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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the provision of food information to consumers

IMPACT ASSESSMENT REPORT ON GENERAL FOOD LABELLING

ISSUES

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1. Executive Summary

Food label is a powerful market tool that allows the consumers to make safe and well informed choices and enables the food operators to highlight the benefit of their products. General food labelling is governed by Directive 2000/13/EC which is a codified version of Directive 79/112/EC. Although one major recent amendment was introduced in 2003 (labelling of allergenic ingredients) most of the provisions date back to 1978. The evolution of both the foodstuffs market and consumers' expectations as to the information given on these foodstuffs renders the update and modernisation of this legislation necessary.

Clearly, food labelling today is a policy problem given that in spite of the existence of many rules there is a general consensus that the current legislation is not working as effectively as it could. Consumers' use of labels is inconsistent and the effectiveness of labelling as a communication tool can be questioned. At the same time, nowadays food labelling legislation is perceived as politically problematic given that the nature of labelling rules tends to be very detailed and technical. Therefore, labelling rules are perceived by many as imposing administrative and financial burdens to manufacturers and look like the sort of rules to be scrutinised within the framework of better regulation. Yet a level of prescription is frequently asked even by economic operators because detailed rules save industry from the trouble of developing its own policy under its own responsibility and offer more legal certainty; yet any judgement as to the required level of prescription has to be made under the viewpoint of the benefits provided to the consumers and to the internal market.

To better identify the important points on which to focus modernisation efforts, a number of surveys and consultations took place over the last years. Although the different consultations show clearly a lack of consensus amongst interested parties as to the way forward, they visibly demonstrated a failure of the current legislation as to the following aspects:

- the volume and dispersal of texts renders the legislation confusing and sometimes incoherent;
- in spite of the important information that appears on the labels, consumers find it difficult to read, understand and use;
- the legislation acknowledges the importance of labelling in providing consumers with information related to health (allergens) but there is a significant part of foodstuffs that do not provide such information;
- legislation should ensure a level playing field for industry and provide consumers with assurance that they are not misled, however, there is a high level of misunderstanding among operators and consumers concerning the use of country of origin labelling;
- there is a legal limbo concerning ingredient listing of alcoholic beverages.
Hence, the challenge for the Commission is how to streamline and simplify the food labelling scene without undermining the high level of consumer protection pursued by the Community. Besides the recasting of the different horizontal labelling rules, the legal updating and clarifications and the introduction of a non statutory "bottom-up" approach for addressing some labelling aspects, four main issues were identified for possible review in the legislation and the implications of the possible solutions to those issues were considered in this impact assessment:

- Improvement of the legibility of the information provided on the labels;
- In general, the lack of provision of information on allergenic ingredients on non-pre-packaged food;
- Need for clarification of the use of country of origin labelling on foods;
- Consistent application of ingredients listing rules.

In addressing these problems, first the possible regulatory framework was considered and it was concluded that the options to deregulate completely or to have regulation only at national level would have not have been effective in achieving the main objectives of the food labelling legislation. Therefore, these regulatory approaches were not considered in relation to the individual policy issues.

The general view of stakeholders during the consultation activities has been that the repeal of the current horizontal labelling Directives, with replacement by one concise Regulation, will provide for better clarity, rationality and consistency of enforcement. The options of not changing the legislation, taking a voluntary approach or including specific requirements in the legislation were considered for each of the policy issues. The different options for each policy issue have been compared in order to provide a basis for the Commission to identify the preferred options.

The result is expected to be a modernisation and simplification package outlining the added value of the new Community act. Finding optimal solutions to the problems identified above through a modern and simpler legislation is expected to contribute to:

- meet the consumers' needs, who want to be better informed when purchasing foodstuffs and to have labels that are simple, legible, understandable and not likely to mislead;
- achieve legal clarity and a harmonised implementation;
- ensure the smooth functioning of the internal market;
• simplify technical requirements and remove unnecessary administrative burden;

• create a pro-competitive market environment in which dynamic, efficient, innovative operators can make full use of the power of labelling to sell their products.

