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Food labelling: Regulations and Public Health implications

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Abstract

Legislators have implemented policies to improve food labelling to protect consumers and to make the presentation of ingredients and nutritional information more transparent. Proper food labelling allows consumers who may suffer from food allergies or intolerances to know exactly what ingredients a product contains, and it also helps them make more informed health and nutrition choices. This paper deals with the most current European and Italian legislation on food labelling, actions taken in non-EU countries to increase health choices, and the expected impact on Public Health.

Introduction

The first report of food, spice, and drug adulteration was made by Pliny the Elder (*Gaius Plinius secundus,* AD 23-70), whose work "*Naturalis historia*" described merchants' wrongdoing and suggested methods to reveal these frauds, which at the time were considered more of a commercial than of health threat.

Starting in the 17th century, parchments and plates were tied to the neck of champagne bottles and were the direct forerunners of today's food labels. The first monochrome labels applied to alcoholic beverage containers appeared in the 18th century, bearing the manufacturer's name, the quantity and the quality of the content. New technologies gave rise to the first colour labels in the early 20th century, which were appreciated among the wine and liquor collectors of *Belle Époque* Paris, since labels had previously been produced by only a limited number of local printers. The goal of this early labelling was to market the food or drink product through captivating graphics rather than to protect the consumer.

In Italy, the fight against fraudulent foodstuffs began in earnest in the 1950s. Today, offenses such as food adulteration or counterfeiting are punishable by the Criminal Code as crimes against public

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safety, public economy, industry and commerce. The growing volume of food produced in one country and sold in another has increased the variety of available products, especially those containing multiple ingredients (1). Moreover, new storage and packaging technologies allow for greater shelf life, and consequently benefit from an unbounded distribution chain. This is the case, for example, for food produced by multinational companies that generally have patented recipes and sell the same products all over the world. For this reason, food labelling plays an increasingly important role for the correct identification of foods.

In 1978, the European Economic Community (EEC) issued a specific directive concerning food labelling for the first time (2). In 1989, an EEC directive laid down general provisions to regulate the labelling of prepacked, non-prepacked and unpacked food for sale (3). The latter was adopted by Italy in 1992, with the issuance of Legislative Decree no. 109/92. This cross-regulation, applicable to all foodstuffs, led to various sectorial rules for specific types of foodstuffs, including beef (4, 5), oil (6) and wine (7).

In 2000, the European Parliament issued its first specific directive (8) aimed at aligning the laws of member states (MS) on the labelling and presentation of foodstuffs. Finally, to make homogeneous the content of food labels across the 28 member countries, Regulation (EU) No. 1169/2011 was issued and fully applied as of 13 December 2014, with the exception of the introduction of the mandatory nutrition declaration, which came into effect 13 December 2016. This legislation is intended to protect and support consumers in making informed food choices with respect to nutritional value and the most common allergenic substances. The global issue of food allergies is the legislators' priority, as reflected by various Public Health interventions (9, 10) aimed at protecting allergy sufferers. This includes the adoption of an effective food labelling system that renders clear and accurate information easily understandable for consumers (11). Although sector legislation is currently harmonised among EU countries (12), foods are not labelled in the same way internationally. Food exports to non-EU countries are subject to international trade obligations, to the importing country's restrictions and authorisations, and to complex customs procedures which include identity, material control and sampling for analysis, as well as a document check to verify health and export certificates issued by relevant authorities.

Regulation (EU) No. 1169/2011: general aspects

Food labelling identifies any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food; it must appear on any packing, document, notice, label, ring or collar accompanying or referring to such food (13) and provides useful information about nutritional value and food safety, including identifying substances which could cause an allergic reaction in the consumer.

Scope and responsibility

The new Regulation is applied to food businesses at all stages of the food chain (from production to marketing) and to all foodstuffs intended for consumers, including meals provided by catering brings the food to market, including the importer, if the product originates from a non-EU country.

