European Union

Bugnion SpA

EU regulations smooth the way for FMCG labelling rules

The EU Regulation on the Provision of Food Information to Consumers creates a bridge between labelling requirements and new obligations to meet the growing demands of the most discerning customers of fast-moving consumer goods

Consumer protection is increasingly relevant and each year the legislature must regulate the available consumer goods information.

Agri-food is a good example of a sector with ever-changing regulations. In 2011 the publication of the EU Regulation on the Provision of Food Information to Consumers (1169/2011) cleared a path between EU labelling rules and the introduction of new obligations to meet the growing demands of the most discerning consumers.

Article 26 of the regulation established general rules and requirements regarding the indication of the country of origin or place of provenance of foods. It aims to prevent misleading and deceitful information regarding food origins. Article 26(2)(a) requires the indication of the country of origin or place of provenance where its omission could mislead consumers, particularly if the information alongside the food or label would otherwise imply that it has a different country of origin or place of provenance.

Country of origin and place of provenance

Article 26(3) provides that where a foodstuff's country of origin or place of provenance is given and this is not the same as that of its primary ingredient, the country of origin or place of provenance of the primary ingredient should also be indicated as being different from that of the food itself. Article 26(3) further states that the abovementioned provisions are subject to the adoption of an implementing act. Finally, in May 2018 – seven years after the adoption of EU Regulation 1169/2011 – EU Regulation 2018/775 was published, laying down rules for the application of Article 26(3). It entered into force on 1 June 2018 and will be enforceable from 1 April 2020. This implementing regulation clarifies the way that the origin of primary ingredients must be labelled when it is different from the given origin of the food as a whole.

According to EU Regulation 1169/2011:

- 'place of provenance' means any place where a food is indicated to come from, and that is not the 'country of origin' as determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92; the name, business name or address of the food business operator on the label shall not constitute an indication of the country of origin or place of provenance of food within the meaning of this Regulation;

- 'primary ingredient' means an ingredient or ingredients of a food that represent more than 50% of that food or which are usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required.

New rules

The country of origin or place of provenance of a primary ingredient that is different from that given in respect of the food itself will be indicated:

a) with reference to one of the following geographical areas:
(i) 'EU', 'non-EU' or 'EU and non-EU'; or
(ii) region, or any other geographical area either within several member states or within third countries, if defined as such under public international law or well understood by normally informed average consumers; or
(iii) FAO fishing area, or sea or freshwater body if defined as such under international law or well understood by normally informed average consumers; or
(iv) member state(s) or third country(ies); or
(v) region, or any other geographical area within a member state or within a third country, which is well understood by normally informed average consumers; or
(vi) the country of origin or place of provenance in accordance with specific union provisions applicable for the primary ingredient(s) as such;
b) or by means of a statement as follows: '(name of the primary ingredient) do/does not originate from (the country of origin or the place of provenance of the food)' or any similar wording likely to have the same meaning for the consumer.

Rules regarding the presentation of the label must be observed. The indication should meet the minimum font size stated in Article 13(2) of EU Regulation 1169/2011, while the label must also be at least 75% of the height of the indication of the country of origin or place of provenance and within the same visual field.

EU Regulation 2018/775 is set to be enforced on 1 April 2020. However, the new regulation poses some interpretational challenges. First, Article 1 clarifies the fact that it applies when the country of origin or place of provenance of a food is given "by any means such as statements, pictorial presentation, symbols or terms, referring to places or geographical areas, except for geographic terms included in customary and generic names where those terms literally indicate origin but whose common understanding is not an

indication of country of origin or place of provenance".

The meaning of 'generic names' remains unclear. The definition of 'primary ingredient' also leaves the individual operator room to interpret the establishment of the "ingredients of a food that represent more than 50% of that food".

Finally, many have severely criticised the exclusion of "registered trademarks where the latter constitute an origin indication", which was postponed to a specific subsequent regulation. The operators are already at work and awaiting clarification from the European Commission.

Hazard labelling

Another regulation that is due to be enforced in Spring 2020 (1 May 2020) is EU Regulation 2018/1480 amending, for the purposes of adaptation to technical and scientific progress, the EU Regulation on Classification, Labelling and Packaging of Substances and Mixtures (1272/2008).

The regulation is based on the UN Globally Harmonised System and aims to ensure a high level of protection for health and the environment, as well as the free movement of substances, mixtures and articles. It requires manufacturers, importers and downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market.

Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers. Hazard labelling allows the hazard classification, including labels and safety data sheets, to be communicated to the user, warning them about the presence of a hazard and the need to manage associated risks.

This amendment (EU Regulation 2018/1480) is the 13th adaptation to the EU Classification, Labelling and Packaging of Substances and Mixtures Regulation regarding technical and scientific progress and contains important changes to the list of chemicals falling under Annex VI.

Among the modified items, the changes to Table 3.1 in Part 3, Annex VI are particularly significant: "Adding 16 completely new entries, including the entry for 2-methylisothiazol-3(2H)-one (MI, CAS 2682-20-4) under index number 613-326-00-9."

Such mixtures must be labelled when they contain more than 0.0015% methylisothiazolinone – a powerful synthetic biocide and preservative in the isothiazolinones group, which is used in numerous personal care products and a wide range of industrial applications. The limit value has been lowered from 1%. Such mixtures must carry the warning: "Contains methylisothiazolinone. May cause an allergic skin reaction." However, the concentration of this compound in cosmetics is already regulated and has been reduced in previous years, while the new standard appears to affect household detergents.

Further, as the regulation does not include rules for disposal, many manufacturers and distributors are adhering to the most restrictive interpretation, which is to have all products labelled according to the former version withdrawn from the market and replaced with the correct ones by 1 May 2020.

Cosmetic claims

Consumers of cosmetics have become increasingly demanding in recent years, while the call for high-performance cosmetics with safe, clean, free-from and green ingredient lists has intensified.

Based on Article 20 of the EU Regulation on Cosmetic Products (1223/2009), EU Commission Regulation 655/2013 established an EU harmonised common criteria in order to assess whether the use of a claim is justified.

In this regard, on 3 July 2017, the Sub-working Group on Claims of the European Commission published a technical document on cosmetic complaints. The document provides guidance for the application of EU Commission Regulation 655/2013, which lays down criteria for the justification of claims used in cosmetic products:

- Annex I provides a detailed description of the common criteria established by EU Commission Regulation 655/2013, including illustrative and non-exhaustive examples of claims.
- Annex II provides for best practices specifically related to the type of evidential support used for the justification of cosmetic claims.
- Annex III provides guidance for the application of the common criteria established by the regulation to free-from claims, including illustrative and non-exhaustive examples.
- Annex IV provides guidance for the application of the common criteria established by the regulation to specific hypoallergenic claims.

In particular, with regard to free-from claims, the 'fairness' criterion "should not be allowed when they imply a denigrating message, notably when they are mainly based on a presumed negative perception on the safety of the ingredient (or group of ingredients)".

The document clarifies that: "Certain parabens are safe when used in accordance to Regulation (EC) No 1223/2009. Considering the fact that all cosmetic products must be safe, the claim 'free from parabens' should not be accepted because it is denigrating the entire group of parabens."

In view of the above, many products in circulation would appear to be subject to legal penalties.

Annex III and IV entered into force on 1 July 2019, but the response of the national authorities is still being awaited. WTR

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