2. **PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES**

2.1. **Evaluation of the food labelling legislation**

In 2003 DG SANCO in close co-operation with the representatives of the Member States, of consumers, of industry and of trade, launched an evaluation of the legislation on food labelling. The aim of this review was to enable the Commission to reassess the effectiveness of its labelling policy and its legal basis, and to identify the needs and expectations of today's consumers for information on food labels, taking into account the technical and logistical constraints for implementation by industry. The conclusions of this study, which were subsequently commented by the Member States, were published in 2004. They identify the key points on which the Commission should focus in view of drawing-up a future proposal aiming at modernising the Community legislation on labelling and meeting the objectives of labelling and consumers' aspirations.

2.2. **Consultations**

DG SANCO launched a public consultation process on labelling in March 2006, by means of a consultative document dealing with different areas of labelling, and among others, identifying on the basis of the above evaluation the major questions that have to be considered in the review of the food labelling legislation. The consultation paper addressed in particular questions related to the strategic goal of labelling, the structure and the scope of the legislation, the legibility of labels, origin labelling and labelling of alcoholic beverages. As part of the consultation process there were discussions within the following groups: the Advisory Group on the Food Chain and Animal and Plant Health; the European Consumer Consultative Group; the Consumer Policy Network of senior consumer officials; and the Health Policy Forum.

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2 "Labelling: competitiveness, consumer information and better regulation for the EU". A DG SANCO consultative document.
3 The consultation paper addressed also other issues: nutrition, animal welfare and GMO labelling as well as health warnings on alcoholic beverages.
The public consultation formally closed on 16 June 2006 and a total of 247 responses were registered, of which 73 were essentially the same. These were counted as one response, so it was considered that 175 contributions were received. 101 of the respondents provided views on the general food labelling aspects of the consultation. The breakdown of organisations were: 21 governmental organisations, 10 consumer groups, 5 public health NGOs, 55 food industry organisations or companies, 4 from individuals. A summary of the responses has been made available on the Commission website.\(^4\)

2.3. Consumers survey (Focus Group)

A qualitative study on labelling was carried out by an external contractor (OPTEM) in 2005 in order to assess consumers' attitudes with respect to labels and their information content, and to analyse consumers' expectations.\(^5\)

2.4. Data collection on behalf of the Commission

Between 26 October and 8 December 2006 there was a Small and Medium Enterprise Panel on Food Labelling organised by DG ENTR in consultation with DG SANCO which sought the opinions and data from small and medium sized enterprises (SMEs) in 19 Member States on certain aspects of general food labelling. Over 800 responses were received during the survey.

Finally, the internal process to develop the impact assessment was supported by an external contract, financed under a framework contract agreement, carried out by RAND Europe. The contractors provided an ex ante assessment on the economic impact of the different policy options identified following the public consultation in 2006 as set out in the task specification. As part of the contract, from 22 March to 16 May 2007 RAND Europe carried out an online consultation of the food industry in order to collect information and data on the possible impacts of the main issues under consideration for the revision of the legislation. More than two hundred responses to the questionnaire were submitted. The report of the contractor in support of the drafting of the impact assessment can be consulted at the web site of the contractor (add details of link when IA published)).

2.5. Inter-Service Steering Group

A Commission Inter-Service Steering Group on the Impact Assessment of the revision of the legislation was established. The Group was led by DG SANCO with the participation of the following Commission Directorate Generals and Services: Agriculture and Rural Development, Enterprise and Industry, Research Technology and Development, Trade and the Secretariat General. The group started its work on 10 January 2007 and met 3 times.

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\(^4\) Summary of results for the consultation document on: "Labelling: competitiveness, consumer information and better regulation for the EU". [http://ec.europa.eu.food/food/labellingnutrition/betterregulation/lab_cons_summary.pdf](http://ec.europa.eu.food/food/labellingnutrition/betterregulation/lab_cons_summary.pdf)

2.6. **Ad hoc consultations**

Member State authorities were consulted on the options for the revision of the legislation in the course of several Expert Working Group on General Food Labelling meetings in 2006-2007. Informal discussions and presentations have been held with various stakeholders groups e.g. representatives of the food industry.

