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Food Safety Authority of Ireland

42

GUIDANCE NOTE

Cocoa and Chocolate Products

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Contents

List of Figures

List of Tables

Glossary and definitions

Terms marked with * denote definitions derived from specific legislation, with the legislation listed where appropriate.

Term	Text
a_w	Water activity.
BPA	Bisphenol A
CCP	Critical control point.
Chocolate bloom	Chocolate bloom is a whitish coating on the surface of chocolate which can be caused by sugar or fat crystal instability. Sugar bloom happens when moisture dissolves and re-crystallises the sugar, creating a grainy texture. Fat bloom occurs when cocoa butter crystals separate and rise to the surface, giving the chocolate white blotches or grey colouring. Poor tempering and/or improper storage conditions can cause this problem. It is a quality issue that can develop into a safety issue over time (e.g. exposure to high humidity can facilitate mould growth).
Chocolate a la taza* Directive 2000/36/EC	Designates the product obtained from cocoa products, sugars and flour or starch from wheat, rice or maize.
Cocoa powder* Directive 2000/36/EC	Cocoa beans that have been cleaned, shelled, roasted and ground, and which after pressing to separate the fat have been converted into powder.
Cocoa butter* Directive 2000/36/EC	The fat obtained from cocoa beans or parts of cocoa beans with certain characteristics as defined in Annex I to Directive 2000/36/EC.
Dry cocoa solids	The non-fat part of the cocoa bean that is used in chocolate production.
Cocoa mass/cocoa liquor/chocolate liquor	Nibs are ground into a thick, liquid paste. ‘Cocoa mass’, ‘cocoa liquor’ and ‘chocolate liquor’ are terms used interchangeably in the chocolate industry to indicate this paste. This document will use the term ‘chocolate liquor’ to avoid confusion.
Conching	The chocolate refining process that blends chocolate liquor and individual ingredients into a smooth liquid or paste. This process develops flavours and changes the texture of the chocolate. Although conching is traditionally a

	lengthy process taking hours to days, modern conching techniques use heavy rollers to finely grind particles, significantly reducing the time needed.
Couverture chocolate* Directive 2000/36/EC	A supplementary term describing either chocolate or milk chocolate with the following compositional requirements: for couverture chocolate, a minimum of 35% total dry cocoa solids, including not less than 31% cocoa butter and not less than 2.5% of dry non-fat cocoa solids; and for couverture milk chocolate, a minimum total fat (cocoa butter and milk fat) content of 31%. (These compositional requirements give the chocolate a glossy finish and enable it to form a thinner shell than other chocolate, so couverture chocolate is often used as a coating around filled chocolates.)
Crystallisation	In the chocolate industry, crystallisation is the process of controlled heating and cooling of chocolate which ensures that the cocoa butter crystals solidify into a stable, desired crystalline structure.
Dry non-fat cocoa solids	What is left after separating cocoa butter from the cocoa liquor.
EHO	Environmental Health Officer.
Enrobing	Enrobing is the process of coating confectionery products with chocolate in a specially designed machine, in which lines of assorted centres (nuts, nougats, fruit or other desired filling) are showered with a waterfall of liquid chocolate.
EU	European Union.
FCM	Food contact materials and articles.
FIC	Food information for consumers.
FSAI	Food Safety Authority of Ireland.
FSMS	Food safety management system: the procedures and processes that a food business has in place to ensure that the food it produces is safe for consumption.
Ganache	Ganache is a mixture made with varying proportions of chocolate and cream. More chocolate creates a firmer ganache for fillings, while more cream makes a softer velvety mixture.
GHP	Good handling practice.
Gianduja* Directive 2000/36/EC	Nut chocolate, which must contain finely ground hazelnuts to make up 20–40% of total weight. Milk chocolate gianduja must contain finely ground hazelnuts to make up 15–40% of total weight.

HACCP	Hazard analysis and critical control point.
Lauric fats	Type of vegetable fat which is high in lauric acid. Coconut oil is an example of a lauric fat.
L. monocytogenes	*Listeria monocytogenes.*
Milk fat	Dairy milk fat addition to some chocolate recipes.
Milk solids	Milk solids are obtained by partly or wholly dehydrating whole milk, semi-skimmed milk, skimmed milk or cream, or by using partly or wholly dehydrated cream, butter or milk fat.
Nibs	Cocoa nibs are the edible portion of the cocoa bean which is separated from the husk after roasting.
Non-lauric fats	Type of vegetable fat which is low in lauric acid. Cocoa butter is an example of a non-lauric fat.
Praline* Directive 2000/36/EC	Single-mouthful individual chocolate consisting of filled chocolate or a single chocolate or combination of chocolate that falls within the categories of sales names listed in Annex I to Directive 2000/36/EC and other edible substances (chocolate ≥ 25% of the total weight of the product).
PRP	Prerequisite programme, part of a food safety management system. These are good hygiene practices that constitute the basic conditions and activities necessary to maintain a hygienic environment, as laid out in Article 4(2) and Annex II of Regulation (EC) 852/2004.
Quality criteria	Additional information or descriptions used to supplement sales names ‘chocolate’, ‘milk chocolate’ and ‘couverture chocolate’ when these products meet superior criteria for cocoa solids/milk solids as laid out in Article 3 of Directive 2000/36/EC.
RTE foods	Ready-to-eat foods.
Spp.	Species.
Sugar	Optional authorised ingredient that can be added to chocolate products. In this context, sugars are not limited only to those covered by Council Directive 2001/111/EC relating to certain sugars intended for human consumption.
Tempering	Tempering is a type of controlled crystallisation of chocolate. Correctly tempered chocolate sets firmly with a smooth surface and distinct snap

	when broken. Properly tempered chocolate facilitates the demoulding process.
Vermicelli/flakes* Directive 2000/36/EC	Cocoa product presented in the form of granules or flakes.
WIP	Work in progress.

Further explanations and compositional requirements are laid out in Section 6.2.

1. Purpose of this guidance note

This guidance note is aimed primarily at Environmental Health Officers (EHOs). However, the guidance note provides useful information to which all food businesses in Ireland involved in the manufacturing or sale of cocoa and chocolate products can refer. This guidance note will help those working in relevant industries to understand and comply with cocoa and chocolate legislation.

2. Legislation

Cocoa and chocolate products are covered under European Union (EU) legislation by Directive 2000/36/EC relating to cocoa and chocolate products intended for human consumption, which is given effect in Irish national law by Statutory Instrument No. 236/2003.

Chocolate manufacturers should ensure that they are compliant with all relevant legislation. EU and Irish legislation can be found on the Food Safety Authority of Ireland (FSAI) website.

3. Introduction

3.1. Products covered by Directive 2000/36/EC

Directive 2000/36/EC applies to cocoa and chocolate products which fall under one of the defined sales names laid down in Annex I to the Directive, and it details the compositional requirements for each sales name. Directive 2000/36/EC states that a cocoa or chocolate product may not be described by one of the sales names unless it meets the relevant compositional requirements. These defined sales names are listed here, but their descriptions can be found in more detail in Section 6.2 of this guidance note.

1. Cocoa butter
2. Cocoa powder
3. Chocolate
4. Milk chocolate
5. Milk chocolate (Ireland and the UK), family milk chocolate (rest of the EU)
6. White chocolate
7. Filled chocolates/chocolates with … filling
8. Chocolate a la taza
9. Chocolate familiar a la taza
10. A chocolate or a praline

3.2. Products not covered by Directive 2000/36/EC

Chocolate products that do not comply with the compositional requirements set out in Annex I of Directive 2000/36/EC cannot use the sales names listed in the Annex and instead must follow the rules for naming food laid out in Regulation (EU) 1169/2011 on the provision of food information to consumers (FIC), hereafter the FIC Regulation. Please refer to Section 6 of this document for general labelling rules.

When chocolate is used as an ingredient – for example chocolate chip cookies or chocolate-covered wafers – the compositional requirements of Directive 2000/36/EC still apply to that ingredient if any of the sales names are used in the final food, for example, as part of the name of the food and/or in the ingredients list. Under the general labelling rules established by the FIC Regulation, food information must not be misleading as regards the characteristics of the food, and it must be accurate, clear and comprehensible for the consumer.

4. Cocoa and chocolate product manufacturing

Directive 2000/36/EC sets out rules for cocoa and chocolate products, including composition, sales names, labelling and presentation. These rules cover a variety of products derived from cocoa beans. More information on this can be found in Section 6 of this guidance note.

Unless otherwise stated, the term ‘chocolate’, as used in this document, refers to chocolate in the form of solid chocolate bars, chocolate ‘sweets’ such as pralines or bonbons, chocolate buttons or chocolate chips, etc.

Chocolate as an ingredient is discussed in Section 3.2.

4.1. Initial processing

Chocolate is a product produced from the beans of the cacao tree, *Theobroma cacao*, which grows in tropical regions such as East Africa and northern parts of South America. After the cacao pods are harvested, the cocoa beans and pulp are subsequently removed and fermented in heaps or in boxes. Fermentation occurs for 4–5 days at temperatures of 45–50 °C to develop further flavour.

