Re-determination of the primary shelf-life of food products: what are the guarantees for the consumer?

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Abstract

Except in rare cases, the determination of the shelf-life of food products is left up to the food business operator. The extension of this period, which for years has been the subject of debate among the various actors in the food chain, has become a topic of fundamental importance also following the recent economic/financial, environmental, and health crises, which have had an inevitable impact on consumption and food waste. While there is no requirement to indicate durability for some categories of food products, for example, those not directly intended for consumers, this debate has raised questions and perplexities about the potential re-evaluation of the origin conditions established by the manufacturer, particularly when it comes to maintaining the guarantees for the consumer in terms of health and hygiene. In addition, the increasing consumer demand for accurate information has prompted the European authorities to request a public consultation on the actual understanding and perception of the mandatory terms on labels such as *use by* or *date of minimum durability* of a food, provided for by Article 9 of Regulation (EU) No. 1169/2011, often not correctly understood, which can assume great significance in the application of rules to reduce food waste. In this regard, it is useful to remember that the recent measures adopted by the European Union legislator, together with the case law of recent years, have led the judges of merit to comply with the principles and requirements of food safety laid down since 2002 in Regulation (EC) No. 178, thus paying greater attention to the analysis, assessment, and management of the risk of the entire production chain. The purpose of this work is to provide technical-legal elements to encourage a possible extension of the shelf-life of food products while ensuring the safety of consumers.

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Introduction

The shelf-life of a food product is conditioned by certain factors such as the characteristics of the food (perishable, heat treatments, additives) and new materials and packaging systems (Tiecco, 2001). In most cases, it is originally determined by the manufacturer, who also uses predictive microbiology in relation to the behavior of certain microbial populations according to the intrinsic factors [*e.g.* pH and water activity (aw)], extrinsic factors (*e.g.* temperature and gas atmosphere) and implicit factors (*e.g.* interactions with competing background microflora) to determine which pathogenic and spoilage microorganisms may grow in the food during storage until consumption (EFSA, 2020). However, in other cases, such as non-prepacked products (exposed meat, semi-finished products, *etc.*) shelf-life can be established by food business operators (FBOs) during post-production processing (Ambanelli, 2021). The concept of *shelf-life* for prepacked food is clearly explained in Regulation (EC) No. 2073/2005, which sets the legal criteria with which FBOs must comply throughout the shelf-life (European Commission, 2005), while Regulation (EU) No. 1169/2011 (European Commission, 2011)) clearly defines the *date of minimum durability* of food as the date until which the food retains its specific properties when properly stored. This is not the case for *use by* foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health (European Commission, 2011). Therefore, this study aims to consider the possibility of re-evaluating the primary shelf-life of food products by reviewing the legislative and technological aspects, and considering commercial, social, and market needs without compromising the guarantees for consumer safety.

Re-determination of shelf-lives as an intervention strategy against food waste

Although new possibilities for a proper and safe extension of

the shelf-life of pre-packed food products placed on the market have been studied for years, it was only recently that the European Food Safety Authority adopted a scientific opinion on hazard analysis approaches for this procedure, even if it refers to small retailers and only for food donations (EFSA, 2018).

With the publication of numerous studies on shelf-life, the same European Commission had established that fresh meat – including preparations and minced meats – had to be frozen without undue delay in an establishment approved by the Community according to the appropriate procedure and using adequate equipment such as a freezing tunnel and before the expiry date (EFSA, 2021). Subsequently, the Union legislature allowed the freezing of meat from domestic ungulates and that of poultry and lagomorphs even at the retail level for redistribution for food donations (Delegated Regulation (EU) No. 2021/1374) (European Commission, 2021). Therefore, freezing is permitted for meat with expiry dates per Regulation (EU) No. 1169/2011 (European Commission, 2011), before expiry and under the following conditions: without undue delay to a temperature of -18°C or lower and ensuring that the date of freezing is documented and indicated on the label or by other means, with the exclusion of meat that has already been thawed (European Commission, 2011).

Finally, the Ministry of Health given the continuing economic difficulties of FBOs, on 5 April 2022, issued a derogatory measure until further notice on the re-determination of the shelf-life of food products (Italian Republic, 2022b).