2.7. **The Impact Assessment Board**

The draft Impact Assessment was submitted to the Board on 27 June 2007 and discussed at the Board meeting of 18 July. The final opinion of the Board included a number of recommendations for the improvement of the impact assessment report, which were largely taken into account prior to the submission of the Commission proposal.

The key amendments made to the impact assessment following the issuing of the Board opinion:

- Clarification of the problem definition by highlighting the main issues that were identified as a concern to various stakeholders during the extensive consultation process and inclusion of a section on the international dimension;
- Clarification about the relationship between the revision of general food labelling and the revision of nutrition labelling legislation;
- Setting out more clearly the expected simplification results in the objectives of the proposal;
- Clarification of the administrative burden.

3. **Problem Identification**

There are two Impact Assessments supporting the Commission draft proposal on the revision of the existing food labelling Community legislation, namely two horizontal pieces of legislation: Directive 2000/13/EC providing for compulsory information on foods and Directive 90/496/EEC setting up harmonised rules on nutrition labelling which is in principle optional.

The main purpose of this labelling legislation - to inform and protect consumers and to ensure the smooth functioning of the internal market - is still valid and has not been questioned by stakeholders during the extensive consultations. The basic contents of the existing requirements are seen as a valuable acquis and there seems no general desire from stakeholders for a change in the core components of the legislation.
There is a general criticism about the piecemeal approach in the delivery of the entire spectrum of Community labelling legislation (horizontal and vertical) and, more specifically, a lack of coordination of implementation dates. For the horizontal food labelling and nutrition labelling legislation concerns have been expressed about the lack of clarity and legal certainty, and the failure of the current rules to address current stakeholders needs and expectations (which have changed over time).

The process of consultation demonstrated clearly that certain main issues are in need of review. However, stakeholders have very different views on how these issues should be addressed.

The label is an important means for information about prepacked foods to be passed to the consumer. The consumers indicate that they would like clear and better information about different aspects of a food product but there needs to be balanced against the space available on the label and increased burdens on the industry. In considering those interests account must be taken of the fact that much of the information on a label is not required by law but is essentially marketing information. Therefore, improving the legibility of the information is not necessarily incompatible with the addition of any new labelling requirements especially since the legislation provides derogations in case of space limitations on the label.

3.1. **Relationship between the revision of the general labelling and nutrition labelling legislation**

- Currently there are two separate, and in certain aspects fairly prescriptive, measures. However, they are both dealing with horizontal labelling issues and it would be important to have a coherent approach in the revision of both legislative measures.

- Two separate impact assessments were presented since it was considered that the presentation of one impact assessment would appear to prejudge the outcome of the impact assessment process so two reports were prepared. Indeed, if the preferred option on nutrition labelling was to make such labelling mandatory then the combination of the two legislative measures would be appropriate. On the contrary, if nutrition labelling was to remain in principle voluntary then consideration would need to be given to whether to maintain separate measures, as is the case with the Regulation on nutrition and health claims, or to combine the two measures.

- Specific areas of overlap between the two impact assessments are:
  - consideration of the regulatory approaches including the alternative flexible approach of the exchange of information and development of best practice;
  - the estimation of the fundamental costs associated with food labelling; and
  - legibility of information on the label.
3.2. Background on Food Labelling

The current Community policy on food labelling was developed during a recent but relatively long historical period, which approximately started in mid-to-late 1970s'. Although the main political will that motivated the first "horizontal" legislative instrument on food labelling (Directive 79/112/EC) was to provide rules for the labelling of foods as a tool for the free circulation of foodstuffs in the Community, the legislation clearly had positive repercussions in terms of consumers' protection. Over time the protection of consumers' rights emerged more and more as a specific objective of the European Community.

Horizontal labelling legislation prescribes compulsory sales descriptions, determines the rules for products where no sales description has been set by law and establishes principles which help to avoid the obstacles to the free movement of products lacking harmonised sales descriptions. The basic horizontal text on food labelling is Directive 2000/13/EC (the "general food labelling" Directive). This is a framework legislation which lays down common labelling requirements applicable to all foodstuffs to be delivered as such to the ultimate consumer, and to foodstuffs supplied to restaurants and mass caterers. This is a codified version of Directive 79/112/EC to which amendments and new requirements were added through the years. The Directive sets down the mandatory information that must appear on food labels (see box below).

