

[Translation from Spanish into English]

DOF: 31 Jan 2022

**Draft Conformity Assessment Procedure for Official Mexican Standard NOM-223-SCFI/SAGARPA-2018, Cheese-Denomination, specifications, commercial information, and test methods, published on 31 January 2019, (This will replace the Draft Conformity Assessment Procedure for Official Mexican Standard NOM-223-SCFI/SAGARPA-2018, Cheese-Denomination, specifications, commercial information and test methods, published on 31 January 2019, published on 4 May 2020).**

In the margin, a seal with the National Emblem, which says: United Mexican States – ECONOMY - Ministry of Economy - Unit for Standards, Competitiveness and Competency - General Directorate of Standards - Department of Agriculture and Rural Development - General Directorate of Agrifoods Standards.

DRAFT CONFORMITY ASSESSMENT PROCEDURE FOR OFFICIAL MEXICAN STANDARD NOM-223-SCFI/SAGARPA-2018, CHEESE-DENOMINATION, SPECIFICATIONS, COMMERCIAL INFORMATION AND TEST METHODS, PUBLISHED IN THE 'DIARIO OFICIAL DE LA FEDERACION' ON 31 JANUARY 2019, (THIS WILL REPLACE THE "DRAFT CONFORMITY ASSESSMENT PROCEDURE FOR OFFICIAL MEXICAN STANDARD NOM-223-SCFI/SAGARPA-2018, CHEESE-DENOMINATION, SPECIFICATIONS, COMMERCIAL INFORMATION AND TEST METHODS, PUBLISHED ON 31 JANUARY 2019", PUBLISHED IN THE 'DIARIO OFICIAL DE LA FEDERACION ON 4 MAY 2020.

ALFONSO GUATI ROJO SÁNCHEZ, Director General of Standards of the Ministry of Economy and JOSE EDUARDO ESPINOSA DE LOS MONTEROS AVINA, Director General of Agrifoods Standards and Chairman of the National Consultative Committee for Agrifoods Standards ('CCNNA') of the Ministry of Agriculture and Rural Development, pursuant to articles 12, 34 sections II, VIII, XIII and XXXIII, 35 sections IV, IX and XXIV of the Organic Law of the Federal Public Administration; article 4 of the Federal Law of Administrative Procedure; articles 94, 99 and 100 of the Law of Sustainable Rural Development; articles 2, 6 sections IV, LIII and LXXI, 113, 114 and 116 of the Federal Law of Animal Health; articles 38 sections II and IX, 39 sections V and XII, 40 sections I, II, XI and XII, 47, final paragraph, 73 and 74 of the Federal Law on Metrology and Standardization; articles 31, 80, 81 and 82 of the Regulations of the Federal Law of Metrology and Standardization; articles 36 sections I, II, IV, IX, XVI, XXI and XXII of the Internal Regulations of the Ministry of Economy; and article 21 of the Internal Regulations of the Ministry of Agriculture and Rural Development, issue for public consultation the DRAFT CONFORMITY ASSESSMENT PROCEDURE FOR OFFICIAL MEXICAN STANDARD NOM-223-SCFI/SAGARPA-2018, CHEESE – DENOMINATION, SPECIFICATIONS, COMMERCIAL INFORMATION AND TEST METHODS, PUBLISHED IN THE 'DIARIO OFICIAL DE LA FEDERACIÓN' ON 31 JANUARY 2019, in order that, within 60 days from the day immediately following its publication in the 'Diario Oficial de la Federación', interested parties may submit their comments to the Ministry of Economy located at 'Calle Pachuca número 189, Colonia Condesa, Demarcación Territorial Cuauhtémoc, C.P. 06140', Mexico City, telephone: 57 29 91 00, ext. 13247, or email address: [dgn.alimentaria@economia.gob.mx](mailto:dgn.alimentaria@economia.gob.mx) ; or to the Ministry of Agriculture and Rural Development located at 'Avenida Municipio Libre número 377, Piso 4 Ala B, colonia Santa Cruz Atoyac, Demarcación Territorial Benito Juárez, C.P. 03310', Mexico City, or to email addresses: [jepinosa@agricultura.gob.mx](mailto:jepinosa@agricultura.gob.mx) or [homobono.perea@agricultura.gob.mx](mailto:homobono.perea@agricultura.gob.mx), in order for them to be considered according to the Law on this subject by the agencies proposing it.

Mexico City, 12 January 2022 – The Director General of Standards of the Ministry of Economy – Alfonso Guati Rojo Sanchez – signature – The Director General of Agrifoods Standards and Chairman of the National Consultative Committee for Agrifoods Standards of the Ministry of Agriculture and Rural Development – Jose Eduardo Espinosa del los Monteros Avina – signature.

