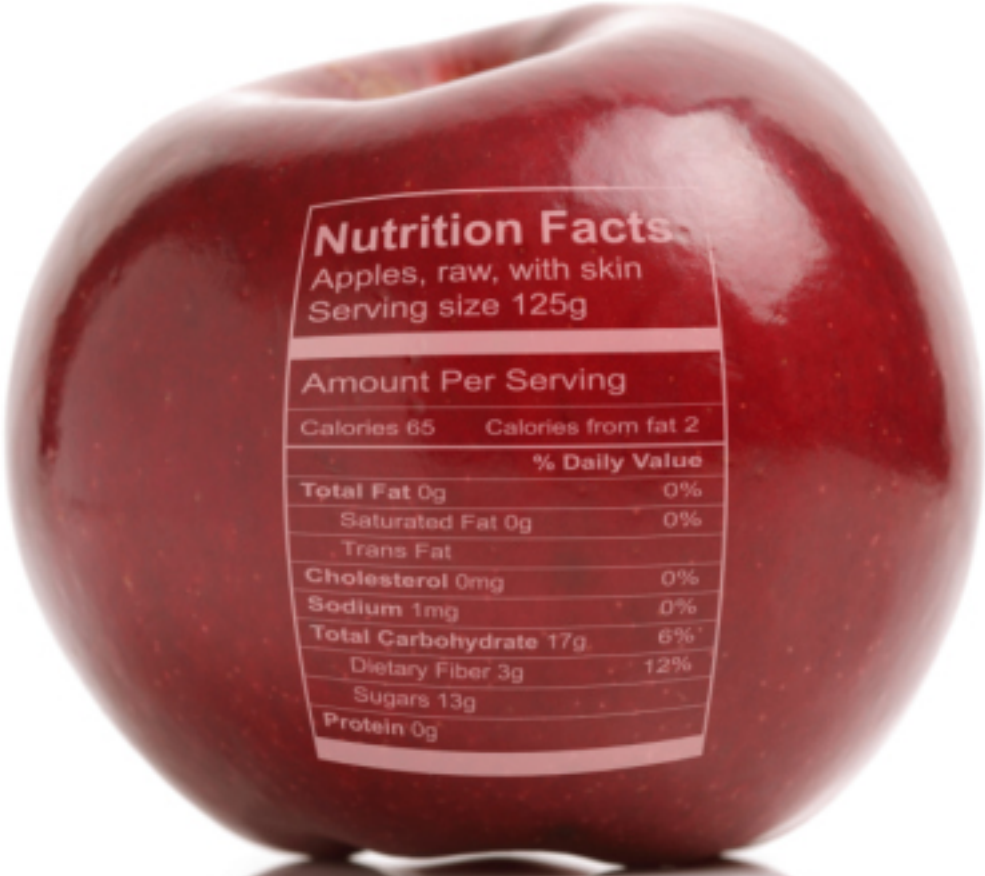
il fatto alimentare

Dario Dongo

The Food Label



Origin, nutrition declaration, ingredients...
All the novelties of the new EU Regulation

This book is for the billion of children, mothers and fathers of all ages who, still today, neither have food and water nor the means to get them.

To those who are concerned about forgotten Billion and provide help with tangible actions.

To anyone who, by reading this book, has contributed to the Horn of Africa aids. And to anyone who, aside from this book, will follow such an example.

Dario

One million and a half children in Somalia are in urgent need of humanitarian assistance, the international community being unable to face such an emergency.

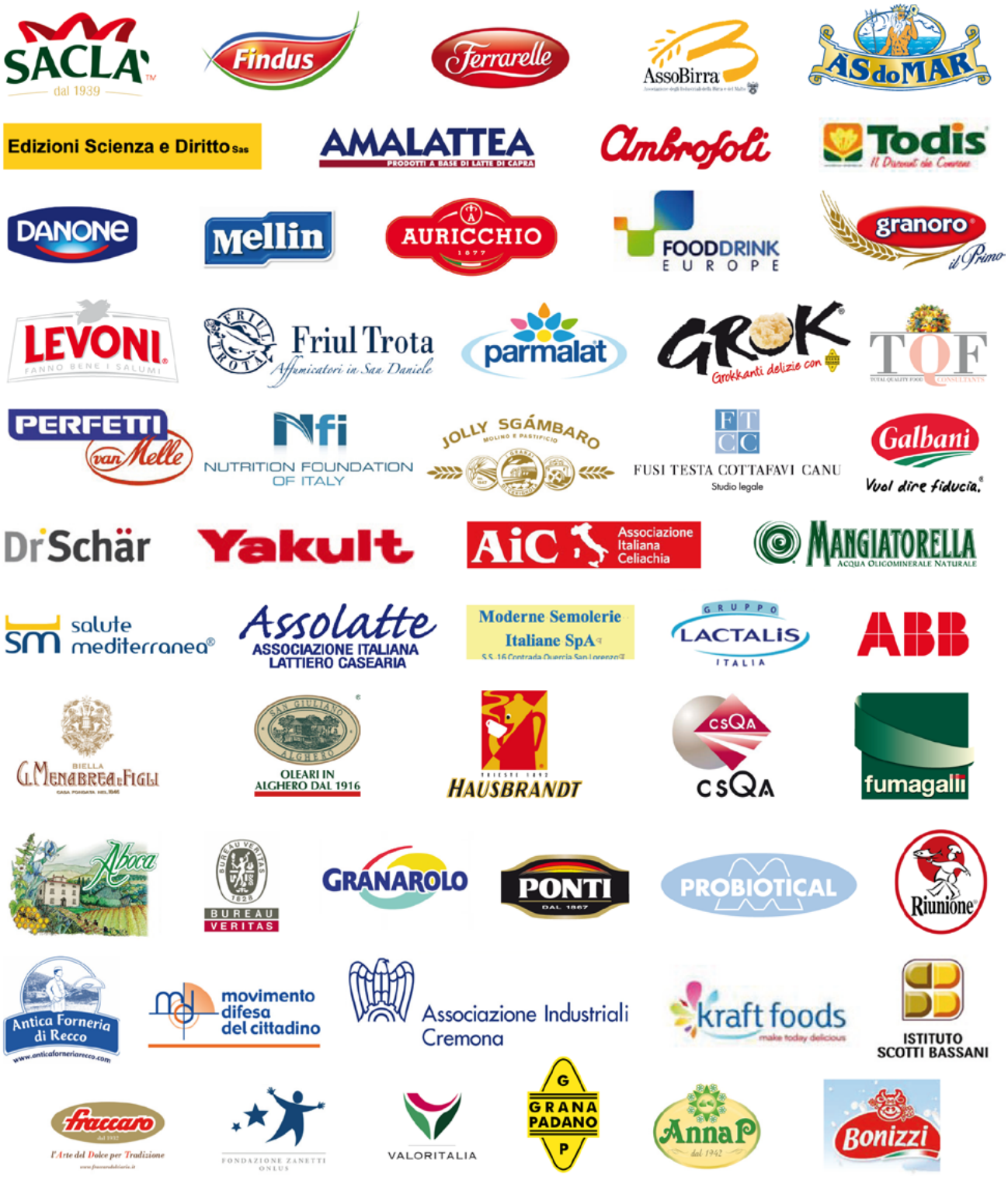
Ilfattoalimentare.it has accepted the proposal of the author to promote donations to the humanitarian aids by publishing the guidebook *"L'Etichetta"*, a 54 pages e-book written by Dario Dongo which illustrates all the novelties of the Regulation (EU) No. 1169/2011 on food information to consumers.

More than 70 operators – businesses, professionals, consultancies, publishers – have welcomed our invitation to support all the initiatives undertaken in the Horn of Africa by *Agire*, *Medici senza Frontiere* and *Oxfam*, raising more than 100,000€. Contributors' brands are reported on page 3 which we consider an "open" space since the crisis is not over yet and we rely on the voluntary contribution of other operators or readers willing to follow the example.

"L'Etichetta" is still *"in progress"* and it is likely to be updated once the European Commission will publish the implementation measures on origin, legibility, nutrition declaration…

Roberto La Pira
November 2011 Director of ilfattoalimentare.it

Special thanks to all those who've joined the solidarity project:



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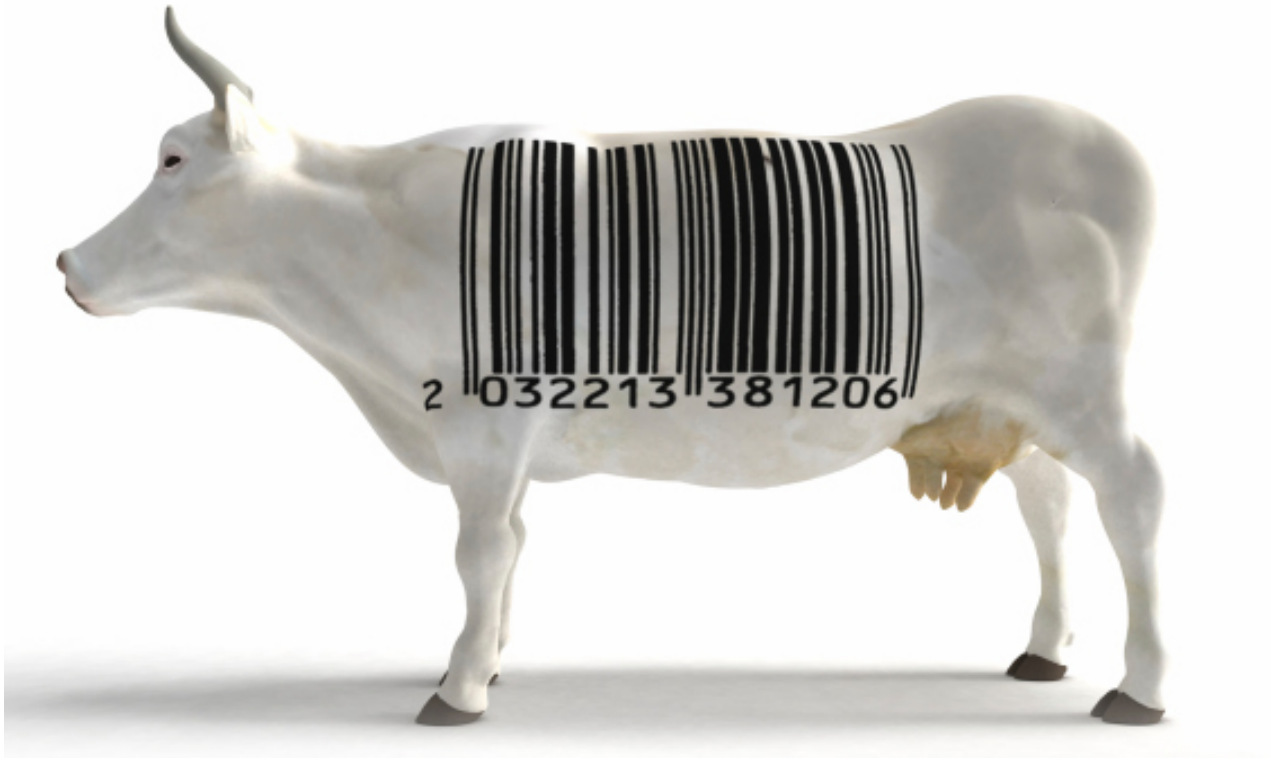

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PART I

Introduction

After thirty-two years' service, the Directive 79/112/EEC[1] - which had established harmonized rules as regards labelling, presentation and advertising of foodstuffs across Europe - pensioned off. This Directive is indeed replaced by the new Regulation EU No. 1169/11 of the European Parliament and the Council on the provision of food information to consumers.

Although the new Regulation does not innovate significantly from the currently applicable legislation, it does contain a few novelties. The new provisions will be applicable after three years from the entry into force of the Regulation, with the only exception of the rules on nutrition labelling which will be of application five years after its entry into force.

This guidebook has been thought and written for the business operators within the food area, notably the first manufacturing sector in Europe. Following the adoption of the new Regulation, concerned operators in the food chain might have to consider reviewing recipes and supply strategies, in addition to labelling and advertising, with a view to promoting more effectively their products across the EU market.

This guidebook can also be of some interest for those consumers who are willing to better understand the characteristics of those foods offered on the shelves (or online).

The guidebook has the following structure:
1) introduction,
2) a short outline of the major novelties brought in by the new Regulation,
3) a more thorough analysis of the new regime on food information to consumers.

1 Directive consolidated in Directive 2000/13/EC and subsequent modifications amongst which Directive 2008/5/EC. These Directives have been transposed into Italian law with d.lgs 27.1.92 n.109 and subsequent modifications

1. The reasons behind the review

After a few years spent pondering the views and the needs expressed by stakeholders (i.e. consumer organizations, Member States' authorities, farmers, manufacturing and retail industry), on 30 January 2008 the EU Commission put forward a proposal on food information to consumers.

There are a number of reasons for which the EU Commission has decided to embark on the review of the existing legislation.

1.1. Simplification. To begin with, the EU legislator has deemed appropriate to regroup in the same legal text provisions relating to:

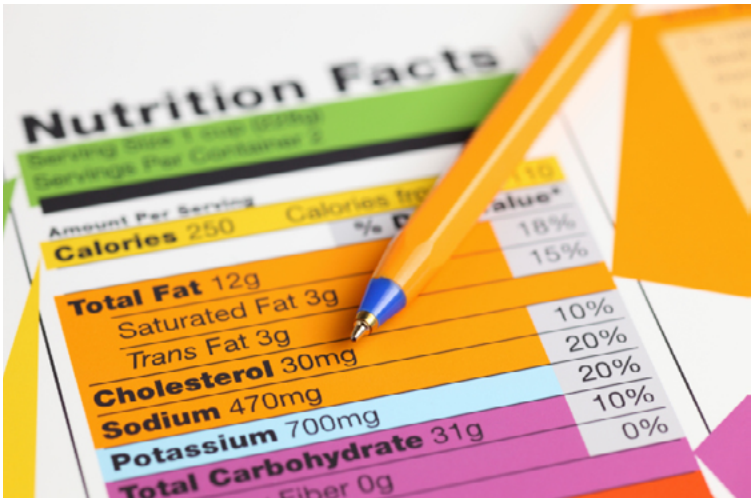
- **labelling, presentation and advertising of foodstuffs,**[2]
- **nutrition labelling,**[3]
- **information on the presence of allergens.**[4]

While doing so, the EU legislator has omitted to include any reference to the Lot Directive.[5] This means that, in accordance with the same Directive, the indication of the lot through labelling remains compulsory, although not listed by the new Regulation amongst the information requirements which are to be considered as mandatory (Article 9).

The EU legislator has also considered opportune to clarify that amongst the general objectives which food information to consumers should pursue there is not only the **free circulation of goods** within the EU market (Article 3, paragraph 2), but, also, a **high level of public health and consumer protection** (Article 3, paragraph 1).

2 The so-called 'Labelling Directive' (Directive 2000/13/EC and subsequent modifications)
3 Directive 496/1990/ EEC and subsequent modifications. The consolidated text can be found at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0496:20081211:IT:HTML
4 Directive 2003/89/ EC and subsequent modifications
5 Directive 1989/396/EEC (amended by Dir. 2011/91/UE) on indications or marks identifying the lot to which a foodstuff belongs

1.2. Legal certainty. Three decades of enforcement of national laws implementing common principles have ultimately shown that the chosen level of harmonization has not delivered the desired results. Against this background, ensuring the uniformity of the applicable rules across the EU has been indicated as the way forward.