**Mandatory Information that must appear on food labels**

1. the name under which the product is sold;
2. the list of ingredients;
3. the quantity of certain ingredients or categories of ingredients;
4. in the case of pre-packaged foodstuffs, the net quantity;
5. the date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the ‘use by’ date;
6. any special storage conditions or conditions of use;
7. the name or business name and address of the manufacturer or packager, or of a seller established within the Community;
8. particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff;
9. instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;
10. with respect to beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume.
The general labelling requirements are complemented by a number of specific provisions applicable to all foodstuffs in particular circumstances or to specific groups of products. The horizontal food labelling texts are the following:

- Directive 2000/13/EC as amended by Directives 2001/101/EC (category name “meat”) and 2003/89/EC (allergenic ingredients);
- Directive 87/250/EEC (indication of alcoholic strength);
- Directive 89/396/EC (lot);
- Directive 94/54/EEC (additional indications on labelling provided for in cases where certain ingredients are present) as last amended by Directive 2004/77/EC (glycyrrhizinic acid);
- Directive 1999/10/EC (indication of the quantity of volatile ingredients);
- Directive 2002/76/EC (foods containing caffeine or quinine).

In addition to the horizontal labelling rules, there are a number of rules of a specific nature which are applicable to certain foodstuffs and are included in the so-called "vertical legislation". Most **vertical legislation** (composition standards or common marketing standards or quality schemes) covers the definition of the sales descriptions of the products concerned and their possible conditions of use: i.e.: a) composition standards for chocolate, coffee, milk, fruit juices, b) common marketing standards for fish, olive oil, eggs etc., quality schemes such as organic food, protected appellations of origin, protected geographical indications. These are technical rules specific to the products concerned and cannot be separated from the other aspects of the standard.

Estimates suggest that there are over 100 pieces of such legislation that contain labelling rules.
3.3. **Affected stakeholders and their needs**

### 3.3.1. Consumers

In relation to consumers' needs and desires, it is important to note that the term "consumer" is an overarching category that covers a variety of characteristics, interests, priorities and concerns. Be this within a country or across countries (see box below). In addition, socio-economic factors, education, and gender can play a role in how consumers view food information and in how they use this information. Consequently trying to meet the needs of all European consumers in terms of food labelling is difficult, if not impossible, and there must be careful consideration of the kind of information that is required. Especially as differences in how consumers use food information do not necessarily translate into how consumers want information to be presented. What is known is that consumers are mostly interested in clear, understandable, simple, comprehensive, usable, standardised and authoritative information.

**Studies on Consumer Interest Labelling**

Research on consumer priorities of the Food Standards Agency of the United Kingdom showed important regional differences in how consumers interpret labelling and how they form priorities. An AC Nielsen survey in 2005 compares how consumers in different countries have different priorities in how they use food labelling. Southern Europeans, in particular Italians, are distinct in wanting to eat 100% wholesome and natural foods, with less regard for calories. For instance, 56% of Italians check for food additives (e.g. preservatives) while only 30% check for calories on food labelling.

### 3.3.2. Industry

The term "industry" is also an overarching category that covers small, medium and large enterprises that manufacture and sell an extensive and diverse range of products (see Annex 1). As with consumers there is also a variety of characteristics, interests, priorities and concerns that categorise different parts of the industry. Therefore, in relation to labelling views will vary and therefore, it would be difficult, if not impossible, to meet the needs of all of the industry. What is clear, however, is that cost is a concern. Not the least as, depending on what is proposed, a change to the legislation could require a change to every label within the European Union.

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3.3.3. *International dimension*

During the consultations the international issues was not identified as a specific issue separate from the general issues for the food industry overall. In fact the basic principle of food labelling means that *traders* need to ensure that the label is in a language that is understandable in the country of marketing, therefore, manufacturers frequently need to amend their labelling to the local markets. Any additional cost associated with the policy options would depend on the need to include additional information or presentational requirements that would lead to a fundamental redesign of their label.

However, third countries can benefit from the harmonisation of the Community approach to labelling issues as it can make it easier for manufacturers to export their products to the Community as they do not need to accommodate their labelling to different approaches at Member State level.

