

1 **Guidance document for CCMAS EWG**

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3 **Comprehensive guidance for the submission of methods of analysis to CCMAS for inclusion in**  
4 **CXS234**

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6 **1. Preamble/Intro**

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8 At CCMAS39, there were a number of discussions on the process for the adoption of methods of analysis  
9 for provisions in Codex standards.

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12 CCMAS agreed:

13 (i) to establish an EWG chaired by USA working in English to develop a discussion paper for  
14 presentation to CCMAS40 which would address and recommend guidance for the  
15 endorsement and designation of empirical methods as Type I and/or Type IV and issues  
16 around two Type II methods for the same provision and commodity. The discussion paper  
17 will address among others the following questions:


- 18 • When there are two empirical (i.e. defining) methods (from different  
19 organizations) and the degree of validation differs (i.e. one method has been subjected to  
20 an international collaborative study, whereas the other method has not), should one  
21 method be Type I and the other method Type IV, or should only one (the best validated)  
22 method be endorsed and be listed as Type I?
  - 23 • Can 2 different empirical methods be endorsed as Type IV for the same  
24 commodity and provision?
  - 25 • Clarify when two different reference methods endorsed as Type II for the same  
26 commodity and provision are identical.
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30 An electronic working group was initiated to develop a discussion paper to recommend guidance for the  
31 endorsement and designation of empirical methods as Type I and/or Type IV and issues around two  
32 Type II methods for the same provision and commodity. The paper will include, but not be limited to,  
33 discussion of determining Typing of methods, when 2 or more empirical methods exist for the same  
34 provision and commodity; if 2 empirical methods can be endorsed as Type IV; and clarify the approach if  
35 2 or more identical Type II methods can be endorsed.

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38 This document addresses these concerns in a comprehensive fashion and provides a simple outline for  
39 the relationship of methods endorsement, the role of the physical endorsement meeting, the plenary  
40 meeting and incorporation of the endorsed methods into CXS234 together with the responsibilities of  
41 member states and SDOs in the Codex community.

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43 There is a need for clarification regarding what makes a method appropriate for inclusion within  
44 CXS234. This document provides integrated guidance on submission to and review of methods of  
45 analysis by CCMAS prior to inclusion in CXS234. These guidelines are intended to assist countries and  
46 SDOs in the submission and review of methods of analysis for inclusion in CXS234. The methods are

47 primarily intended as international methods for the verification of provisions in Codex standards<sup>1</sup>.  
48 Excerpts from the *Twenty-sixth edition of Codex Alimentarius Commission Procedure Manual* are  
49 included within this Guidance.

50  
51 Sections of text from the Procedural Manual are placed in a text box as follows: 

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53 Sections from the report of CCMAS39 are placed in a text box: 

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55 Considerations raised by ISO/IDF/AOAC during the review of the methods in the Dairy Products Package  
56 (in doc CX/MAS 18/39/4/Add. 1):

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## 58 **2. Definitions**

59 Definitions used in the description of methods and their performance characteristics should conform to  
60 CAC/GL 72-2009 and the relevant source (e.g. ISO, VIM, Eurachem, etc.) Other descriptors have been  
61 used in Codex discussions such as Identical, Technically Identical, Technically Equivalent or Equivalent  
62 and are defined below:

- 63 ○ Identical
  - 64 ▪ The candidate method is identical to the current one in terms of technology, its  
65 performance for the intended use and in writing. “Identical” indicates that the same  
66 text was published by two or more SDO, either separately or jointly.
- 67 ○ Technically identical
  - 68 ▪ The candidate method is identical to the current one in terms of technology and its  
69 performance for the intended use. “Technically identical” indicates that the method  
70 uses the same principle, the same chemicals in the same concentrations, in the same  
71 procedure/sequence and the same measuring equipment, but it is written in a  
72 different style as per the originating SDO. Applies to all types of Codex methods<sup>2</sup>.
- 73 ○ Technically equivalent
  - 74 ▪ The candidate method is equal to or superior to the current one in terms of its  
75 performance (sensitivity, accuracy, and precision (i.e., reproducibility)). Technically  
76 Equivalent methods use the same principle but may use different equipment, e.g.  
77 GC-FID vs GC-MS.
  - 78 ▪ The candidate method shall be capable of allowing an analyst/expert to make an  
79 equivalent decision regarding the provision consistently. Applies to Type II, Type III  
80 and Type IV methods; Type IV methods may lack complete validation data. Such  
81 methods may be suitable for use in the Criteria Approach and could be adjudicated  
82 against accepted/expected performance criteria.
- 83 ○ Equivalent
  - 84 ▪ The candidate method is equal to or superior to the current one in terms of its  
85 performance (sensitivity, accuracy, and precision (i.e., reproducibility)).
  - 86 ▪ The candidate method shall be capable of allowing an analyst/expert to make an  
87 equivalent decision regarding the provision consistently.

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<sup>1</sup> Twenty-sixth edition of Codex Alimentarius Commission Procedure Manual, p 77 (2018)

<sup>2</sup> See footnote 1, p 79, and section on Method Typing below.

- 88                   ▪     Applies to Type III and Type IV methods; Type IV methods may lack complete  
89                   validation data.

90 **Commentary:** eWG to check and accept these definitions and their uses

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92 **3. Description of method submission from the Procedural Manual**

**General Criteria for the Selection of Methods:**

- a. Official methods of analysis elaborated by international organizations occupying themselves with a food or group of foods should be preferred.
- b. Preference should be given to methods of analysis which include performance criteria such as: selectivity, accuracy, precision (repeatability, reproducibility), limit of detection, sensitivity, practicability and applicability under normal laboratory conditions, or other criteria which may be selected as required.
- c. The method selected should be chosen on the basis of practicability and preference should be given to methods which have applicability for routine use.
- d. All proposed methods of analysis must have direct pertinence to the Codex Standard to which they are directed.
- e. Methods of analysis which are applicable uniformly to various groups of commodities should be given preference over methods which apply only to individual commodities.

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95 **Commentary:** Special attention should be given to Criterion (c) when selecting a method of analysis.

96 Criterion (e) may need revision as the determination of certain provisions in some specific matrices may

97 require special sample handling prior to the use of a general method of analysis e.g. fat in different

98 foods. In order of importance: d, a, b, c, e.

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When inter-laboratory validated methods are not available or are not applicable, the **General Criteria for the Selection of Methods** shall be met in addition to:

- a. the method is validated according to an internationally recognized protocol (e.g. those referenced in the harmonized IUPAC Guidelines for Single-Laboratory Validation of Methods of Analysis)
- b. the use of the method is embedded in a quality system in compliance with the ISO/IEC 17025 Standard or Principles of Good Laboratory Practice;
- c. The method should be complemented with information on accuracy demonstrated for instance with:
  - regular participation in proficiency schemes, where available;
  - calibration using certified reference materials where applicable;
  - recovery studies performed at the expected concentration of the analytes;
  - verification of results with other validated method where available.

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102 **Commentary:** These criteria should be used when determining the acceptability of a procedure for  
103 application to a matrix not already covered in the Scope of the method. The extent to which these  
104 criteria apply to Type III and Type IV methods should be left to the expertise of the relevant SDO(s).  
105 Additional information for bullet c.: “The method shall be complemented...” and new bullet  
106 “a comparison against a designated reference method”... and in addition to bullet 4 “other validated or  
107 designated methods”  
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#### 109 **4. Description of Method Typing from Procedural Manual<sup>3</sup>** 110

## Methods of Analysis

Definition of types of methods of analysis

### (a) Defining Methods (Type I)

Definition: A method which determines a value that can only be arrived at in terms of the method per se and serves by definition as the only method for establishing the accepted value of the item measured.