Fermented beans are sun-dried, or dried using specialised equipment, in order to remove moisture and prevent mould growth. Dried beans are sorted and roasted at controlled temperatures to further enhance flavour and aroma. Roasting times and temperatures are specific to the individual manufacturer and type of cocoa bean, in order to bring out desired flavours. However, most processors will roast cocoa beans to a surface temperature of 120 °C, which will eliminate the majority of microbiological pathogens.

The roasted cocoa beans are cracked to separate the outer husk (shell) from the cocoa nibs. This process is called winnowing. Following this, the cocoa nibs are ground. The heat generated by grinding causes the cocoa butter to melt and form a fine paste or liquid known as chocolate liquor.

> ‘Chocolate liquor’, ‘cocoa liquor’ and ‘cocoa mass’ are terms used interchangeably in the chocolate industry to indicate the paste that results from grinding cocoa nibs. This document will use the term ‘chocolate liquor’ to avoid confusion.

Chocolate liquor is the pure, unadulterated chocolate. It is composed of roughly 50% cocoa butter (fat) and 50% dry non-fat cocoa solids, which hold the chocolate flavour compounds. Chocolate liquor is intensely bitter due to its lack of sugar and other ingredients.

Chocolate liquor undergoes a pressing process to divide it into two components: cocoa oil and cocoa cake. The cocoa oil is filtered and cooled to produce cocoa butter. The cocoa cake is first coarsely crushed and then finely crushed to obtain dry non-fat cocoa solids, also known as cocoa powder.

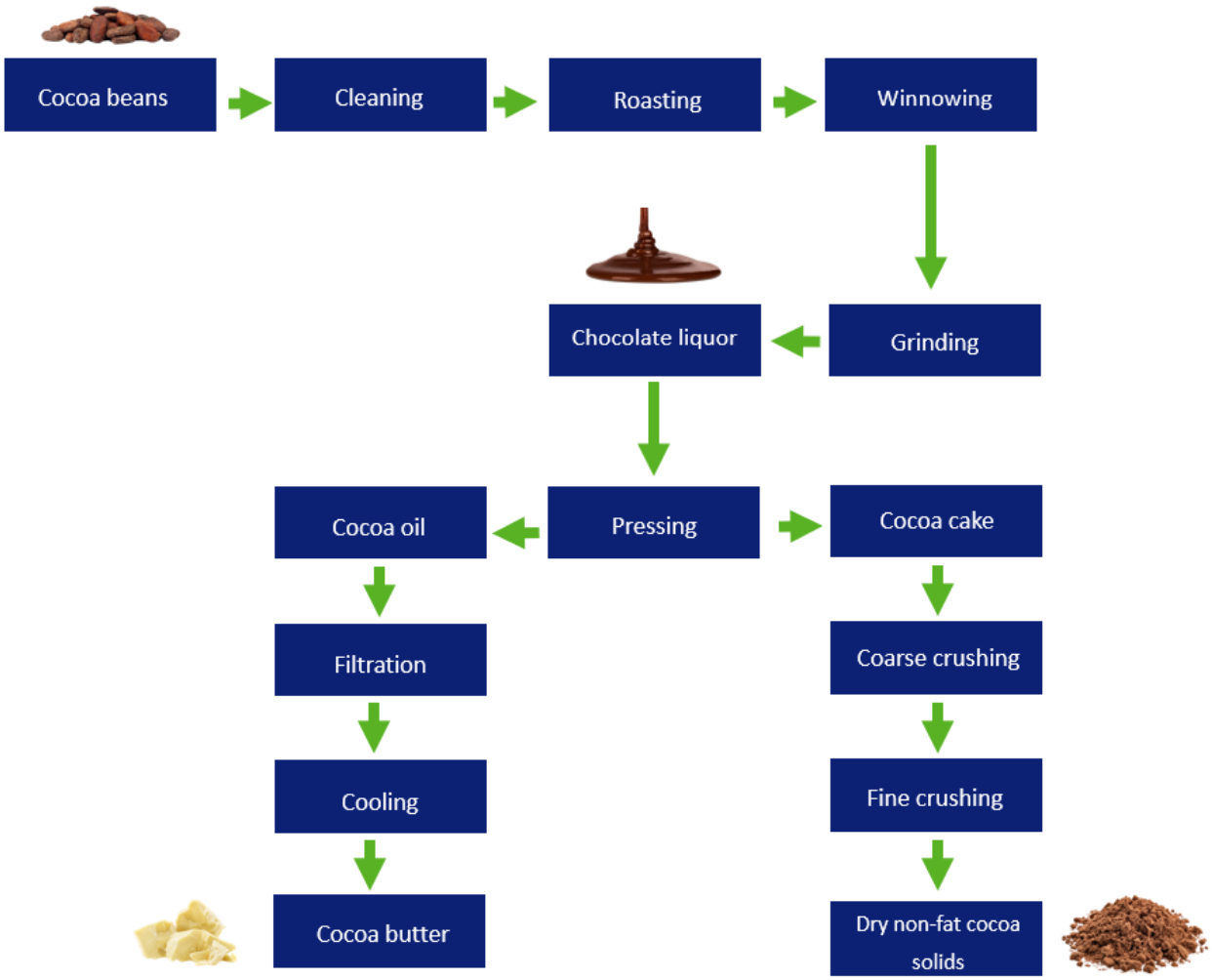

Figure 1 Process flow of cocoa beans to cocoa butter and cocoa powder

Generally, these initial stages of the chocolate manufacturing process occur at a large chocolate manufacturing site. In Europe, these processes are commonly carried out in France and Belgium.

'Total cocoa solids' is a term used to describe a combination of cocoa butter and dry non-fat cocoa solids.

Chocolate liquor or cocoa solids are mixed with sugar, milk (for milk chocolate), vanilla and other flavourings, and this mixture is then continuously kneaded in a process called 'conching'.

4.2. Process flow (further processing)

Liquid chocolate and solid chocolate blocks are dispatched to other chocolate food business operators for further processing and used to make chocolate bars, individual chocolates, etc.

Figure 2 shows the steps from intake to final product in chocolate manufacturing.

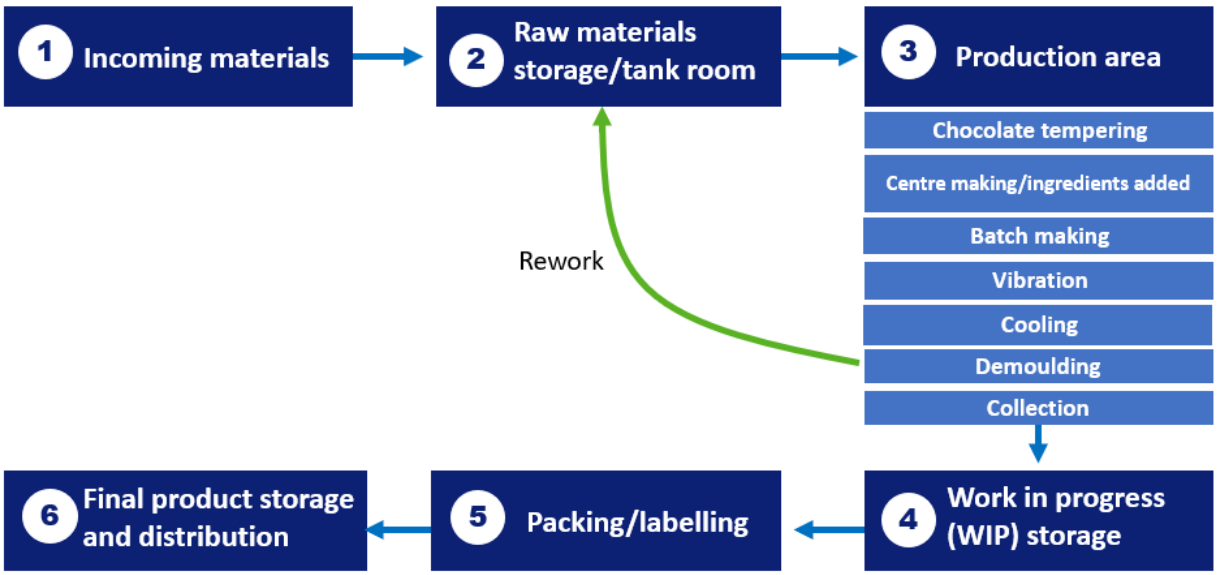

Figure 2 Process flow of chocolate production from intake to final product

The process flow outlined above (Figure 2) illustrates the stages undertaken by the majority of large and small chocolate manufacturers in Ireland. It does not include the process of roasting cocoa beans as outlined in Figure 1.

Incoming materials: These encompass all raw ingredients, packaging and other supplies required for the production and distribution of chocolate products. Liquid chocolate is transported in temperature-controlled tankers and transferred into designated storage tanks upon arrival. Solid chocolate is delivered in boxes and stored in a designated area at ambient temperature.

Storage: Raw materials should be stored in clean, dry and appropriately protected areas or tanks. It is important to clearly mark delivery dates on containers and use stock in rotation. Tanks are heated to keep chocolate in liquid form.

Production area: Chocolate is brought to the production area to be tempered in the tempering machines. The chocolate is tempered by heating and cooling at controlled temperatures to ensure the cocoa butter crystals solidify into the desired stable crystalline structure.