In accordance with this new approach, the principles in the area of food information have been gathered under the same text, which has the form of a **EU Regulation** i.e. a legal act which is translated in the 23 official languages, enters into force at the same time and is applied uniformly in all Member States.

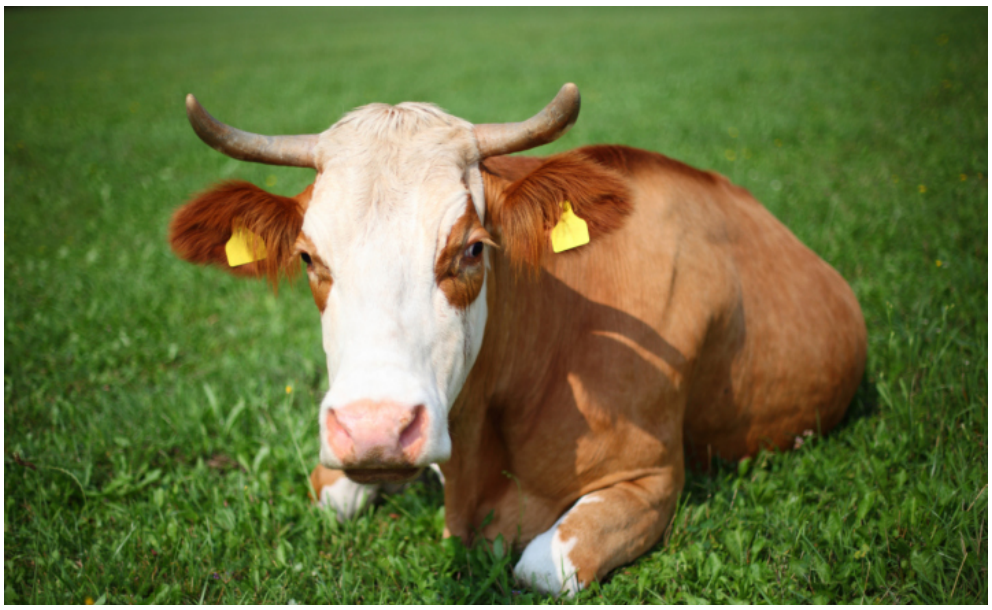
Lastly, the new Regulation aims at bringing clarity once for all as regards **responsability** of food business operators in relation to information which is provided through labelling and advertising. On this point, the new Regulation provides that, in case of foodstuffs which are produced or packed by a supplier upon demand of a food business operator and bear the name or the business name of this latter (e.g. *private labels*), it is the operators' obligation to ensure that any information regarding these products is complete and thrustworthy. As far as foodstuffs are imported into the EU from third countries, the same obligation lies with the importer.

1.3. Responding to stakeholders' demands. In the framework of the consultations which the EU Commission has carried out throughout the last years, stakeholders had the opportunity to express their views and calls for review of the existing legislation. Overall, the main issues raised have been:

• **legibility of essential information requirements**. The general criterion set out in the legislation currently in force did not succeed in ensuring the effective legibility of the information provided through labels. In an attempt at improving legibility of labels, the EU legislator has therefore opted for laying down more prescriptive requirements e.g. minimum font size, stroke-width, light and colour contrast between print and background,

• **nutrition information**. Over the years the range of food products available on shelves has significantly increased and, at the same time, recipes and characteristics have evolved in turn. Meanwhile, in Europe as in other areas of our planet, overweight and obesity rates together with diseases associate with unhealthy lifestyles have reached dramatic proportions. In response to this worrying trend, the Commission has deemed appropriate that consumers are given accurate information on energy and nutrition values of all food products on the market with only a few exceptions and that national authorities lead on raising-awareness campaigns with a view to improving people's lifestyles,

• **information concerning the presence of allergens**. According to the stud-



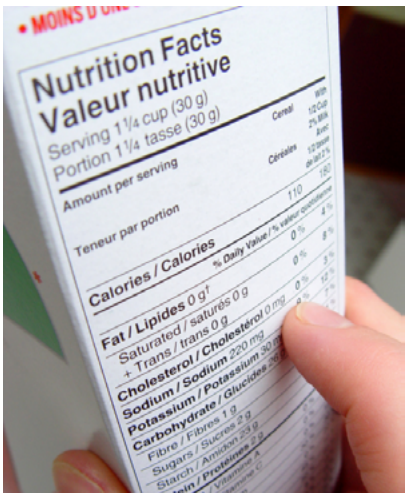
ies carried out on the basis of the so-called 'Allergens' Directive',[6] consumers with food allergies and intolerances represent 3-4% of the adult population and 7-8% of the children within the EU. Based on other statistics, 50% of daily meals is normally consumed outside. In light of this, the Commission has considered necessary that, as vulnerable consumers, people affected by food allergies should be given systematically information which is essential to them and this also in relation to foods sold loose and foods delivered by mass- caterers,

• origin and provenance of certain products and of their raw materials Considering the interest that consumers have today in receiving information about the origin and/or the provenance of foodstuffs with close link with the primary production, the EU legislator has introduced the obligation of disclosing origin information for all types of meat (i.e. bovine, ovine, caprine, swine and poultry). In addition, the new Regulation has entrusted the EU Commission with the task of assessing whether provision of origin information would be appropriate also for other products (e.g. products composed by a single ingredient, milk and derived products, meat when used as an ingredient in composite products). The assessment by the Commission will take into consideration consumers' interests, the technical feasibility of the considered options and a cost-benefit analysis of the implications that any proposal requiring the disclosure of the origin might have on concerned operators throughout the food chain (e.g. agriculture and breeding sector, processing and retail industry),

• specific information concerning the composition and the characteristics of certain products. With a view to increasing transparency about product composition, the new Regulation provides for mandatory labelling of vegetable oils, mandatory information as to whether the product in question has been previously defrosted and a few other requirements which will be dealt with further ahead in this guidebook.

6 Directive 2003/89/EC and subsequent amendments

2. Some missed opportunities



In the context of the review under discussion, while seeking to ensure improvements in a number of areas, the EU legislator has neglected to address satisfactorily a few issues.

2.1. Limiting Member States' legislative competences. During the last thirty years the European Court of Justice has consistently held that the principle of free circulation of goods[7] implies the prohibition for Member States to adopt national laws which deviate from common rules agreed at European level. This with the only exception of national provisions adopted on the basis of public policy grounds (e.g. public health concerns) and provided that they are proportionate as to the foreseen means and duration.

The EU legislator appears to have ignored the consolidated EU case-law mentioned above, by introducing the possibility for Member States to lay down technical rules going beyond the level of harmonization set at EU level (Chapter VI of the new Regulation). In the long term, this approach may lead to market distortions, potential discriminatory treatments between economic operators of different Member States as well as different levels of consumer protection across the EU.[8]

2.2. *Database* of existing legislation relating to labelling and advertising of foodstuffs. As referred above,[9] the new Regulation gathers in a single text all the provisions of general nature applicable to labelling and advertising, nutrition labelling and information concerning the presence of allergens in foodstuffs.

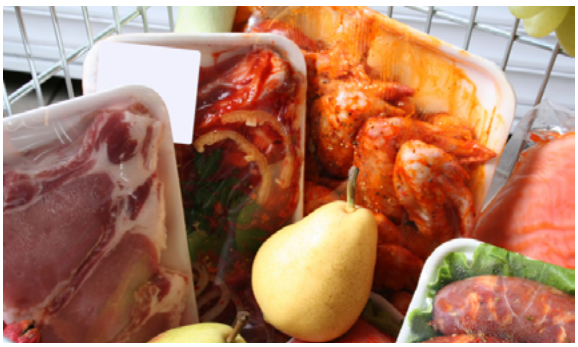
Notwithstanding this, provisions governing marketing and advertising of foodstuffs are still scattered through several hundreds of EU and national legal texts either with a horizontal scope (e.g. nutrition and health claims)[10] or with a vertical one (e.g. provisions applicable to single products or categories of products such as cocoa products and chocolate).[11] Because of their inherent specificity, such provisions take precedence over those having a more general nature.[12] This at times gives rise to inconsistencies in the way they are interpreted and applied.

As a result business operators, consumers, and enforcement authorities are faced with a conundrum of rules which differ one from the other as to their origin (e.g. for history, timeline, legislator) and application. Sometimes identifying which rules should be complied with is no easy task.

In line with what referred above, during the first reading on the draft of the new Regulation, the European Parliament proposed that the Commission should be tasked with: gathering in a single database, accessible to the public all

7 Article 34 TFEU (Treaty on the functioning of the European Union)
8 For more details see Part II, paragraph 2 *(Member States' legislative competences)*
9 See paragraph 1.1 *(Simplification)*
10 Regulation (EC) No 1924/2006
11 Directive 2000/36/EC, transposed into Italian law with d.lgs. 178/2003
12 In accordance with the principle *lex specialis derogat legi generali*

the legal instruments, horizontal and vertical, which are applicable to commercial information on foodstuffs; verifying the consistency of what contained in such instruments against the general principles set in the new Regulation; putting forward proposals for amending any of the instruments which so require with a view to ensuring consistency with the overall system. Eventually, the suggestions advanced by the European Parliament have not been retained during the discussions which followed at Council level.



2.3. Food packed at retail premises. Unfortunately, the majority of mandatory information requirements set in the new Regulation will be not applicable in case of food products that are packed at retail premises for direct sale.

The decision of derogating from the general regime for this category of foods lacks of any reasonable justification. As a result, consumers will not be able to find essential information in relation to products such as meat, cheese and delicatessen,[13] which retailers slice and pack directly on their premises and put on sale next to manufacturers' products (which, on the contrary, display a comprehensive set of information (Article 2.2 letter 'e').

It remains therefore be hoped that the Member States will bridge this gap and, by so doing, ensure full enforcement of the 'right to know' consumers have in relation to products on sale (Article 42.1).

2.4. Nutrition information, continuity with existing schemes. The 'Nutrition Labelling Directive'[14] has introduced in Europe an information system based on two options:

- *Big 4*. Energy, proteins, carbohydrates and fats,
- *Big 8*. Energy, proteins, carbohydrates, sugars, fats, saturated fats, fibre, sodium.

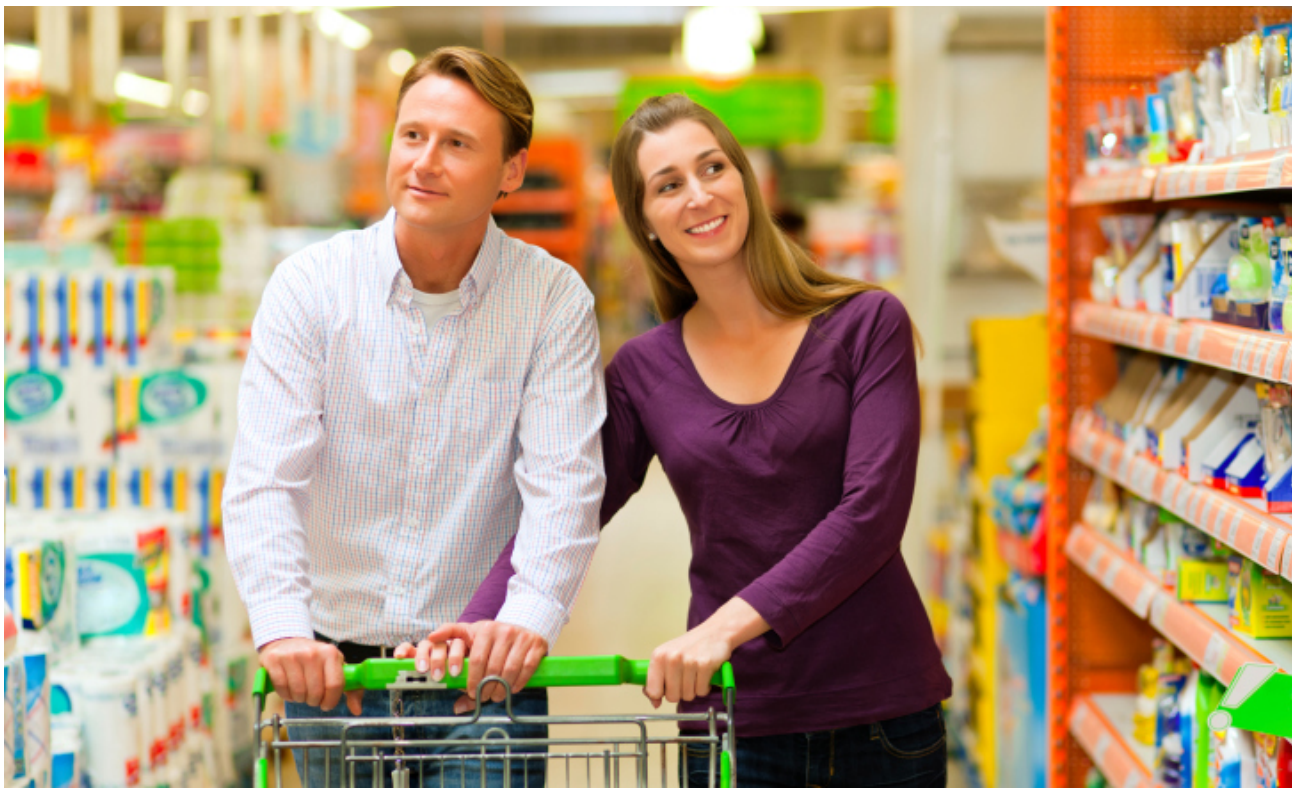
According to this system, providing the relevant values - to be expressed per 100g/ml, and in case per portion - is a voluntary choice of the producer. Providing such information is however compulsory whenever through labelling or advertising reference is made to the nutrition properties of the product in question (e.g. 'reduced fat content', 'rich in fibre' i.e. in case a nutritional claim is made).[15]

In this respect, it is worth mentioning that since 2006 the Confederation

13 Another example of unjustified derogation in favour of the retail sector is the exemption of that sector from the application of additional hygiene requirements aimed at ensuring the safety of products of animal origin (Regulation (EC) n. 853/ 2004)

14 Directive 90/496/EEC and subsequent amendments, which has been transposed in Italy with d.lgs. n 77/1993

15 Nutrition and health claims are currently regulated in Regulation (EC) n. 1924/2006 and subsequent modifications



of the food and drink industry in Europe (FoodDrinkEurope) has committed to providing, on a voluntary basis, nutrition information on all food products in accordance with the two nutrition panels foreseen by Directive 1990/496/EEC. Additionally, it has been foreseen that, where appropriate, nutrition values should be coupled with information indicating in which percentage a portion of a given product contributes to the average recommended daily intake of the considered value. This latter set of information, known as Guideline Daily Amounts (GDA's), is based on parameters set by Eurodiet, validated by EFSA[16] and to be applied uniformly in the whole EU.

European consumers have got familiar with the way nutrition information has been provided in the last twenty years. Now, with the new Regulation coming into force, the well-established order of values will be altered and food operators will be required to provide the GDA value for energy either per portion and per 100g/ml. Such a value per 100g/ml has no means in all cases of products which are normally consumed in quantities that are well below (e.g. chewing-gum, a spoon of olive oil to dress a salad) or over (e.g. the can of a drink) that threshold.

16 European Food Safety Authority established with Regulation (EC) No. 178/2002

NOVELTIES

The EU Regulation on food information to consumers was endorsed by the European Parliament in second reading on 6 July 2011,[17] following the agreement reached on 22 June 2011 between representatives from Parliament, Council and the Commission.[18] The text is available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF

The main novelties are dealt with here below, with critical elements highligted in red:

1. Scope

The Regulation applies to all food products intended for the final consumer, including products delivered by mass-caterers (e.g. restaurants, canteens, hospitals, catering establishments)[19] as well as products intended for supply to mass-caterers (Article 1.3 and Article 8.7).