**DRAFT CONFORMITY ASSESSMENT PROCEDURE FOR OFFICIAL MEXICAN STANDARD NOM-223-SCFI/SAGARPA-2018, CHEESE-DENOMINATION, SPECIFICATIONS, COMMERCIAL INFORMATION AND TEST METHODS, PUBLISHED IN THE ‘DIARIO DE LA FEDERACION’ ON 31 JANUARY 2019, (THIS WILL REPLACE THE “DRAFT CONFORMITY ASSESSMENT PROCEDURE FOR OFFICIAL MEXICAN STANDARD NOM-223-SCFI/SAGARPA-2018, CHEESE-DENOMINATION, SPECIFICATIONS, COMMERCIAL INFORMATION AND TEST METHODS, PUBLISHED ON 31 JANUARY 2019”, PUBLISHED IN THE ‘DIARIO DE LA FEDERACION’ ON 4 MAY 2020).**

## **PREFACE**

This Draft Conformity Assessment Procedure was developed in accordance with Articles 73 and 74 of the Federal Law of Metrology and Standardization and articles 30, 62, 69 and Transitory Articles Two, Four, Five, Six, Eight and Nine of the Decree which issues the Quality Infrastructure Law and revokes the Federal Law of Metrology and Standardization, by the following Standardization Authorities:

Ministry of Economy [Secretaría de Economía].

- Unit for Standards, Competitiveness and Competency [‘Unidad de Normatividad, Competitividad y Competencia’].
  - Department of Standards [‘Dirección General de Normas’]

Ministry of Agriculture and Rural Development (SADER) [‘Secretaría de Agricultura y Desarrollo Rural’]

- Undersecretariat for Food Self-Sufficiency [‘Subsecretaría de Autosuficiencia Alimentaria’]
  - Department of Agrifood Standards [‘Dirección General de Normalización Agroalimentaria’].

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## INTRODUCTION

In accordance with the provisions of the Transitory Article Two of Official Mexican Standard NOM-223-SCFI / SAGARPA-2018, Cheese - Denomination, Specifications, Commercial information and Test Methods, published in the 'Diario Oficial de la Federación' on 31 January 2019, the Ministry of Economy and the Ministry of Agriculture and Rural Development began the development of a Conformity Assessment Procedure prior to 31 March 2019, which would allow to demonstrate compliance with the NOM of all the products denominated as cheese that are marketed within the national territory, of both domestic or foreign manufacture, after consultation with the interested sectors and in accordance with the procedure established in the Federal Law on Metrology and Standardization.

Pursuant to the above, there was published on 4 May 2020 in the 'Diario Oficial de la Federación' a DRAFT Conformity Assessment Procedure for Official Mexican Standard NOM-223-SCFI/SAGARPA-2018, Cheese-Denomination, specifications, commercial information and test methods, published on 31 January 2019, which contained substantial changes regarding the Conformity Assessment Schemes, and which will now be replaced by this Draft Conformity Assessment Procedure.

This Draft Conformity Assessment Procedure establishes non-discriminatory treatment between domestic and foreign manufacturers in accordance with the international agreements signed by Mexico with respect to technical barriers to trade, and it allows the pursuit of public policy objectives at a level considered appropriate by the Ministry of Economy and the Ministry of Agriculture and Rural Development, in compliance with the provisions of Chapter 28 - Good Regulatory Practices of the Agreement between Mexico, the United States and Canada (USMCA), and with the purpose of preventing information that misleads consumers and of encouraging fair competition between manufacturers.

Non-compliance with the NOM by products marketed in the national territory and denominated as cheese, that has been documented through the various Quality Studies of the Federal Consumer Protection Agency, as well as verified by the Ministry of Economy and the Ministry of Agriculture and Rural Development, make this Conformity Assessment Procedure indispensable for promoting fair competition between manufacturers and for preventing practices that may mislead or deceive consumers in the national territory.

## 1. Purpose and Scope of application

The purpose of this Conformity Assessment Procedure is to establish the procedure by which manufacturers or persons responsible for products that are subject to Official Mexican Standard NOM-223-SCFI / SAGARPA-2018, Cheese - Denomination, Specifications, Commercial information and Test methods, of either domestic or foreign manufacture, shall demonstrate the conformity of their products with the aforementioned Official Mexican Standard when marketed within the national territory, for any use or consumption, whether it is as a bulk product, prepackaged product or raw material.

## 2. Normative References

The following Official Mexican Standards, Mexican standards and International Standards and Foreign Standards, their amendments or replacements, are indispensable for the application of this Procedure:

- 2.1 NOM-051-SCFI/SSA1-2010, General labeling specifications for prepackaged foods and non-alcoholic beverages - Commercial and sanitary information, published in the 'Diario Oficial de la Federación' on 5 April 2010
- 2.2 NOM-223-SCFI/SAGARPA-2018, Cheese - Denomination, specifications, commercial information and test methods, published in the 'Diario Oficial de la Federación' on 31 January 2019.
- 2.3 NMX-EC-17020-2014, Conformity assessment - Requirements for the operation of different types of units (bodies) that conduct verification (inspection) - Declaration of entry into effect published in the 'Diario Oficial de la Federación' on 6 June 2014.
- 2.4 NMX-EC-17025-IMNC-2018, General requirements for the competence of testing and calibration laboratories - Declaration of entry into effect published in the 'Diario Oficial de la Federación' on 9 August 2018.
- 2.5 NMX-EC-17065-IMNC-2014, Conformity assessment - Requirements for bodies that certify products, processes and services - Declaration of entry into effect published in the 'Diario Oficial de la Federación' on 6 June 2014.
- 2.6 NMX-F-718-COFOCALEC-2017, Milk Product System - Food - Dairy - Milk and milk products - Sampling guide - Declaration of entry into effect published in the 'Diario Oficial de la Federación' on 22 August 2018.
- 2.7 NMX-Z-012/2-1987, Sampling for inspection by attributes - Part 2: Sampling methods, tables and graphs - Declaration of entry into effect published in the 'Diario Oficial de la Federación' on 28 October 1987.
- 2.8 ISO/IEC 17020:2012, Conformity assessment — Requirements for the operation of various types of bodies performing inspection.
- 2.9 ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.
- 2.10 ISO/IEC 17065:2012, Conformity assessment — Requirements for bodies certifying products, processes and services.
- 2.11 ISO 707:2008, Milk and milk products — Guidance on sampling.

- 2.12 ISO 14156:2001, Milk and milk products — Extraction methods for lipids and liposoluble compounds.
- 2.13 ISO 15884:2002, Milk fat — Preparation of fatty acid methyl esters.
- 2.14 ISO 15885:2002, Milk fat — Determination of the fatty acid composition by gas-liquid chromatography.
- 2.15 AOAC 933.05, Fat in cheese.
- 2.16 AOAC 996.06, Fat (total, saturated and unsaturated in foods), section C: Cheese.
- 2.17 AOAC 2001.14, Determination of Nitrogen (Total) in Cheese.
- 2.18 SMEDP 15.131, Protein, Kjeldahl Standard, Traditional Milk (Class A1), Other Products (Class 0).
- 2.19 SMEDP 15.132, Protein, Kjeldahl, Block Digestor Method Milk (Class A1), Other Products (Class 0).

### **3. Terms and Definitions**

For the purposes of this conformity assessment procedure, the following terms and definitions must be applied, in addition to those already established in the NOM (see Normative Reference 2.2):

#### **3.1 Materials Accounting** **['balance de materiales']**

The activity of determining that the amount of milk used to make a product that is subject to the NOM corresponds to the amount of cheese produced by the manufacturer, or of identifying the use of raw materials and ingredients that are not permitted in the NOM and its Normative References, through the review of documents concerning the acquisition of the raw materials and ingredients used to make the cheese, as provided to a conformity assessment body by the manufacturer or person responsible for the product.

#### **3.2 Certificate of conformity** **['Certificado de conformidad']**

The document that indicates the conformity assessment of a product subject to the NOM and, in which a Certification Body determines the compliance of the product with the NOM and its Normative References, and which may also be known as a Product Certificate.

#### **3.3 Marketing**

The activity of buying and selling the products that are subject to the NOM (see Normative Reference 2.2), in the territory of the United Mexican States, of domestic or foreign origin, for any use or consumption.

#### **3.4 DGN**

'Dirección General de Normas' [Department of Standards] of the Ministry of Economy.

### **3.5 Declaration of conformity ['Dictamen de conformidad']**

The document that indicates the assessment of conformity of a product subject to the NOM and in which an Inspection Unit determines the compliance of the product with the NOM and its Normative References, and which may also be known as a Declaration of Compliance ['Dictamen de Cumplimiento'].

### **3.6 Conformity assessment**

The technical process that allows to demonstrate compliance with the Official Mexican Standards, [Mexican] Standards, International Standards referenced herein, or other legal provisions. It includes, inter alia, the procedures for sampling, testing, inspection, assessment and certification.

### **3.7 Family of products**

Products that are subject to the NOM that have the same denomination, the same brand, the same manufacturing plant, and with different forms of presentation.

### **3.8 Importer**

Natural person or legal entity under the terms of the Federal Civil Code that legally introduces a foreign product into the United Mexican States.

### **3.9 Inspection**

Visual observation or verification by means of sampling, measurement, laboratory tests or the examination of documents that is carried out by the inspection units in order to assess conformity at a determined time, at the request of the interested party.

### **3.10 Test laboratory**

Body that conducts conformity tests using this CAP.

### **3.11 Law**

Quality Infrastructure Law, published in the 'Diario Oficial de la Federación' on 1 July 2020.

### **3.12 Lot**

The quantity of a product manufactured in one same cycle, composed of homogenous units and identified with one specific code.

### **3.13 Sampling**

Procedure by which various units of product are selected from a lot, in accordance with the provisions of Mexican Standard NMX-Z-012/2-1987 (see Normative Reference 2.7 of this CAP).

### **3.14 NOM**

Official Mexican Standard NOM-223-SCFI/SAGARPA-2018, Cheese - Denomination, Specifications, Commercial information and Test methods, published in the 'Diario Oficial de la Federación' on 31 January 2019, and its amendments or replacement.