3.3.4. *Member States Authorities*

*Member States* obviously wish to balance the needs of consumers and industry with respect to the general food labelling legislation, taking account, where necessary, of any consumer or industry issues that are specific to their particular country. However, their capacity to act and the effectiveness of the implementation of labelling legislation depends on the design of the labelling legislation. Therefore, in terms of governance, there is a trade-off for the Member States between the desire for flexible solutions to labelling and the requirements of the single market and the desire of industry for a unified regulatory framework.

3.4. *Rationale for the revision of the legislation*

In considering problems with the current situation, and how they can be addressed, it is important to reflect on why legislation in this area is needed, i.e. why is there a need to provide information on food labels. The most important reasons relate to health and safety issues. For example, the provision of durability dates on food (e.g. “use-by” dates), information on the presence of ingredients to which certain consumers are allergic or intolerant (e.g. nuts or gluten), storage conditions and conditions of use. Label is clearly helpful in allowing consumers to make an informed choice about the products they purchase. In addition, it can also minimise the chance of them being misled. Having such legislation at Community level supports the internal market which is beneficial for food business and also for consumers.
The need for a revision has been brought to the fore by consumers and industry, over a period of some years, expressing dissatisfaction with certain aspects of the current legislation. These concerns are by no means consistent nor is it obvious that the concerns expressed are actually valid. However, put simply, consumers tend to press for more and "better" information on food labels; industry consider that there are simply too many labelling requirements which involve the industry having to implement detailed, technical rules but at the same time, they ‘voluntarily’ add extra information which cuts back on space for the mandatory information. In addition, the volume and dispersal of texts gives the impression that the legislation is confusing and that there is a proliferation of binding provisions lacking any real coherence.

The responses to the consultation in 2006 confirmed the polarisation of views on a number of issues and demonstrated that the labelling legislation and the label itself are not used to their full potential. More specifically criticism focuses on the following:

- In spite of the many detailed rules, the current legislation is not working as effectively as it could;
- In spite of the important and interesting information that appears on the labels, consumers find it difficult to read and understand;
- In spite of the fact that legislation acknowledges the importance of labelling in providing consumers with information related to health (allergens), there is a substantial part of foodstuffs from which such information is still missing;
- In spite of the plentiful rules that should ensure a level playing field for industry and provide consumers with assurance that they are not misled, origin labelling today is a problematic area.

The above lead the Commission to pay particular attention, in the context of the revision to issues related to the simplification of the structure of the legislation, the lack of information about allergens in non pre-packaged food, a complex situation in the market regarding origin labelling and ineffective rules concerning certain aspects of labelling of alcoholic beverages. Bringing optimal solutions to these problems is expected to streamline the food labelling landscape.
3.5. **The Scope of the Impact Assessment**

To resolve the problems encountered by the piecemeal legislation, the need for simplification of the current legislative scene is obvious. Restructuring the legislation would be feasible. Such an approach seeking to present, simplify and clarify the horizontal labelling provisions spread across these texts. Making the legislation more accessible through reducing the number of legislative texts has the potential of reducing the information costs for food businesses. The available evidence suggests however, that costs of gathering information constitute a small part although not negligible of the overall costs of administrative burdens related to food labelling. Information costs are estimated to contribute up to 5 percent to labelling costs in Denmark and up to 13 percent of all food legislation in the United Kingdom. Changes in the structure of the legislation thus should have a modestly positive impact on the cost of producing labels, this impact is however likely to be small.

There are, however, other potential direct impacts for stakeholders if the issues that have been identified in the various consultations over the last few years are addressed in the revision. For some issues ("problems"), the impacts for the different stakeholders could be significant and these are the focus of this impact assessment, namely:

- Legibility of information;
- Lack of information on allergenic ingredients on non-prepacked food;
- Clarification of the use of origin labelling on foods;
- Consistent application of ingredients listing rules.

