



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME  
FAO/WHO COORDINATING COMMITTEE FOR ASIA**

**Twenty-third Session**

**REVIEW OF THE SAMPLING PLANS IN REGIONAL STANDARDS (Asia)**

(Prepared by Japan)

**BACKGROUND**

1. CCMAS42 (2023) forwarded to CAC46 the revised *General Guidelines on Sampling* (CXG 50-2004) for adoption at Step 8, and then CAC46 adopted the Guidelines at Step 8. At the session, CCMAS42 also agreed to inform relevant Codex committees of the revised Guidelines and request these committees to review their sampling plans in light of the revised Guidelines.<sup>1</sup>

2. Among regional standards (Asia), the following one contains sampling plan. Since CCASIA is an active committee, CCASIA is responsible to review it in light of the revised Guidelines.

- *Regional Standard for Non-Fermented Soybean Products* (Asia) (CXS 322R-2015)

3. For the following regional standards (Asia), CCASIA has not developed sampling plans yet. However, these standards include "METHODS OF ANALYSIS AND SAMPLING" section with the text "for checking the compliance with this standard, the methods of analysis and sampling contained in the *Recommended Methods of Analysis and Sampling* (CXS 234-1999) relevant to the provisions in this standard shall be used." In contrary, sampling plans for the commodities covered by these regional standards are not available in CXS 234. To fix the contradiction, CCASIA, which is responsible for these regional standards, should develop sampling plans to be included in CXS 234.

- *Regional Standard for Fermented Soybean Paste* (Asia) (CXS 298R-2009)
- *Regional Standard for Edible Sago Flour* (Asia) (CXS 301R-2011)
- *Regional Standard for Tempe* (Asia) (CXS 313R-2013)
- *Regional Standard for Laver Products* (Asia) (CXS 323R-2017)
- *Regional Standard for Soybean Products Fermented with Bacillus Species* (Asia) (CXS 354R-2023)
- *Regional Standard for Cooked Rice Wrapped in Plant Leaves* (Asia) (CXS 355R-2023)

4. In addition, CCASIA is developing *Regional Standard for Quick Frozen Dumpling*, which CCASIA23 will discuss at Step 7. Taking into account that CCASIA22 had already agreed on the quality criteria and classification of "defectives", discussion on the sampling plans at the current CCASIA is beneficial for finalization of this proposed draft standard.

**GENERAL CONSIDERATIONS**

5. Japan considered general matters in developing sampling plans in light of the revised Guidelines as follows.

6. Since the purpose of sampling plans in regional standards is to decide whether importing country should accept lots based on the conformity to standards, the approach should be "sampling based on statistical principles" and "acceptance sampling" (See Section 2.2 of CXG 50).

7. Sampling plans can roughly be divided into two categories: attributes plans and variables plans (See Sections 4.2 and 4.3 of CXG 50, respectively). The first step is to determine which category is more appropriate. In short, attributes plans are defined as the *n* (number of samples to be taken) and *c* (the maximum number of marginal samples allowed for acceptance of the lot), and variables plans use the measurement values – means and standard deviations – to check conformity. Variable plans require less number of samples than attribute plans to accomplish the same the producer's risk quality level (PRQ) and the consumer's risk quality

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<sup>1</sup> REP 23/MAS, para. 81

level (CRQ). However, variables plans can be used only if the data type is numerical values (e.g. net weight, analytical values etc).

8. According to Section 3.2 of CXG 50, the following factors should also be taken into account.

#### **Stringency (Section 3.2.1)**

9. Stringency is the ability of a sampling plan to control consumers' risks (CRs) and producers' risks (PRs), of incorrectly accepting or incorrectly rejecting a lot, at any specified quality level. Producer's risk and consumer's risk are specified by PRQ and CRQ and their associated probabilities of wrongly rejection (PR) and acceptance (CR), respectively. It is possible to establish plans to specify both PRQs and CRQs. However, in many plans such as those in ISO 2859 and ISO 3951, only PRQs are specified as acceptance quality limit (AQL) and such plans work properly. Since simpler approach is easier to understand, Japan supports to take the "AQL approach".