1.1. Foods not pre-packed. The EU legislator has opted for leaving to Member States the competence of deciding which information should be provided as for foods sold loose and foods packed at retail premises, in addition to the modalities to be followed while providing such information.[20] The only deviation from this general principle is the requirement of providing information on the presence of allergens, in the ingredients and/or in the food improvement agents (Article 44.1.a).

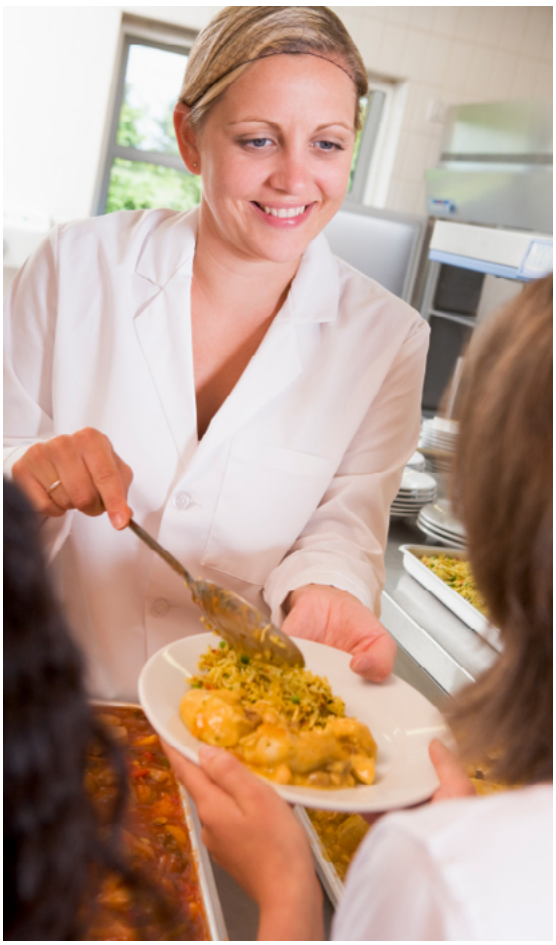
17 A first assessment of the outcome of the discussions in Strasbourg is available at http://www.ilfattoalimentare.it/parlamentonuovo-regolamento-ue-etichette-pubblicità-alimenti.html

18 The adoption of the Regulation under discussion is subject to the co-decision procedure. This implies the agreement of the three EU institutions on all its parts

19 The Regulation even applies to *'catering services provided by transport undertakings when the departure takes place in the territories of the Member States to which the Treaties apply'* (Article 1.3)

20 i.e. foods which are packed directly at retail premises or at premises next to the point of sale

From the above it can be inferred that business operators and consumers will be faced with 27 (soon 29) different systems. Needless to say, this approach is not in line with the general objectives of the Regulation.[21]



1.2. Mass-caterers, cantines, catering establishments. The precise modalities according to which mass-catererers should provide food information are still to be defined.

In any event the Regulation sets that mandatory food information shall be available and shall be easily accessible, in accordance with its provisions for all foods (Article 12.1).

1.3. B2B information.[22] Food business operators have the obligation to transfer mandatory information[23] (on pack, label or commercial documents)[24] where:

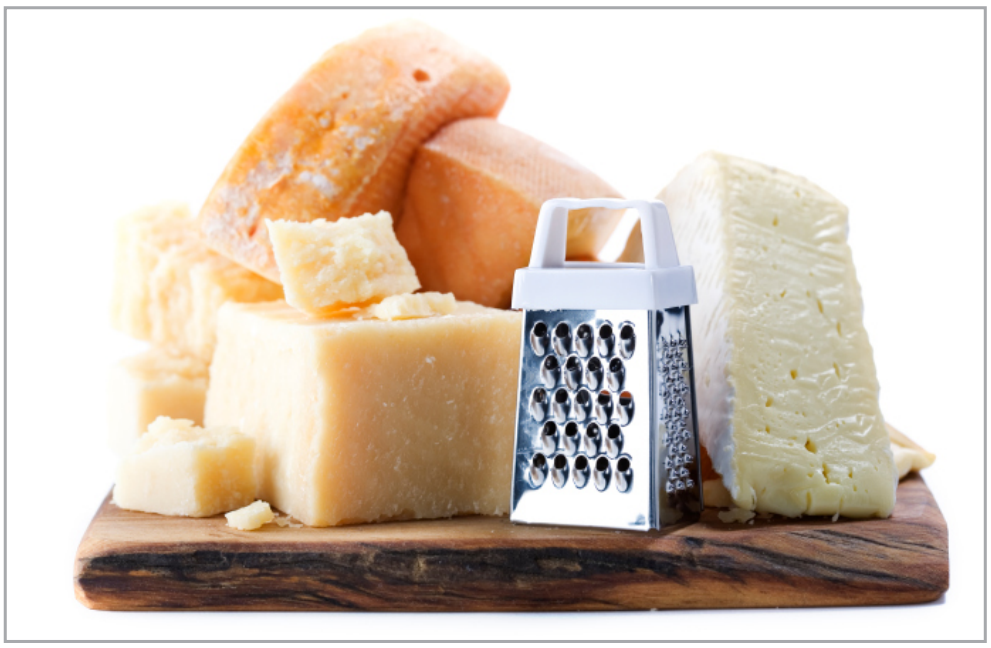
- pre-packed food is intended for the final consumer, but marketed at a stage prior to sale to the final consumer,

- pre-packed food is intended for supply to mass-caterers for preparation, processing, splitting or cutting up (Article 8.7).

1.4. Distance selling. Under these circumstances, the concerned food business operator has to provide part of the mandatory information through the means supporting the sale (e.g. a website in case of on-line purchases, a leaflet in case of contracts concluded over the phone) or with other appropriate means (Article 14.1.a). All mandatory information will have then to be made available at the time of delivery (Article 14.1.b).[25]

An issue remains, however, to be clarified and namely whether in case of home delivery of ready-made foods (e.g. pizzas) mandatory information should be provided also through on-pack labels in addition to having to be made available beforehand.

21 See Part I , paragraph 1.1 *(The reasons behind the review - Simplification)*
22 Here reference is made to all the information which has to be transferred from a food business operator supplying other food operators who will ultimately be selling foods to the final consumer
23 In this respect, see Part III, paragraph 2 *(Mandatory information)*
24 *'Where it can be guaranteed that such documents either accompany the food to which they refer or were sent before or at the same time as delivery'*
25 These requirements are curiously not applicable to *'foods offered for sale by means of automatic vending machines or automated commercial premises'* (Article 14.3)



2. Member States' legislative competences

As previously highlighted,[26] the EU institutions have opted for leaving to Member States the freedom of supplementing the new legislation with national provisions on specific products or categories of products as for aspects which are not covered by the general rules (Chapter VI).[27]

Accordingly, it is foreseen that *'Member States may adopt national measures concerning matters not specifically harmonised by this Regulation provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation'* (Article 38).[28]

2.1. Additional mandatory information requirements. The Regulation goes even further when establishing that Member States may introduce *'measures requiring additional mandatory particulars for specific types or categories of foods, justified on grounds of at least one of the following:*

a) the protection of public health;
b) the protection of consumers;
c) the prevention of fraud;
d) the protection of industrial and commercial property rights, indications of provenance, registered designations of origin and the prevention of unfair competition' (Article 39.1).[29]

26 See Part I, paragraph 2.1 *(Some missed opportunties - Limiting Member States' legislative competences)*
27 See Chapter VI of the Regulation *(National provisions)*
28 See in this respect Article 38 of the Regulation *(National provisions)*
29 See in this respect Article 39 of the Regulation *(National provisions on additional mandatory particulars)*

The Member State willing to adopt a measure based on this provision must notify the draft proposal to the Commission. The measure in question can be implemented only after three months following the notification, unless the Commission has issued a negative opinion. It will be therefore up to the Commission to preserve the integrity of the internal market, in the interest of business operators and consumers alike, by ensuring the respect of the principle of the uniform application of EU law.

2.2. National requirements on origin and provenance. According to the new regime, national legislators may introduce national provisions requiring further information as to origin or provenance of certain foods where there is *'a proven link between certain qualities of the food and its origin or provenance'* (Article 39.2).

The only limit foreseen in order to avoid proliferation of national regimes is found in Article 38.1 of the Regulation. This provision sets that national measures must not pose obstacles to the free movement of goods and not discriminate as regards food products from other Member States. This provision appears however unrealistic. Indeed, the introduction of additional information particulars, as opposed to those requirements which are uniformly applicable, inherently leads to:

- greater costs for business operators and SMEs in particular (e.g. update of production processes to ensure compliance with national provisions in different Member States, sourcing and processing the additional information required, review of existing labels),

- a competitive advantage in the market for certain products (consumers may effectively be inclined to prefer products which comply with those particular information requirements chosen by their national legislator).

It should be finally that the link between the qualities of foods and their origin or provenance has already given protection in Regulations (EC) 509/2006 and 510/2006 on geographical indications (PDO, PGI, TSG).

3. Alcoholic beverages

Since they are subject to a specific EU regime, alcoholic beverages (≥1.2% vol.) are exempted from the information requirements concerning nutrition information and the ingredients list, except for allergens (Article 16.4).

During the three years following the entry into force of the Regulation, the Commission will produce a report addressing *'whether alcoholic beverages should in future be covered, in particular, by the requirement to provide the*

information on the energy value'.[30] In this context, the EU institution will also consider the appropriateness of introducing a definition for the so-called *alco-pops* (Article 16.4).

4. Responsibility of business operators

The clarification brought in this area constitute a major improvement as opposed to the current situation. In line with the criteria set in the General Food Law (Regulation EC No. 178/2002), the food business operator under which name or business name a food product intended for the final consumer is marketed is responsible for the completeness and the trustworthiness of the information provided in relation to that product.

In case of products originating from outside the EU, the responsibility for the information provided lies with the importer (Article 8).

5. Mandatory information to be provided on labels

In addition to the currently applicable mandatory information requirements to be provided for all foods, the new Regulation sets that nutrition and origin information must also be given with the modalities described in the following paragraphs (Article 9.1).

5.1. Information in the same field of vision. It is worth mentioning that the name of the food, the net quantity and, where appropriate, the alcohol strength must be placed in the same field of vision (Article 13.5).

On the other hand, the new Regulation no longer requires the information on durability of a product to be placed in the same field of vision. Considering the importance of such information, this omission does not seem justified.[31]

30 Meanwhile, *'Member States may, pending the adoption of the Union provisions referred to in Article 16(4), maintain national measures as regards the listing of ingredients in the case of beverages containing more than 1,2 % by volume of alcohol'* (Article 41 - Alcoholic beverages)

31 More precisely, the Regulation foresees the possibility of providing the durability date by referring to another part of the label where that date is printed (See Part III, paragraph 2.6, *Minimum durability or 'use-by' date*)

6. Symbols and alternative means of information

The Commission may introduce symbols or pictograms - as opposed to words and numbers - to present mandatory information to be provided on labels (Article 9, paragraphs 2-4).

The possibility of allowing in future information means other than labelling (e.g. interactive screens on shelves, smart-phones applications Article 12.3, 3.a) is also foreseen.

7. Name of the food

As it is already foreseen in the current legislation, the name of the food must be accompanied by particulars as to the physical condition of the food or the specific treatment which it has undergone[32] in all cases where omission of such information could mislead the purchaser (Annex VI, Part A, point 1).

The main novelties in this area are:

7.1. 'Defrosted'. In the case of a product that has been frozen before sale and is then sold defrosted, the name of such a product shall be accompanied by the designation 'defrosted'. This requirement shall not apply to 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 in terms of safety and quality (Annex VI, Part A, point 2).

7.2. 'Ingredient used for substitution'. Should an ingredient normally used (e.g. eggs in mayonnaise) or naturally present in a product be replaced by another ingredient (e.g. vegetable fibres in the product in question), the ingredient that has been used for substitution[33] must be placed in close proximity to the name of the product by using a font size not lower than 75% of the name of the product (Article 7.1 letter d) and Annex VI, part A, point 4, letter b).

7.3. Added water in meat or fish products. Meat products, meat preparations and fishery products which have the appearance of a slice, filet or portion in which added water makes up more than 5% of the weight must provide information about presence of such a water next to the name of the concerned product (Annex VI, part A, point 4b).

32 For example, powdered, refrozen, freeze-dried, quick-frozen, concentrated, smoked

33 The concept of 'ingredient used for substitution' is actually less clear than in the example given above, considering the variety and the amount of food products available on the EU market. It would be appropriate to determine in which cases the only appearance of the product, regardless images, pictograms and wording, may mislead the consumer as to the presence of a certain food or ingredient. A uniform interpretation in this area would be useful so as to avoid 27 different enforcement approaches at national level

7.4. 'Formed meat' and 'Formed fish'. Meat products, meat preparations and fishery products which have the appearance of a slice, filet or portion, but actually consist of different pieces of meat/fish combined together by other ingredients (e.g. additives and enzymes) must bear the above wording.

7.5. Sausages with inedible casing. In case of inedible casing, sausages must have this information displayed next to the name of the product (Annex VI, part B, a).

8. Legibility[34]

The Regulation clarifies that legibility of labels depends on a number of factors, amongst which *'font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and a significant contrast between the print and the background'* (Article. 2.2 letter m).[35]

Particulars for which the new Regulation requires mandatory provision through labels must be given in characters using a font size at least of 1.2 mm (average x-height).[36] As regards small packages (i.e. whose the largest surface has an area of less than 80 cm²), characters must have a font size of at least 0,9mm (Article 13, 2-3).

Furthermore, *'mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material'*. (Article 12.1).

The Commission will develop recommendations aimed at ensuring increased legibility of labels (Article 13.5).

34 On this subject see also Part III, paragraph 2 *(Mandatory information)*
35 In this respect, see also Guidelines on legibility of mandatory information on labels elaborated by FoodDrink Europe and available at http://www.ciaa.be/documents/positions/Guidelines%20for%20the%20Legibility%20of%20Labelling.pdf
36 On this point see Annex IV *(Definition of x-height)* of the Regulation

9. Ingredients

9.1. Allergens. Where several ingredients or processing aids of a food originate from the same allergen, this latter must be mentioned on the labelling for each ingredient or processing aid concerned (Article 21.1, third indent).

The labelling of allergens must be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example, by means of the font, style or background colour (Article 21.1 b).

Labelling of allergens, however, is not required in cases *'where the name of the food clearly refers to the substance or product concerned'* (Article 21.1 last indent).[37]

9.2. Oils and fats of vegetable origin. The provision of these ingredients on label must be followed by the indication of the specific nature of the concerned oil or fat.[38] When blended, the wording 'in varying proportions' may be used as opposed to the option of listing them in a descending order according to weight (Annex VII, part A, points 8 and 9).

9.3. Oils and fats of animal origin. The Regulation contemplates the possibility of listing them by referring to the specific animal origin as opposed to the generic name (Annex VII, part B, points 1 and 2).

9.4. Added water and volatile products. They shall be indicated only when their presence in the finished product - i.e. the difference between the total amount of the finished product and the total amount of the other ingredients used - is higher than 5%. Their labelling is, on the other hand, compulsory in case they are added to meat, meat prepara-

37 E.g. milk, butter, cheese, barley (soluble), etc.
38 E.g soya, palm, peanut

tions, unprocessed fishery products and unprocessed bivalve molluscs (Annex VII, Part A, point 1).