### **3.15**

#### **Certification body ['Organismo de certificación']**

Third party conformity assessment body that operates certification schemes in accordance with the provisions of this CAP.

### **3.16 CAP**

Conformity Assessment Procedure.

### **3.17 Manufacturer**

Natural person or legal entity that manufactures the products subject to the NOM and which markets them within the national territory as bulk product, prepackaged product or raw material, by itself or through third parties.

### **3.18 Person responsible for the product**

Natural person or legal entity that manufactures, imports, acquires, or orders to be made using a third party, a product that is subject to the NOM and which markets it within the national territory as a bulk product, prepackaged product or raw material.

### **3.19 SINEC**

'Sistema Integral de Normas y Evaluación de la Conformidad' [Integrated System for Standards and Conformity Assessment], or the system that replaces it.

### **3.20 Inspection unit**

Body that conducts the inspection of conformity established in this CAP.

## **4. Conformity assessment procedure**

### **4.1 Conformity assessment schemes**

The manufacturer or person responsible for the product must carry out the conformity assessment of the products that are subject to the NOM, of domestic or foreign manufacture, and marketed in the national territory, through one of the three possible schemes established in this procedure and through the following conformity assessment bodies:

**a)** By lot of product or product family (see section 4.3.1 of this CAP). Through a Type A Inspection Unit that is accredited and approved (domestic), or one that is recognized by the competent authority in the country of origin (foreign), and a Testing Laboratory that is accredited and approved (domestic) or recognized by the competent authority in the country of origin (foreign), which guarantees impartiality and the absence of conflicts of interest.

**b)** By periodic testing of the product or product family and assessment of the product manufacturing process (see section 4.3.2 of this CAP). Through a Type A Inspection Unit that is accredited and approved (domestic) or one that is recognized by the competent authority in the country of origin (foreign), and an accredited and approved Testing Laboratory (domestic) or recognized by the competent authority in the country of origin (foreign), which guarantees impartiality and the absence of conflicts of interest.

**c)** By product certification under the scheme of periodic testing of the product and auditing of the production control process (see section 4.3.3 of this CAP). Through a Certification Body that is accredited and approved (domestic) or recognized by the competent authority in the country of origin (foreign). The Certification Body can carry out the activities of the certification scheme with its own internal resources or with other resources under its direct control.

## **4.2 Requirements that apply to conformity assessment bodies**

Conformity assessment bodies must demonstrate capacity and technical knowledge with respect to the NOM, in order to be accredited and approved, or in order to be recognized by the applicable competent authority in the country of origin of the product. In accordance with the above, conformity assessment bodies must be accredited or be recognized by the competent authority for the following standards, as applicable:

**4.2.1** Inspection Units for Mexican Standard NMX-EC-17020-IMNC-2014 (see Normative Reference 2.3 of this CAP) or for International Standard ISO/IEC 17020:2012 (see Normative Reference 2.8 of this CAP).

**4.2.2** Test Laboratories for Mexican Standard NMX-EC-17025-IMNC-2018 (see Normative Reference 2.4 of this CAP) or for International Standard ISO/IEC 17025:2017 (see Normative Reference 2.9 of this CAP).

**4.2.3** The Product Certification Bodies for Mexican Standard NMX-EC-17065-IMNC- 2014 (see Normative Reference 2.5 of this CAP) or with International Standard ISO/IEC 17065:2012 (see Normative Reference 2.10 of this CAP).

## **4.3 Activities of the conformity assessment schemes**

### **4.3.1 By product lot or product family**

#### **4.3.1.1 Inspection**

**4.3.1.1.1** The manufacturer or person responsible for the product must request the service of an accredited and approved Inspection Unit (domestic) or one that is recognized by the competent authority in the country of origin of the product (foreign), and must inform it of the quantity of lots, together with lot number identifier and product family, for which the conformity assessment is intended prior to the marketing thereof within the national territory, in order for the inspection unit to schedule the inspection visit.

**4.3.1.1.2** The inspection visit must be conducted at the premises of the manufacturer or person responsible for the product.

#### **4.3.1.1.3 Review of the control of materials accounting**

At the inspection visit, the manufacturer or person in charge of the product that is subject to the NOM must provide to the inspector the invoices or documents that certify the acquisition of the raw material and ingredients for manufacturing cheese, in order to enable the proper inspection of the following information:

**a)** The amount of milk and identification of ingredients used in the manufacturing process of a product that is subject to the NOM, by product family.

**b)** The amount of caseins, caseinates or milk protein concentrates that are incorporated or used to produce a product that is subject to the NOM, by product family, which must not be greater than 2.0%, or in accordance with the NOM.

**c)** The proportion and use of raw materials and ingredients for the manufacture of cheese that enables



to determine if the family of product that is being inspected complies with the NOM and its Normative References, as well as its destination or intended use in terms of being a raw material, for sale in bulk or as a prepackaged product, and

**d)** The amount of milk used to make one kilogram of a product that is subject to the NOM, by product family and its production yield, in order to identify that the product family complies with the NOM in terms of the use of raw materials and ingredients.