Surplus and food waste

Every year in Europe, an increasing amount of food in good hygienic and edible conditions is lost along the agri-food chain (about 89 million tons - 179 kg *per capita*), mainly during distribution, retail, and consumption. In Italy, there are 5,5 million tons of foodstuffs to be recovered each year, for a value of EUR 12.3 billion, and more than half of these foodstuffs are lost between producers and traders (58%). Of all surplus food only 6.4% is given to non-profit organizations (food banks, charities), 1.1% goes to secondary markets (discount stores), 11.5% is turned into fertilizer or animal food and the rest is destroyed (Micheli, 2012). It has also been estimated that about 10% of the 88 million tons of food waste generated annually in the European Union is linked to the date on the label (European Commission, 2018), and 18% of people in Europe do not fully understand the wording *best before* and how it differs significantly from the *use by*, thus supporting the recommendation of introducing a double shelf-life (*best before* and *use by*) (Italian Republic, 2016a). On 8 March 2023, the European Commission presented a proposal for adding the wording *often good after* to the label to prevent useless waste (change of the Regulation (EU) No. 1169/2011) (European Commission, 2011).

Italian Law No. 166 of 19 August 2016 and subsequently Article 26-ter of Law No. 25 of 28 March 2022 (Italian Republic, 2016b, 2022a) formalized the measures to support producers and combat waste together with the introducing provisions on food donations and distribution for social solidarity purposes. For both food surpluses and food waste products that are close to their expiry date can be used, as well as those that are unsold for various other reasons (alterations in packaging, errors in production planning, *etc*.) or not served. This applies to both highly perishable products labeled *use by* and those labeled *best before* as long as the primary packaging is intact and they have been stored appropriately (Italian Republic, 2016b). Alternatively, they may be further processed to produce products intended for animal consumption together with other agricultural products, raw materials, and foodstuffs like fresh milk, fresh meat, fish, *etc*.). A uniquely Italian anomaly, worth mentioning, is the obligation to set the expiry date for fresh pasteurized milk and high-quality fresh pasteurized milk at six days after heat treatment, unless the producer indicates a shorter expiry (Italian Republic, 2004). This decision is contrary to Regulation (EU) No. 1169/2011 on the responsibility of the producer and the mandatory information provided to the consumer and the principle of free movement of goods according to the Treaty on the Functioning of the European Union, with all the consequences in terms of food waste (Dongo, 2019).

Food safety requirements

Regulation (EC) No. 178/2002, in Article 14, establishes when foodstuffs should be considered unsafe: i) injurious to health; ii) unfit for human consumption (European Parliament, 2002).

However, it is evident that the FBOs, when re-determining the original shelf-life of the product, must ensure that the food placed on the market is safe by taking all the necessary precautions to prevent specific adverse health effects for the consumer and to guarantee a product conforming to the set standards. The same article sets out the criteria for determining whether a food is to be considered unacceptable for human consumption, as in the case of those products with defects/alterations which, while not entailing a harmful effect, cannot be considered edible due to altered organoleptic characteristics or merely because they look repulsive (European Parliament, 2002).

Warranty and liability for operations

The European Union legislator has designated the FBO as the natural or legal person responsible for managing the food business under its control, at all stages of production, processing, and distribution through preventive measures and instructions for proper use (European Parliament, 2002). Consequently, it is the producer/manufacturer himself who sets the criteria for establishing the durability of a food product, as we are reminded by the Ministry of Health (Italian Republic, 2010a). It is obvious, however, that a food with a predefined history and commercial life cannot be considered marketable indefinitely as it is, disregarding the microbiological and shelf-life guarantees issued by the FBOs from time to time. Therefore, the FBOs establish the shelf-life based on the product's history, the available scientific literature, and their technological knowledge, above all in the case of processed products, for which they carry out specific laboratory and sensory investigations into the appropriate implementation of food safety plans.

The revaluation of unsold products and commercial returns

The withdrawal from the market of unsold foodstuffs, close to their expiry date, is a customary practice in the food industry and has become increasingly widespread in recent years also due to the recurring economic crises that inevitably lead to a reduction in demand and an increase in unsold goods (Albertini *et al.,* 2011). This significant practice is undertaken not only by the producers or

distributors but also by other operators who purchase these products directly from large-scale retail trade chains and then send them back if they fail to sell. A large portion of these unsold returns follow a compulsory path after being classified as or downgraded to, either waste or raw material to be used for animal feed (Albertini *et al.,* 2011). Next to this category of foodstuffs, we also find what are known as commercial returns, which are sent back due to defects in presentation (*e.g*. irregularities in labeling, packaging), and which, during the post-collection assessment, are considered in the same way as pre-packaged foodstuffs that are in any case complaint from an intrinsic point of view, except in the case of omitted or incorrect indication of substances potentially causing allergies and/or food intolerances (Italian Republic, 2017).