9.5. Caffeine. Beverages other than tea, coffee and tea/coffee-based drinks with a caffeine content higher than 150 mg/l must display in the same field of vision the warning *'Not recommended for children or pregnant or breast-feeding women'*, preceded by the indication *'High caffeine content'*, already introduced in 2002.[39]

Solid foods to which caffeine is added for physiological purposes (e.g. food supplements) must also bear in the same field of vision of the name of the product the wording *'Contains caffeine. Not recommended for children or pregnant women'*.

9.6. Flavourings. They must be indicated as 'flavourings' or by a more specific name or description as set in Article 3 of Regulation (EC) No. 1334/2008 (flavouring substances, flavouring preparations, thermal process flavouring, smoke flavouring, flavouring precursor, food ingredient with flavouring properties). The term 'natural' for the description of flavourings must be used in accordance with Article 16 of the Regulation mentioned above (natural flavouring 'x', natural flavouring 'x' with other natural flavourings, natural flavouring) (Annex VII, part D).

9.7. Nano-materials. The Regulation introduces, for the first time ever, a definition of nano-materials.[40] When used in food ingredients or additives, their use is subject to the novel foods regime.[41]

'All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets' (Article 18.3).

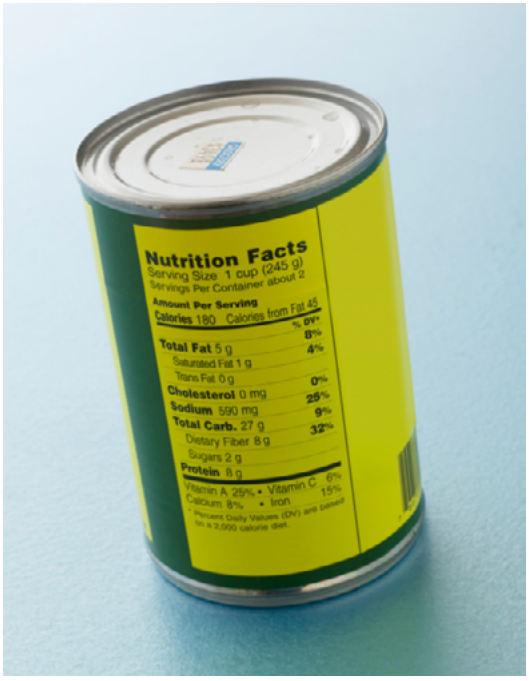
39 Directive 2002/67/EC which has been transposed into Italian law with d.lgs. 181/2003 amending d.lgs. 109/92

40 *Engineered nanomaterial means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale*

41 The so-called Novel Foods Regulation, (EC) No 258/97, is currently under review. For more information see http://www.ilfattoalimentare.it/novelfoods-gli-alimenti-da-animali-clonati-fanno-saltare-il-negoziato-per-un-nuovo-regolamento.html

10. Net weight

Where the food has been glazed, as it happens for certain frozen foods, the declared net weight must not take into account the glaze (Annex IX, point 5).[42]



11. Minimum durability date and 'use by' date

The Regulation sets out that the Commission may adopt more precise rules concerning the modalities regarding the provision of the minimum durability date[43] ('Best before', see Article 24.3).

The 'use by' date must be indicated on each individual pre-packed portion (Annex X, point 2) and no longer therefore on the packaging containing the single packs.

12. Date of freezing

In case of meat, meat preparations and unprocessed fishery products, the Regulation provides for the obligation of indicating on labels the date of the first freezing i.e. day/month/year (Annex III.6, Annex X.3).

This requirement does not seem to be relevant for the consumer since the obligation of providing the production date of other products with long durability is not foreseen. On the other hand, enforcement authorities are in the position to retrieve the production date of any food product through traceability records which any operator has to make available to them.[44]

13. Origin and provenance

Provision of the origin of the products (i.e. the place where the product has undergone the last significant transformation)[45] or of the place of provenance remains mandatory where its omission is likely to mislead the consumer (e.g. a mozzarella produced in Germany but sold in Italy).

The Regulation further clarifies that the obligation of mentioning the origin of the product applies also *'if the information accompanying the food or the label as a whole would otherwise imply that the food has a*

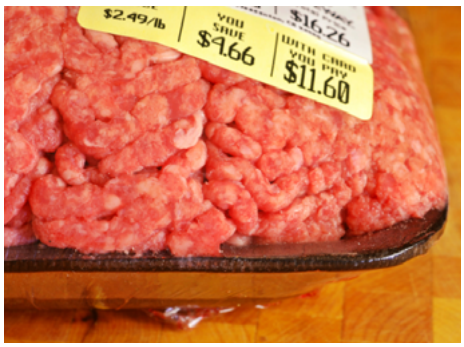
42 It remains, however, to be clarified to what extent this requirement is compatible with what the Regulation foresees in relation to added water and volatile products (see paragraph 9.4)

43 'Termine minimo di conservazione' is the wording the Italian legislator has been using for thirty years now. It is an incorrect translation of the concept of minimum durability date expressed in the orignal French text of Directive 112/79/EEC

44 In accordance with Article 18 of the General Food Law (Regulatin (EC) no, 178/2002. On this point, see also Federalimentare Guidelines for the traceabiliity of food products which is available at www.federalimentare.it, area 'Documenti', item 'Linee Guida'

45 With respect to the country of origin of a product (art. 2.2 g) the Regulation refers to the Common Custom Code (namely articles 22-23 Regulation (EC) no. 2913/1992)

different country of origin or place of provenance' (Article 26.2.a). This provision seems useful in order to prevent cases where products are presented as 'made in… (e.g. Italy)', with explicit claims or through images and symbols, when in fact they have been produced elsewhere.[46]



The main novelties in this area are:

13.1. Origin and provenance of the food other than that of its primary ingredient.[47] Where the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient,[48] the country of origin or place of provenance of the primary ingredient in question must also be given or the country of origin or place of provenance of the primary ingredient shall be indicated as being different to that of the food.

It is also clarified that the mere indication of the name of the food business operator and the place where he is located should not be regarded as 'origin' to the effect of these provisions (Article 25.3).

At this stage, it can hardly be said whether reading that the origin of the primary ingredient is different from the origin of the product will change consumer attitudes, will have an impact on the market, or will benefit local production. In any event, what is certain is that labels - already crowded with information - will have to provide a further bit.

13.2. Origin of meats.[49] The Regulation requires the mandatory provision of the provenance of fresh and frozen meats, in particular pork, sheep, goat, and poultry (Article 26.2.a). Within two years from the entry into force of the Regulation, the Commission will lay down in details the modalities.

In the same exercise, the Commission will have also to consider the opportunity of extending the mandatory origin requirement to meat used as an ingredient in finished products (Article 26.5a - 7).

13.3. Origin of other categories of products.[50] Within three years from the entry into force of the Regulation, the Commission will have to carry out an impact assessment as to the appropriateness of extending the

46 The 'made in Italy' issue is a rather complex one. In this respect, see for example http://www.ilfattoalimentare.it/agromafie-coldiretti-notizie-eurispes-giornalisti-acritico.html

47 For more details on this subject see Part III, paragraph 2.10.2 *(Origin and provenance of the product when different from that one of the primary ingredient)*

48 For primary ingredient it is meant either the ingredient which present in more than 50% or the ingredient characterising the product (Article 2, paragraph 2 letter o). *Which of the two ought to be considered?*

49 For more details on this subject, see Part III, paragraph 2.10.3 *(Origin of meat)*

50 Fore more details on thsi subject, see Patrt III, paragraph 2.10.4 *(Origin of other categories of products)*

mandatory provision of origin information to the following products: meat other than that for which the origin requirement is already applicable,[51] milk, milk used as an ingredient in dairy products, unprocessed foods,[52] single-ingredient products, ingredients used in quantity higher than 50% (Article 26.5).

Some stakeholders claim that extending mandatory provision of origin information to an increased number of products may turn around the agriculture in the EU. If that was the case, such an extension would be certainly to be supported. The issue is actually a rather complex one. It also presents the risk of impacting negatively on local production[53] because of the inherently weak competitiveness of such production systems. Farmers' trade organizations would better focus their efforts on other issues that are crucial to their members such as retailers' unfair commercial practices towards their suppliers.[54]

On the other hand, nothing prevents business operators from providing, on a voluntary basis, additional information concerning the origin or raw materials of their products.[55]

14. Nutrition information[56]

14.1. Mandatory nutrition declaration. All pre-packed foods, with a few exceptions,[57] must bear in the same field of vision of the label a nutrition chart listing values for energy (kcal/kj), fats, trans-fats, carbohydrates, sugars, proteins and salt (Article 30. 1).

51 In essence, equine, donkey, mule meat, some birds (e.g. pigeons), rabbit, wild-farm gamed animals, frogs, and snails

52 As defined in Regulation (EC) No 852/2004 (Regulation Hygiene I)

53 In this regard, it is worth referring to the crisis of the olive growing sector in Spain, the first olive oil producing country. There providing information on the origin of olives used in virgin and extra-virgin olive oil production has not resulted in counteracting effectively aggressive market practices by large retailers (See the article *'Squeze hits Spanish olive farmers'* by Miles Johnson, *Financial Times*, 1.5.11, http://www.ft.com/intl/cms/s/0/47ba2bf6-741c-11e0-b788-00144feabdc0.html#axzz1gWCgvuki)

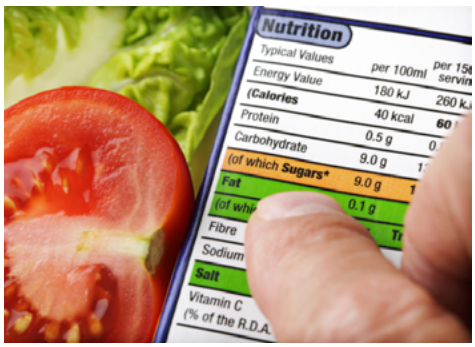
54 See in this respect http://www.ilfattoalimentare.it/grande-distribuzione-concorrenza-sleale-europarlamento-strapotere.html, http://www.ilfattoalimentare.it/il-coordinamento-europeo-via-campesina-contro-le-pratiche-commerciali-scorrette-della-grande-distribuzione-organizzata.html, http://www.ilfattoalimentare.it/il-parlamento-europeo-con-jos.html, http://www.ilfattoalimentare.it/i-prezzi-dei-prodotti-scendono-ma-occorre-riconoscere-il-valore-del-cibo.html, http://www.ilfattoalimentare.it/il-parlamento-ue-contro-la-concorrenza-sleale-dei-supergruppi-della-gdo.html

55 This is what, for example, Casinò, a French retailer, has done. This latter has opted for providing voluntarily the national origin of its own brand UHT milk

56 For more details, please see Part III, paragraph 2.13 *(Nutrition declaration)*

57 Namely, unprocessed products, products that are subject only to maturing, water, herbs, spices and mixtures thereof, salt, coffee, tea, herbal infusions which do not contain other added ingredients than flavourings, vinegars, flavourings, food improvement agents, enzymes, gelatine, jam setting compounds, yeast, chewing gum, foods in small packs whose the largest surface has an area of less than 25cm^2. This list includs also alcoholic beverages as referred in Part II, paragraph 3

These values must be expressed per 100 mg/ml and, as an option, per portion (Article 33).



The Commission will adopt, through implementing acts, rules on the expression per portion or per consumption unit for specific categories of foods (Article 33.4).[58]

14.2. Information that can be repeated. Food business operators may repeat, on a voluntary basis, the following information:

• energy values (kcal) expressed per 100 g/ml and, where possible, per portion (Article 33.2),

• relevant values concerning fats, saturated fats, sugar and salt (Article 30.3). Information may be displayed in a way other than in a table (article 35.3) and be expressed solely per portion, without prejudice to the obligation of expressing energy per 100g/ml (Article 33.2).[59]

14.3. GDA's. The Regulation explicitly admits the possibility of using references intake, namely the so-called *Guideline Daily Amounts*,[60] on a voluntary basis with the objective to express in percentage the contribution which a portion of a given food towards the average recommended daily intake. Food business operators will have however to specify that this latter is the *'reference intake of an average adult (8400 kJ/2000 kcal)'* (Article 31.4 a new).

To this end, a recommended average daily intake for proteins (50g) is foreseen (Annex XIII).

The Commission will develop guidelines for provision of GDA's for specific population groups (Article 36, paragraph 3, lett c). Until then, Member States may introduce measures on the voluntary provisions of such GDA's (Article 43).

58 Laying down rules on portions would be in contradiction with the relatively recent Directive 2007/45/EC, whereby the existing standards (weight/volume) for sale units of foods products have been abolished with the objective of allowing the free circulation of pre-packed foods in any nominal quantity (in this respect, see http://www.ssica.it/index2.php?option=com_docman&task=doc_view&gid=424&Itemid=34). The debate on portions is not new in this context and does not seem an easy one to tackle (see http://www.ilfattoalimentare.it/porzioni-chi-le-decide-i-diversi-punti-di-vista-di-consumatori-aziende-e-enti-istituzionali-hanno-d.html)

59 On the other hand, the repetition of the energy value per 100g/ml is not required in case of foods that are not pre-packed. The rationale behind this derogation and others foreseen by the Regulation in favour of prepacked foods is however far from being clear

60 For more information see http://gdalabel.com

The Commission may also adopt specific provisions on tolerances as regards to nutrition declarations (Article 31.4).

14.4. Additional nutrition information. On the top of the novelties illustrated above, the Regulation allows in principle for the provision of additional nutrition information provided that this latter is based on scientific data, accepted by the majority of stakeholders, non-discriminatory and does not hamper the free circulation of goods.

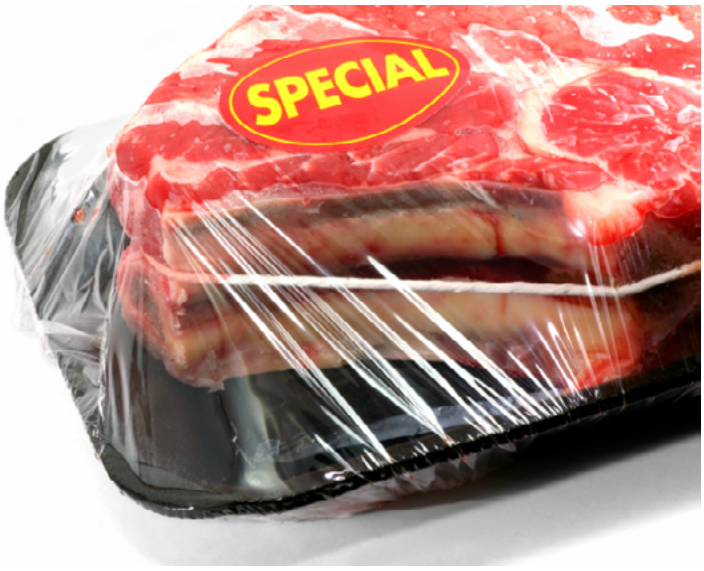
14.5. Trans-fatty acids. Within three years from the entry into force of the Regulation, the Commission will produce a report concerning the appropriateness of providing, on a mandatory basis, information about trans-fatty acids on the tabular nutrition declaration. The report may eventually be accompanied by a legislative proposal.

Until then, the provision of information on trans-fatty acids will not be allowed not even on a voluntary basis (Articles 30.7 and 54. 2-3). This prohibition is likely to be an issue for those food business operators who use the same packaging also for the US market, where indication of these substances on label is compulsory. Should the Commission not succeed in producing this report reasonably ahead of the application of the Regulation, many packs will have inevitably to be disposed of.