#### **Fitness for purpose (Section 3.2.2)**

10. Fitness for purpose includes fairness and practicality. If both CRQs and PRQs are lowered, the plan ensures better fairness, but such plan is likely to require more samples to be analyzed, resulting in lower practicality. If the provision is related to food safety, CRQ should be reduced as much as possible to protect consumers' health; then lowering AQL is essential for ensuring food safety. For quality provisions, although low CRQ is preferable for fair trade, we have to consider reducing time and cost for sampling and analysis to the reasonable level. Thus, we may consider to use relatively high AQL for quality provisions.

11. In sampling plans internationally recognized (e.g. ISO 2859, ISO 3951 and sampling plans previously developed by Codex), AQL values are between 0.65 and 6.5%. Therefore, we can use the "default" AQL values of 6.5% for quality factor and 0.65% for safety factor, unless different value is considered to be more appropriate according to specific factors depending on the commodity and analyte, such as very high toxicity, prices of the commodity, practicability etc.

#### **Specification limits (Section 3.2.3)**

12. Specification limits may be considered for safety factors. Since provisions in regional standards are for quality, we do not have to consider them for regional standards.

#### **Lot homogeneity (Section 3.2.4)**

13. It is reasonable to assume that commodities described in regional standards are homogeneous. However, random sampling is still recommended.

#### **Distribution of the characteristic (Section 3.2.5)**

14. There is no prior information on the distribution of a characteristic. For attribute plans, we can use binomial distribution as a "default" assumption. For variable plans, further consideration is needed.

#### **Lot standard deviation (Section 3.2.6)**

15. No information is available on lot standard deviation for provisions in regional standards.

#### **Measurement uncertainty (Section 3.2.7)**

16. In regional standards, the maximum/minimum levels are 0.1% or higher. The expanded measurement uncertainty (coverage factor of 2) estimated by Horwitz equation (Table 1) does not affect significantly the results on whether the importer should accept the lot.

**Table 1 Expanded measurement uncertainty (coverage factor of 2)**

| Concentration                           | 10%  | 5%   | 1%   | 0.5% | 0.1% |
|-----------------------------------------|------|------|------|------|------|
| Estimated MU<br>(2 × RSD <sub>R</sub> ) | 5.7% | 6.3% | 8.0% | 8.9% | 11%  |

#### **Lot size (Section 3.2.8)**

17. Lot size is not normally an input required for the design of sampling plans intended to control both CR and PR in acceptance sampling. However, a lot size has been built into the design of the sampling plans in ISO 2859 and ISO 3951. Since it is reasonable to take smaller number of samples for smaller lots and beneficial to reduce the risks of making incorrect decisions for larger lots, we propose to take into account the lot size when applicable.

## General Considerations - summary

18. Sampling plans for Asian regional standards should be acceptance sampling and based on statistical principles. In the consideration on factors for selecting sampling plan described in CXG 50, sampling plans for Asian regional standards should be based on ISO 2859 (attributes plans) or ISO 3951 (variable plans) unless special needs are identified, taking into account the fact that it is recommended to use an international standard. Since provisions in all of the Asian standards are for quality, AQL of 6.5% is most likely to fit for purposes. Samples are likely to be homogeneous, but distribution of characteristic is unknown. Due to the level of maximum/minimum levels (0.1% or higher), measurement uncertainty is not significant.

19. During the discussion on each regional standard, the followings should be considered:

- i. Whether attributes or variables plans should be used; and
- ii. Specific factors/situations that have to be considered, in particular that may alter AQLs from the default

## DISCUSSION

### ***Regional Standard for Non-Fermented Soybean Products (Asia) (CXS 322R-2015)***

20. In this Regional Standard, the provisions to decide whether the lots should be accepted for the commodities are four qualitative provisions (flavor, odour, colour and texture) and three quantitative provisions (moisture content, protein content, and net weight).