This tempered chocolate is then carefully poured into moulds to create the desired shapes. When making filled chocolates, the shell is poured first, followed by the centre and finally the base. To solidify the chocolate products, they undergo a vibration step and then a cooling step. Finally, the solid chocolates are gently demoulded from their moulds and put briefly into storage before being wrapped and packaged.

Work in progress (WIP) storage: In industry, demoulded chocolates can be considered as 'work in progress' (WIP). At this point, the chocolates are ready to eat as they await the final stage of packaging and labelling. WIP chocolates are stored in a climate-controlled room with regulated temperature and humidity, and they should be suitably covered to prevent physical contamination.

Packing and labelling: Use food-grade packaging materials that are suitable for the characteristics of chocolate for any packaging that comes into direct contact with the chocolate product. Labels must include all legally required information, such as product name, ingredients list and allergen information. More information on labelling can be found in Section 6 of this document.

Final product storage and distribution: Store finished products in a clean, dry and cool environment. Stock rotation should be considered when dispatching products. Transport products safely in order to prevent damage and maintain quality.

4.3. Ingredients added to chocolate products

Ingredients can be added to chocolate products in accordance with rules specified in the following sections.

4.3.1. Optional authorised ingredients (Part B, Annex I, Directive 2000/36/EC)

Part B of Annex I to Directive 2000/36/EC allows optional authorised ingredients to be added to some designated products (chocolate, milk chocolate, family milk chocolate, white chocolate, chocolate a la taza, chocolate familiar a la taza), but the quantity of those added edible substances may not exceed 40% of the total weight of the finished product. This does not apply to filled chocolates, as fillings are not subject to Directive 2000/36/EC.

However, these additional ingredients cannot be sourced from animal fats and their preparations unless they are sourced from milk (i.e. only milk-derived fats can be added to the products described above).

The addition of flours, or granular or powdered starch, shall only be authorised where the addition is in accordance with the definitions of ‘chocolate a la taza’ or ‘chocolate familiar a la taza’. These products are further defined in Section 6.2 of this guidance.

4.3.2. Vegetable fats other than cocoa butter

Vegetable fats other than cocoa butter are permitted to be used in the production of chocolate products. Directive 2000/36/EC specifies that when vegetable fats are used in addition to cocoa butter the following statement must be provided: ‘**Contains vegetable fats in addition to cocoa butter**’. This statement shall be located in the same field of vision as the list of ingredients, clearly separated from that list, in lettering at least as large as that used for the list and formatted in bold with the sales name nearby.

The specified vegetable fats are permitted to be used in a proportion of up to 5% of the chocolate portion of the product, once the weight of the other ingredients has been deducted.

The calculation of vegetable fat content must be based on the total of the compulsory ingredients (this distinction is crucial for products such as chocolate a la taza and gianduja), explicitly excluding any optional ingredients.

Table 3 lists the vegetable fats permitted in the legislation. All these vegetable fats are non-lauric fats, and the characteristics of these fats must be compatible with cocoa butter's physical properties (e.g. melting point and crystallisation temperature, melting rate and need for a tempering phase).

Table 1 Vegetable fats in addition to cocoa butter permitted in the legislation

Usual name of vegetable fats	Scientific name of the plants from which the fats listed can be obtained
Illipe, Borneo tallow or Tengkawang	*Shorea* spp.
Palm oil	*Elaeis guineensis* *Elaeis oleifera*
Sal	*Shorea robusta*
Shea	*Butyrospermum parkii*
Kokum gurgi	*Garcinia indica*
Mango kernel	*Mangifera indica*

It is important to note that the use of these vegetable fats must not reduce the minimum content of cocoa butter or total dry cocoa solids in a product. A 'like for like' replacement is not permitted, as the product must still meet any compositional requirements for minimum cocoa solids or cocoa butter content, even with the presence of any other vegetable fat.

Food business operators may label chocolate products to voluntarily indicate that the product contains no vegetable fats other than cocoa butter, provided the information is accurate and does not mislead the consumer.

4.3.3. Sugars (Part D, Annex I, Directive 2000/36/EC)

Sugars are allowed to be added to chocolate products according to Directive 2000/36/EC, and these are not limited to only those 'sugars' covered by Council Directive 2001/111/EC relating to certain sugars intended for human consumption.

4.3.4. Food additives and Food flavourings

Food additives are substances added intentionally to foodstuffs to perform certain technological functions, for example, to sweeten or to preserve. The food additives used in chocolate and chocolate products must comply with Regulation (EC) 1333/2008 and in particular with the conditions set out in Part E of Annex II to that Regulation, which lists the foods and the conditions of use in which additives may be used.

Chocolate products covered by Directive 2000/36/EC: The additives used in these products must comply with the conditions set out in Food Category 5.1, “Cocoa and chocolate products as covered by Directive 2000/36/EC”, from the amended Annex II to Regulation (EC) 1333/2008.

- Colours are currently not permitted for direct use in products in this food category and are explicitly prohibited from being present in products covered by Directive 2000/36/EC from carry-over in accordance with Table 2 in Part A of Annex II to Regulation (EC) 1333/2008. Colours may be used for surface decoration or in fillings, but they must not penetrate or carry over into the chocolate itself.

Cocoa-based products not covered by Directive 2000/36/EC: The additives used in these products must comply with the conditions set out in Food Category 5.2, “Other confectionery including breath freshening micro-sweets”, from the amended Annex II to Regulation (EC) 1333/2008.

Decorations and fillings: The decorations used on chocolates and the fillings in chocolates are treated separately to the chocolate itself. The following food categories may be relevant:

- Food Category 4.2.4: Fruit and vegetable preparations, excluding products covered by Food Category 5.4 (e.g. pectin in strawberry compote filling)
- Food Category 5.4: Decorations, coatings and fillings, except fruit-based fillings covered by Food Category 4.2.4 (e.g. silver and gold used as decoration)

The 2024 European Commission’s *Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives* may prove useful when determining the food categories that food belongs to.

Flavourings: Flavourings that are permitted in chocolate and chocolate products are regulated by Regulation (EC) 1334/2008, which outlines the general requirements for their safe use. There are no restrictions on what flavourings are permitted for use in chocolate, provided that their use complies with Regulation (EC) 1334/2008. However, to avoid misleading the consumer, flavourings that mimic the taste of chocolate or milk fat are not permitted in certain chocolate products covered by Directive 2000/36/EC, namely cocoa powders, chocolate, milk chocolate, family milk chocolate, white chocolate, chocolate a la taza and chocolate familiar a la taza.

Colours used in flavourings (e.g. strawberry flavouring) must not carry over into the chocolate.

The labelling of food additives and flavourings should comply with Parts C and D of Annex VII to Regulation (EU) 1169/2011, respectively.

4.3.5. Novel foods

A novel food is defined as a food or an ingredient that has not been consumed to a significant degree by humans in the EU before May 1997 (when the first novel food legislation entered into force). They can be newly developed, innovative foods/ingredients or produced using new technologies and production processes, or they can be foods traditionally eaten outside of the EU. Regulation (EU) 2015/2283 on novel foods lays down the procedures for obtaining authorisation to place a novel food on the EU market. Once the novel food is authorised, it will be included in the Union list of novel foods, established under Commission Implementing Regulation (EU) 2017/2470. The current Union list of novel foods contains a number of novel foods that have been authorised to be added to confectionery, including chocolate products, for example, chia seeds (*Salvia hispanica*) and xylo-oligosaccharides.

4.4. Food contact materials

Cocoa and chocolate products come into contact with many different materials and articles during their manufacturing, storage and distribution. These are referred to as food contact materials and articles (FCMs) and include any materials or articles that:

- Are intended to be brought into contact with cocoa and chocolate products (e.g. equipment used in manufacturing)
- Are already in contact with cocoa and chocolate products (e.g. packaging)

- Can reasonably be expected to come into contact with cocoa and chocolate products (e.g. kitchen utensils or equipment).

The above can encompass both direct and indirect contact.

Business operators at all stages of the production, processing and distribution of chocolate products have a responsibility to ensure that the FCMs in use in their business are compliant with legislation on FCMs, and they must incorporate information on FCMs into their traceability systems.

General rules for all FCMs are covered under Regulation (EC) 1935/2004, which provides the general principles of safety and inertness (i.e. non-reactivity) that must be followed to ensure that FCMs do not endanger human health; bring about an unacceptable change in the composition of the food; or bring about a deterioration in the organoleptic characteristics of the food.

Commission Regulation (EC) 2023/2006 provides rules on good manufacturing practice for FCMs. Specific rules which apply to certain FCMs – such as plastics (including recycled plastic), ceramic materials, regenerated cellulose film, Bisphenol A (BPA), as well as active and intelligent materials – are covered by specific EU measures. These rules may be subject to change (e.g. there were changes to rules on the use of BPA in 2024), and food business operators should seek out the most recent legislation to ensure compliance. There are also specific rules on some starting substances used to produce FCMs and products originating or consigned from China or Hong Kong (specifically polyamide utensils).

4.5. Shelf life

The FSAI's *Guidance Note 18: Validation of product shelf-life* (GN18) outlines good practice for food business operators to estimate, set and verify the safety of food over the course of its shelf life. GN18 is designed for food business operators applying 'use by' dates to their products. However, the principles contained within the document can also be used for setting and validating shelf life in products which require a 'best before' date.