The sorting and re-assessing of returned foodstuffs mostly still takes place in the same production plants, with due authorization, although there is an increasing number of separate approved establishments identified as autonomous repackaging plants (re-wrapping). Clearly, FBOs that engage in the recall and reconditioning of food products must provide evidence of organoleptic characteristics, shelf-life, and compliance with microbiological criteria before marketing the 'new' food product with new durability (Italian Republic, 2009). When withdrawing and revaluing a food product produced by a third party, FBOs must obtain the formal guarantee of possible reuse and thus the unconditional final use.

The necessary checks to evaluate the suitability and compliance of the products

Considering the common health and commercial objectives of the food business, such as the protection of the end consumer and the guarantee of a safe product of acceptable quality, it is clear that, the vast heterogeneity of the food products involved, with or without individual consumer information and specific preservation methods, requires a significant depth of skills and knowledge, as befitting of a professional FBO.

In this context, the scientific bibliography of sector studies conducted for the various products (shelf-life studies, challenge tests), together with analytical data, descriptive-quantitative sensory analyses as per ISO 20613 (2019) (panel tests), and the use of food safety information systems (ARS Alimentaria) (Daminelli, 2012) is particularly important.

Re-evaluation is implemented in compliance with food hygiene and safety procedures that are part of the company's food safety plan based on Hazard Analysis and Critical Control Points (European Parliament, 2004), together with the verification of the process and food safety criteria of Regulation (EC) No. 2073/2005 as amended by the implementing ministerial guidelines (European Commission, 2005).

To a greater extent in perishable foodstuffs and a lesser extent in non-perishables (Italian Republic, 1993), the main parameter for assessing microbiological suitability is aw. Meat products, generally vacuum-packed or in modified-atmosphere packaging, such as fermented sausage and those made from a single piece of meat (ham, *coppa*, *bresaola*, *etc*.), whether short, medium, or long maturation, are considered stable and microbiologically safe due to the simultaneous combination of different factors including aw, pH, relative humidity time/temperature, NaCl percentage, type of microflora, processing technique and in some cases preservative (Tiecco, 2001). Significant microbial multiplication hardly ever occurs in this type of product due to the low aw value, even if present in origin. In a packet of sliced raw ham, aw <0.92 does not allow the development of pathogens, and prolonged shelf-life further lowers this value with the consequent dehydration of the product (Cantoni, 2006). If present, coagulase-positive *Staphylococcus aureus* can also develop at temperatures <12°C, but toxins can only be produced at concentrations of 10^5 and, in any case, even with an aw >0.88, it needs decidedly more oxygen than that normally available in the packages (Iacumin *et al.,* 2018). For this type of product, greater attention must instead be paid to chemical degradation (oxidation), which occurs even in the absence of oxygen at the origin, due to the very slow and inevitable penetration of this gas into the packaging. It is essentially oxidation that determines the organoleptic deterioration of the food product, lowering its acceptability threshold, which occurs more in sliced meats due to the greater surface area exposed and because of the oxygen remaining in the packaging even if in minute quantities (Romagno, 2011). The same high-pressure processing treatment, which can significantly prolong the microbiological shelf-life of food (Bonilauri, 2018), can cause chemical changes due to the high temperatures reached (Pezzuto *et al.,* 2021). Therefore, oxidation tests for peroxides and free radicals (thiobarbituric acid <1-1.5) and internal quantitative descriptive sensory analyses could be useful for a complete and accurate assessment of the suitability of such products (Cantoni, 2012).

In the case of cooked meat products, microbial contamination can also be of technological origin and is almost exclusively lactic acid altering bacteria, which can lead to sensory defects such as discoloration, fat exudation, viscosity formation, white patina, and slime with deterioration and reduction of shelf-life (Cantoni, 2011). For its part, the industry has succeeded in prolonging the economic life of these products through the use of bio-protective cultures that inhibit the development of both pathogens and indigenous lactobacilli, along with optimizing packaging that eliminates oxygen residues, thus minimizing product oxidation (Cantoni, 2011). Some meat products, such as pre-cooked Italian *zampone*, are deemed equivalent to cured products in terms of their stability over time; it is sufficient to check the shelf-life studies conducted by the manufacturer and ensure that the original packaging remains intact (personal observations). Also in the case of milk-based products, the presence of molds and yeasts in hard cheese gratings is due to upstream technology and is facilitated by a high aw which also favors the growth of other bacteria (Rondinini, 2008). For highly perishable fresh products, it is instead the microbial population already present at the time of manufacture that influences their evaluation (Tiecco, 2001). Finally, it is worth mentioning the importance of vacuum packing, which is more protective because it extracts the residual oxygen present - though even in modified atmosphere packaging, a small percentage of the residual oxygen is always present - and thus achieves greater stabilization.