Although the consultation in 2006 also covered the question of a specific animal welfare labelling, the development of possible policy options is not sufficiently advanced to submit them to an impact assessment at this stage. For other issues, impacts would not be expected to be significant essentially changes that will be part of an overall objective of renovating and modernising the legislation, such as rationalisation (update and clarification) of the compulsory information required by Article 3.1 of Directive 2000/13/EC; spelling out the principles of food labelling and the food operators’ responsibilities; clarification of the provision of information in case of foodstuffs sold by internet or catalogues.
3.5.1. Policy Issue 1 – Legibility of information

Summary

The current legislation requires certain aspects of labelling information to be marked on the labels of a food product "in a conspicuous place in such a way as to be easily visible, clearly legible and indelible". However, as any visit to a supermarket will demonstrate the extent to which this is followed is questionable. There are numerous examples where it would be difficult for the consumer to read, for example, the ingredients list of a product. As such information is there to help in making purchasing decisions, and in some cases these relate to health issues (e.g. allergens), there would appear to be failure of the current legislation in relation to the legibility of information.

Background

Food labels have to be clear and comprehensible in order to be useful for consumers wanting to make better-informed food and diet choices. They are of little benefit if difficult to read and indeed there are studies that show that legibility is an important element in “maximizing the possibility that labelled information will influence its audience”⁹. And yet, this is one aspect of labelling that is continually being criticised by consumers and consumer organisations. The failure of products to properly comply with the legibility provisions in the current legislation is a common complaint in the various Commission consultations, and this is backed up by consumer research. For example, a review of various European studies of label usage amongst consumers found that one of the main causes of consumer dissatisfaction is that the size of print is often too small¹⁰ and in the Commission funded OPTEM study, legibility was reported as a serious problem for short sighted or elderly consumers who represent an increasing part of the population.

Although difficult to prove, the situation with legibility has perhaps become worse over the last couple of decades because of the internal market and increased cross border trade. Manufacturers seek new markets for their products, yet to keep costs down aim to use the same label in many countries. The consequence of this being that multi-lingual labelling is very common. Whilst there do not appear to have been any detailed studies looking at the number of languages appearing on labels, the RAND survey showed that 2 is relatively common (27%) and 9 not uncommon (5%). Obviously there is limited space on a label and consequently an inverse relationship between the number of languages and the size of the text.

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In discussing legibility, text size is the factor that is most commonly mentioned. However, there are other factors which also affect the ease of use of a label. For example the colour of the print contrast with the background and the type face/font. These should not be forgotten in relation to considering changes to the current legislation.

3.5.2. **Policy Issue 2 – Lack of information on allergenic ingredients on non-prepacked food**

**Summary**

Consumers that have allergies or intolerances to certain food ingredients are well served by the current legislation in relation to the provision of information on pre-packed foods. However, these foods make up only part of the diet of such consumers and increasingly there are demands to extend the pre-packed requirements to non-prepacked food. Especially as there are potential health implications if the wrong information is provided or is implied.

**Background**

Non prepacked food covers a range of products produce by a range of businesses, as summarised in the table below. In relation to information on allergenic ingredients, it is clear that this will only be relevant to certain parts of this table and if action in this area is to be considered, it should be targeted to those products which are seen to be of the greatest risk. There is information available that can be used in this regard, for example studies from medical research show that 74% of allergen related food incidents can be linked to foods sold loose (in shops and in restaurants)\(^\text{11}\).

**Table 1:**

<table>
<thead>
<tr>
<th>Example of products include:</th>
<th>Examples of outlets include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Products available at delicatessen counters</td>
<td>• Multiple and independent food retailers</td>
</tr>
<tr>
<td>• Home meal replacements</td>
<td>• Delicatessens</td>
</tr>
<tr>
<td>• Bakery and cakes</td>
<td>• Butchers</td>
</tr>
<tr>
<td>• Fruit and vegetables</td>
<td>• Fishmongers</td>
</tr>
<tr>
<td>• Confectionery</td>
<td>• Greengrocers</td>
</tr>
<tr>
<td>• Fish and meat</td>
<td>• Bakers</td>
</tr>
</tbody>
</table>