5. Food safety hazards and controls associated with cocoa and chocolate product manufacturing

5.1. Introduction

A hazard is a biological, chemical (including allergens) or physical agent in food or feed that has the potential to cause an adverse health effect. A food safety management system (FSMS) refers to the procedures and processes that a food business has in place to control these hazards and ensure that the food it produces is safe for consumption.

Regulation (EC) 852/2004, as amended, lays down general rules for food business operators on the hygiene of foodstuffs. Chocolate manufacturers shall ensure that all stages of production, processing and distribution under their control satisfy the relevant hygiene requirements outlined in Regulation (EC) 852/2004, including:

- General hygiene requirements/prerequisite programmes (Article 4(2) and Annex II)
- Specific hygiene requirements (Article 4(3) and Annex II), and
- The application of the HACCP (hazard analysis and critical control) Principles (Article 5).

Implementation of an effective FSMS, in line with Regulation (EC) 852/2004, is crucial for the control of hazards that may occur in chocolate manufacturing.

Regulation (EC) 852/2004 recognises that in certain food businesses it is not possible to identify critical control points (CCPs) and that, in certain cases, prerequisite programmes (PRPs) and good hygiene practice (GHP) are sufficient to control hazards. As laid down in Article 5 of Regulation (EC) 852/2004, food business operators have an obligation to put in place, implement and maintain a permanent procedure or procedures based on the HACCP Principles. Food business operators are obligated to carry out a hazard analysis and consider whether CCPs can be identified, in line with principles 1 and 2. In cases where the food business operator has determined there are no CCPs, it may be concluded that PRPs and GHP are sufficient to control hazards. This does not preclude the need for the monitoring, validation and verification of certain GHP.

Commission Notice 2022/C 355/01 provides more information on the implementation of FSMSs, covering GHP and procedures based on the HACCP Principles.

5.2. Microbiological hazards

Under Regulation (EC) 178/2002, it is the responsibility of the food business operator to ensure that the food they place on the market is safe. Accordingly, the food business operator must be familiar with their product and its physico-chemical characteristics (e.g. pH and water activity (a_w)). The food business operator should document the physico-chemical characteristics of all products they manufacture in order to determine what hazards are relevant to each product type.

Salmonella spp.

Salmonella spp. is the most common microbiological hazard associated with cocoa and chocolate products.

Chocolate has been implicated in high-profile *Salmonella* outbreaks, for instance, the 2022 multi-country outbreak of monophasic *Salmonella* Typhimurium ST34 linked to chocolate products (ECDC-EFSA, 2022). While chocolate is a low-moisture food, *Salmonella* has been shown to survive and cause outbreaks for the following reasons:

- The low water content and high fat content in chocolate increase the ability of *Salmonella* to survive temperature treatment.
- High temperatures needed to eliminate *Salmonella* cannot be used in chocolate-making, as this would impact quality (e.g. the use of high temperatures needed to eliminate *Salmonella* spp. may lead to burning of the cocoa solids or a bitter taste).
- *Salmonella* has been shown to survive in chocolate for more than 1 year.
- Low numbers of *Salmonella* can cause illness.

The FSAI's *Guidance Note No. 3: Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market* (GN3) provides guideline limits that can be used if legal microbiological criteria do not exist for a particular combination of food and microorganism, such as *Salmonella* in chocolate. As per GN3, the presence of pathogens at unsatisfactory levels in ready-to-eat (RTE) foods means that the food is considered unsafe under Article 14 of Regulation (EC) 178/2002. The presence of *Salmonella* in RTE foods, such as chocolate, is considered unsatisfactory and therefore unsafe. Food which is considered unsafe must be withdrawn/recalled under Article 19 of Regulation (EC) 178/2002.

Listeria monocytogenes

RTE foods are commonly associated with *Listeria monocytogenes* (*L. monocytogenes*). Low a_w foods, such as chocolate, present a low risk in terms of *L. monocytogenes.*

Commission Regulation (EC) 2073/2005, as amended, lays down microbiological criteria for certain foodstuffs. Cocoa and chocolate products fall into category 1.3: Ready-to-eat foods unable to support the growth of *L. monocytogenes*. As per footnote 4, regular testing against the criterion is not required for cocoa and chocolate products under normal circumstances. This is because the a_w of most chocolates will not support the growth of *L. monocytogenes.* As of February 2025, there have been no reported outbreaks or illness related to *L. monocytogenes* linked to the consumption of chocolate. However, chocolate-containing products which have a higher a_w, such as chocolate desserts and chocolate milk, have been found to contain *L. monocytogenes*.

Control of microbiological hazards in chocolate manufacturing

Chocolate-making is a complex process which differs in many ways from other manufacturing processes. Control of microbiological hazards is carried out predominantly through PRPs.

In Ireland, the majority of chocolate manufacturers begin their process from liquid or solid chocolate (i.e. they do not process the cocoa beans). The only microbiological CCP in chocolate-making is the roasting step. This step is unique to each chocolate supplier, who use different combinations of time and temperature to bring out specific chocolate flavours. Suppliers generally roast cocoa beans to a surface temperature of approximately 120 °C for microbiological kill, which is sufficient to eliminate *Salmonella*.

Chocolate manufacturers who choose to roast their cocoa beans should ensure that their roasting process is sufficient to eliminate *Salmonella*. The roasting process should be considered a CCP in the manufacturer's FSMS. Critical limits should be established and monitored, and corrective actions identified in the event that the CCP is not under control. More information on the implementation of a HACCP system can be found on the FSAI website, in Regulation (EC) 852/2004 and in Commission Notice 2022/C 355/01.

After the roasting step, it is important to prevent the reintroduction of *Salmonella* into the chocolate, particularly for Irish food business operators, as the majority will not roast cocoa beans in-house. Good supplier control and GHP is essential to prevent recontamination.

Receiving goods

Supplier control is essential in chocolate manufacturing to avoid the introduction of pathogens into chocolate products. Chocolate manufacturers should choose reliable suppliers, set specifications for the goods they receive and request evidence of conformity (e.g. certificates of conformance with manufacturing standards, and laboratory analyses to demonstrate legal compliance with

applicable compositional requirements, microbiological and chemical criteria, etc). It is important that backup suppliers are approved and audited in the same way as primary suppliers.

'Mix ins' added to chocolate, such as nuts, dried fruit, etc., may be a source of contamination. For example, studies have shown that these types of products may be contaminated with *Salmonella* spp. Information from the Rapid Alert System for Food and Feed (RASFF) shows that products in the 'nuts, nut products and seeds' category are commonly contaminated with *Salmonella* spp.

Filled chocolates

Filled chocolates (e.g. pralines) require more handling, which may present greater risks for contamination. Fillings are typically made in batches, where ingredients are added by hand and the process is controlled by the operator. Therefore, there is a higher risk of contamination due to human error, and GHP is of the utmost importance. Equipment used in making these fillings is generally easier to clean and should be cleaned after each batch, from both a safety and quality standpoint (e.g. to avoid the transfer of allergens and flavours from one batch to another).

The food business operator should establish, monitor and document a target a_w for their filled centres. To achieve the desired a_w and preserve the quality and safety of the product, some operators may adjust their recipe by adding ingredients such as invert sugar or preservatives. It is crucial to ensure that any added ingredients, including preservatives, are approved for use in chocolate manufacturing. More information on additives can be found in Section 4.3.4 of this guidance note.

Filled chocolates have a higher moisture content and a_w:

- Solid chocolate: approximately 0.4 a_w
- Filled chocolates: 0.5–0.7* a_w

*Chocolates with alcohol centres may have a higher a_w than other filled chocolates. It is the responsibility of the food business operator to demonstrate that a higher a_w does not constitute a higher risk over the shelf life of the product.

The food business operator may choose not to make their own fillings, but instead to buy them from another supplier. In this case, good supplier control is important, as well as ensuring good operator hygiene during the use of these pre-made fillings.

5.3. Chemical hazards

Chemical hazards may have different origins in relation to the manufacture of cocoa and chocolate products, and businesses should identify those hazards in their FSMS.

These hazards, for example, can include contaminants (e.g. heavy metals in the soils used to produce cocoa beans and mycotoxins) and residues (e.g. plant protection products, such as pesticides, used in the production of cocoa beans and residues from cleaning and sanitation products used in chocolate manufacture).

Chemical contamination can also be caused by the materials and packaging with which the chocolate products come into contact. Migration of chemicals from equipment or packaging materials, such as mineral oil hydrocarbons should also be identified as hazards (more information on food contact materials can be found in Section 4.4 in this guidance note).

Cocoa and chocolate product businesses should identify all relevant chemical hazards in their FSMS. It is also important that appropriate supplier verification procedures are in place to ensure compliance of raw materials (such as cocoa beans, chocolate, milk, etc.) with specific legislation.

In terms of heavy metals, chocolate manufacturing suppliers should carry out testing to verify compliance with Commission Regulation (EU) 2023/915, which sets out maximum levels for certain contaminants in food. Commission Regulation (EU) 2023/915 also sets a maximum level for ochratoxin A (a type of mycotoxin) in cocoa powder. Chocolate manufacturers should be aware that in general, cocoa powder has higher levels of heavy metals than cocoa butter.