The invoices or documents that certify the purchase of raw materials and ingredients to manufacture cheese may be provided by e-mail to the Inspection Unit.

#### **4.3.1.1.4 Review of the information contained in the labels of the product or product family**

**4.3.1.1.4.1** The manufacturer or person in charge of the product must provide to the Inspection Unit, either via e-mail or physically, the label(s) of the product or product family prior to it being marketed in the national territory, in order to evaluate its level of compliance with the provisions of the NOM (see Normative Reference 2.2 of this CAP).

##### **4.3.1.1.4.1.1 Prepackaged products**

The Inspection Unit must assess the level of compliance of the information contained in the label(s) in accordance with the provisions of Normative Reference 2.1 and Section 7 of Normative Reference 2.2 of this CAP.

##### **4.3.1.1.4.1.2 Bulk products or raw material**

The Inspection Unit must assess the level of compliance of the information contained in the label(s) in accordance with the provisions of Section 7 of Normative Reference 2.2 of this CAP.

**4.3.1.1.4.2** If the manufacturer or person responsible for the product has previously obtained a Declaration of conformity of the information contained in their labels from an Inspection Unit, it must provide this to the Inspection Unit that is performing the conformity assessment in order for it to be recorded in the report or official record (see section 4.3.1.1.6 of this CAP), and it is then not necessary to review the label information again.

#### **4.3.1.1.5 Sampling**

The sampling of the product or product family must be carried out randomly in accordance with Normative Reference 2.7 of this CAP, ensuring the representativeness of the sample, in duplicate and taking the number of pieces or the quantity of product that is strictly necessary for the analysis of the physicochemical parameters established in the NOM (see Normative reference 2.2 of this CAP) as applicable, and it must be identified as an official sample or a witness sample. The first must be delivered to the testing laboratory (see section 4.3.1.2 of this CAP) and the second must be retained by the manufacturer or person responsible for the product, so that, if necessary, it can be used as a third party. Likewise, the sample must be properly identified, and the traceability thereof must be ensured.

**4.3.1.1.5.1** The general guidelines for sampling of a product subject to the NOM, whether prepackaged, raw material or in bulk, are described in item 17 of Normative Reference 2.6 of this CAP and in item 16 of Normative Reference 2.11 of this CAP.

#### **4.3.1.1.6 Report or Official Record of the inspection visit**

A report or official record must be prepared about the inspection activities, describing the conditions under which the inspection visit was carried out and the results of the review of the materials accounting, and it must be sent to the Inspection Unit to be considered in the assessment of conformity.

The Report or Official Record must contain the following:

- a) Control of materials accounting for manufacture of a product subject to the NOM, per product or product family.
- b) Use of caseins, caseinates or milk protein concentrates in the manufacture of a product that is subject to the NOM, by product or product family.
- c) Level of compliance with the information contained in the product label or product family label in accordance with the provisions of section 4.3.1.1.4 of this CAP and its subsections, as applicable.
- d) The conditions under which the sampling was conducted.
- e) The facilities that the visited party made available to the inspection personnel in order to conduct the inspection visit.
- f) Statement of the visited party concerning its position.

#### **4.3.1.2 Testing**

**4.3.1.2.1** The Inspection Unit must send the samples of product or of product family to a Testing Laboratory that guarantees impartiality and no conflict of interest, under appropriate conditions for their analysis, together with the order of request for the tests that are to be conducted and the chain of custody sheet for the product.

**4.3.1.2.1.1** The Inspection Unit must request the tests for each of the physicochemical parameters established in the NOM (butterfat, protein and moisture content), as well as the fatty acid profile, using the applicable test methods established in the NOM and in this CAP.

**4.3.1.2.2** The results of the tests that have been conducted must be integrated into a report of test results and sent to the Inspection Unit for consideration as part of the conformity assessment.

#### **4.3.1.3 Assessment of conformity**

The Inspection Unit must determine the conformity of the product or product family with the NOM based on the report or official record of the inspection visit and the test results report, including the following results:

- a) Issuance of a Declaration of Conformity [‘Dictamen de Conformidad’] due to having sufficient elements to demonstrate the compliance of the product by family of product with the NOM and its applicable Normative References
- b) Issuance of Declaration of Non-Conformity [‘Dictamen de Non Conformidad’] due to not having sufficient elements to demonstrate compliance of the product by family of product with the NOM and its

applicable Normative References.

The Inspection Unit must inform the manufacturer or person responsible for the product of the result of the conformity assessment within a period of no more than 10 business days, and in the event of a Declaration of Non-Conformity, it must inform this and clearly describe the detected defects.

The manufacturer or person responsible for the product can only correct the defects of the information declared on the label(s) within a period of no more than 10 business days in order to be able to continue with the procedure with the Inspection Unit.