In view of the potential health concerns with non-prepacked food it is perhaps valid to question why this was not dealt with when the legislation was first proposed. In fact, non-pre-packaged food is not excluded from the General Food Labelling legislation, this leaving it to the Member States to adopt detailed rules concerning the manner in which the mandatory requirements are to be shown for non-repacked food. The reason for this situation lies in the roots of the current EU legislation, which was designed to ensure the functioning of the internal market. Selling non-prepacked food or packaging food on the sales premises at the consumers’ request has therefore been considered to be a matter for national authorities to legislate. (i.e. of minimal relevance to the internal market). However, with the adoption of specific rules on allergen labelling for pre-packed food in 2003, there is now a potential inconsistency with non-prepacked food. Consequently Member States’ abstention from introducing national labelling requirements for allergenic ingredients on such products is, potentially, depriving consumers from having important information related to health and safety.

There are, of course, practical issues which must be considered if there is any extension of the labelling rules to certain non-prepacked foods. Industry, quite rightly, points out that there are difficulties in providing information at point of sale. This is very different to providing information on-pack and will vary depending on the product and the type of business. In addition, it is perhaps inaccurate to assume that those businesses which might be affected will have ready access to information on the presence of allergens in the non-prepacked foods. So there might be additional costs in obtaining the information as well as passing it on to the consumer.

3.5.3. Policy issue 3 – Clarification of the use of origin labelling on foods

Summary

Details about the origin of products are often found on food labels, either because legislation requires that this is present or a company voluntarily decides to provide such information. Although detailed data is unavailable, it would seem that more and more products contain some indication of origin. This leads to expectations from consumers to both more origin labelling and assurances that when it is provided they can be certain that the information is not false or misleading. The latter issue is also of interest to the industry, not least as the use of origin labelling can give a competitive advantage, i.e. will influence consumer choice. Consequently they would wish to have a level playing field across the EU, with clear 'rules' on origin labelling. However, at the horizontal level of legislation such rules are not in place.
Background

For certain products, legislative requirements relating to origin labelling are set out in vertical legislation (which falls under DG AGRI responsibility). These texts contain provisions about the mandatory indication of origin/provenance, where this is likely to be related to certain qualities of the product (e.g. wine, fruits and vegetables, fish, eggs, honey). The texts also cover quality schemes, i.e. "Protected Designation of Origin" (PDO) and "Protected Geographical Indication" (PGI), where again some indication of origin would be expected on the labelling. Beef labelling is a particular case where origin labelling is required. The intention being to improve the transparency of the beef market, and to restore consumer confidence, following the BSE crisis.

In relation to the General Food Labelling Directive, origin and provenance are mentioned twice. First, labelling must not be such as to mislead the consumer 'as to the characteristics of the foodstuff and, in particular, as to its ... origin or provenance'. Second, 'particulars of the place of origin or provenance [shall be compulsory] where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff'. However, the legislation provides no definition of origin or provenance – leading to uncertainty and ambiguity for both consumers, industry and Member States.

A related, but perhaps separate, issue is that of consumers' demands for more origin labelling. There is no doubt that the literature indicates strong support for such labelling (see box below). Indeed, demand for the origin of foodstuffs to be indicated more frequently is a recurrent theme of the Commission's consultations, being confirmed in the 2003 evaluation and in the focus groups surveys of April 2005 (OPTEM study). However, it is important to note that in research where the consumers are unprompted, i.e. asked simply to indicate what influences their purchasing decisions, origin labelling is generally not mentioned as a major factor.
Consumer studies on origin labelling

Across the European Union consumers like to see country of origin information on food products as various studies show. A consumer study conducted in the Nordic countries in 2006\(^{12}\) found strong support for country of origin information on foodstuffs. 78 percent of the consumers considered country of origin an important information to be found on foodstuffs. This replicates results from earlier Nordic studies, in which 86 percent respondents wanted country of origin labelling to be mandatory.\(^{13}\) Research conducted in the UK provides a similar preference for mandatory country of origin labelling for all foodstuffs, with 80 percent of respondents considering it important to always label country of origin on foodstuffs.\(^{14}\) Interesting in this research however is, that country of origin is not a major factor taken into account by the consumers in their purchasing decision. Indeed only 2 percent of consumers mentioned it spontaneously, that is unprompted as an area of concern for them. A study conducted for Food Standards Australia / New Zealand reports a similar behaviour; consumers reported country of origin information as being very important for them only after being prompted by the facilitators of focus groups.\(^{15}\)