Examples: Howard Mould Count, Reichert-Meissl value, loss on drying, salt in brine by density.

### b) Reference Methods (Type II)

Definition: A Type II method is the one designated Reference Method where Type I methods do not apply. It should be selected from Type III methods (as defined below). It should be recommended for use in cases of dispute and for calibration purposes. Example: Potentiometric method for halides.

### (c) Alternative Approved Methods (Type III)

Definition: A Type III Method is one which meets the criteria required by the Committee on Methods of Analysis and Sampling for methods that may be used for control, inspection or regulatory purposes.

Example: Volhard Method or Mohr Method for chlorides

### (d) Tentative Method (Type IV)

Definition: A Type IV Method is a method which has been used traditionally or else has been recently introduced but for which the criteria required for acceptance by the Committee on Methods of Analysis and Sampling have not yet been determined.

Examples: chlorine by X-ray fluorescence, estimation of synthetic colours in foods.

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**Commentary:** eWG should find new examples to replace those listed for each type of method. Perhaps remove Howard Mould Count and Reichert-Meissl from (a)? Find replacement methods for examples in (c).

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## 5. Points raised by AOAC/IDF/ISO analysis of relevant methods of analysis presented in CX/MAS 18/39/4 Add. 1

- *Is it necessary to have precision figures for a Type I method?*

During CCMAS39 there was general agreement that moving forward, any new method proposed for Type I should contain precision figures as part of the data reviewed during the endorsement process. However, there was also agreement that while having such data for previously endorsed methods would be beneficial, lack of such data would not cause a change in the method type or revocation of a method.

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119 **Commentary:** Submission of a candidate method should include a statement regarding the validation  
120 status of the method from the responsible SDO (ownership may be apparent from the method  
121 identifier). See General Criteria for the Selection of Methods (above). Methods already endorsed by  
122 CCMAS and included in CXS 234 are retained if validation data is unavailable when supported by the  
123 relevant SDO(s) and considered to be in common usage.  
124

○ *If a defining method has been subjected to an international collaborative study involving dairy commodities A, B and C, and the method is generally known to work on commodity D, but this commodity was not included in the study, should the method then be listed as Type I or Type IV in STAN 234 for commodity D?*

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During CCMAS39 it was agreed that a general rule to extend or not extend the typing is not appropriate. Because the decision would depend on the matrices involved as well as the analytical procedure, the typing should be done on a case-by-case basis. The expertise from the SDOs in providing information on the applicability of the method for a non-validated matrix will be important in this.

127 **Commentary:** Reflecting the comment captured in the notes from CCMAS39, a decision on extending  
128 the scope of a method to include a new matrix (commodity) requires validation and performance data  
129 on the new matrix and review by the SDO(s) originating the method in question. If not brought to the  
130 attention of CCMAS by the SDO(s), the issue of a scope extension should be highlighted in CCMAS  
131 meeting documents so that SDO(s) can investigate and provide a review prior to the Endorsement WG  
132 and Plenary meetings.  
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○ *Clarify for the situation where there are two defining methods (from different organisations) and the degree of validation differs (i.e. one method has been subjected to an international collaborative study, whereas the other method has not), whether one method be Type I and the other method Type IV, or only one (the best validated) method should be accepted and be listed as Type I.*

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During CCMAS39 there was no consensus reached on this question and delegates suggested that discussion around the terms “technically equivalent” and “technically identical” should be resolved prior to further discussion on this question.

138 **Commentary:** See Definitions above; eWG to refine definitions  
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- *Clarify for those cases where a provision is not specifically listed in the Commodity Standard, what decision process is to be followed to determine whether or not to include such provision in CXS234 (e.g., see provisions for iron in milk products, lead in edible casein products, and MSNF in cream).*

141

During CCMAS39 it was agreed that some ‘indication’ in the Commodity Standard should exist in order for a provision to be listed in CODEX STAN 234. This ‘indication’ does not have to be a specific provision in the standard, but may also be a general text, for example a referral to contaminants.

