup> Codex Alimentarius Commission