21. For the first four qualitative provisions, the analytical result is the presence or absence of the characteristics of each item, so attribute plan is appropriate. For the latter three quantitative provisions, analytical results are numerical values, so both attribute and variable plans are possible. However, it is not practicable to conduct independent sampling to collect samples separately for the first four provisions and for the latter three provisions. Noting that attribute plans can cover all provisions, the same attribute plans should apply to all the provisions for the commodity.

22. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

23. It should be noted that the current Regional Standard, including an attribute plan of ISO 2859-1 with an AQL of 6.5%, may have been used in trade, and that making significant changes may adversely affect the current trade practices.

24. CCMAS42 identified that the sampling plan currently included in the Regional Standard, which is excerpted from Table 10 of the previous CXG 50, contains some errors<sup>2</sup>. With correction in line with Appendix II of the revised CXG 50, Japan proposes to use sampling plans in Appendix I for commodities covered by the Regional Standard, retaining an attribute plan of ISO 2859-1 with an AQL of 6.5%.

### ***Regional Standard for Fermented Soybean Paste (Asia) (CXS 298R-2009)***

25. The provision to decide whether the lots should be accepted for the commodities is four qualitative provisions (flavor, odour, colour and texture) and four quantitative provisions (total nitrogen, amino nitrogen, moisture content and minimum fill (product should occupy not less than 90 percent of the water capacity of the container)). Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

26. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

27. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

### ***Regional Standard for Edible Sago Flour (Asia) (CXS 301R-2011)***

28. The provisions to decide whether the lots should be accepted for the commodities are four qualitative provisions (flavours, odours, filth and colour) and six quantitative provisions (moisture content, Ash inorganic extraneous matter, acidity, starch content, crude fibre, and particle size). Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

29. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

30. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

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<sup>2</sup> REP23/MAS, para. 80

**Regional Standard for Tempe (Asia) (CXS 313R-2013)**

31. The provisions to decide whether the lots should be accepted for the commodities are five qualitative provisions (texture, colour, flavor, odour, and foreign matters) and four quantitative provisions (moisture content, protein content, lipid content and crude fibre). Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

32. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

33. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

**Regional Standard for Laver Products (Asia) (CXS 323R-2017)**

34. The provisions to decide whether the lots should be accepted for the commodities are two qualitative provisions (flavours and colours) and three quantitative provisions (moisture content, acid value and net contents). Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

35. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

36. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

**Regional Standard for Soybean Products Fermented with Bacillus Species (Asia) (CXS 354R-2023)**

37. The provisions to decide whether the lots should be accepted for the commodities are basically four qualitative provisions (flavours, odours, colours and texture of the product) and a qualitative provision (net weight). In addition, products that belong to subcategory need to meet additional quantitative provisions (moisture, protein and lipid content for *Natto* and *Cheonggukjang*, and moisture and protein content for *Thua Nao*.) Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

38. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

39. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

**Regional Standard for Cooked Rice Wrapped in Plant Leaves (Asia) (CXS 355R-2023)**

40. The provision to decide whether the lots should be accepted for the commodities are some qualitative provisions (shape, size, properly wrapped, smell and taste, leakage of filling, foreign taste and foreign matters) and two quantitative provisions (peroxide value and net weight). Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

41. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

42. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

**Regional Standard for Quick Frozen Dumpling (Step 7)**

43. The provision to decide whether the lots should be accepted for the commodities are some qualitative provisions (wrapped in an appropriate form, foreign matters and leakage of filling) and two quantitative provisions (ratio of filling to total and net weight). Like the earlier discussion on *Regional Standard for Non-Fermented Soybean Products*, it is necessary to use attribute plans for the commodity to avoid duplicate sampling.

44. Since no specific needs are identified, the default AQL for quality factor of 6.5% is appropriate.

45. Japan proposes sampling plans in Appendix I for commodities covered by the Regional Standard (ISO 2859-1 with an AQL of 6.5%).