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143

144 **Commentary:** General text could cover additives, contaminants and issues of authenticity testing and be  
145 included in the statement directing the standard user to refer to CXS234 for specific methods of analysis.

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- *Apply a consistent approach in listing provisions that require a calculation based on two or more analyses. In some cases, all concerned methods are listed; in other cases only a single method*

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During CCMA39 it was agreed that all methods should be listed and separated by the word “and”.

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149 **Commentary:** See section 6.7.ii on Presentation of methods for incorporation into CXS234.

150

- *Consistent use of the vertical line and forward slash to express the relationship between standards developed by several organisations (not raised by ISO/IDF/AOAC but brought up during CCMAS39 with the discussion on the Review/Revision (Update) of CXS 234-1999)*

When the methods are in the same line separated by a vertical bar “|”, they are identical and published in a single document by different standards development organisations. When they are separated by a forward slash “/”, they are technically identical and published in separate documents that may have different formats.

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153 **Commentary:** See section 6.7.ii on Presentation of methods for incorporation into CXS234.

154

155 **6. Process for the submission of methods of analysis for provisions in Codex Commodity**  
156 **Standards**

157 **6.1 Steps in the process**

- 158 i. Signaling and capturing the need for a method when a new or amended provision  
159 or reference to it is incorporated in a Codex standard.
- 160 ii. Initiative of one or more SDOs or other Codex related entities to identify an existing  
161 candidate method or to develop and validate the candidate method.
- 162 iii. Submission of the candidate method to the concerned Codex Commodity  
163 Committee or a Codex General Subject Committee.
- 164 iv. Review of the method suitability (fitness for purpose) by the concerned Codex  
165 Commodity Committee or a Codex General Subject Committee and submission to  
166 CCMAS for endorsement.
- 167 v. Review, assign typing, endorsement of the method by CCMAS including decision on  
168 submission of a proposal to CAC for adoption of the method and inclusion in  
169 CXS234, optionally indicating replacement or retyping of already listed method(s) in  
170 CXS234. (See Section 5.2)
- 171 vi. Decision on adoption by CAC and inclusion in CXS234, optionally replacing or editing  
172 already listed method(s) in CXS234.
- 173

174 **6.2 Acceptance of methods of analysis**

175 In line with the Procedural Manual, methods submitted for endorsement by the CCMAS for  
176 adoption by Codex Alimentarius should be proposed by the relevant commodity or other  
177 sponsoring committee. Codex specifications for products in commercial trade between  
178 countries need to be defined by each committee.

- 179 i. Each provision in a specification needs to have a value (limit value, maximum or  
180 minimum level) and a suitable method of analysis for use should a dispute arises.  
181 Other methods used for purposes of product authenticity may also be referenced.
- 182 ii. When a committee works on a specification during the development process and  
183 before submission to CCMAS, the experts should determine:
- 184 a. If a suggested method of analysis is “fit for purpose”
- 185 b. If there are validation data available for the method and analyte in the  
186 commodity or food.
- 187 c. If the suggested method of analysis has been studied by one or more  
188 SDOs.
- 189 d. If the SDOs have been consulted on the status and applicability of the  
190 method [Commentary: committees often refer to older versions or  
191 withdrawn versions of methods].
- 192 iii. Proposal of methods of analysis to CCMAS for adoption should be carried out with  
193 the knowledge that the methods of analysis meet the above criteria (II. a-d).  
194 [Commentary: It is not the role of CCMAS to research the methods and determine if  
195 the method is fit for purpose, since this is the role of the SDOs].