If a complaint or appeal arises about the test results, the manufacturer or person responsible for the product may request and obtain a repetition of the tests by a third party.

**4.3.1.3.1** The Inspection Unit must inform the DGN and the Ministry of Agriculture and Rural Development via SINEC about the Declarations of Non-Conformity at the time that they are issued.

#### **4.3.2 By periodic testing of the product or product family and assessment of the product manufacturing process**

##### **4.3.2.1 Inspection**

**4.3.2.1.1** The manufacturer or person responsible for the product must request the service of an Inspection Unit that is accredited and approved (domestic), or one that is recognized by the competent authority in the country of origin (foreign) and inform them of the product or product family for which they are seeking to assess conformity, so that inspection visits can be scheduled two times per year (on a semi-annual basis).

**4.3.2.1.2** The inspection visits must be carried out at the facilities of the manufacturer or person responsible for the product.

##### **4.3.2.1.3 Review of the process control and materials accounting**

At each inspection visit, the manufacturer or person in charge of the product that is the subject of the NOM must provide the inspector with information about the process control and the invoices or documents that prove the acquisition of raw materials and ingredients for manufacturing cheese, in order to allow the following information to be properly inspected:

**a)** Process control

**b)** The amount of milk and identification of ingredients used in the manufacturing process of a product that is subject to the NOM, by product family.

**c)** The amount of caseins, caseinates or milk protein concentrates that are incorporated or used to produce a product that is subject to the NOM, by product family, which must not be greater than 2.0%, or in accordance with the NOM.

**d)** The amount and use of raw materials and ingredients for the manufacture of cheese that allows to determine if the family of product that is being inspected complies with the NOM and its Normative References, as well as its destination or intended use in terms of being a raw material, for sale in bulk or a prepackaged product, and

e) The amount of milk used to manufacture one kilogram of a product that is subject to the NOM, by product family and its production yield, in order to identify that the product family complies with the NOM in the use of raw materials and ingredients.

The invoices or documents that prove the purchase of raw materials and ingredients for manufacturing cheese can be provided via e-mail to the Inspection Unit.

#### **4.3.2.1.4 Review of the information contained in the labels of the product or product family.**

**4.3.2.1.4.1** The manufacturer or person in charge of the product must provide to the Inspection Unit, via e-mail or physically, the label(s) of the product or product family prior to the marketing thereof in the national territory, in order to evaluate its level of compliance according to the provisions of the NOM (see Normative Reference 2.2 of this CAP).

##### **4.3.2.1.4.1.1 Prepackaged products**

The Inspection Unit must evaluate the level of compliance with the information contained in the label(s) in accordance with the provisions of Normative Reference 2.1 and Section 7 of Normative Reference 2.2 of this CAP.

##### **4.3.2.1.4.1.2 Bulk products or raw materials**

The Inspection Unit must evaluate the level of compliance with the information contained in the label(s) in accordance with the provisions of Section 7 of Normative Reference 2.2 of this CAP.

**4.3.2.1.4.2** If the manufacturer or person responsible for the product has previously obtained a Declaration of Conformity of the information contained in its labels by an Inspection Unit, it must provide this to the Inspection Unit that is conducting the assessment of conformity in order to record it in the report or official record (see section 4.3.2.1.6 of this CAP), and it is then no longer necessary to review the label information again.

#### **4.3.2.1.5 Sampling**

The sampling of the product or product family must be carried out randomly in accordance with Normative Reference 2.7 of this CAP, ensuring the representativeness of the sample, in duplicate and taking the number of pieces or the quantity of product that is strictly necessary for the analysis of the physicochemical parameters established in the NOM (see Normative reference 2.2 of this CAP) as applicable, and it must be identified as an official sample or a witness sample. The first must be delivered to the testing laboratory (see section 4.3.2.2 of this CAP) and the second must be retained by the producer or person responsible for the product, so that, if necessary, it can be used as a third party. Likewise, the sample must be properly identified, and the traceability thereof ensured.

**4.3.2.1.5.1** The general guidelines for sampling of a product subject to the NOM, whether prepackaged, raw material or in bulk, are described in item 17 of Normative Reference 2.6 of this CAP and in item 16 of Normative Reference 2.11 of this CAP.

#### **4.3.2.1.6 Report or Official Record of the inspection visit**

A report or official record must be prepared about each inspection visit, describing the conditions under which the inspection visit was carried out and the results of the review of the process control and of the materials accounting, and it must be sent to the Inspection Unit to be considered as part of the conformity assessment.

The Report or Official Record must contain the following:

- a) Information about the process control.
- b) Control of materials accounting for manufacture of a product subject to the NOM, per product or product family.
- c) Use of caseins, caseinates or milk protein concentrates in the manufacture of a product that is subject to the NOM, by product or product family.
- d) Level of compliance with the information contained in the product label or product family label in accordance with the provisions of section 4.3.2.1.4 of this CAP and its subsections, as applicable.
- e) The conditions under which the sampling was conducted.
- f) The facilities that the visited party made available to the inspection personnel in order to conduct the inspection visit.
- g) Statement of the visited party concerning its position.