Suppliers to chocolate manufacturers should also provide specifications showing compliance with Regulation (EU) 396/2005 with regard to maximum residue levels of pesticides in or on food and feed of plant and animal origin.

5.4. Physical hazards

Physical hazards include particles or items that are not part of the intended ingredients, and can come from sources such as raw materials, equipment, packaging or personnel. Foreign body hazards in chocolate are a serious concern for manufacturers, as they can pose risks to consumer safety.

Common examples of foreign bodies include:

- **Environmental contamination:** Metal shavings, plastic debris, pests, etc.

- **Contamination from equipment or maintenance:** Broken seals, machine parts, rubber fragments, etc.
- **Contamination through packaging:** Adhesive residue, cardboard fibres, etc.
- **Contamination from personnel:** Hair, buttons, clothing fibre, etc.

In order to reduce or eliminate the presence of physical hazards, strict controls must be put in place. A thorough hazard analysis must be conducted at each stage of the manufacturing process in order to identify and mitigate all potential sources of foreign body contamination. Some outcomes of the analysis might be:

- **Supplier management:** Work with suppliers who have measures in place to prevent foreign body contamination.
- **Raw material inspection:** Thoroughly inspect all incoming ingredients.
- **Equipment maintenance:** Regularly maintain and inspect processing equipment and utensils. Discard any equipment which can lead to foreign body contamination.
- **Foreign body detection programme:** For example, implement a metal detector, filters, sieves or magnets that will help to identify foreign bodies during the manufacturing process.
- **Hygiene and pest control:** Maintain a clean and hygienic production environment with effective pest control measures.
- **Employee hygiene and training:** Train employees on proper hygiene practices and prevention of foreign body contamination.
- **Quality control checks:** Conduct regular quality checks and audits throughout the production area and discard any possible source of foreign material contamination.

5.5. Allergens

Food allergens can be added intentionally as an ingredient in the manufacture of a food or they can be present in the final food unintentionally as a contaminant. To prevent allergen cross-contamination in food production, companies must manage risks beyond mislabelling, including product composition, scheduling, handling, cleaning and employee training and supervision.

Of the 14 priority food allergens that must be declared for all foods in the EU, the primary allergens used at chocolate manufacturing sites include soya beans, milk and nuts. Eggs, peanuts and

cereals containing gluten are used less frequently. To safeguard consumers and ensure compliance with food safety regulations, it is imperative for chocolate manufacturers to implement a comprehensive allergen control programme. This programme should encompass, but not be limited to:

- **Allergen identification:** Rigorous identification of all potential allergenic ingredients within the chocolate manufacturing environment and at the supplier facility
- **Allergen management:** Strict protocols for the handling, storage and use of allergenic ingredients in order to prevent cross-contamination
- **Production planning:** Scheduling production so as to reduce any cross-contamination (e.g. starting with production of products that contain no allergens and finishing with products that contain food allergens)
- **Cleaning and sanitation:** Using validated cleaning procedures and dedicated cleaning equipment for equipment and production areas in order to eliminate food allergen residues and avoid cross-contamination. When it is not possible to wet or dry-clean equipment, flushing the remaining chocolate from the equipment can reduce cross-contamination, although small traces of allergens may remain.
- **Labelling information:** When any of the EU 14 priority food allergens is used as an ingredient in the manufacture of a food and is still present in the final food, it must be labelled accordingly in the list of ingredients. Please see Section 6 for further information.
- **Precautionary allergen labelling**: When there is a risk of unintentional low-level presence of food allergens in a food due to cross-contamination, food businesses sometimes provide information about this risk at their discretion. This voluntary information is referred to as precautionary allergen labelling and includes statements such as “May contain (food allergen)”, “Prepared in a kitchen that uses (food allergen)” or “Packed on a line that also handles (food allergen)”. In Ireland, the FSAI recommends that the use of precautionary allergen labels should be judicious and based on a risk assessment. Food allergen information, whether mandatory or voluntary, must be accurate so the consumer can make informed food choices.
- **Employee training:** Training of all personnel on food allergen awareness, handling procedures and the importance of adhering to the food allergen control programme.

By integrating a food allergen identification system, stringent handling protocols, strategic production planning, validated cleaning procedures, accurate food labelling information and

comprehensive employee training, chocolate product manufacturers can significantly reduce the risk of food allergen cross-contamination.

5.6. Rework

Rework is the process of reusing out-of-specification or leftover chocolate, which is still safe for consumption, in subsequent batches. Rework is a common practice in the chocolate industry. While it can offer economic and environmental benefits by reducing waste, it also presents potential risks that must be carefully managed.

Risks associated with rework

Microbiological and physical contamination: Reworked chocolate may be more susceptible to microbial growth or physical contamination if it has been exposed to the environment or improperly stored. Similarly, reworked chocolate may be subject to more handling. This can introduce pathogens or spoilage organisms into subsequent batches or can allow contamination of processing equipment.

Allergen cross-contamination: If rework involves different types of chocolate or ingredients, there is a risk of cross-contamination with allergens.

Quality deterioration: Repeated reworking can affect the chocolate's quality, including its flavour, texture and appearance.

Traceability challenges: Tracking the origin and processing history of reworked chocolate can be complex, potentially hindering traceability efforts in case of a recall or food safety incident. To maintain safety standards, food business operators shall implement adequate traceability systems for their reworked chocolate in line with Article 18 of Regulation (EC) No 178/2002. These systems should provide key details such as the specific batches used, the processing methods employed and the dates on which the rework material was manufactured. A rework identification system ensures traceability throughout the production chain and maintains the safety and quality of the product.

Control of risks associated with rework

To ensure the safety and quality of chocolate products containing rework, manufacturers should consider the following factors:

Type of rework: The source of the rework material (e.g. leftover tempered chocolate, misshapen products, out-of-specification batches) influences the potential risks and appropriate handling procedures.

Storage conditions: Proper storage of rework material is crucial to preventing contamination and quality deterioration.

Rework limits: Establish clear limits on the amount of rework that can be used in a batch in order to maintain product quality and safety.

Documentation: Maintain traceability records of rework usage, including the source of the material, quantity used and any quality control checks performed.

Verification: Implement rigorous quality control checks on rework material and finished products (such as looking for any signs of contamination, discolouration or inconsistency in texture that can affect the quality of the final product) to ensure they meet standards.

To minimise risks and maximise the benefits of rework, chocolate manufacturers should prioritise reducing the generation of rework material by optimising production processes. When rework is necessary, ensuring traceability can help prevent cross-contamination and other food safety risks. Detailed employee training on proper rework procedures, including hygiene and quality control, is essential to maintain safety and quality standards.

5.7. Cleaning and validation of hygiene procedures

Chocolate manufacturing is a very specialised process. As a low-moisture production process, cleaning and maintenance procedures will differ from those of other manufacturing operations. Cleaning in chocolate manufacturing environments may be more complex, as introduction of moisture can impact the quality and safety of the final product. If *Salmonella* is present in chocolate, the addition of water to the chocolate can cause *Salmonella* to grow.

Cleaning and maintenance in the chocolate manufacturing environment is important for food safety, and the following guidelines should be followed:

- All cleaning and maintenance procedures should be documented in the food business operator's FSMS, including frequency of cleaning, cleaning method, precautions needed (e.g. personal protective equipment), chemicals used and appropriate dilutions and contact times, etc.

- Equipment used will vary from one chocolate manufacturer to another. These pieces of equipment may be made from different materials and, accordingly, have different cleaning instructions. The chocolate producer should adhere to instructions provided by the equipment manufacturer. Factors to consider when determining cleaning frequency are detailed in Section 5.7.1.
- If cleaning verification is based on visual inspection, cleaning cards may be useful to ensure that the level of cleaning is consistent.
- Cleaning should be verified by microbiological testing at a frequency based on risk.
- Cleaning and maintenance of equipment should be carried out regularly.

Recommended best practice is to have a cleaning schedule or checklist in place based on risk, indicating the areas and/or equipment to be cleaned, the cleaning frequency and the cleaning agents to be used, and signed off by the person performing the cleaning process. Where appropriate, cleaning instructions should be clearly displayed.

Food business operators should consider the risks associated with each phase of the manufacturing process in order to determine the most suitable type of cleaning. Some chocolate processing equipment should be cleaned without the use of water – using vacuum cleaners, scrapers and similar tools to remove all chocolate and other processing dirt – followed, when necessary, by disinfection with food-grade disinfectants. When cleaning with water and/or other cleaning agents is possible and essential, it must be done cautiously to avoid contact with chocolate, after which equipment should be disinfected and immediately thoroughly dried. Food business operators may use the information provided in Section 5.7.1 to determine the frequency of cleaning. Information on cleaning and maintenance for specialised equipment is discussed in Section 5.7.2.

It is the responsibility of the food business operator to ensure their cleaning and maintenance plan is sufficient to ensure safety of the final product.

5.7.1. Factors to consider when determining cleaning frequency

Effective cleaning in chocolate production depends on a thorough understanding of several factors:

Chocolate type: Different chocolates have different compositions (e.g. dark, milk, white) and ingredients (e.g. presence of milk solids or non-dry fat cocoa solids). Planning and cleaning are crucial to reducing any possible cross-contamination when changing from one chocolate type to another.