Mandatory indications

Food information must be clear and understandable to assist consumers who want to make better-informed food and dietary choices. It must not mislead the consumer, particularly by reference to characteristics or properties not found in the food.

Mandatory indications include:

• the name of the food (accompanied, where appropriate, by particulars as to the physical condition or any processing it has undergone, e.g., "powdered", "frozen", "refrozen", "freeze-dried", "concentrated", "smoked");

• the list of ingredients (by descending order of weight);

• the net quantity (expressed in litres, centilitres, millilitres, kilograms or grams);

• the instructions for use and, if necessary, the name and address of the Food Business Operator (FBO) and the nutrition declaration;

• the date of minimum durability or the "use by" date;

• the date of freezing, in the case of frozen food.

Directive 2011/91/EU also made an indication of the product's lot mandatory (14).

In the case of foods that have been frozen before sale and which are sold defrosted, the name of the food shall be accompanied by the designation "defrosted", with the exception of ingredients present in the final product, foods for which freezing is a technologically necessary step of the production process and foods for which the defrosting has no negative impact on the safety or quality of the food.

Foods treated with ionising radiation shall bear the indications "irradiated" or "treated with ionising radiation".

Additional compulsory information must be provided for specific types of food matrices, including those containing sweeteners, high levels of caffeine and ammonium salts, and beverages containing more than 1.2% by volume of alcohol for which the actual alcoholic strength must be expressed.

Mandatory indications must appear in a language that is understandable to the consumer of MS where the food is marketed and must be clearly visible, legible and, where appropriate, indelible. Indications shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

In addition, the same information must be provided to consumers who purchase food online (15).

Among the novelties contained in the Regulation, the lack of mandatory indications for data on producers and food establishments addresses represents an important topic, considering that these obligations were in force with the previous regulation system in Italy. Consequently to investigative actions and proceedings, according to the Treaty on the Functioning of the European Union, the Italian Government requested to maintain preexisting national rules despite the harmonized regulation, based on motivated and justified needs, including those related to the protection of public health. In September 2017, the Italian Council of Ministers approved the Legislative Decree (16) which obliges to indicate data on producers implants or packaging factories, for all prepacked foodstuffs intended for the final consumer.

This measure provides a transitional 180 days period from publication in the Italian Official Gazette, useful to sell out already printed labels and food products already placed on the market before the entry into force of the Decree. The reintroduction of the preexisting obligation in our country is useful to provide more detailed information to consumers, including a complete traceability, and to make official controls easier. The Italian Ministry of Agriculture and Forestry Policies - Department of Central Inspectorate for Quality Safeguarding, foodstuff anti-fraud and agricultural products - is responsible for control and enforcement of penalties.

Non-prepacked foods

Foods packed at retail at the consumer's request or prepacked for direct sale are called "non-prepacked". Typical examples include products displayed in gourmet shops, rotisseries, and bakeries, where the buyer directly

chooses which item to purchase and the FBO, generally after portioning, packages the food and sells it to the final consumer.

In contrast, prepacked food refers to any single item for presentation to the final consumer and to mass caterers which consists of the food and the packaging into which it was put before being offered for sale, whether this packaging encloses the food completely or only partially, such that the contents cannot be altered without opening or changing the packaging. Prepacked foods must be accompanied by mandatory indications concerning any ingredients that may cause allergies or intolerances.

Exemptions

Regulation (EU) 1169/2011 allows for exemptions under three main categories: the list of ingredients, the nutritional declaration and the obligation to indicate the origin of raw materials for specific food categories.

It is not mandatory to provide the list of ingredients for fresh fruit and vegetables, carbonated water, fermentation vinegars derived exclusively from a single basic product, dairy products, such as cheese, butter, cream and fermented milk (to which no ingredients have been added other than lactic products), and foods consisting of a single ingredient, provided that the name of the food is identical to the denomination of the ingredient or allows one to clearly determine the nature of the ingredient.