Non-prepacked commercial food products and semi-finished products

There are different conditions for food products for which, during marketing, there is no obligation to indicate durability: i) non-prepacked items (*e.g.* fresh meat on display); ii) rind milk products (*e.g*. cheeses); iii) whole cured meats (*e.g*. salami, coppa); iv) cured raw ham on the bone. Alongside non-prepacked products, we find semi-finished products, *i.e.* products intended for further processing by FBOs. These products, briefly illustrated in Article 8 of Regulation (EU) No. 1169/2011 (European Commission, 2011) - on B2B operations - are better described in Legislative

Decree No. 231/2017, which reiterates the non-compulsory nature of displaying the *use by* and the *date of minimum durability* (Ambanelli, 2021). This is not an oversight on the part of the legislator, who establishes that the FBOs who use these products as ingredients in food processing are in any case obliged to ensure their suitability for processing, both in terms of safety and quality. Although not compulsory, it is nevertheless common for suppliers to attach durability labels voluntarily, often copying the forms of the date of minimum durability of a food (Ambanelli, 2021).

Official controls

Whilst the FBOs are the main players in the implementation of food laws and regulations, the health authority serves as a control and guarantee body. Indeed, FBOs are responsible for preparing and applying self-checking procedures and carrying out studies on the shelf-life of their products to establish durability and compliance with the microbiological criteria laid down in Regulation (EC) No. 2073/2005 (European Commission, 2005); while it is up to the competent authority to verify the adequacy of the procedures implemented by the FBOs and the proper management of possible food hazards, through surveillance to ensure that the requirements of food law are fulfilled at all stages of production, processing, and distribution (European Parliament, 2002).

For the re-determination of the commercial life of a foodstuff subject to reworking and/or processing in particular, the shelf-life of a product is determined according to the intrinsic qualities of the food (pH, aw, *etc*.), the processing conditions, the type of packaging as well as the storage conditions (Italian Republic, 2009).

Normally, the shelf-life of a food product is determined using predictive microbiology and laboratory inoculation tests (challenge tests), studies on the stability of the product (technological microorganisms, pH, and aw parameters), and also studies on the activity of spoilage microorganisms (yeasts, molds, sulfite-reducing clostridia). The shelf-life is accompanied by indications on how the food should be stored and consumed (instructions for use) (Daminelli, 2012).

If the shelf-life is re-determined directly in the same production plant, it is easier for FBOs to perform the risk analysis and studies required for the shelf-life and durability of the new product, as they are already familiar with the food history. However, if these operations are undertaken at stand-alone repackaging or processing plants, greater precautions are required with a particular focus on managing the traceability of batches of different origins, especially if they are not homogeneous (*e.g*. returns management) (Albertini *et al.,* 2011).

Technical and legal considerations

The re-determination of the shelf-life of foodstuffs at or near their commercial expiry date needs to be reconsidered in the light of the latest scientific knowledge and current food legislation, which provide us with specific technical and legal tools and identifies tasks and responsibilities at all stages in the food's economic life (manufacture/production, marketing/sales). Undoubtedly, in terms of impact on the consumer's health, fundamental aspects include the verification of the characteristics of the product and the assessment of the risk associated with the microbiological evolution of the food.

In defining the date of minimum durability of a foodstuff, the legislator only mentions the specific characteristics without referring to the wholesomeness of the product, for which there are no legal safeguards, including no administrative sanctions (Italian Republic, 2017). The Court of Justice with sentence No. 229/2001 has, incidentally, admitted that foodstuffs with expired date of minimum durability may be kept on the market with additional wording to describe this circumstance (Forte and Marinuzzi, 2018). The situation is different for highly perishable foodstuffs, which once expired may represent a consumer health hazard: such foods may only be processed following Regulation (EC) No. 852/2004 before the expiry date (Andreis and Andreis, 2011).