Production volume: Cleaning requirements for small-scale chocolate-making equipment may differ from large-scale chocolate making equipment. More versatile equipment may require different cleaning procedures compared to large, specialised machinery. These differences in equipment, along with variations in frequency of use and throughput, impact cleaning protocols.

Equipment usage: Having dedicated equipment for specific chocolate types simplifies cleaning. Having equipment that is shared across varying types of chocolate demands rigorous cleaning to prevent cross-contamination when used to make products containing different types of chocolate.

Process nature: Handmade operations may allow for more manual cleaning and total dismantling of equipment, while more automated production lines require specialised cleaning systems and strict user guidance, to preserve the service life of the machinery and ensure the safety of the product.

Water and cleaning agents: Residual water derived from cleaning processes can increase food safety risks, if it comes in contact with the chocolate product. It is crucial to select and use appropriate cleaning agents in order to avoid these risks.

Manufacturer instructions: Adhering to manufacturer guidelines for both chocolate and equipment is essential for effective cleaning.

It is important to consider these factors and their potential risks when implementing cleaning protocols tailored to the specific production system. This ensures product safety and quality across the complex production process.

5.7.2. Cleaning and maintenance of specialised equipment

Specialised/complex equipment requires additional training for staff to ensure it is cleaned correctly. Specialised equipment (e.g. tempering machine, moulds, hoppers, nozzles) should be thoroughly cleaned as per manufacturer instructions at a frequency based on risk (see Section 5.7.1).

When wet cleaning is required, it should be carried out in dedicated areas using either manual or automated techniques. Equipment should be routinely inspected and repaired or replaced as necessary to maintain food safety.

Cooling tunnels in production lines should allow for visual inspection and easy interior cleaning access.

For equipment cleaned via clean-in-place systems, it is essential to adhere to the guidelines provided by both the equipment manufacturer and the supplier of the cleaning solutions.

Tempering machines

In larger food businesses, liquid chocolate is often delivered in bulk tanks and piped directly to the tempering machine through a closed system. From there, the tempered chocolate is transferred to a hopper in the production area for use. These tempering machines are typically closed units with automated processes.

In other food businesses, chocolate is often delivered in a solid state, and smaller tempering machines may be used. These machines may have an exposed tank and require more hands-on operation (e.g. adding solid chocolate for tempering). In these cases, it is important to ensure that operators are trained in proper machine use and hygienic handling of the product.

Cleaning and maintenance

Tempering machines require specialised cleaning and maintenance, with procedures varying depending on the machine's design, the type of chocolate processed (e.g. white versus dark) and production volume.

Food business operators should do the following:

Consult manufacturer instructions: Refer to the manufacturer's validated cleaning instructions, including recommended cleaning agents and tools.
Understand production needs: Consider the types of chocolate used, production volumes and equipment characteristics. If shared equipment is used, production plans should minimise risk of allergen cross-contamination, for example, by flushing chocolate from machines between production of different types.
Conduct a risk assessment: Perform a risk assessment to determine the appropriate cleaning and maintenance plan, including the frequency of full disassembly and cleaning of machines. Document and regularly review this plan. See Section 5.7.1 for more information.

By combining manufacturer recommendations with a thorough risk assessment, food businesses can ensure their tempering machines are maintained effectively, safeguarding both product quality and consumer safety.

Chocolate moulds

Chocolate moulds are typically made with a specialised layer and materials that ensure easy release of the chocolate product. When chocolate is tempered correctly and the mould coating is intact, the chocolate should release cleanly, leaving little or no residue. Chocolate moulds with damaged coatings can harbour chocolate residue, potentially leading to food safety issues. Therefore, preservation of this mould coating is important.

Conventional cleaning methods and agents can damage the specialised coating of chocolate moulds. However, maintaining the hygiene of moulds is essential, especially when moulds are shared between different types of chocolate.

To determine the appropriate cleaning method for chocolate moulds, food business operators should consider the following:

Dedicated versus shared moulds: Dedicated moulds for specific chocolate types may require less frequent cleaning.
Risk assessment: Conduct a risk assessment to establish a cleaning schedule based on factors like manufacturer cleaning instructions, type of chocolate, production volume and cleaning methods (e.g. dedicated mould washer versus manual washing). This assessment should include validation of the chosen washing/cleaning process. See Section 5.7.1 for more information.
Cleaning methods: Cleaning with hot water (60–80 °C) and a subsequent drying step is a common practice. However, the specific method and frequency of cleaning should be determined by the risk assessment and the mould manufacturer's validated cleaning instructions.
Cleaning and mould replacement frequency: The chosen cleaning frequency and mould inspection and replacement schedule should be clearly documented within the food business operator's FSMS. Routine checks should be carried out on moulds in order to assess, based on risk, when they need to be replaced. Always follow the manufacturer's instructions for cleaning and replacing moulds.

> Guidance on best practice for hygiene in low-moisture environments can be found in Codex Alimentarius CXC 75-2015 *Code of hygienic practice for low-moisture foods* read in conjunction with Codex Alimentarius CXC 1-1969 *General Principles for food hygiene*.

6. Labelling of chocolate products

6.1. General labelling requirements

The FIC Regulation sets out the general principles, requirements and responsibilities governing food information and in particular food labelling.

The provision of food information must protect consumer health and interests by providing a basis for consumers to make appropriate use of a food as well as make informed choices, with particular regard to health, economic, environmental, social and ethical considerations.

Food information provided to consumers must be accurate, clear and easy to understand. It must not be misleading, particularly:

(a) As to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, or method of manufacture or production
(b) By attributing effects or properties to the food, which it does not possess
(c) By suggesting that the food possesses special characteristics when in fact all similar foodstuffs possess such characteristics, in particular by emphasising the presence or absence of certain ingredients and/or nutrients
(d) By suggesting – by means of the food's appearance, description or pictorial representations – the presence of a particular food or ingredient which is a component naturally present or an ingredient normally used in that food, when in reality this component or ingredient has been substituted with a different component or ingredient.

Additionally, the FIC Regulation establishes font size rules depending on the area of the packaging.

6.1.1. Mandatory information required for prepacked products

Subject to particular exceptions indicated in each subsection, the following list details the mandatory information that must appear on the packaging of prepacked cocoa and chocolate products, or on an attached label. These requirements are in line with Article 9 of the FIC Regulation:

(a) **The name of the food**

The FIC Regulation stipulates that the name of the food shall be its legal name (Article 17). Cocoa and chocolate products are regulated under Directive 2000/36/EC, which clearly defines specific food categories with their legal names and compositional requirements. Please refer to Section 6.2 for a detailed description of these categories. Any product that does not meet the definition of one of the categories set forth in Annex I to Directive 2000/36/EC must be named with a 'customary name' or, in its absence, with a 'descriptive name', i.e. a name which provides a sufficiently clear description of the food so as to enable consumers to know its true nature. The products falling under categories 'chocolate', 'milk chocolate' and 'couverture chocolate' may be supplemented by information or descriptions relating to quality criteria. Please refer to Section 6.3 for further information.

(b) **A list of ingredients**

All ingredients used in the manufacture of chocolate products must be included in a list of ingredients, including those referred to in point (c) below. Ingredients must be listed in descending order of weight, as recorded at the time of their use in the manufacture of the food.

In accordance with Article 19 of the FIC Regulation, a list of ingredients is not required for foods consisting of a single ingredient, such as cocoa butter or cocoa powder.

Part B of Annex I to Directive 2000/36/EC allows for the use of additional ingredients in specific chocolate product categories. These are described in Section 4.3.1.

(c) **Any ingredient or processing aid listed in Annex II of the FIC Regulation or derived from a substance or product listed in Annex II causing allergies or food intolerances which has been used in the manufacture or preparation of a food and is still present in the finished product, even if in altered form**

The most common food allergens used as ingredients in chocolate products are milk, soya, nuts and peanuts, but cereals containing gluten can also be found as ingredients in 'chocolate a la taza' and 'chocolate familiar a la taza'. When any of the EU's list of 14 priority food allergens is used in the manufacture of a chocolate product and is still present in the final food, it must be included in the list of ingredients with a reference to the specific name of the substance as listed in Annex II to the FIC Regulation. These food allergens must be emphasised in the list of ingredients through a typeset that clearly distinguishes them from the rest of the ingredients, for example, through a different font, style or background colour. For example, if pistachio nuts are used in the manufacture of a milk chocolate bar, both milk and pistachio nuts must be emphasised in the ingredients list as these two substances are listed in Annex II to the FIC Regulation. In this case,

the ingredients list could read as follows: “Ingredients: Sugar, whole **milk** powder, cocoa butter, cocoa mass, roasted **pistachios** (15%), vegetable fat (sunflower oil)”.

If several ingredients originate from the same substance or product listed in Annex II to the FIC Regulation, the list of ingredients shall make it clear for each ingredient concerned.

(d) **The quantity of certain ingredients or categories of ingredients**

Under FIC Regulation, it is mandatory to declare the quantity of an ingredient or category of ingredients used in the manufacture of chocolate products where the ingredient or category of ingredients concerned:

(a) appears in the name of the food
(b) is emphasised on the labelling in words, pictures or graphics, or
(c) is essential to characterise a food and to distinguish it from products with which it might be confused because of its name or appearance.