15. Ritual slaughter

No specific indication on label is foreseen for meat of animals subject to ritual slaughter *(kosher, halal)*. The suggestion of requiring an indication saying *'product derived from an animal subject to slaughter without stunning'*, which was put forward by some members of the European Parliament during the Regulation's first reading, was not eventually taken forward.

While reviewing the relevant EU legislation in this area, it would be appropriate to try to strike a balance between rituals and religious beliefs, on one hand, and animal welfare concerns, on the other one. The Commission will produce a study on this subject (recital 50).



16. Small packages

Whenever the largest surface of a package is less than 10 cm², the Regulation sets that provision of essential information is sufficient: name of the product, allergens which might be pre-

sent, net weight, minimum durability date ('Best before...') or 'use by' date.[61]

The list of ingredients can be provided with other modalities (e.g. in shops) and must be in any case available upon consumers' request (Article 16.2).

17. Glass bottles intended for reuse indelibly marked

Mandatory information requirements are: name of the product, allergens, net weight, minimum durability date or 'use by' date and nutrition information (Article 16.1).

18. Controls

The Regulation entrusts Member States with the responsibility of organising official controls on food information to consumer *'in accordance with Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules'* (recital 52).

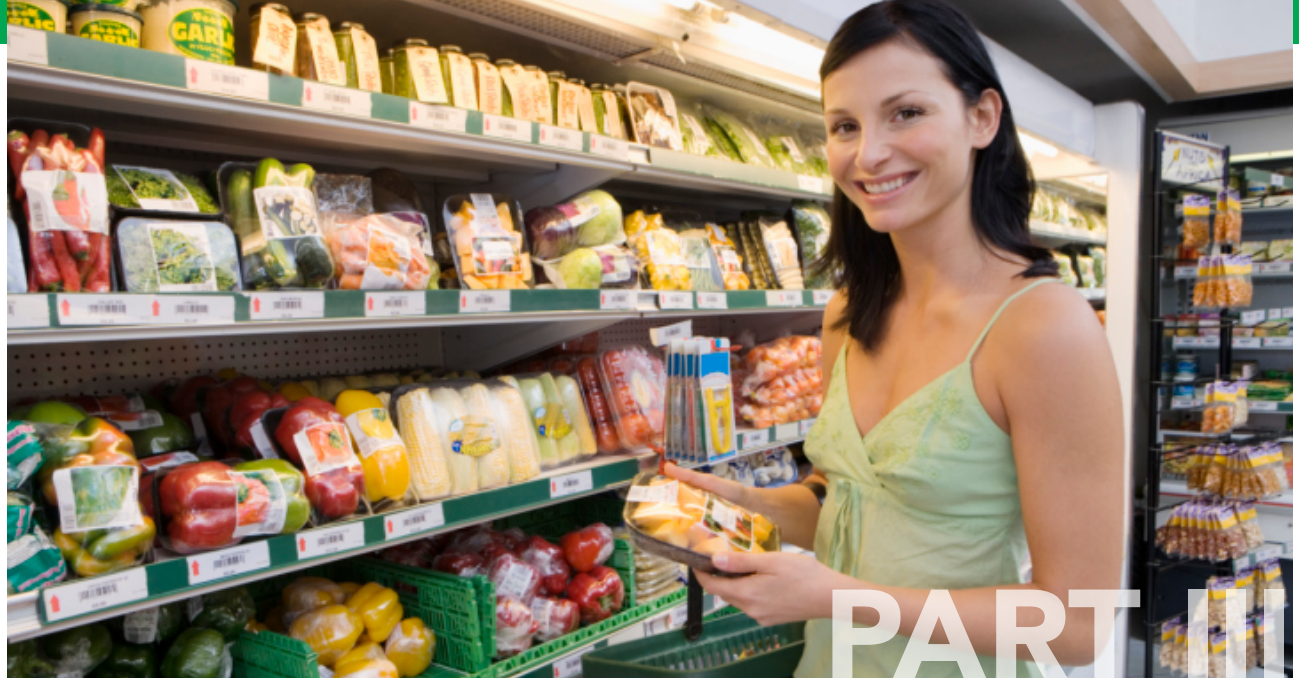
19. Application

The Regulation (EU) No. 1169/2011 went into effect on December 13, 2011 and the new provisions will be applicable after three years (with the exception of the rules on nutrition information which will apply after 5 years).

61 Small packs as defined above are also exempted from the requirement of placing in the same field of vision name of the product, quantity and, where appropriate, alcoholic strenghts (Artcle 13.6)

All the food products labelled in conformity with the legislation currently applicable will be marketable until exhaustion of stocks (Article 54.1). Appropriate transitional periods (*'except in duly justified cases'*) in addition to the possibility of exhausting stocks of products placed on the market before the end of the transitional period, will have to be considered for any future revision (Article 3.3).

The Regulation does not foresee the possibility for food business operators to comply with the new requirements before the application of the Regulation (a possibility which is however allowed only in case of nutrition information, Article 55). A clarification is needed, otherwise food business operators would have to use the 'old' labels until the day before the Regulation becomes applicable and be ready to introduce the 'new' ones as from the following date. This scenario also poses a risk for the environment in terms of waste production. Food information in fact, is not only printed on sticky labels, but also on paper packaging, plastic materials and lithographed aluminium. As a result, all the supporting materials which will not be exhausted by the date of the entry into application of the Regulation will therefore have to be disposed of.



ANALYSIS

1. General principles

Any information of commercial nature relating to food products must be *'accurate, clear, and easy to understand for the average consumer'* (Article 7.2).

1.1. Principle of fair information. *'Food information shall 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, method of manufacture or production;
b) by attributing to the food effects or properties which it does not possess;
c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients,[62]
d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient' (Article 7.1).

62 This prohibition, which was already set in Directive 79/112/EEC, does not however seem to be consistent with principles defined in Regulation (EC) No 1924/2006 and subsequent amendments on nutrition and health claims. This latter in fact foresees the possibility of using nutrition claims on all foods which are covered by its provisions (with the exception of foods intended for special nutrition purposes and alcoholic beverages), provided that compliance with relevant requirements is ensured. This is also when the claimed nutrition properties are common to the food category the product belong to. As a *lex specialis*, the Regulation should prevail on the general principles. This considered, it would be useful to have a uniform interpretation at EU level

These principles *'shall also apply:*
a) advertising
b) the presentation of foods, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed'. (article 7.4).

1.2. Language requirements. Without prejudice to the cases for which the Commission will establish the possibility of using symbols and pictograms[63] to indicate certain information, mandatory information must appear *'in a language easily understood by consumers in the Member States in where the food is marketed'*.[64]

Member States may require that mandatory information is provided in their territories *'in one or more official languages of the EU'*. This requirement applies without prejudice to the possibility of using multi-lingual labels (Article 15).

2. Mandatory information

Food labels can provide mandatory or voluntary information. The Regulation lists as mandatory information the following elements (Article 9):

'a) the name of the food;
b) the list of ingredients;
c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;
d) the quantity of certain ingredients or categories of ingredients;
e) the net quantity of the food,[65]
f) the date of minimum durability or the 'use by' date;
g) any special storage conditions and/or conditions of use;
h) the name or business name and address of the food business operator referred to in Article 8(1);
i) the country of origin or place of provenance where provided for in Article 25;
j) instructions for use where it would be difficult to make appropriate use

63 In this respect, see Part II, paragraph 6 *(Symbols and alternative means of information)*
64 Instead of this solution, the EU institutions could have foreseen for mandatory information to be systematically provided in English, the language mostly understood by European consumers
65 N.B. The net quantity (and, where appropriate, the alcoholic strenght) must be provided in the same field of vision of the name of the products (see Part II, paragraph 5.1, *Information in the same field of vision*)

of the food in the absence of such instructions;
k) with respect to beverages containing more than 1.2% by volume of alcohol, the actual alcoholic strength by volume;
l) a nutrition declaration.'

Mandatory food information must be available and be easily accessible for all foods (Article 12), except for foods which are not prepacked (i.e. foods sold loose or packed for direct sale).[66]

In particular, *'mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material'* (Article 13.1).

Furthermore, *'the mandatory particulars [...] shall be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height,[67] as defined in Annex IV, is equal to or greater than 1.2 mm'* (Article 13.2).

'In case of packaging or containers the largest surface of which has an area of less than 80 cm², the minimum x-height [...] shall be equal to or greater than 0.9 mm' (Article 13.3).

The Commission is finally empowered to establish further rules for legibility[68] with the possibility of extending the relevant requirements *'to additional mandatory particulars for specific types or categories of foods'* (Article 13. 4-5).[69]

2.1. Name of the product. Consumers must be in the position to un-

66 In this regard see Part I, paragraph 2.3. *(Food packed at retail premises)* and footnote 59. N.B. In any event, *'**food business operators**, within the businesses under their control, **shall not modify the information accompanying a food if such modification** would mislead the final consumer or otherwise **reduce the level of consumer protection and the possibilities for the final consumer to make informed choices**. Food business operators are responsible for any changes they make to food information accompanying a food.'* (Article 8.4). In the absence of an authoritative interpretation by the EU legislator or by EU case-law in this regard, from the above mentioned provision it could be inferred that a retailer who unpacks, portions and repacks a food date must not omit to indicate the 'best before' or 'use-by' date. To be placed on the label, under the responsibility of the retailer who should also consider the impact of his activities (i.e. slicing of the ham) on the shelf-life of the product

67 See Annex IV *(Definition of x-height)*

68 For example, type and color of font size, stroke-width, contrast with the background etc. See in this respect *'Guidelines for legibility of labelling'* published by FoodDrink Europe (formerly CIAA) on 20 November 2008. See also footnote 35

69 See Article 13 *(Presentation of mandatory particulars)*

derstand the nature of the food on sale through the name of the product.

The new Regulation makes a distinction between:

• **Legal name:** *'legal name' means the name of a food prescribed in the Union provisions applicable to it*[70] *or, in the absence of such Union provisions, the name provided for in the laws, Regulations and administrative provisions applicable in the Member State*[71] *in which the food is sold to the final consumer or to mass caterers'* (Article 2.1 n),

• **Customary name:** *'customary name' means a name which is accepted as the name of the food by consumers in the Member State in which that food is sold,*[72] *without that name needing further explanation'* (Article 2.1. o).

The legal name must be provided in the first place. When this latter is not available, the customary name must be provided. Should the customary name be also absent, a **descriptive name**[73] must be then supplied (Article 17.1).

In any event, *'the name of the food shall not be replaced with a name protected as intellectual property, brand name or fancy name'* (Article 17.4).

2.2. List of ingredients. The list of ingredients must be preceded a suitable heading including the word 'ingredients' (e.g. 'ingredients', 'list of ingredients').

2.2.1. Indication of the ingredients. The list must include *'all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food'*, provided that they are still present in the finished product, even in an altered form: *'residues shall not be considered as 'ingredients'* (Article 2.2 f).[74]

Ingredients must be designated, where applicable,[75] by their specific name (Article 18).[76]

70 E.g. extra-virgin oil, under Regulation (EC) n. 1019/2002 and subsequent modifications
71 E.g. some cured meats (regulated in Italy by the Ministy of Industry Decree 21.9.05)
72 E.g. cantucci, typical Italian biscuits
73 E.g. 'spreadable nuts cream'
74 The QUID rule *(Quantitative ingredients declaration)* continues therefore to apply
75 This provision seems to imply that shortening the name of certain ingredients (e.g. 'nut cream' instead of 'spreadable nut cream') would be permitted. This is what is actually foreseen by the Italian decree of implementation of the s.c. Labelling Directive
76 In accordance with what described in paragraph 2.1 (Article 17) as well as in Annex VI *(Name of the food and specific accompanying particulars)* and VII *(Indication and designation of ingredients)*

2.2.2. Foods exempted from the obligation of providing the list of ingredients. This category includes:

'a) fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated;
b) carbonated water, the description of which indicates that it has been carbonated;
c) fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;
d) cheese, butter, fermented milk and cream, to which no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or in the case of cheese other than fresh cheese and processed cheese the salt needed for its manufacture;
e) foods consisting of a single ingredient, where:
i) the name of the food is identical to the ingredient name; or
ii) the name of the food enables the nature of the ingredient to be clearly identified' (Article 19).

2.2.3. Substances exempted from the obligation of providing the list of ingredients. Without prejudice to the obligation of indicating allergens which may be present in the food,[77] the following constituents of a food are not required to be included in the list of ingredients:

'a) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;
b) food additives and food enzymes:
i) whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food,[78] [...] provided that they serve no technological function in the finished product; or
ii) which are used as processing aids;
c) carriers and substances which are not food additives but are used in the same way and with the same purpose as carriers, and which are used in the quantities strictly necessary;
d) substances which are not food additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in an altered form;
e) water:[79]
i) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form; or
ii) in the case of a liquid medium which is not normally consumed.' (Article 20).

77 See in this respect paragraph 2.3 *(Labelling of substances or products causing allergies or intolerances).*
78 *'in accordance with the carry-over principle referred to in points (a) and (b) of Article 18(1) of Regulation (EC) No 1333/2008'*
79 As regards added water, see Part II, paragraph 9.4 *(Added water and volatile products)*

2.3. Labelling of certain substances or products causing allergies or intolerances. The presence of substances or products causing allergies or intolerances must always be signalled,[80] even when their presence is residual,[81] in traces or in altered form.

2.3.1. List of allergens. Food allergies and intolerances originate from a multitude of substances. Nevertheless, the EU legislator, in line with *Codex Alimentarius*,[82] has come up with an exhaustive list of substances and products that are subject to a specific information requirement (Annex II).[83] Such a list is subject to periodical revision by the European Commission (Article 21. 2).

2.3.2. Modalities of provision. Substances and products causing allergies or intolerances must feature in the list of ingredients with a clear indication of the name of the substance or of the product as listed in Annex II.[84]

The new Regulation sets out a further requirement:[85] the name of the substance or of the product in hand must be *'**emphasised** through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example, by means of the font, style or background colour'* (Article 21.1.b).

When the food is not subject to the mandatory provision of the list of ingredients on labels,[86] the information concerning the presence of substances or products causing allergies or intolerances must be provided with the wording *'Contains'* immediately followed by the name of the substance or the product as listed in Annex II.[87]

The Regulation introduces also the obligation of repeating the presence of

80 The new Regulation extends such a requirement to all food business operators of the food chain. See Part II, paragraphs 1 *(Scope)* and 4 *(Responsibility)*

81 For example, in case an ingredient with allergen properties is present in processing aid substances used for preparation of the food or in additives or carry-over additives. See in this regard, 'Federalimentare Guidelines for allergen labelling' (availabe at www.federalimentare.it, area 'Documenti', item 'Linee Guida')

82 See *'Codex Standard for General Standard for the Labelling of Pre-packaged Foods'*, paragraph 4.2.1.4 available on http://www.codexalimentarius.net

83 See in this respect Annex II of the Regulation *(Substances or products causing allergies or intolerances)*

84 N.B. The indication should refer to the substance (e.g. almonds), rather than to the general food category (e.g. dried fruit in shell)

85 As opposed to Directive 2003/89/EC

86 See paragraph 2.2.2. *(Foods exempted from the obligation of providing the listing of ingredients)*

87 For example, on the label of wine (as such not subject to the obligation of listing ingredients), whenever content of sulphites is equal or greater than 10 mg/l, the wording' 'contains sulphites' must be provided

an allergen when more than one ingredient or processing aid contains it.