- 196 iv. Committees are encouraged to offer proposals for the Typing of a method and the  
197 Principle (definition of the technique) according to the requirements of CXS234.  
198 CCMAS will confirm these proposals and also consider the advice of relevant SDOs.  
199 v. Method proposals should be supplied to CCMAS well in advance of a physical  
200 meeting to enable receipt of comments from interested parties. [Commentary:  
201 Nations and/or SDOs/observers should be strongly encouraged to provide written  
202 comments in a timely fashion to enable translation].  
203 vi. The recognition that a method is obsolete, inappropriate (no longer fit for purpose)  
204 or has been withdrawn by the relevant SDO should be brought to the attention of  
205 CCMAS. [Commentary: This is the duty of both commodity and horizontal  
206 committee members, observers and SDOs].  
207 vii. The committee originally proposing the method of analysis should be informed and  
208 should find a replacement and bring it to the attention of CCMAS. [Commentary:  
209 The SDO should make the commodity committee aware of changes it makes].  
210 viii. The SDO should bring the information directly to CCMAS if the committee is  
211 adjourned or otherwise inactive/unresponsive. [Commentary: CCMAS may  
212 determine what further action is warranted or discuss the SDO proposal in session].  
213 ix. Proposals for a replacement are encouraged and will be deliberated by CCMAS.  
214

215 6.3 Acceptance of a proposed method of analysis by CCMAS is a two-stage process:

- 216 i. Methods together with their Typing and Principle are discussed and endorsed by  
217 the Physical Working Group on Methods Endorsement immediately prior to CCMAS  
218 [Commentary: SDOs are encouraged to make contributions to this meeting,  
219 however, the proposal of Identical, Technically Identical, Technically Equivalent and  
220 Equivalent methods should be made in writing prior to this meeting according to  
221 CCMAS timelines and should not be a feature of this meeting].  
222 ii. CCMAS discusses the report of the Methods Endorsement WG in plenary.  
223 [Commentary: SDOs are encouraged to contribute to this discussion and provide  
224 explanations if required].  
225 iii. Methods endorsed by CCMAS are forwarded to CAC for final approval.  
226

227 6.4 The role of SDOs in Commodity/Horizontal/Regional Committees

228 To play a positive role in the maintenance of methods of analysis for use in the Codex system,  
229 SDOs wishing to maintain ownership and exercise their rights as methods providers (intellectual  
230 property and copyright issues) should undertake the following oversight activities:

- 231 i. Have Codex Alimentarius observer status  
232 ii. Follow the activities of relevant Codex committees  
233 iii. Contribute timely written comments on relevant issues  
234 iv. Contribute oral comments during plenary proceedings  
235 v. Inform Codex of changes in SDO activities (for instance in a report/brief news item  
236 or through joint contributions of the InterAgency meeting)

- 237 vi. Bring to the attention of CCMAS actions at a commodity or other committee which  
238 may lead to a change in requirements for a method of analysis  
239 vii. Bring to the attention of a commodity or other committee actions by CCMAS which  
240 may lead to a change in requirements for a method of analysis  
241 viii. Provide Codex Alimentarius with assistance when deliberations involve technical  
242 details or a deeper understanding of analytical issues  
243 ix. Encourage horizontal and regional committees to seek the advice of relevant SDOs  
244 on analytical issues at all stages of standard development, including contacting  
245 those organizations not participating during a discussion.  
246 x. Ascertain that references in CXS234 to their standards are correct and kept up to  
247 date.  
248

#### 249 6.5 The role of SDOs at CCMAS in the methods endorsement process

250 SDOs should be:

- 251 i. The provider of accurate information regarding the status of an analytical method  
252 and its stage within the organization’s method evaluation process (e.g. publication  
253 status, SLV, full collaborative study or anecdotal or PT data collection) and its fitness  
254 for purpose.  
255 ii. In agreement when methods are “Identical” or “Technically Identical” or have  
256 sufficient differences to affect the analytical outcome. SDOs are to provide this  
257 assurance to CCMAS.  
258 iii. Able to consider scope and scope extension vs “Codex general methods” [IAM  
259 members need to consider this issue and perhaps develop commentary and/or  
260 guidance].  
261 iv. Able to provide advice on method typing as these criteria are specific to Codex, and  
262 not generally used by SDOs outside of CCMAS.

