ANNEX III

SAMPLING AND ANALYSIS REQUIREMENTS FOR THE MONITORING REFERRED TO IN ARTICLE 4

I.Sampling

1. The sample shall be representative for the sampled batch.

2. FBOs shall ensure that they undertake representative sampling and analysis of their products for the presence of acrylamide to verify the effectiveness of mitigation measures, i.e. the levels of acrylamide are consistently below the benchmark levels.

3. FBOs shall ensure that a representative sample of each product type is taken for analysis of acrylamide concentration. A 'product type' includes groups of products with the same or similar ingredients, recipe design, process design and/ or process controls where these have a potential influence acrylamide levels in the finished product. Monitoring programmes shall prioritise product types that have the demonstrated potential to exceed the benchmark level and shall be risk-based where further mitigation measures are feasible.

II. Analysis

1. FBOs shall provide sufficient data to enable an assessment of the level of acrylamide and of the likelihood that the product type might exceed the benchmark level.

2. The sample shall be analysed in a laboratory that participates in appropriate proficiency testing schemes (which comply with the 'International Harmonised Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories'[(1)] developed under the auspices of IUPAC/ISO/AOAC) and uses approved analytical methods for detection and quantification. Laboratories shall be able to demonstrate that they have internal quality control procedures in place. Examples of these are the 'ISO/AOAC/IUPAC Guidelines on Internal Quality Control in Analytical Chemistry Laboratories'[(2)].

Wherever possible the trueness of analysis shall be estimated by including suitable certified reference materials in the analysis.

3. The method of analysis used for the analysis of acrylamide must comply with the following performance criteria

Parameter	**Criterion**
Applicability	Foods specified in this Regulation
Specificity	Free from matrix or spectral interferences
Field blanks	Less than Limit of Detection (LOD)
Repeatability (RSD_r)	0,66 times RSD_R as derived from (modified) Horwitz equation
Reproducibility (RSD_R)	as derived from (modified) Horwitz equation
Recovery	75-110 %
Limit of Detection (LOD)	Three tenths of LOQ

Limit of Quantification (LOQ)	For benchmark level < 125 µg/kg: ≤ two fifths of the benchmark level (however not required to be lower than 20 µg/kg) For benchmark level ≥ 125 µg/kg: ≤ 50 µg/kg

4. Analysis of acrylamide can be replaced by measurement of product attributes (e.g. colour) or process parameters provided that a statistical correlation can be demonstrated between the product attributes or process parameters and the acrylamide level.

III. **Frequency of sampling**

1. FBOs shall, undertake sampling and analysis at least annually for products that have a known and well-controlled acrylamide level. FBOs shall carry out higher frequency sampling and analysis of products having the potential to exceed the benchmark level and shall be risk-based where further mitigation measures are feasible.

2. Based on this assessment referred to in point II.1, the FBOs shall specify appropriate frequencies for analysis for each product type. The assessment shall be repeated if a product or process is modified in a way that could lead to a change in the acrylamide level in the final product.

IV. **Mitigation**

If the analytical result, corrected for recovery but not taking into account the measurement uncertainty, indicates that a product has exceeded the benchmark level, or contains acrylamide at a level higher than anticipated (taking into account previous analyses, but lower than the benchmark level), then the FBOs shall carry out a review of the mitigation measures applied and shall take additional available mitigation measures to ensure that acrylamide level in the finished product is below the benchmark level. This must be demonstrated by the undertaking of a new representative sampling and analysis, after the introduction of the additional mitigation measures.

V. **Information to competent authorities**

FBOs shall make the analytical results obtained from the analysis every year available on request to the competent authority together with descriptions of the products analysed. Details of mitigation measures taken to reduce levels of acrylamide below the benchmark level shall be provided for those products exceeding the benchmark level.

(**1**) M. Thompson et al, Pure and Applied Chemistry, 2006, 78, pp. 145-196.

(**2**) Edited by M. Thompson and R. Wood, Pure and Applied Chemistry, 1995, 67, pp. 649-666.

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Commission Regulation (EU) 2017/2158, ANNEX III.