The indication is not required only when *'where the name of the food clearly refers to the substance or product concerned'*[88] (Article 21).

2.4. Quantity of certain ingredients or categories of ingredients. The quantity of an ingredient or of a category of an ingredient[89] must be provided as a percentage value[90] - within the name of the product, or immediately next to the name of the food or in the list of ingredients - *'where the ingredient or the category of ingredients concerned:*

a) appears in the name of the food[91] *or is usually associated with that name by the consumer;*[92]
b) is emphasised on the labelling in words, pictures or graphics;[93] *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'[94] (Article 22).[95]

2.5. Net quantity of the food. The net quantity of a food is expressed by using, as appropriate, litre, centilitre, millilitre, kilogram or gram:

a) in units of volume in the case of liquid product,
b) in units of mass in the case of other products (Article 23).

The technical rules for indication of the net quantity, including cases in which this is not be provided, are laid down in Annex IX *(Indication of the net quantity).*

88 E.g. milk, soluble barley, wheat flour. The European Commission in its Guidelines for the application of the allergen Directive (2003/89/EC and subsequent modifications) has clarified that it is not necessary to indicate the allergen (e.g. milk) also in case of products (yoghurt, cream, butter, cheese) whose name is easily associated by the average consumer with the allergen in question (http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/guidelines_6_10.pdf). In line with this approach, see also Federalimentare Guidelines (http://www.federalimentare.it/Documenti/LineeGuida/Allergeni_rev2_6nov09.pdf).
89 i.e. the quantity of the ingredient or of the ingredients at the time of their use
90 According to the criteria laid down in Annex VIII of the Regulation, points 3 and 4
91 E.g. ravioli with ricotta and spinach
92 E.g. in Italy almonds in torrone, potatoes in gnocchi pasta
93 E.g. the image of the egg on a pack of mayonnaise
94 E.g. milk and nuts in a cocoa spreadable cream
95 The specific rules for the quantitive indication of ingredients, *'including specific cases where the quantitative indication shall not be required in respect of certain ingredients'*, are set in Annex VIII *(Quantitive indication of ingredients)*

It is also recalled that *'where a solid food is presented in a liquid medium, the drained net weight of the food must also be indicated'*.[96]

As regards semi-solid foods,[97] *'in the absence of Union provisions [...] Member States may maintain national measures adopted before'* the date of entry into force of the Regulation (Article 42).[98]

Finally, a novelty: *'where the food has been glazed, the declared net weight of the food shall be exclusive of the glaze'* (Annex IX, point 5).

2.6. Minimum durability or 'use-by' date. Provisions of minimum durability date remains mandatory and must be expressed with the wording *'Best before end...'*[99] (so-called 'best before' date)[100] or - *'in the case of 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* - with the wording 'use-by' (so-called 'use-by' date).

The modalities of provision on label of these terms are set in Annex X (*Minimum durability date, 'use-by' date and date of freezing*). In this respect, the following elements must be noted:

- the new obligation of indicating the **'use-by' date on each individual pre-packed portion**[101] (Annex X, 2. d),
- the clarification as to the possibility to refer to a different part of the packaging or of the label where such a date is provided (Annex X, 1 b, 2b),[102]
- *'if need be, these particulars shall be followed by a description of the storage conditions which must be observed if the product is to keep for the specified period'* (Annex X, 1.b, last indent).[103]

96 *'For the purpose of this point 'liquid medium' shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine, aqueous solutions of food acids, vinegar, aqueous solutions of sugars, aqueous solutions of other sweetening substances, fruit or vegetable juices in the case of fruit or vegetables'*

97 E.g. sauces (mayonnaise, mustard, kecthup), ice-creams

98 Consumers are used to see information (including nutrition table) based on the weight of these products in some Member States, based on the volume in some others

99 'Best before...' when the date includes the indication of the specific day

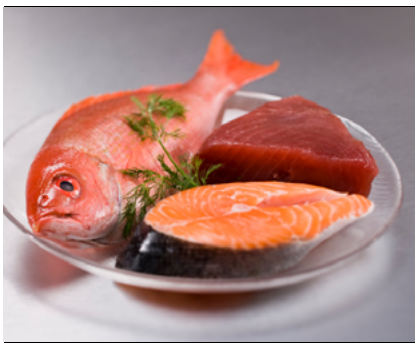
100 For modalities of indication see footnote 31

101 N.B. The 'use-by' date will have then to be printed also on the packaging of the sealed individual portions that are contained in a multi-pack packaging

102 E.g. 'Best before: see date on cap'

103 N.B. It is worth underlining that the business operator is responsible for the safety of his products as well as for their conformity with the carachteristics claimed for the entire durability period which is given on the label. It is therefore advisable to provide any information aimed at avoiding that the product in question perishes because of inapproriate storage (e.g. 'To be stored away from light and heat', which applies to a wide range of foods)

The new Regulation sets that *'after the 'use by' date a food shall be deemed to be unsafe in accordance with Article 14 paragraphs 2 to 5 of Regulation (EC) No. 178/2002'* (Article 24.1). Besides not being in line with the provisions above referred to,[104] this provision entails a further and unjustified inconsistency: while the obligation of indicating the 'use-by' date is applied rigorously in case of pre-packed foods (i.e. pre-packed by producers), the same obligation does not apply to foods sold loose or packed at retail premises.[105]



2.7. Date of freezing. As anticipated, and despite some criticism,[106] the Regulation introduces the mandatory requirement of providing the date of freezing for *'meat, meat preparations and unprocessed fishery products which have been frozen'* (Annex III. 6).

The date (day, month, year) of freezing or first freezing (for products that have been frozen more than once) must be preceded by the wording *'Frozen on...'*.[107] Also in this case the Regulation allows for redirecting to another part of the packaging where the date is printed.[108]

2.8. Storage conditions and/or conditions of use. *'In cases where foods require special storage[109] conditions and/or conditions for use,[110] those conditions shall be indicated'*.

A novelty: *'to enable appropriate storage or use of the food after opening the package, the storage conditions and/or time limit for consumption shall*

104 Regulation (EC) n 178/2002, the so-called General Food Law, is based on the principle of the risk assessment: when a food poses any actual danger to consumer health (taking into consideration the possible medium term effects, the impact which may have on descendants, the vulnerability of certain consumer categories and the accompanying information), it is subjected to corrective actions (i.e. withdrawal, notification by the competent health authority, consumer information campaigns, and recall as foreseen by Article 19 of the same Regulation). The presumption by law introduced by the new Regulation is not coherent with risk assessment principle. It is even unrealistic as generally operators tend to be rather prudent while fixing the 'use-by' date under their own responsibility. As a result, it is highly unlikely that the product is effectively dangerous as of the day following the 'use-by' date. On the opposite, this approach may lead to an undesired scenario where operators risk incurring in major sanctions also for minor carelessnesses (e.g. a cafeteria's owner who forgets disposing of the milk that has reached the sell-by date before the evening closing) and, in so doing, prompt unjustified alerts about the existence of a public health risk

105 See Part I, paragraph 2.3 *(Foods packed at retail premises)* and the Part III, paragraph 2 *(Mandatory information)*. See also the following article http://www.alimentibevande.it/attualita.aspx?id=82434

106 See Part II, paragraph 12 *(Date of freezing)*

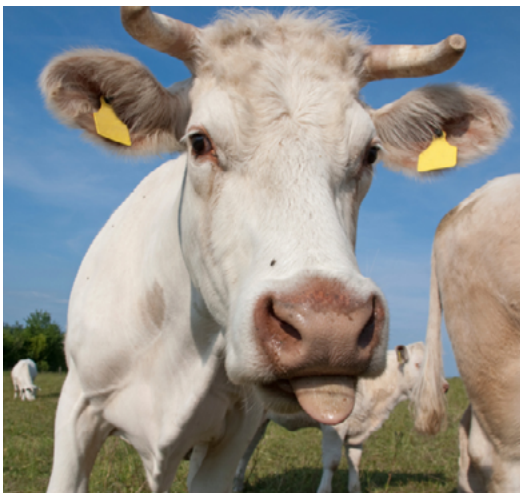
107 According to the modalities laid down in Annex X .3 *(Minimum durability date, 'use-by' date and date of freezing)*.

108 E.g. 'Frozen on: see on opening side'

109 N.B. In this case it is relevant what suggested in footnote 103

110 N.B. In accordance with Artcle 14 of Regulation (EC) 178/2002, the safety of a food is to be considered against its normal conditions of use. Indications of special conditions of use (e.g. 'eat after cooking' on a pack of minced meat) are relevant also while assessing the safety of the product (as to the example referred above, cooking permits to eliminate salmonella and lysteria, which could represent a risk for the consumer if the meat was to be eaten raw)

be indicated, where appropriate' (Article 25).[111]



2.9. Name or business name and address of the operator. The label must bear the name or the business name and the address of *'the operator whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market'* (Article 8.1).

This operator is **responsible** for the information provided on its products and *'shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions'* (Article 8.2).[112]

As opposed to the regime currently applicable in Italy,[113] two elements are worth noting:

- the possibility of identifying the operator only through a registered trade mark is excluded,
- the obligation of indicating the place where the production or packaging site is located is no longer required.[114]

2.10. Country of origin and place of provenance. As already anticipated,[115] the new Regulation introduces some novelties as regards the obligation of providing the origin and/or the provenance of foodstuffs.

2.10.1. General rule. The indication of the origin of a food (i.e. the place where the product underwent its last transformation)[116] remains voluntary, except for:

- labelling requirements applicable to certain products or categories of

111 It is the so-called *'Period After Opening'* (PAO), a mandatory requirement which has been introduced on chemical and pharmaceuticals products since 2005. This information, based on shelf-life laboratories, tends to not be fully precise as the durability of a food product depends on its conditions of use in the relevant supply stages i.e. logistics, marketing and after sale

112 See paragraph 2 *(Mandatory information)* and in particular footnote 65

113 D.Lgs. 27.1.92 n.109 and subsequent modifications

114 The address of the production and packaging site could already be omitted in case of products bearing the identification mark. This mark is constitued by an oval form which includes: the abbreviation of the State of production or packaging (es. IT to indicate Italy), the registration number of the plant (or the indication of the part of the label in which such a mumber has been printed, and the acronym of the European Community (EC). In this respect, see also http://www.ilfattoalimentare.it/nome-ragione-sociale-marchio-registrato-dubbio-etichettatura.html

115 See paragraph 2.13 *(Origin and provenance)*

116 In accordance with article 2.3 of the Regulation, the definition of the place of origin is the one provided by the Common Custom Code. In particular, the reference is made to Regulation (EEC) n. 2913/1992 , artcle 23-26. As from 23 June 2013 the Code currently applicable will be formally replaced by Regulation (EC) No. 450 of 23 April 2008, published in OJ L 145 of 4 June 2008. The relevant provision which identifies the origin of the product with the place where it underwent its last substantial transformation is Article 36

products set by specific EU provisions,[117]

- PDO (protected designations of origin), PGI (protected geographical indications),[118] TSG (traditional specialities guaranteed),[119]

- *'where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole*[120] *would otherwise imply that the food has a different country of origin or place of provenance'*, (Article 26.2.a).

2.10.2. Origin and provenance of the product when different from that one of the primary ingredient. *'Where the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient:*[121]

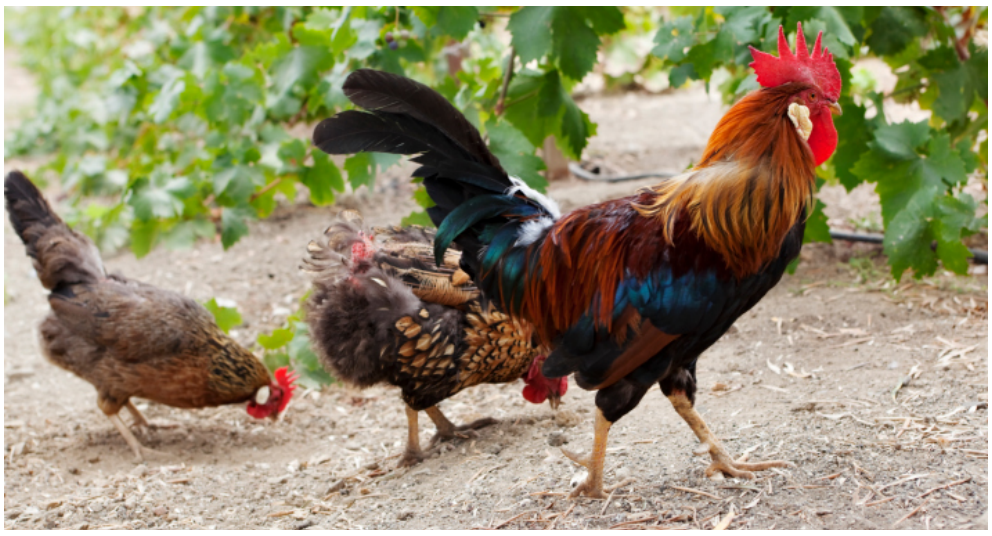
a) the country of origin or place of provenance of the primary ingredient in question shall also be given; or
b) the country of origin or place of provenance of the primary ingredient shall be indicated as being different to that of the food.'

The application of this provision is subject to adoption of the implementing acts by the European Commission within two years from the entry into force of the Regulation (Article 26.3).

2.10.3. Origin of meat. The Regulation introduces the obligation of providing the origin of meat[122] - fresh, chilled or frozen - of the following types: swine, sheep and goats, and poultry of the CN code 0105.[123]

Also in this case, the application of this provision is subject to adoption of the implementing acts by the European Commission within two years from

117 E.g. bovine meat (Reg. EC no. 1760, 1825/2000), fruit and vegetables (Reg. EC no. 2200/96 and 1580/07), fresh fishery products (Reg. EC no. 104/00 and 2065/01), honey (Dir. 2001/110/EC), virgin and extra-virgin oils (Reg. EC no.1019/2002)
118 Regulation (EC) No. 510/2006
119 Regulation (EC) No. 509/2006
120 For example, in case of symbols, pictogramms or images commonly associated with a country although the product has been produced in a different country
121 *'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'* (Article 2.2.letter q)
122 This concerns meat with the CN codes listed in Annex XI *(Types of meat for which indication of the country of origin or place of provenance is mandatory)*
123 Cocks, hens, ducks, geese, turkeys and guinea-hens. Curiously, quails have been forgotten (!)



the entry into force of the Regulation (Article 26.2.b).[124]

The Commission will have also to consider *'the options for the modalities of expressing the country of origin or place of provenance of those foods, in particular with respect to each of the following determining points in the life of the animal:*

a) place of birth,
b) place of rearing,
c) place of slaughtering.' (Article 26.9).[125]

Finally within two years from the entry into force of the Regulation, *'the Commission shall submit a report[126] to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance for meat used as an ingredient'* (Article 26.6).[127]

2.10.4. Origin of other categories of products. Within three years from the entry into force of the Regulation, *'the Commission shall submit reports to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance for the following foods:*

124 The provision in Article 26.4 whereby *'within five years from the date of application of point (b) of paragraph 2, the Commission shall submit a report to the European Parliament and the Council to evaluate the mandatory indication of the country of origin or place of provenance for products referred to in that point'* would seem therefore to be a typo

125 E.g. in case of bird meat, origin information could be a single one as generally place of birth, rearing and slaughtering are the same

126 To this end, the Commission will have to take into account *'the need for the consumer to be informed, the feasibility of providing the mandatory indication of the country of origin or place of provenance and an analysis of the costs and benefits of the introduction of such measures, including the legal impact on the internal market and the impact on international trade'* (Article 26.7)

127 E.g. meat used as ingredient in delicatessen products, Vienna sausage, filled pasta, ready-to eat meals, meat sauces

a) types of meat other than beef and those referred to in point (b) of paragraph 2;
b) milk;
c) milk used as an ingredient in dairy products;
d) unprocessed foods;
e) single ingredient products;
f) ingredients that represent more than 50% of a food' (Article 26.5).