Even though it is a purely commercial aspect, it is understood that even products marketed after the expiry of the date of minimum durability must maintain a certain quality profile, regardless of the guarantees of methods of preservation. This information appears to be in line with the principles of fair trading established by our legal system and European Union food law, which aim to protect the interests of consumers also through the obligation to provide the necessary information (Micheli, 2012). In the case of *use by*, the shelf-life of a product should never be longer than whichever is the shortest between the sensory shelf-life and the safe shelf-life. The first concerns change in quality, due to microbial growth, and the second concerns food safety (EFSA, 2020).

Unfortunately, for many years, national Italian case law viewed all violations of the expiry of pre-packed products as criminal offenses, mostly falling under the offenses set out in Article 5 of Law No. 283/1962 or the crimes of negligence set out in Articles 444 and 452 of the Penal Code (placing on the market or distribution for consumption of foodstuffs dangerous to public health) (Correra, 2019). It was only recently that several rulings addressed this issue in an interdisciplinary manner, confirming principles that are now well established in our legal system, with the Supreme Court itself reiterating that failure to respect the expiry date of a foodstuff does not automatically constitute a criminal offense without proof of alteration or non-genuineness, but may be considered merely an administrative offense (Pacileo, 2012).

The legislator's exception *unless the act constitutes a criminal offense*, stated in the provisions for sanctioning failure to observe the expiry date, often leads to confusion and misinterpretations because the evidence refers to the diagnostic tests on the expired product (Correra, 2019). Sentence No. 17063/2019 specifies that the marketing of packaged foodstuffs that require a best-before or use-by label after their expiry is deemed an administrative offense unless it is specifically proven that the foodstuffs are in a poor state of preservation (Italian Republic, 2019).

Currently, unless the act constitutes a criminal offense, the law foresees an administrative fine of between EUR 5,000 and EUR 40,000 (Italian Republic, 2017). This was also supported by the Court of Cassation, Section III, Order No. 26413/13 (Forte and Marinuzzi, 2018), and again, the Court of Cassation Section III (Sentence No. 16108 of 21/04/2018 - hearing on 21 March 2018), and also the Third Section of the Supreme Court (Sentence No. 38841 of 20/09/2016) (Forte and Marinuzzi, 2018). Lastly, it is not deemed a criminal offense to sell a product obtained from returns that are past the date of minimum durability, as this does not necessarily imply a lack of wholesomeness and freshness (Sentence No. 572/2013 of the Court of Varese) (Forte and Marinuzzi, 2018).

Therefore, while it is essential that a criminal offense be established where there is a concrete and existing danger to health, *i.e*. not merely assumed, it is also true that alongside the real harmfulness, there is a formal unfitness for consumption, regardless of the possible hazard to public health.

Conclusions

In relation to the re-determination of the shelf-life of foodstuffs, the aspect that is of most interest and debate remains the recovery and possible re-marketing, for human consumption, of products that remain unsold on the shelves. This - at least for perishable pre-packed products marked with a *use by* label - can only be considered possible after a subsequent technological treatment (European Parliament, 2004). It is worth remembering, however, that FBOs have always sought to recover self-produced foodstuffs: raw hams cured on the bone revealed to have technological defects are used for mince in fresh stuffed pasta mixtures; or edible rinds, offcuts, and other cheese leftovers are collected and sorted for reprocessing in the production of grated cheeses, processed cheeses or as ingredients in more complex foodstuffs. Certainly, the fact that these products may originate from companies only subject to registration under Regulation (EC) No. 852/2004 (European Parliament, 2004), such as retail establishments, generates the need to identify the hypothetical conditions for recovery, reprocessing and resale of such products (Italian Republic, 2010b). In the case of the sale of a product to a third party, with a subsequent re-evaluation of the shelf-life, there is an inevitable transfer of legal responsibility, for the aspects which concern it, from the original producer to the subsequent processor.

By virtue of the above, the re-determination of shelf-life for expired food products must include a careful assessment and management of possible health risks both by the FBOs and by the health authority in charge of official controls (Micheli *et al.,* 2011).

Ultimately, it is up to the FBOs to define under their responsibility the time limit within which the foodstuff can be safely consumed based on adequate risk analysis and appropriate shelf-life tests, and this power, and obligation, is conferred on it by Regulation (EU) No. 1169/2011 (European Commission, 2011).

It is true, that alongside the ultimate objective of ensuring the safety of food produced and placed on the market, a proper understanding of the topic is essential, especially with regard to the sensory shelf-life and safe shelf-life and more generally how long food can be considered fit for human consumption. In this way, all actors involved (FBOs, official control authorities, and consumers) can act properly with the right knowledge and make informed choices.

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