#### **4.3.2.2 Testing**

**4.3.2.2.1** The Inspection Unit must send the samples of product or of product family to a Testing Laboratory that guarantees impartiality and no conflict of interest, under appropriate conditions for their analysis, together with the order of request for the tests that must be conducted and the chain of custody sheet for the product

**4.3.2.2.1.1** The Inspection Unit must request the test for each of the physicochemical parameters established in the NOM (butterfat, protein and moisture content), as well as the fatty acid profile, using the applicable test methods established in the NOM and in this CAP

**4.3.2.2.2** The results of the tests carried out must be integrated into a report of test results and sent to the Inspection Unit for consideration as part of the conformity assessment.

#### **4.3.2.3 Assessment of conformity**

The Inspection Unit must determine the conformity of the product or product family with the NOM based on the report or official record of the inspection visit and the test results report, including the following results:

- a) Issuance of a Declaration of Conformity due to having sufficient elements to demonstrate the compliance of the product by family of product with the NOM and its applicable Normative References
- b) Issuance of Declaration of Non-Conformity due to not having sufficient elements to demonstrate the compliance of the product by family of product with the NOM and its applicable Normative References.

The Inspection Unit must inform the manufacturer or person responsible for the product of the result of the conformity assessment within a period of no more than 10 business days, and in the event of a Declaration of Non-Conformity, it must inform this and clearly describe the detected defects.

The manufacturer or person responsible for the product can only correct the defects of the information declared on the label(s) within a period of no more than 10 business days in order to be able to continue the procedure with the Inspection Unit.

If a complaint or appeal arises about the results of the test, the manufacturer or person responsible for the product may request and obtain a repetition of the tests by a third party.

**4.3.2.3.1** The Inspection Unit must inform the DGN and the Ministry of Agriculture and Rural Development via SINEC about the Declarations of Non-Conformity at the time that they are issued.

### **4.3.3 By means of Certification of the product under the periodic product testing scheme and auditing of the production process control.**

**4.3.3.1** The manufacturer or person responsible for the product must request the service of a product Certification Body that is accredited and approved (domestic) or one that is recognized by the competent authority in the country of origin (foreign) and must inform it of the product or product family for which they are seeking an assessment of conformity, so that it can schedule the activities.

**4.3.3.2** Activities of inspection, testing, auditing of the production process control and assessment of conformity.

#### **4.3.3.2.1 Inspection**

The Inspection activities must be carried out by personnel of the Certification Body or by personnel subcontracted by it who comply with the competence requirements (see paragraph 4.2 of this CAP).

##### **4.3.3.2.1.1 Review of documents**

At the inspection visit, the following information must be reviewed for each denomination of cheese that is being assessed:

- a) The amount of milk and identification of ingredients used in the process of making a product that is subject to the NOM, by product or family of products.
- b) The amount of caseins, caseinates or milk protein concentrates that are incorporated or used to produce a product that is subject to the NOM, by product or family of products, which must not be greater than 2.0% or in accordance with the NOM.
- c) The proportion and use of raw materials and ingredients for the production of cheese that allows to determine if the product or family of products that is being inspected is in conformance with the NOM and its Normative references, as well as its destination or intended use in terms of being a raw material, for sale in bulk or a pre-packaged product, and
- d) The amount of milk used for the production of one kilogram of a product that is subject to the NOM, by product family and its production yield, in order to identify that the product family complies with the NOM in the use of raw materials and ingredients.
- e) Information related to the control of the production process.
  - a. Raw materials
    - i. Register of milk producers

- ii. Milk supply program
  - iii. Proof of delivery of milk
  - iv. Control of raw materials and ingredients.
- b. Process
  - i. Standardization of the milk
  - ii. Control of operations such as: heat treatment, addition of ingredients, coagulation, cutting, pressing, packaging, ripening.
  - iii. Control of the finished product.
- c. Traceability and consistency of information, from the volume of milk received to the manufacture of the finished product.

#### **4.3.3.2.1.2 Sampling**

The sampling of the product or product family must be carried out randomly in accordance with Normative Reference 2.7 of this CAP, ensuring the representativeness of the sample, in duplicate and taking the number of pieces or the quantity of product that is strictly necessary for the analysis under the physicochemical parameters established in the NOM (see Normative reference 2.2 of this CAP) as applicable, and be identified as an official sample and a witness sample. The first must be delivered to the testing laboratory (see section 4.3.3.2.2 of this CAP) and the second must be retained by the visited party (manufacturer or person responsible for the product), so that, if necessary, it can be used as a third party. The sample must also be properly identified and the traceability of it ensured.

**4.3.3.2.1.2.1** The general guidelines for sampling of cheese, whether prepackaged, raw material or in bulk, are described in item 17 of Normative Reference 2.6 of this CAP and in item 16 of Normative Reference 2.11 of this CAP.