Such reports[128] will have to be drafted by taking into account the following elements:

- *'the need for the consumer to be informed,*
- *the feasibility of providing the mandatory indication of the country of origin or place of provenance and*
- *an analysis of the costs and benefits of the introduction of such measures, including the legal impact on the internal market and the impact on international trade'* (Article 26.7).

2.11. Instructions for use. *'The instructions for use of a food shall be indicated in such a way as to enable appropriate use to be made of the food'* (Article 27.1).[129]

The Regulation leaves to the Commission the possibility of adopting implementing acts establishing specific rules for conditions of use for certain foods (Article 27.2).[130]

2.12. Alcoholic beverages, alcohol strength. The obligation of providing the actual alcohol strength for beverages with a strength higher than 1.2% is maintained.

For products classified under CN Code 2204, the modalities of indication are those laid down by the relevant EU specific provisions applicable to such products (Article 28.1).

For beverages with an alcoholic strength more than 1.2% by volume of alcohol other than those above referred, modalities of provision of such an information are laid down in Annex XII (Article 28.2): the strength is to be expressed by a figure with no more than one single decimal place immediately followed by *'% vol'*, which may be preceded by the word *'alcohol'* or by the equivalent abbreviation *'alc'*. Alcohol strength is determined at 20°C according to the specific tolerances foreseen.[131]

128 As the report referred to in paragraph 2.10.3 *(Origin of meat)* as regards the indication of the origin of meat used as an ingredient
129 E.g. time and preparation of a frozen ready-to-eat product or of a freeze-dried soup
130 One could imagine the EU institutions to establish a single symbol for pasta's cooking time
131 See Annex XII *(Alcohol strenght)*

2.13. Nutrition declaration. The major novelty in this area is the requirement of a **mandatory nutrition declaration** - with a few variations as opposed to the currently applicable nutrition panels[132] - together with the voluntary provision of nutrition information expressed in GDA values.[133]

Food supplements[134] and mineral waters[135] are exempted from the requirements in question.

These rules apply without prejudice to EU provisions concerning foodstuffs intended for particular nutritional uses.[136]

Values are to be expressed by 100g or 100ml (Article 32.2) and, where possible, by portion (Article 33.1.a). *'The portion or unit used shall be indicated in close proximity to the nutrition declaration'* (Article 33.3).[137] The Regulation entrusts the Commission with the task of adopting by means of implementing acts rules on the expression per portion or per consumption unit for specific categories of foods, taking into account actual consumption behaviour of consumers as well as dietary recommendations (Article 33.4).[138]

If space permits, values are to presented in tabular format with the numbers aligned. Where space does not permit, the declaration shall appear in linear format (Article 34.2).

2.13.1. Mandatory nutrition declaration. The following elements must be provided on a mandatory basis:

- energy value, and
- values for fats, saturated fats, carbohydrates, sugars, proteins and salt.

"In cases where the energy value or the amount of nutrient(s) in a product is negligible, the information on those elements may be replaced by a statement such as "Contains negligible amounts of…" and shall be indicated in close proximity to the nutrition declaration when present." (art. 34.5). The Commission may adopt implementing acts regarding the energy value and

132 See Part I, paragraph 2.4 *(Some missed opportunties - Nutrition information, continuity with existing schemes)*
133 See Part II, paragraph, 14.3 *(GDA's)* and in particular the relevant footnotes
134 Directive 2002/46/EC (transposed in Italy with d.lgs. n. 169/ 2004 and subsequent modifications. See in particular http://www.salute.gov.it/alimentiParticolariIntegratori/paginaInternaMenuAlimentiParticolariIntegratori.jsp?id=995&menu=integratori)
135 Directive 2009/54/EC. The Italian draft transposition law is currently under the scrutiny of the national Parliament. In this respect see http://parlamentosalute.osservatorioistituzioni.it/articles/4532-atto-governo-379-schema-di-decreto-legislativo-recante-attuazione-della-direttiva-2009-54-ce-sull-utilizzazione-e-la-commercializzazione-delle-acque-minerali-naturali)
136 Directive 2009/39/EC and other there referred to. As regards national provisions, see http://www.salute.gov.it/alimentiParticolariIntegratori/paginaInternaMenuAlimentiParticolariIntegratori.jsp?id=985&menu=dietetici). With reference to the revision of the relevant EU regime see the following articles http://www.ilfattoalimentare.it/prodotti-dietetici-la-commissione-propone-di-ridimensionare-la-categoria-.proteste-dei-celiaci.html, http://www.ilfattoalimentare.it/celiachia-malattia-dieta-nuove-normative.-intervista-caterina-pilo-associazione-italiana.html, http://www.alimentibevande.it/attualita.aspx?id=82553
137 E.g. '1 biscuit equal to 15g', '1 glass equal to 125 ml'
138 In this respect see footnote 58

amounts of nutrients which can be regarded as negligible.

'Where appropriate, a statement indicating that the salt content is exclusively due to the presence of naturally occurring sodium may appear in close proximity to the nutrition declaration' (Article 30.1).

2.13.2. Voluntary information. The nutrition declaration as described in the above paragraph may be supplemented, on a voluntary basis, with information about *'the amounts of one or more of the following:*
a) mono-unsaturated fats;
b) polyunsaturated fats;
c) polyols;
d) starch;
e) fibre;
f) any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII'[139] (Article 30.2).

N.B.: the provision of **cholesterol** value is not any more admitted.

These elements - in addition to being expressed per 100g/ml and, where possible, per portion (Article 33.1.b) - may be indicated *'as a percentage of the reference intakes set out in Part A of Annex XIII point 1'* (Article 32.4).

In relation to **foods packed at retail premises** the nutrition declaration may be provided on a voluntary basis (without prejudice to specific national provisions)[140] and *'be limited to:*

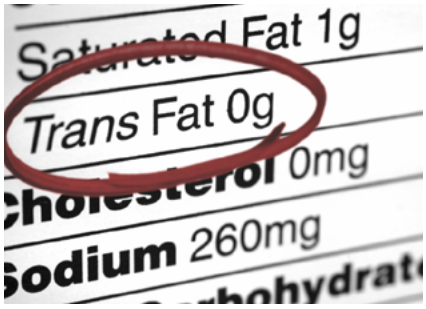
a) the energy value;
b) the energy value together with the amounts of fat, saturates, sugars, and salt' (Article 30.5). The provision in a tabular form is not required in this case (Article 34.4).

Alcoholic beverages are exempted from the obligation of providing the nutrition declaration.[141] However, where the labelling provides a nutrition declaration, the content of this latter may be limited to the energy value only (Article 30.4).

2.13.3. Nutrition information in the principal field of vision. Where the labelling of a pre-packed food provides the mandatory nutrition declaration, the following information may be repeated:

a) the energy value; or
b) the energy value together with the amounts of fat, saturates, sugars, and salt (Article 30.3).

139 See Annex XIII *(Reference intakes)*
140 See Article 44 of the Regulation
141 Article 16.4. See Part II, paragraph 3 *(Alcoholic beverages)*



The information above mentioned is to be expressed in a clearly legible way[142] (with a font size with a x-height of at least of 1.2 mm)[143] and be placed in the principal field of vision[144] (Article 34.3). The provision of such an information in a tabular format is not required (Article 34.4).

In this case, the amount of nutrients - with the exception of the energy value which has to be provided also per 100g/ml in accordance with Article 33.2)[145] - *'and/or the percentage of the reference intakes'*[146] may be expressed on the basis of per portion or per consumption unit alone (Article 33.2).

2.13.4. Calculation of nutritional values and tolerances. *'The energy value shall be calculated using the conversion factors listed in Annex XIV'* (Article 31.1).[147]

'The energy value and the amounts of nutrients […] shall be those of the food as sold. Where appropriate, the information may relate to the food after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption' (Article 31.3).

The values declared by the business operator, according to the individual case, must be the *'average values based on:*

a) the manufacturer's analysis of the food;
b) a calculation from the known or actual average values of the ingredients used; or
c) a calculation from generally established and accepted data' (Article 31.4).

The Commission may adopt, through implementing acts, detailed rules for defining in an uniform manner tolerances between *'the declared values and those established in the course of official checks'* (Artcle 31.4, last indent).

2.13.5. GDA's.[148] In addition to the form of expression referred per 100g/ml, *'the energy value and the amounts of nutrients [...] may be expressed, as appropriate, as a percentage of the reference intakes set out in Part B of Annex XIII in relation to per 100 g or per 100 ml*[149] [and/or per portion,

142 With a font size with a x-height as defined by Annex IV which is equal to or greater than 1,2 mm (in accordance with Article 13.2)
143 In conformity with Article 13.2
144 *'Principal field of vision' is the field of vision of a package which is most likely to be seen at first glance by the consumer at the time of purchase and that enables the consumer to immediately identify a product in terms of its character or nature and, if applicable, its brand name. If a package has several identical principal fields of vision, the principal field of vision is the one chosen by the food business operator'* (Article 2.2 letter l)
145 With the exception of foods pre-packed at retail premises in accordance with Article 33.3
146 The so-called GDA's values. See also paragraph 2.13.4 *(Calculation of nutritional values and tolerances)*
147 See Annex XIV *(Conversion factors)*
148 See Part II, paragraph 14.3 *(GDA's)* and the relevant footnotes
149 See Annex XIII *(Reference intakes)*, Part B *(Reference intakes for energy and selected nutrients other than vitamins and minerals, adults)*

as foreseen by Article 33.1.c]' (Article 32.4).

Under such circumstances, the following additional information must *'be indicated in close proximity to it: 'Reference intake of an average adult (8400 kJ/2000 kcal)'* (Article 32.5).

"I read all package labels for my health. Now my eyes are shot!"

2.13.6. Additional forms of expression of nutrition information. The Regulation introduces the possibility of indicating the energy value and the amounts of nutrients *'by other forms of expression and/or presented using graphical forms or symbols in addition to words or numbers provided that the following requirements are met:*

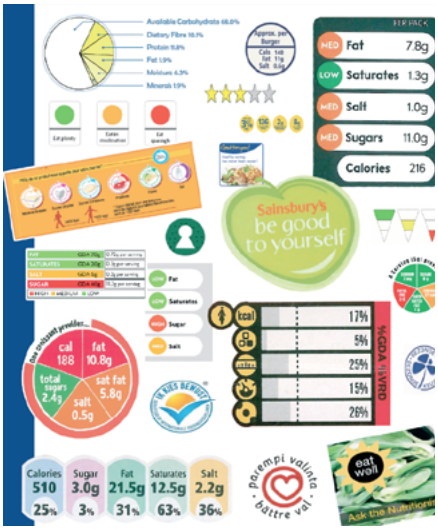
a) they are based on sound and scientifically valid consumer research and do not mislead the consumer as referred to in Article 7;
b) their development is the result of consultation with a wide range of stakeholder groups;
c) they aim to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet;
d) they are supported by scientifically valid evidence of understanding of such forms of expression or presentation by the average consumer,
e) in the case of other forms of expression, they are based, either on the harmonised reference intakes in Annex XIII (i.e. GDA's), or in their absence, on generally accepted scientific advice on intakes for energy or nutrients,
f) they are objective, non-discriminatory; and
g) their application does not create obstacles to the free movement of goods' (Article 35. 1).

To this end, the Regulation provides that *'Member States may recommend to food business operators the use of one or more additional forms of expression or presentation of the nutrition declaration that they consider as best fulfilling the requirements laid down in points (a) to (g) of paragraph 1.'* (Article 35.2).[150]

Thanks to this last provision some Member States have thought to be able to preserve their national signposting schemes such as the *'traffic light'* in the United Kingdom, the *'healthy logo'* in the Netherlands, the *'keyhole'* in Sweden, Finland and Denmark.[151] However, none of such schemes - independently from any evaluation of their scientific basis - is compatible with the new

150 Member States are also required to monitor the use of such additional forms of expression and presentation in their territories and provide the Commission with detailed information (Article 35. 2-3)
151 In this respect see the following articles http://www.ilfattoalimentare.it/crociata-semafori-etichetta-regno-unito-usa-e-ritorno.html and http://www.ilfattoalimentare.it/danimarca-romania-semafori-etichette-alimentari.html

Regulation for the following reasons:



• *'the other forms of expression and presentation'* are admitted only as regards *'the energy value and the amounts of nutrients'*[152] (Article 35.1). In light of this, it would be possible to present proteins with the logo of Popeye, but not to express any judgement on the healthy nature of the product based on the presence of proteins,[153]

• the national signposting schemes above referred inherently formulate judgement on the nutritional characteristics of foodstuffs and, in so doing, discriminate between foods as if there were 'good', 'less good' and 'bad' foods It is evident that this approach goes against the principle of free circulation of goods.[154]

Within six years from the entry into force of the Regulation, *'in the light of the experience gained, the Commission shall submit a report to the European Parliament and the Council on the use of additional forms of expression and presentation, on their effect on the internal market and on the advisability of further harmonisation of those forms of expression and presentation'* (Article 35.5).[155]

2.13.7. Trans-fatty acids. Within three years from the entry into force of the Regulation *'the Commission, taking into account scientific evidence and experience acquired in Member States, shall submit a report on the presence of trans fats in foods and in the overall diet of the European population.*[156] *The aim of the report shall be to assess the impacts of appropriate means that could enable consumers to make healthier food and overall dietary choices or that could promote the production of healthier food options offered to consumers, including, among others, the provision of information on trans fats to consumers or restrictions on their use. The Commission shall accompany this report with a legislative proposal, if appropriate'* (Article 30.7).[157]

152 i.e. the substances which feature in the mandatory nutrition declaration (fats, saturated fats, carbohydrates, sugars, proteins and salt) and in the voluntary declaration (mono-unsaturated and/or polyunsaturated fats, polyols, starch, fibre, minerals and vitamins). Trans-fats - which are generally included in national signposting schemes - are on here clearly excluded

153 The indication of nutritional properties of foodstuffs is subject to harmonized rules with the specific objctive of ensuring the effective functioning of the internal market and a high level of consumer protection (see the 'Claims' Regulation, (EC) No. 1924/2006, Article 1.1, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF)

154 This is in clear contrast not only with the conditions set in Article 35.2, letters f) and g), but also with the nutrition science. According to such a science, there is not such a thing as a bad or a good food, but it is a balanced variety of foods which contributes to a healthy diet and lifestyle

155 Although European consumers have stilll to fully digest the requirements set by the new Regulation, the EU legislator alraeady at this stage foresees to add further complications on their plate...