For example, for a chocolate bar containing raspberries as an ingredient, where pictures of raspberries appear on the label or the name of the food includes the word ‘raspberry’ or ‘raspberries’, it is mandatory to include the quantity of raspberries in the final product, expressed as a percentage, in the list of ingredients.

Directive 2000/36/EC requires that products using the sales names categories 2(c), 2(d), 3, 4, 5, 8 and 9 (see Table 2) are labelled with the following declaration of the cocoa solids content: “Cocoa solids: … % minimum”. Sales names categories 2(b) and 2(d) must also indicate the cocoa butter content, while the following declaration regarding milk solids, “Milk solids: … % minimum”, is required for products falling under the category of ‘family milk chocolate’ (category number 5, Table 2), but which are labelled as ‘milk chocolate’ on the Irish, UK and Maltese markets. The calculation of the required solids content percentages shall be conducted after the weight of any additional ingredients is deducted from the total weight of the product, i.e. the calculation is based on the chocolate portion of the recipe.

Moreover, the quantitative indication is not required in respect of an ingredient or category of ingredients which is used in small quantities for the purposes of flavouring.

It is important to note that Part B of Annex I to Directive 2000/36/EC allows for the addition of edible substances only to specific chocolate categories, and the quantity of those edible substances may not exceed 40% of the total weight of the finished product. Please refer to Section 4.3.1.

(e) **The net quantity of the food**

This must be expressed in metric units, i.e. in units of volume (e.g. millilitres, Litres) in the case of liquid products or in units of mass (e.g. grams, Kilograms) in the case of other products, and in the same field of vision as the name of the food.

It is important to note that where a prepacked item consists of two or more individual prepacked items containing the same quantity of the same product, the net quantity shall be indicated by stating the net quantity contained in each individual package and the total number of such packages. The indication of those particulars shall not, however, be mandatory in cases where the total number of individual packages can be clearly seen and easily counted from the outside, and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside.

(f) **The date of minimum durability (i.e. 'best before' date) or 'use by' date**

Chocolate products usually carry a 'best before' date, meaning the date until which the food retains its specific quality properties when properly stored. Certain rules apply with regard to the expression of the 'best before' date depending on the length given to the product's durability (Annex X of the FIC Regulation).

(g) **Any special storage instructions and/or conditions of use**

Where necessary, labelling must provide a description of the storage conditions which must be observed by the consumer.

Moreover, to enable appropriate storage or use of the product after the package is opened, labelling shall indicate the storage conditions and/or time limit for consumption, where appropriate.

(h) **The name or business name and address of the food business operator**

These are the details of the food business operator responsible for the food information. When that operator is not established in the EU, the details must be those of the importer on the EU market. The contact details must be sufficiently precise to facilitate communication with the named business, where necessary.

(i) **The country of origin of the foodstuff**

It is mandatory to indicate the country of origin only in cases where failure to indicate it might mislead the consumer. It is common for the origin of the cocoa beans to be included on the label of a chocolate product, but this should not be interpreted as the country of origin of the final food.

In fact, if the country of origin of the final food is stated on the label, and is different from that of the primary ingredient, the country of origin of the primary ingredient must also be provided or at least

indicated as being different from that of the final food. For cocoa and chocolate products, the primary ingredient must be understood to be the ingredient or ingredients derived from the cocoa beans, as those are the ingredients that consumers commonly associate with the name of the food. For example, if a chocolate bar, produced using cocoa beans originating outside Guatemala, contains a statement indicating that it has been 'Made in Guatemala' or contains any other information likely to indicate to consumers that it has been produced in Guatemala, e.g. a Guatemalan flag, then the origin of the cocoa products must also be provided or at least indicated as not being Guatemalan.

The descriptor 'Belgian' that is used in some chocolate products does not necessarily mean that the country of origin of the final food is Belgium. According to the Belgian Chocolate Code, which was introduced by the Royal Belgian Association of the Chocolate, Pralines, Biscuits and Confectionery Industries (Choprabisco), products labelled as 'Belgian chocolate' must be refined and moulded in Belgium. However, the grinding of the beans and the production of chocolate liquor and cocoa powder and butter can occur elsewhere.

(j) **Instructions for use**

These are required in cases where it would be difficult to make appropriate use of the food in the absence of such instructions. Instructions for use must be included on the label for certain food categories, for example, for 'chocolate a la taza' and 'chocolate familiar a la taza', as these products are intended to be consumed after reconstitution in water or milk.

(k) **A nutrition declaration**

A nutrition declaration must be presented in a tabular format unless the space does not permit, in which case the declaration can appear in linear format. The nutrition declaration shall include the following parameters:

(a) energy value; and
(b) the amounts of fat, saturates, carbohydrate, sugars, protein and salt.

The amount of monounsaturated fats, polyunsaturated fats, polyols, starch, fibre and any of the vitamins or minerals listed in point 1 of Part A of Annex XIII to the FIC Regulation – and present in significant amounts as defined in point 2 of Part A of that Annex – can also be added to the nutrition declaration.

Specific rules apply to the means of expression and presentation of the nutrition declaration (Articles 32–35 and Annex XV of the FIC Regulation).

6.1.2. Mandatory food information required for non-prepacked products

Non-prepacked foods are foods offered for sale to the final consumer without pre-packaging, as well as those that are packed on the sales premises at the consumer's request or prepacked for direct sale. For example, pralines offered for sale individually for consumers to pick. The only mandatory information requirement for non-prepacked food is the allergen declaration. However, a food business selling non-prepacked food must have the other mandatory food information available at consumers' request. In Ireland, an allergen declaration must be provided for non-prepacked food as stipulated in S.I. No. 489/2014.

6.1.3. Voluntary food information

Food business operators can provide consumers with additional food information on a voluntary basis, for example, in relation to the risk of the unintended presence of food allergens in a food, or a claim regarding its suitability for vegetarians or vegans. Voluntary statements must not take up space needed for mandatory food information and must not mislead the consumer, be ambiguous or confusing, and, where appropriate, must be based on relevant scientific data. This is in line with Articles 36 and 37 of the FIC Regulation.

When any of the particulars described in Section 6.1.1. are provided voluntarily, they must still meet the same requirements as if they were mandatory.

Additional rules apply, for example, in relation to nutrition and health claims made on food, or regarding the absence or reduced presence of gluten in food.

6.2. Specific labelling requirements associated with specific compositional requirements

Annex I to Directive 2000/36/EC lists 10 categories of cocoa and chocolate products with specific sales names and compositional requirements (see Table 2).

Table 2 Sales names and compositional requirements defined in Annex I to Directive 2000/36/EC

	Min. total dry cocoa solids	Min. dry non-fat cocoa solids	Min. cocoa butter	Min. dry milk solids	Min. milk fat	Min. total fat: cocoa butter and milk fat	Other additional requirements
1. Cocoa butter	The fat obtained from cocoa beans or parts of cocoa beans with (i) a free fatty acid content (expressed as oleic acid) of ≤ 1.75% and (ii) unsaponifiable matter (determined using petroleum ether) of ≤ 0.5%, except in the case of press cocoa butter, where it shall be ≤ 0.35%						
2(a) Cocoa powder or cocoa	-	-	20% *	-	-	-	≤ 9% water
2(b) Fat-reduced cocoa, fat-reduced cocoa powder	-	-	< 20% *	-	-	-	≤ 9% water
2(c) Powdered chocolate, chocolate in powder	-	-	-	-	-	-	Mixture of sugars and ≥ 32% cocoa powder
2(d) Drinking chocolate, sweetened cocoa, sweetened cocoa powder	-	-	-	-	-	-	Mixture of sugars and ≥ 25% cocoa powder If fat-reduced, cocoa butter < 20% of cocoa content
3. Chocolate	35%	14%	18%	-	-	-	Sugars
3(a) Chocolate flakes	32%	14%	12%	-	-	-	
3(b) Chocolate couverture	35%	2.5%	31%	-	-	-	

	Min. total dry cocoa solids	Min. dry non-fat cocoa solids	Min. cocoa butter	Min. dry milk solids	Min. milk fat	Min. total fat: cocoa butter and milk fat	Other additional requirements
3(c) Chocolate gianduja	32% †	8%†	-	-	-	-	20–40 g finely ground hazelnuts per 100 g of finished product. Other nuts can be added for a max. nut content of 60%. Milk and/or dry milk solids can be added for a max. 5% dry milk solids.
4. Milk chocolate [(a)]	25%	2.5%	-	14%	3.5%	25%	Sugars, milk or milk products
4(a) Milk chocolate flakes	20%	2.5%	-	12%	3.5%	12%	
4(b) Milk chocolate couverture	25%	2.5%	-	14%	3.5%	31%	
4(c) Milk chocolate gianduja	25%†	2.5%†	-	10%†	3.5%†	25%†	15–40 g finely ground hazelnuts per 100 g of finished product. Other nuts can be added for a max. nut content of 60%.
5. Family milk chocolate [(b)]	20%	2.5%	-	20%	5%	25%	Sugars, milk or milk products
6. White chocolate	-	-	20%	14%	3.5%	-	Sugars, milk or milk products

	Min. total dry cocoa solids	Min. dry non-fat cocoa solids	Min. cocoa butter	Min. dry milk solids	Min. milk fat	Min. total fat: cocoa butter and milk fat	Other additional requirements
7. Filled chocolates/chocolates with … filling	Filled product, the outer part of which consists of one of the products defined in 3, 4, 5 and 6 above. The outer chocolate portion of products with this sales name shall constitute not less than 25% of the total weight of the product.						
8. Chocolate a la taza	35%	14%	18%	-	-	-	Sugars and ≤ 8% flour or starch from wheat, rice or maize
9. Chocolate familiar a la taza	30%	12%	18%	-	-	-	Sugars and ≤ 18% flour or starch from wheat, rice or maize
10. A chocolate or a praline	Product in single-mouthful size, consisting of a filled chocolate (category 7 above), or a single chocolate or a combination or mixture of chocolate (within the meaning of the definitions given in 3, 4, 5 or 6) and other edible substances, provided that chocolate constitutes not less than 25% of the total weight of the product						

(a) If the word 'milk' in 'milk chocolate' is replaced by the word 'cream', the product must have a minimum milk fat content of 5.5%, and if replaced by the word 'skimmed milk' the product must have a milk fat content ≤ 1%.