**4.3.3.2.1.3** A report or official record must be prepared about the inspection activities, describing the conditions under which the inspection visit was carried out and the results of the assessment of the process control, as applicable, and it must be delivered to the Certification Body in order to be considered as part of the conformity assessment.

#### **4.3.3.2.2 Testing**

**4.3.3.2.2.1** The tests must be carried out in laboratories that are accredited and approved (domestic) or that are recognized by the competent authority in the country of origin (foreign) for the test methods established in the NOM or in this CAP (see section 4.2 of this CAP). If the test laboratory does not have the technical capacity for a specific test method, the test can be carried out in other test laboratories chosen by the Certification Body, provided that they are accredited and approved (domestic) or recognized by the competent authority in the country of origin (foreign).

**4.3.3.2.2.2** The test laboratory must receive the samples from the Certification Body under appropriate conditions for analysis, together with the order of request for the tests that must be carried out and the chain of custody sheet for the product.

**4.3.3.2.2.3** The results of the tests carried out must be integrated into a report of test results and sent to the Certification Body for consideration as part of the assessment of conformity.

#### **4.3.3.2.3 Assessment of conformity**

**4.3.3.2.3.1** Based on the inspection report or official record and the report of test results, the Certification Body must make the assessment of conformity and determine the compliance or conformity of the product with the NOM:

- a) Issuance of a Certificate of Conformity ['Certificado' de Conformidad] due to having sufficient elements to demonstrate the compliance of the product by family of product with the NOM and its applicable Normative References.
- b) Issuance of Certificate of Non-Conformity ['Certificado de No Conformidad'] due to not having sufficient elements to demonstrate compliance of the product by family of product with the NOM and its applicable Normative References.

The Certification Body must inform the manufacturer or person responsible for the product about the result of the conformity assessment within a period of no more than 10 business days.

If a complaint or appeal arises about the results of the test, the manufacturer or person responsible for the product may request and obtain a repetition of the tests by a third party.

**4.3.3.2.4.2** The manufacturer or person responsible for the product must correct the non-compliance with the requirements for obtaining the certification within the period of time established by the Certification Body, in order to assess if the non-compliance has been corrected and if the Certificate of Conformity can be granted.

**4.3.3.2.4.3** The period of validity of the certificate of product or product family is 3 years. During the period of validity of the certificate, the product Certification Body must monitor that the certified product maintains the conditions under which the certificate was issued.

**4.3.3.2.5** However, the information contained in the labels of the product or product family cannot be certified in order to document compliance with Normative Reference 2.1 of this CAP (prepackaged) and Section 7 of Normative Reference 2.2 (raw material, bulk and prepackaged). As a requirement of the certification program, the manufacturer or person responsible for the product must deliver to the Certification Body a copy of the Declaration of Conformity of the information contained on the labels of the products that are subject to certification.

**4.3.3.2.6** The Certification Body must inform the DGN and the Ministry of Agriculture and Rural Development, through SINEC, about the Certificates of Non-Conformity at the time of their issuance.

#### **4.4 Submittal of the Declaration of Conformity or Certificate of Conformity of the Product to the Standardization Authority**

The manufacturer or person responsible for the product must have the Declaration of Conformity or Certificate of Conformity that demonstrates the compliance of their products or family of products with the NOM prior to the marketing thereof in the national territory, in accordance with the following:

- a) Products of domestic manufacture: The Inspection Unit or Certification Body must register with SINEC and upload the Declaration of Conformity or Certificate of Conformity, as applicable, in PDF file format, which covers the products subject to the NOM prior to the marketing thereof in the national territory, and it must specify the name of the manufacturer or person responsible for the product, as well as the products that are covered by the Declaration of Conformity or Certificate of Conformity.



b) Products of foreign manufacture: The manufacturer, person responsible for the product, the Inspection Unit or the Certification Body, must attach to the import request a copy of the Declaration of Conformity or Certificate of Conformity at the point of entry into the country.

#### **4.5 Self-declaration of conformity**

The Ministry of Economy and the Ministry of Agriculture and Rural Development will determine the schemes for self-declaration of conformity for the manufacturer or person responsible for the product that has demonstrated compliance with this Conformity Assessment Procedure four years after its entry into effect.

### **5 Surveillance**

The Ministry of Economy and the Ministry of Agriculture and Rural Development are responsible for surveillance of the conformity assessment bodies in order to ensure that their actions are in accordance with the provisions of the Quality Infrastructure Law.

For purposes of surveillance, verification activities are those which are carried out by the Federal Consumer Protection Agency ['Procuraduría Federal del Consumidor'], the Ministry of Economy and the Ministry of Agriculture and Rural Development, separately and according to their responsibilities, and under the terms of the Collaboration Agreements that they make.

Mexico City, 12 January 2022 – The Director General of Standards of the Ministry of Economy – Alfonso Guati Rojo Sanchez – signature – The Director General of Agrifoods Standards and Chairman of the National Consultative Committee for Agrifoods Standards of the Ministry of Agriculture and Rural Development – Jose Eduardo Espinosa del los Monteros Avina – signature.