CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 8 **CX/MAS 20/41/10 Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

PROPOSED DRAFT CRITERIA TO SELECT TYPE II METHODS FROM MULTIPLE TYPE III METHODS

Comments at in reply to CL 2020/31-MAS

Comments of Canada, Japan, Thailand and USP

NOTE: CCMAS41 has been postponed to 17 – 21 May 2021. In order to ensure work continuity, CL 2020/31/OCS was issued requesting comments. See background information in the aforementioned CL. The comments compiled in this document will be made available to Switzerland for further consideration and preparation of a revised version of the of the criteria to select Type II methods from multiple Type III methods for consideration by CCMAS41.

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2020/31-MAS issued in May 2020. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENTS	
~~Criteria~~ Rules to select Type II methods from multiple Type III methods	**Japan** Japan appreciates the efforts of Switzerland in preparing the discussion paper on criteria to select Type II methods from multiple Type III methods.
Canada This document describes a process for deciding which method of analysis may be selected as Type II from multiple submissions. Overall, it presents a process for the selection of a method with better performance and other positive attributes. The decision process is rather prescribed and does not take into consideration regional preferences or the regular use of such methods in international trade or recommended by international organizations in trade contracts	
Specific comments	
Inclusion criteria for Type III chemical or physical Methods	
Inclusion ~~criteria~~ rule for Type III chemical or physical Methods	**Japan** When CCMAS uses the term “method criteria” or simply “criteria”, the term is used in the meaning of the numeric criteria of method performance. In order to avoid confusion between requirements in this paper and criteria approach, Japan proposes to change the term “criteria” in the title into “requirement” or “rule” or other appropriate terms.
	Canada The decision process appears to favour methods specifically developed for analysis of an analyte in a single matrix rather than the approach of adoption of Codex General Methods
i. A potential Type III method should fulfil the following criteria, in addition to the general criteria for the selection of methods of analysis (cf. Procedural Manual, p. 76)	
	Japan The points listed in the discussion paper can be classified into two categories: (i) prerequisite for Codex Type III methods; and (ii) additional consideration for multiple Type III methods. In addition, CCMAS should consider whether the Criteria Approach, rather than prescribing multiple Type III methods, is suitable . Bullet vi in the discussion paper reads, “vi. Check results of proficiency testing in order to detect systematic differences between methods (e.g. NIST https://nvlpubs.nist.gov/nistpubs/ir/2019/NIST.IR.8266.pdf)”.

	However, availability of proficiency testing data on multiple candidate Type III methods may not be always available . Japan proposes to delete this requirement because CCMAS has not considered the data on proficiency testing (PT) for the existing multiple Type III methods. Japan proposes addion and rearrangement of the items as shown in track changes.
Prerequisite for Codex Type III methods i.The method is validated according to an internationally recognized protocol and the validation data published ii.The method should fulfil the general method performance criteria in the Procedural Manual iii.The method is easily accessible, e.g. from SDO websites Additional consideration for multiple Type III method iv. All methods should measure the same analyte (chemical entity). v. If the methods contain differing analysis steps (e.g. Vitamin B6 with or without enzymatic digestion), verify that these methods still measure the same provision. vi. The methods are preferably validated on the same matrices. vii. The validation covers the analytical range for the provision (e.g. ML). viii. Criteria approach cannot be taken for some reason (e.g. request from Commodity Committee, need of specific principle, etc.)~~A potential Type III method should fulfil the following criteria, in addition to the general criteria for the selection of methods of analysis (cf. Procedural Manual, p. 76):~~	**Japan**
~~The method is easily accessible, e.g. from SDO websites~~ ~~The method is validated according to an internationally recognised protocol and the validation data published~~ ~~All methods should measure the same analyte (chemical entity).~~ ~~The validation covers the analytical range for the provision (e.g. MRL).~~ ~~The methods are preferably validated on the same matrices.~~ ~~If the methods contain differing analysis steps (e.g. Vitamin B6 with or without enzymatic digestion), verify that these methods still measure the same provision.~~	**Japan**
v. If the methods contain differing analysis steps (e.g. Vitamin B6 with or without enzymatic digestion), verify that these methods still measure the same provisions	
	USP Utilizing differing analysis steps equates to a different analytical approach based on the example provided. This is acceptable, but a method equivalence study should be conducted. The use of the