(b) In Ireland, the sales name 'milk chocolate' can be used instead of 'family milk chocolate' provided that the amount of dry milk solids is indicated on the label as "milk solids …% minimum".

Note: The symbol (*) denotes *in dry matter*
Note: The symbol (†) *denotes content in chocolate portion*
Note: The symbol (-) means that Directive 2000/36/EC does not set a minimum amount.

Directive 2000/36/EC requires that products using the sales names categories 2(c), 2(d), 3, 4, 5, 8 and 9 (see Table 2) are labelled with a declaration of the cocoa solids content, formatted as 'Cocoa solids: … % minimum'. The cocoa solids content shall be calculated after the weight of any additional ingredients is deducted, i.e. the calculation is based solely on the chocolate portion of the recipe. Products using the sales names categories 2(b) and 2(d) must also declare the cocoa butter content.

For products using sales names categories 7 and 10 (see Table 2), the minimum contents shall be calculated after deducting the weight of the added ingredients as well as the weight of the filling.

In these two categories, the outer chocolate portion shall constitute not less than 25% of the total weight of the product.

6.3. Quality descriptors for certain products

Article 3(5) of Directive 2000/36/EC allows for the supplementation of the sales names 'Chocolate' (category 3), 'Couverture chocolate' (category 3(b)) and 'Milk chocolate' (category 4) with information or descriptions relating to quality criteria as long as those three product categories meet specific compositional requirements (see Table 2).

Table 3 Compositional requirements when quality descriptions are used

	Min. total dry cocoa solids	Min. dry non-fat cocoa solids	Min. cocoa butter	Min. dry milk solids	Min. milk fat	Min. total fat: cocoa butter and milk fat
3. Chocolate	43%	14%	26%	-	-	-
3(b) Couverture chocolate	35%	16%	31%	-	-	-
4. Milk chocolate	30%	2.5%	-	18%	4.5%	25%

Note: The symbol '-' means that Directive 2000/36/EC does not set a minimum amount.

There are no specific rules that define 'quality criteria'; rather, it is to be understood that they refer to products of higher quality, as the additional compositional requirements mandate higher quantities than the minimum required for the applicable categories in Annex I of Directive 2000/36/EC (see Table 2). These additional declarations are voluntary food information and hence subject to the applicable provisions laid out in the FIC Regulation (see Section 6.1.3). Some examples of these quality descriptors include 'extra fine chocolate', 'extra fine milk chocolate' and 'premium couverture chocolate'.

6.4. Chocolates containing alcohol as an ingredient

Unlike the cocoa and chocolate Directive of 1973 which preceded it (Council Directive 73/241/EEC), Directive 2000/36/EC does not contain any provisions relating to liqueur chocolates or to chocolate products filled with an alcoholic beverage. The addition of alcohol as an ingredient may require compliance with additional pieces of legislation, including:

(a) **Regulation (EU) 2019/787** *on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages.* This piece of legislation defines the sales names, compositional requirements (e.g. minimum alcoholic strength by volume and specific ingredients) of spirit drinks.

(b) **FIC Regulation** as it relates to the mandatory declaration of the quantity of certain ingredients or category of ingredients.

6.5. Products sold in assortments

Where the products defined in Directive 2000/36/EC, Annex I (A), (3), (4), (5), (6), (7) and (10) (see Table 2 in Section 6.2) are sold in assortments, the defined sales names may be replaced by ‘assorted chocolates’, ‘assorted filled chocolates’ or similar names. Where chocolates are sold in assortments, there may be a single list of ingredients for all the products in the assortment.

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Useful resources

The FSAI website (www.fsai.ie) has a publication section where all FSAI publications, including guidance referenced in this document are published.

Links to Irish and EU legislation about specific kinds of foods and related items are also available on the legislation section of the website.

The FSAI Learning Portal provides users with training courses, resources and materials to keep up to date with food safety: Home | Food Safety Authority of Ireland Learning Portal (link correct at date of publication).

Readers should seek the latest consolidated versions of European legislation at https://eur-lex.europa.eu/homepage.html

Appendix I

Example of a chocolate product label

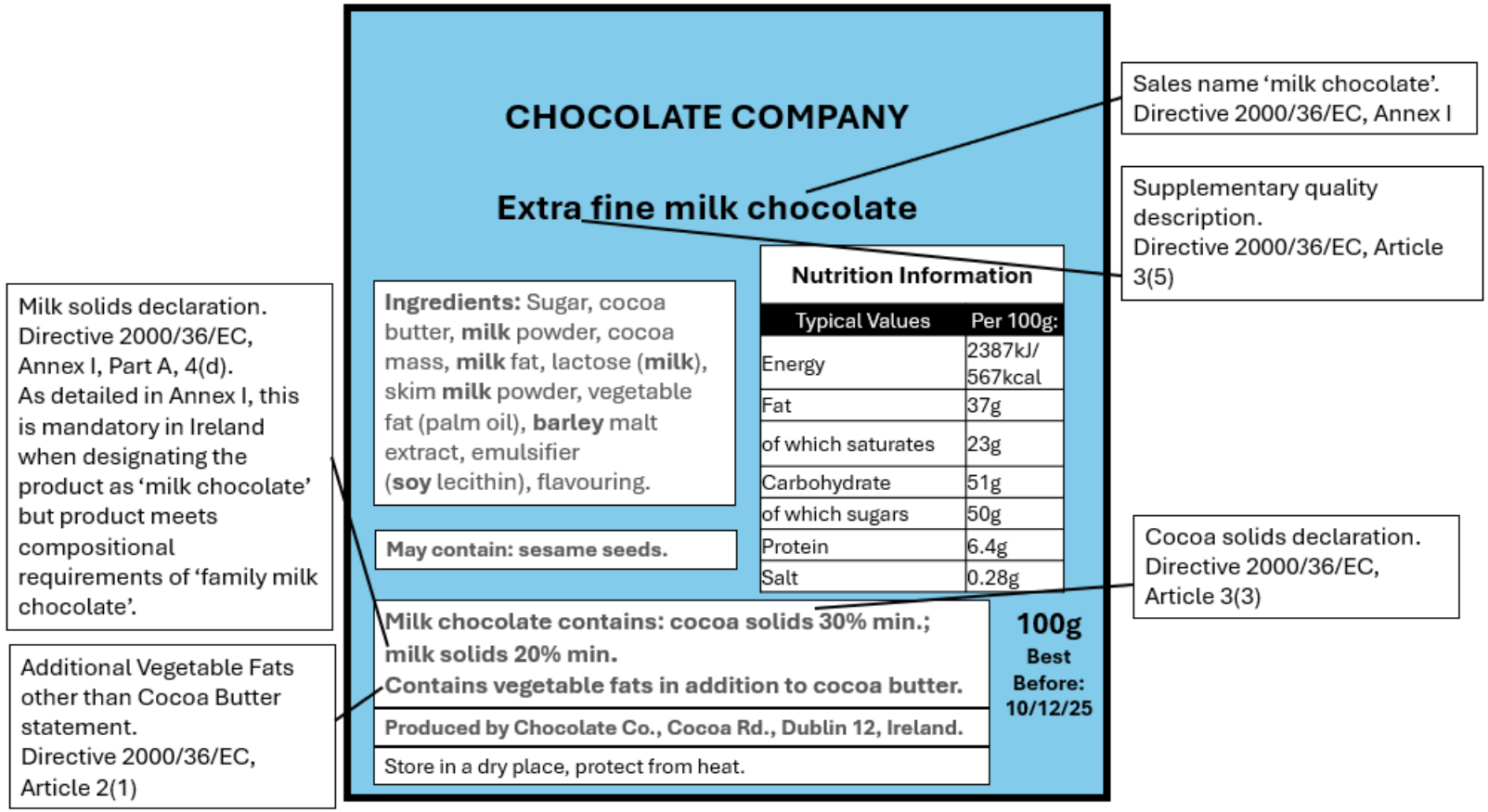

Figure 3 Example of chocolate product label

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