Foods that are exempted from the mandatory nutrition declaration requirement include: unprocessed products that comprise a single ingredient or category of ingredients; waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings; herb, spices or mixtures thereof; salt and salt substitutes; table top sweeteners; coffee extracts and chicory extracts, whole or milled coffee beans and whole or milled decaffeinated coffee beans; herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea or tea extract, decaffeinated instant or soluble tea or tea extract, which do not contain any added ingredients other than flavouring which does not modify the nutritional value of the tea; fermented vinegars and substitutes for vinegar, including those where the only added ingredients are flavourings; flavourings, food additives, processing aids, food enzymes, gelatin, jam setting compounds, yeast, chewing-gums; food in packaging or containers, where the largest surface has an area of less than 25 cm^2; food, including handcrafted food, directly supplied by the manufacturer in small quantities to the final consumer or to local retail establishments directly supplying the final consumer.

Recently, Italy's Ministry of Economic Development (MED) clarified that the obligation to indicate the origin of raw materials for milk and milk products does not apply to certain FBOs. These include those that provide ingredients containing milk used in the processing of prepacked dairy products, and to those using milk and milk products manufactured abroad as ingredients in products manufactured in Italy. These cases are exempt because the milk products are not intended for the final consumer and because of the principle of mutual recognition, which makes it impossible to extend an obligation on producers resident outside the national territory (17, 18).

Protection of allergic or intolerant individuals

The Regulation makes it mandatory to indicate any ingredient or technological adjuvant that causes an allergic reaction or intolerance used in the manufacture or preparation of a food and which is still present in the finished product, albeit in an altered form.

Information on the presence of such substances must be affixed at a point where they are clearly visible, legible and, if necessary, indelible. Moreover, the designation of such substances must be highlighted in a

font that is distinct from the one used for the other ingredients, for example by size, style or background colour.

The same Regulation identifies the following substances or products based on these substances as causing allergic reactions or intolerances: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk and milk products (including lactose), nuts (e.g., almonds, hazelnuts, walnuts, pistachios), celery, mustard, sesame seeds, lupins, molluscs, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 sulphurous anhydride and sulphites in concentrations above 10 mg/kg or 10 mg/litre.

Discussion

Food safety rules apply in all areas of the supply chain, which demonstrates that the consumer protection objective is a priority for the European Parliament. The White Paper on Food Safety and the main Regulations that have evolved over time have laid the foundation for implementing and perfecting a control system ranging from primary food production to food contact materials, from the traceability obligation to the rapid alert system for foods that need to be recalled or withdrawn if they are considered unsafe or not in compliance with legislation (19-21).

Regulation 1169/2011 on food labelling obligations introduces important consumer protection measures, and guarantees uniformity and transparency between member states. These procedures could also positively affect certain aspects of home hygiene, helping peoples in the correct management of foods (22).

While the consumer benefits from better information, FBOs have greater obligations and, consequently, official controls on food safety (23) must be conducted in a uniform and targeted way to enforce compliance with legislation. After Regulation 1169/2011 entered into force, FBOs had to modify their documentation and management practices. Adapting to the new regulatory regime has been easier for large food businesses that already have staff dedicated to hazard analysis and critical control points processes than for small businesses, which have largely turned to external consultants. The main problem is that the Regulation is, in some aspects, generic and does not specify how a business might comply with the new legislation. The Regulation states what is practically mandatory, but does not always prescribe a process to resolve the non-compliance issues. In Italy, the Ministry of Health (MH) has recently clarified responsibilities for indications warning of the presence of allergens in food imported from elsewhere within the European Community (24), declaring that the FBO is responsible for food information and for ensuring the presence and accuracy of this information. In particular, any FBO providing ready-to-eat foods within a facility, including restaurants, canteens, schools, hospitals and catering services, must supply the final consumer with the required information.