	term "verify" could be interpreted as vague and may not allow for true comparison of equivalence.
	Canada Because Type II and Type III methods might use different approaches, suggest include 'a demonstration of equivalence', to provide stronger wording than “verify” . . .
vi. Check results of proficiency testing in order to detect systematic differences between methods (e.g. NIST https://nvlpubs.nist.gov/nistpubs/ir/2019/NIST.IR.8266.pdf)	
~~Check results of proficiency testing in order to detect systematic differences between methods (e.g. NIST https://nvlpubs.nist.gov/nistpubs/ir/2019/NIST.IR.8266.pdf).~~	**Japan**
	USP We are not certain this will be feasible in many cases as the proficiency testing schemes may not allow for detailed comparison of methods; more likely one will only have access to general information regarding the technique utilized but not full transparency unless a common, published industry method is the used within the PT scheme.
	Canada Not all proficiency schemes include a method breakdown so this check is difficult/impossible to perform. Proficiency schemes may be based on the more relevant method which is used by industry and then guide the choice of method for Type II towards the method that is used more often.
Decision criteria for choosing the best method (=Type II) among multiple Type III methods	
	Thailand We, propose to include the followings to the decision criteria: 1) The method with lower measurement uncertainty should be preferred. 2) Information on the recent technical review of method should be submitted.
Decision ~~criteria~~ rule for choosing the best method (=Type II) among multiple Type III methods	**Japan** Japan proposes the use of term “rules” instead of “criteria” for better clarity. Japan suggests the following: (1) Bullet iii: The use of CRM should not be mandatory for Type II method because related certified reference material (CRM) is not always available for the target matrix-analyte combination. CCMAS has not considered data on analytical result of CRM when

	CCMAS endorses Type II methods. (2) Bullets iv and v: Data for comparison of specificity or precision among multiple type III methods may not obtained by method validation studies according to the international harmonized protocol agreed to by CCMAS. We should be aware that the concentration of analyte and analyte/matrix combinations are always deferent among method validation studies. For direct method comparison, a study (or studies) specifically designed for comparison is necessary, and CCMAS should take more time for endorsement. CCMAS has endorsed multiple Type III methods when analytical methods are internationally validated and meet the existing method performance criteria. (3) Availability of analytical instruments or economic costs is important. For this reason, the rule, "Method with lowest economic cost should be preferred", which is referred in the latter part of this section, should be moved to the first list as a new bullet. (4) CCMAS should ask the relevant Commodity Committee(s) to select only one Type II method from multiple type III methods, rather than CCMAS to make its own decision. This should be added among the rules.
i. The method explicitly validated for the commodity stated should be preferred: e.g. if a method for copper in infant formula is required, a method specifically validated for this commodity should be preferred to a method validated for milk powder.	
	USP Decision criteria (i) and (ii) seem contradictory. Is the intent that a method that is explicitly validated for the commodity stated AND validated for a "larger panel" of other matrices should be preferred? If so, it is unclear why this would be preferred - presuming the method is explicitly validated for the commodity of concern, it may be advantageous in some ways to utilize a method also validated for other matrices, but this should not rise to the level of preference within the decision criteria.
ii. The method validated for the larger panel of matrices should be preferred.	
	USP There are likely other considerations of concern to users in industry, regulators, etc. - for instance, availability of required equipment and instrumentation, experience with a given technique, how widely utilized and accepted one of the methods may be, etc. We agree a method validated for a larger panel of matrices MAY be

	advantageous, but for various reasons it may not be preferred for the specific commodity in question.
	Canada In the above point, the preferred method should be for a specific matrix application, but this point indicates that a method applicable to a broad group of matrices is preferable; this seems incongruous.
iii. The method where a certified reference material, preferably from a matrix similar to that used in the scope of the method, was included in the validation should be preferred.	
	Canada Certified reference materials may not have been available at the time of the development of a given method and inclusion of this parameter might favor a more recent method, even if the newer method has lesser performance which is something noted in the review of fats & oils workable package.
iv. The method with the better specificity should be preferred.	
	USP In many cases a matrix matched CRM will not have been available at the time of validation of the method. Providers of such reference materials often do not develop those materials until after a market need has been established. The preference for a method validated with a matrix-based CRM disadvantages many older and well-established methods in favor of techniques that may not have superior performance. The use of a matrix based CRM in the validation is, again, advantageous, but it should not confer preference over other methods based solely on this criterion.
v. The methods with the better precision data (if this precision difference is relevant to the question asked) should be preferred	
The method with the better precision data (if this precision difference is relevant to the question asked) should be preferred. vi. Methods with lowest economic costs should be preferred.	**Japan** Japan also proposes the following points: 3) Availability of analytical instrument or economic cost is important. For this reason, the rule "Method with lowest economic cost should be preferred" which is referred in the latter part of this section should be moved into the first list as a new bullet. 4) Rather than making decision only by CCMAS, CCMAS should ask opinions of Commodity Committees to choose one Type II method from multiple type III methods. This viewpoint should be added in the rule.
	USP Generally, of course, the method with better precision data may be preferred, but we do find there are other considerations. For

	instance, has the precision been measured and compared on the same matrix and at the same range of concentrations? If not, the method with the better precision may not suit the needs of the user fully.
	Canada Selecting the method with the better precision may be in conflict with the applicability and fitness for purpose of the method over the expected range of analyte concentration.
Additional considerations for selection Type II when several Type III methods fulfil all above criteria	
	USP Please consider: method relevance or use by industry (including industry associations); regional preferences for specific methods.
~~Methods with lowest economic costs should be preferred.~~	**Japan**
Methods with lowest economic costs should be preferred.	**USP** Should this be the third bullet point under "Additional considerations..."?
Methods with lowest economic costs should be preferred. • It is important that the trade as well as competent authorities should be consulted to determine the Type II method.	**Canada** No mention is made of regional preferences in deciding Type II methods, but this may be a factor for some methods.