**CONCLUSION**

46. Japan reviewed sampling plans for Asian regional standards in light of the revised CXG 50. In any cases, random sampling should be used. For the commodities defined in the following regional standards, attribute plans described in Appendix I (in accordance with ISO 2859-1 with an AQL of 6.5%) are appropriate:

- *Regional Standard for Fermented Soybean Paste (Asia) (CXS 298R-2009)*
- *Regional Standard for Edible Sago Flour (Asia) (CXS 301R-2011)*

- *Regional Standard for Tempe (Asia) (CXS 313R-2013)*
- *Regional Standard for Non-Fermented Soybean Products (Asia) (CXS 322R-2015)*
- *Regional Standard for Laver Products (Asia) (CXS 323R-2017)*
- *Regional Standard for Soybean Products Fermented with Bacillus Species (Asia) (CXS 354R-2023)*
- *Regional Standard for Cooked Rice Wrapped in Plant Leaves (Asia) (CXS 355R-2023)*
- *Regional Standard for Quick Frozen Dumpling (Asia) (Step 7 at this session)*

**RECOMMENDATION**

47. CCASIA23 is invited to:
- i. consider sampling plans for the commodities defined in the regional standards (Asia) in light of the revised CXG 50, referring to the discussion in this paper; and
  - ii. forward sampling plans, with amendment following the discussion at CCASIA23 if necessary, to CCMAS for endorsement

**Inspection by attributes plans in accordance with ISO 2859-1 (AQL=6.5%)**

| Lot size<br>(number of<br>packages, each<br>containing 1 or<br>more units) | Inspection level   |                          |      |     |                    |                          |      |     |
|----------------------------------------------------------------------------|--------------------|--------------------------|------|-----|--------------------|--------------------------|------|-----|
|                                                                            | Normal             |                          |      |     | Tightened          |                          |      |     |
|                                                                            | Sample<br>size (n) | Acceptance<br>number (c) | CRQ  | PRQ | Sample<br>size (n) | Acceptance<br>number (c) | CRQ  | PRQ |
| 2-15                                                                       | 2                  | 0                        | 68.4 | 2.5 | 3                  | 0                        | 53.6 | 1.7 |
| 16-50                                                                      | 8                  | 1                        | 40.6 | 4.6 | 13                 | 1                        | 26.8 | 2.8 |
| 51-90                                                                      | 13                 | 2                        | 36.0 | 6.6 | 13                 | 1                        | 26.8 | 2.8 |
| 91-150                                                                     | 20                 | 3                        | 30.4 | 7.1 | 20                 | 2                        | 24.5 | 4.2 |
| 151-280                                                                    | 32                 | 5                        | 27.1 | 8.5 | 32                 | 3                        | 19.7 | 4.4 |
| 281-500                                                                    | 50                 | 7                        | 22.4 | 8.2 | 50                 | 5                        | 17.8 | 5.4 |
| 501-1 200                                                                  | 80                 | 10                       | 18.6 | 7.9 | 80                 | 8                        | 15.7 | 6.0 |
| 1 200-3 200                                                                | 125                | 14                       |      |     | 125                | 12                       |      |     |
| 3 201 and over                                                             | 200                | 21                       |      |     | 200                | 18                       |      |     |

Note:

- If sample size n equals to or exceeds lot size, carry out 100% inspection.
- The number of samples to be analyzed is n. If the number of samples that do not meet criterion is less than or equal to c, the lot should be accepted. Otherwise, the lot should be rejected.
- Producer's risk and consumer's risk are specified by the producer's risk quality level (PRQ) and the consumer's risk quality level (CRQ) and their associated probabilities of rejection (PR=5%) and acceptance (CR=10%), respectively. For example, in the sampling plan for a lot consist of 501-1200 items at normal inspection level (n=80 and c=10), the lot is wrongly rejected at the probability of 5% (PR) if 7.9% (PRQ) of the items are nonconforming, and the lot is wrongly accepted at the probability of 10% (CR) if 18.6% (CRQ) of the items are nonconforming.
- CRQ and PRQ are calculated using <https://codex-testing.shinyapps.io/codex-testing-SamplingPlan/>