156 EFSA has already intervened on this subject with its opinion on nutrient profiles for foodstuffs (see http://www.efsa.europa.eu/en/efsajournal/pub/644.htm), acknowledging that use of ingredients containing trans-fatty acids has been already significantly reduced in Europe mainly because of the initiatives undertaken by industry in this area

157 See on the same subject Part II, paragrapah 14.5 *(Trans-fatty acids)*, last indent

3. Voluntary information.

As for mandatory information, the general requirements of trustworthiness and completeness, fairness and accessibility by consumers apply to voluntary information when this latter is provided.[158]

The Regulation clarifies that voluntary information must neither be ambiguous nor misleading for the consumer. Where appropriate, it must be *'based on relevant scientific data'* (Article 36.2)

The Commission is tasked with the adoption of implementing acts to *the following voluntary food information:*

a) information on the possible and unintentional presence in food of substances or products causing allergies or intolerances,[159]
b) information related to suitability of a food for vegetarians or vegans,[160]
c) the indication of reference intakes for specific population group(s) in addition to the reference intakes referred to in Annex XIII'[161] (Article 36.3).[162]

The Commission may introduce rules for additional cases of provision of voluntary food information (Article 36.4).[163]

As to presentation, the Regulation provides that *'voluntary food information must not be displayed to the detriment of the space available for mandatory food information'* (Article 37)[164]

In this context, it is finally important to recall two further elements:

158 See Part I, paragraph 1 *(General principles)*
159 i.e. Criteria and modalities to express informatiion such as 'it may contain... (name of the allergen)', in line with what foreseen by Guidelines elaborated by the Food Standards Agency in the United Kingdom http://www.food.gov.uk/multimedia/pdfs/publication/allergenlabelguidance09.pdf), but also those produced by FoodDrinkEurope, the European trade organization of the food industry
160 Also in this respect, see Guidelines *'Clear Food Labelling'* by UK Food Standards Agency http://tna.europarchive.org/20100910172942/http://www.food.gov.uk/foodindustry/guidancenotes/labelregsguidance/clearfoodlabelling)
161 This is the case, for example, of GDA's for children for products which are targeted to them
162 *'Pending the adoption of the Union provisions referred to in point (c) of Article 36(3), Member States may adopt national measures on the voluntary indication of reference intakes for specific population groups'* (Article 43 - *Voluntary indication of reference intakes for specific population group)'*
163 The Commission could for example specify instructions for use of certain claims such as 'natural', 'natural ingredients' (e.g. Guidelines by UK Food Standard Agency available at http://www.food.gov.uk/multimedia/pdfs/fresh.pdf), 'home-made product' (e.g. Italian Ministry of Industry Circular No. 168/2003)
164 Although the rationale of such a provision can be shared, its practical implications need further clarification. On the ther hand the new Regulation has already introduced clear rules on legibility criteria of mandatory information (see previous paragraphs 2, *Mandatory information*, and Part II, paragraphs 8, *Legibility*)

• the commitments undertaken on a voluntary basis by several food business operators, in particular in the framework of European platforms such the *'EU Platform for Action on Diet, Physical Activity and Health'*.[165]

• the role of independent authorities in ensuring fairness of commercial practices, information and advertising.[166]

4. Controls and sanctions

4.1. Official controls. As already mentioned, the Regulation leaves to Member States the competence of organising official controls in the area of food information to consumers with the same modalities as for official controls on food safety.[167]

This provision represents a major step forward in ensuring the effective functioning of the internal market as it entails the designation and the coordination of national authorities designed to carry out controls and the setting up of procedures for this purpose.

The authority designated by each Member State will have to produce annual reports on the audits carried and, based on their evaluation (e.g. localization, categories of operators, products and areas with higher non-compliances rates) plan controls for the future audit cycles.

From its side, the European Commission will monitor audit activities by national authorities, by receiving reports of specific audits and programs as well as by carrying out its own audits with the aim of verifying the effectiveness of controls performed at national level.

Commercial information concerning foods is also relevant in two further aspects:

• fairness of competition amongst businesses and of business practices in their relation with consumer,
• responsible communication and advertising.

165 See http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm, http://www.ilfattoalimentare.it/la-piattaforma-europea-su-dieta-attivit.html and further articles on http://ilfattoalimentare.it/kelloggs-e-nestl%C3%A9-reclamizzano-i-loro-prodotti-nei-programmi-tv-per-bambini-%C3%A8-corretto.html

166 Unfair commercial information may be sanctioned by different authorities, as described in the following paragraph 4, *Controls and sanctions.* For an example of various interventions on the same case by 'Istituto per l'autodisciplina Pubblicitaria' and of the 'Autorità Garante per la Concorrenza e il Mercato' (AGCM) in Italy see http://www.ilfattoalimentare.it/lantitrust-censura-pool-pharma-200-mila-€-di-multa-per-le-bugie-di-kilocal.-ii-media-ignorano.-vergo.html

167 See Part II, *Novelties*, paragraph 18 *(Controls)*

4.2. Competition and fair commercial practices. Surveillance and enforcement of EU rules on competition and unfair commercial practices lies with independent authorities institutional bodies at national level[168] as it is the case in Italy for *'Autorità garante per la Concorrenza e il Mercato (AGCM)'*.[169] These authorities and bodies all operate under the supervision of the European Commission, Directorate-General for Competition and - as far as unfair commercial practices are concerned - Directorate-General of Health and Consumers.[170]

These authorities intervene following a complaint - generally put forward by a consumer, a business, or their representative bodies - or, when foreseen by the national law, by their own initiative.[171]

Following the opening of proceedings, a preliminary investigation is carried out. Should any violation emerge from such an investigation, this may lead to a sanction against the offender which may entail:

• the obligation for the offender to undertake the necessary remedial actions i.e. eliminating or modifying the information (conveyed through labelling or advertising) which is deemed incorrect.[172]

168 The authorities are independent from the political, legislative and judiciary powers

169 The *'Competition Commission'* in the United Kingdom, the *'Autorité de la Concurrence'* in France, the *'Bundeskatellamt'* in Germany, the *'Comision Nacional de la Competencia'* in Spain, etc.

170 See http://ec.europa.eu/competition/index_en.html

171 The AGCM contributes to clarifying the criteria to follow to ensure the appropriateness of consumer information, in certain cases even ahead specific rules are laid down. This is what happened, for example, in the case of nutrition and health claims: well before the entry into application of Regulation 1924/2006 the AGCM has intervened on the guidelines by the Italian Ministry of Health and of the 'Istituto Nazionale di Ricerca su Alimenti e Nutrizione' (INRAN) to define some essential principles. To start with, the prohibition of commercially promoting certain foods as capable to cure e.g. constipation, ulcers, sexual disturbs or cardiovascular diseases (PI/3588-2002, PI/4563-2004, PI/6008-2007, PB/582 e PS/3689 in 2010). Furthermore, the prohibition of advertising certain products as capable of reducing calories absorption, cholesterol, cell ageing without making reference to the need of a healthy diet in association with the practice of a regular physical activity (PI/3128, PI/3418, PI/3162, PI/3323, PI/2551B e PI/3495 in 2001, PI/3742, PI/3803, PI/3849 e PI/3588 in 2002, PI/4257, PI/3972, PI/4258 e PI/4214 del 2003, PI/4519, PI/4355 e PI/4398 in 2004, PI/4944, PI/4681, PI/4495, PI/4597, PI/4783, PI/4850 e PI/4868 in 2005, PS/195 e PS/917 in 2008, PS/5595 in 2010). Finally, the obligation of providing appropriate information about the risk associated with products (PI/2551B, PI/3162, PI/3348 e PI/3128 in 2001, PI/2551C; PI/3634; PI/3588; PI/3776 e PI/3778 in 2002, PI/5001 in 2005, PI/6008 in 2007 e PS/3689 in 2010). As regards the misleading nature of food labels, the AGCM has intervened in a number of occasions (PS/5582, PS/5851, PS/6425, PS/6691, PS/6813, PS/6863, PS/6892 (2011), PS/411 e PB/11 (2008), PI/5375, PI/5156, PI/5216 (2006), PI/4767 (2005), PI/4590 (2004), PI/4237 (2003), PI/3894, PI/3709, PI/3614, DP/4373 (2002), DP/4162, DP/4165, PI/3458, DP/4921 (2001). In the area of traditional specialities and geographical indications (PS/4850 (2011), PI/4817, PI/4818, PI/4819, PI/4847 (2005), PI/4087, PI/4162, PI/3997 (2003). In order to search for the above AGCM measures is sufficient to digit the number and the year in the search field at http://www.agcm.it/consumatore/consumatore-delibere.html

172 See, for example, the following measures PI/3634 E PI/3742 (2001), where AGCM has suspended by its own initiative some advertisments. See also PI/4519 (2004), PI/6008, PI/6088 (2007), where AGCM, besides suspending an advertisement, has imposed to the offender to publicly rectify the content of the relevant advertsiment. While imposing to the offender to correct or eliminate the ascertained violation, AGCM gives a deadline (generally of 90 days) to the offender to put in place the necessary remedial actions. Where insufficent efforts no action at all have been undertaken by the offender within the established legal timeframe, AGCM may adopt an additional fine (see PI/5156, 2007)

• a pecuniary sanction (which in Italy ranges from 5.000 to 500.000 euros).[173]

The authorities regularly publish their measures[174] and their annual reports.[175]

These activities have the two-fold aim of raising awareness amongst operators and drawing the attention of the national legislator to issues or interests which may require legislative intervention.

Normally, a range of means for out-of-court dispute settlement between economic operators or between economic operators and consumers are foreseen at national level. The Italian system for example foresees:

• the undertaking of commitments: during the preliminary investigation, the economic operator can propose to the authority the undertaking of specific commitments (e.g. elimination or correction of the commercial practice in question). Should the authority consider the proposed commitments adequate, the case can be closed following the verification of their actual implementation,

• the *'moral suasion'*: where the violation does not appear to be of a serious nature, the authority can open an informal procedure and invite the offender to modify the commercial practice being questioned.[176] Should the offender accept the invite from the authority, the former formally gives up the right to defend his/her own conduct: in doing so however, it avoids incurring in serious financial sanctions (which can have far more negative repercussions on the offender's reputation).

4.3. Responsible communication and advertising.

Commercial communication targeting general public is supervised by independent authorities, as described in the previous paragraphs, but also by some self-Regulation bodies.

The *'European Advertising Standard Alliance'*[177] coordinates a network of

173 In this respect see http://www.ilfattoalimentare.it/pubblicita-ingannevole-mangostano-xango-multata-antitrust-succo-efficace-malattie-cancro-alzheimer.html, http://www.ilfattoalimentare.it/ingannevole-pubblicità-vini-giordano-70-mila-euro-multa-2011-antitrust-250-mila-euro-consumatori.html

174 The weekly bullettin of AGCM is available at http://www.agcm.it/bollettino-settimanale.html

175 See http://www.agcm.it/relazioni-annuali.html

176 Currently the publication of measures based on *'moral suasion'* is not foreseen, but AGCM is considering this possibility (see http://www.ilfattoalimentare.it/lantitrust-studia-modifiche-alla-moral-suasion-pi.html). AGCM 2008 annual report contains some examples where the *'moral suasion'* procedure has been used to correct some unfair practices of minor seriousness. In particular, the following indications have been removed: 'without dangerous residues' and 'from the first year of age' from the label of a fruit juice; 'burns fats' has been removed from a dietetic bar; the acronym 'DOC' on a product in order to avoid any possible confusion with the concept of protected origin for wine; finally the reference to the 'uniqueness' of a beverage with no hydrogenated fats (!)

177 See http://www.easa-alliance.org

self-Regulation bodies in Europe, amongst which *'Istituto di Autodisciplina Pubblicitaria'*[178] in Italy, the *'Advertising Standard Authority'* in the United Kingdom, the *'Deustcher Werberat'*[179] in Germany and many others. The ultimate objective is to develop and update harmonized procedures, evaluation methods, intervention tools, in order to ensure a uniform level of consumer protection across the internal market.

These bodies are composed by a college of experts, independent from the advertising industry, who are called to evaluate commercial communications by business operators. They intervene following complaints or by their own initiative. Following preliminary investigation, they can:

- intimate to the operator to stop immediately the broadcast of an advertising message which is not compliant with the rules set in self-Regulation codes of conduct,
- in case of serious violations or when the order to stop broadcasting has not been complied with, decide for the publication of a summary of its decision in order to make consumer and other operators aware of the outcome of the proceedings.[180]

The system is voluntary and therefore based on the willingness of operators to accept the decisions of the self-Regulation body and comply with them. In Italy, for example, the following operators may decide to adhere to the *'Istituto di Autodisciplina Pubblicitaria'* (IAP):

- individual businesses, directly or indirectly through their professional organizations,
- communication agencies,
- broadcasting operators and their trade organizations,
- press,
- web-communication agencies,
- concessionary/dealership operators,
- billposting operators,
- social communication organizations.

In practice, the effectiveness of such a system goes beyond any expectation: in Italy, for example, IAP monitors 90% of the volume of the advertising done in traditional media. Its decisions do not require lengthy waiting times (on an average three weeks).[181]

178 See www.iap.it
179 For the full list see http://www.easa-alliance.org/page.aspx/55
180 Decisions of IAP are public and available on-line (http://www.iap.it/it/indingiu.htm). In the food sector, the following decisions and injunctions are worth mentioning: decisions No. 96, 66, 44, 15 (2011), No. 132, 24 (2010), No. 122, 117, 109, 33, 18 (2009), injunctions No. 104, 100, 13 (2011), No. 92 (2010), No. 82, 15 (2009)
181 For some examples of decisions taken by IAP see http://www.ilfattoalimentare.it/coca-cola-giurì-lorella-cuccarini-pubblicità-mascherata.html, http://www.ilfattoalimentare.it/pubblicità-ingannevole-detokal-dimagrire.html, http://www.ilfattoalimentare.it/pubblicità-ingannevole-birra-corona-censura-giurì.html, http://www.ilfattoalimentare.it/giurì-pubblicità-censura-revidox-integratore-alimentare.html

IAP's portfolio of activities covers mainly the following areas i.e. cosmetics, pharmaceuticals, food supplements and dietetic foods, aesthetic surgery, financial operations, tourism and toys.

5. Conclusions

The new Regulation has established a set of principles, which only partially innovate as opposed to the currently applicable regime. Furthermore, the EU legislator has tasked the European Commission with the establishment of implementing rules in several areas. Further requirements may be introduced on the basis of impact assessments and reports by the Commission (to the European Parliament and Council) accompanied, as appropriate, by legislative proposals.

This guidebook will have therefore to be updated after three-five years from the entry into force of the Regulation.

At this stage, the only conclusion which could be drawn is that - despite the considerable amount of efforts and resources which have been put into the review process of the legislation in the area of food labelling[182] - we are eventually confronted with a regime which is far from being clear, comprehensive and coherent as many were hoping for.

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Dario Dongo

182 In order to understand to which extent the review has been complex and resource-demanding, some articles concerning the latest stage of the political debate can be a useful reading http://www.ilfattoalimentare.it/le-etichette-di-bruxelles.html, http://www.ilfattoalimentare.it/le-ipotesi-sulle-nuove-etichette-formulate-dal-parlamento-europeo.html, http://www.ilfattoalimentare.it/indicazione-dorigine-accordo-tra-i-governi-degli-stati-membri-e-la-commissione-europea.html, http://www.ilfattoalimentare.it/nuove-regole-europee-per-le-etichette-dei-prodotti-alimentari-origine-obbligatoria-per-polli-carne-di-maiale-e-ovini.html, http://www.ilfattoalimentare.it/consiglio-agricoltura-ue-lorigine-dovrà-essere-indicata-anche-sulle-carni-suine-ovine-caprine-e-avicole.html, http://www.ilfattoalimentare.it/etichette-alimentari-sicurezza-origine-e-più-informazioni-chiede-la-commissione-envi-del-parlamento-europeo.html, http://www.ilfattoalimentare.it/etichette-alimentari-tabella-nutrizionale-novità-commissione-origine-scadenza-acidi-trans-oli-grassi.html

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