This information is to be placed on menus, registers, signs or other equivalent systems, and must be visible to the consumer where he can easily access it. Since electronic systems may not be available to the whole population, they are not suitable for this purpose.

The obligation is also fulfilled when the FBO posts a message in a clearly visible place that "information on the presence of substances or products that cause allergies or intolerances are available by contacting the staff," and when the FBO places a notice on the menu or register a statement that "for any information on substances and allergens you can consult the relevant documentation that will be provided on request by the staff".

In both cases, it is necessary that compulsory information be found in appropriate written documentation that is easily

accessible to consumers and food inspectors (25). The FBO can choose the most appropriate way to inform consumers that suits the business' size and organisation. In preparing the statement, the FBO is free to indicate the presence of allergens in relation to the individual preparations according to the manner that it deems most appropriate.

The FBO therefore has wide discretion in how it complies with the legislation, and official control procedures must take into account this flexibility. Other critical issues are:

• the lack of specific disciplinary sanctions for violations. In Italy, the MED has provided guidance on the application of sanctions related to violations of the provisions of the Regulations and disseminated the concordance tables (26). This is a useful link between pre-existing state legislation (27) and the new Community provisions. Among the administrative penalties, non-compliance with compulsory indications imposes a penalty of up to €9,500; the omission of the ingredient list and designation imposes a penalty of up to €3,500; and the omission of the indication of the country of origin or place of origin imposes a penalty of up to €18,000 in the event that its omission may mislead the consumer;

• the obligation of the nutrition declaration for FBOs that provide food to the final consumer. In this regard, the MED, by common accord with the MH, has issued application instructions (28) on foods for which the nutrition declaration obligation does not apply, with particular reference to small and medium-sized enterprises (29).

Many observers agree that, despite investments that FBOs have made to comply with the provisions of the Community Regulation, the changes have not led to significant variations in the choices and behaviour of consumers (30). There have been a number of attempts to improve labelling over time, even in countries where the Regulation does not apply. This is the case with the US Food and Drug Administration (31), which has often emphasised the nutritional claims and their potential for causing confusion, and institutes that have independently promoted experiments such as the use of emolabelling (the use of emoticons to provide health information) regarding the calorie count of specific foods (32). Affixing the "smiley face" in proximity to the nutrition label appears to increase consumers' awareness of the nutritional content. The use of "traffic lights" was also developed to increase consumers' awareness of healthy food choices (33), as well as more complex methods (e.g., five different colours on the label) to distinguish the different characteristics and the nutritional quality of specific food matrices (34-37). Nevertheless, some marketing strategies can encourage the purchase of unhealthy foods (38), especially in disadvantaged socio-economic communities (39).

Conclusion

The European Parliament has introduced specific, harmonised sectorial legislation governing food labelling that has brought many benefits to consumers, despite some initial difficulties in applying the new criteria. Some of these difficulties are, unfortunately, common to other European directives regulating the food sector, which determine practical issues for the protection of health (40-43). A global policy (44) to standardise food labelling internationally would allow consumers to safely consume foods daily from all over the world.

Riassunto

Etichettatura dei prodotti alimentari: aspetti normativi e ricadute in Sanità Pubblica

Nel corso degli ultimi decenni sono state adottate politiche volte al miglioramento dell'etichettatura degli alimenti e a rendere la presentazione dei valori nutrizionali e degli ingredienti più trasparente. Una corretta

etichettatura degli alimenti può, infatti, consentire a consumatori che soffrano di patologie allergiche o di intolleranze di conoscere quali ingredienti un prodotto alimentare contenga aiutandoli a compiere scelte più salutari. Il presente articolo prende in considerazione le principali normative comunitarie e nazionali riguardanti le modalità di etichettatura di alimenti, gli interventi già attuati in Paesi extra-UE per incrementare scelte salutari, e le ricadute attese in termini di Salute Pubblica.

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