#### 263 6.6 Type IV methods and their transitioning to other method types

- 264 i. New candidate methods may only be typed as Type I, II or III when submitted with a  
265 full set of validation data, e.g. precision data obtained in conformity with  
266 internationally accepted standards. With the submission of other lesser validation  
267 data these methods will be listed as Type IV.  
268 ii. Existing Type I methods without a full set of validation data are to be considered on  
269 a case-by-case basis by the relevant SDO(s) on:  
270 a. the feasibility of collecting and submitting the missing validation data to  
271 Codex  
272 b. the availability of an alternative candidate-method to become the Type I  
273 method  
274 c. the rationale for keeping the existing Type I method in place as is  
275 d. the rationale for retyping the method or revocation of the method.  
276

- 277 iv. A method typed as Type IV may transition to another type after the submission of  
 278 acceptable validation data to the SDO and its adoption. Submission to and  
 279 endorsement by CCMAS is required. A method should not remain as Type IV  
 280 indefinitely.
- 281 v. Where two methods are proposed as Type I for a particular provision, the relevant  
 282 SDOs shall determine if the methods are Technically Identical (in which case they can  
 283 both be listed) or if, based on the performance data or other information, one better  
 284 meets the required criterion than another. In cases where there is a regional  
 285 preference for one method over another, the relevant commodity committees and/or  
 286 regional committees should decide which method to put forward to CCMAS.

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 288 6.7. Presentation of methods for incorporation into CXS234

289 CXS234 is a summary document that contains all the methods of analysis that cover provisions  
 290 contained in Codex Commodity standards, but excludes methods for food additives,  
 291 contaminants, pesticides and veterinary drug residues. In time this will be the sole reference for  
 292 these methods. [Insert reference to eWG on CXS234 for introduction]  
 293

294 i. Information required:

- 295 a. A provision in a Codex standard with a limit/range of values  
 296 b. A suitable method for the analysis, preferably from an accepted SDO  
 297 c. Principle  
 298 d. Codex Typing  
 299 e. Assurance that sufficient testing has been carried out to generate  
 300 precision data  
 301 f. Fitness for purpose [Commentary: assurance by SDO that the method  
 302 will perform adequately on the expected range of analyte  
 303 concentrations based on performance data, studies, publication(s)]  
 304

305 ii. Definition of separators between methods presented in CXS234

Separator	Meaning	Example	Type
	A method published jointly by two or more SDOs as a single publication	ISO 5534   IDF 4	All Types
/*	A <b>Technically Identical</b> method published by two or more SDOs separately	ISO 3960 / AOCS Cd 8b-90	All types
and	Two or more methods required to calculate the required answer	ISO 5534   IDF 4 and ISO 1735   IDF 5	All Types
Separate line	Two or more <b>(Equivalent)</b> methods capable of giving the same answer using	AOAC 967.21 IFUMA 17 ISO 6557-2	Type II, III, IV (does not

	similar or different technologies		apply to Type I)
<b>or**</b>	Two or more <b>Technically Equivalent</b> methods capable of giving the same answer published by two or more SDOs separately	COI/T.20/Doc. no. 11 or ISO 15788-1 or AOCS Cd 26-96	Type II, III, IV (does not apply to Type I)
* The current version of Codex Stan 234 (CXS234) contains “/”, “or” and “separate lines” for the same Type I method for a single provision			
** The current version of Codex Stan 234 (CXS234) contains “or” and “...; or” when used as a divider between methods.			

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**Commentary:** Should this proposal be accepted, it will be important to check CXS234 for the correct separator in lists of methods for use for the same provision.

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