It should also be noted that the preference of consumers for origin labelling is not evenly spread across different food categories or different countries (see box below). Generally the origin of beef, other meat and fresh and raw products seem to be the prime concern of consumers. A further problem, which was seen during the consultations and relates mainly to meat and meat products, is that of linking origin with safety. In fact, in considering any action on origin labelling the reasons for consumer demand for such labelling have to be taken into account. Whilst there are "justified" reasons for wanting to know the origin of a product (e.g. support for local produce, characteristics of the product, ethical and environmental concerns), other reasons that have been quoted are not justified. This is the case specifically with the linking of origin and safety as products produced or imported into the EU are, by definition, "safe". This last point is of particular importance in relation to world trade, where origin labelling is often considered as a barrier to trade.

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\(^{15}\) Donovan Research (2001), *Food Labelling Issues – Consumer Qualitative Research*, Study prepared for the Australia New Zealand Food Authority.
The evaluation of food labelling conducted in 2003 on behalf of DG SANCO found that consumers in France, UK and Italy value origin information in particular for meat and primary products. The OPTEM study found an interest in labelling for meat but on other products such as soft drinks the consumers were however indifferent, as they primarily rely on the brand for their purchase decision. In the Nordic countries this picture is similar. 92 percent of consumers consider the origin of meat important or very important, and this even holds for meat products (smoked ham 88%, sausage 86%, pizza 79%) and for fruit and vegetables (79 %). The meat content of ready meals was also the most important ingredient the consumers wished to be labelled in an UK study.16

3.5.4. Policy issue 4 – Consistent application of ingredients listing rules

Summary

Currently, alcoholic beverages (i.e. those with more than 1.2% by volume of alcohol) are not required to bear full listing of ingredients. This situation is not the result of an explicit derogation granted by Directive 2000/13/EC to these products but of a legal limbo rooted in the acknowledgement that specific rules are needed for ingredient listing of alcoholic beverages because of their particular characteristics and production methods. So, whilst there is in the current legislation a theoretical obligation for alcoholic beverages to label their ingredients, in reality this requirement never became operational due to the lack of specific rules. The level of consumer interest in ingredient labelling of alcoholic beverages is unclear and contradictory; this is not surprising especially since, in relation to health and safety aspects and in particular allergenic ingredients, alcoholic beverages are treated the same as all other food products. So consumers are informed about the presence of an allergenic ingredient in alcoholic beverages.

The revision of the current legislation offers the opportunity to correct the legal inconsistency described above. In addition, the continued presence on the market of the so-called 'alcopops', which tend to be pre-mixed alcoholic/non-alcoholic products is an issue to consider. The inconsistency in the ingredients of a soft-drink not having to be declared on the label if they are mixed with alcohol, where they would have to do so without the alcohol, is indeed considered by many to be quite unjustified.

Background

Whilst there has been an obligation on the Commission to present a proposal on ingredients listing, it has proved difficult to get agreement on a way forward. The issue goes back to Directive 79/112/EC (the first 'horizontal' labelling legislation) where Article 6 (3) states that 'In the case of beverages containing more than 1.2% by volume of alcohol, the Council, acting on a proposal from the Commission, shall, before 22nd December 1982, determine the rules for labelling ingredients'.

16 Mori (2000), Importance and Impact of Country of Origin of Food, Research study conducted for the Ministry of Agriculture, Fisheries and Food, United Kingdom.
The Commission presented proposals to fill this gap in 1982 and 1992 but the Council could not agree on any of those proposals. The Commission then presented a new proposal in February 1997, which was finally put on the agenda of a Working Group in December 2002 (under the Danish Presidency). At this meeting, the majority of delegations agreed that:

- alcoholic beverages had been unregulated for too long;
- the labelling of ingredients of alcoholic beverages should be more in line with the general labelling rules in Directive 2000/13/EC than in the proposal put forward by the Commission.

Subsequent to these discussions, specific requirements have been introduced by Directive 2003/89/EC for labelling ingredients which may cause allergies or intolerance. As these provisions apply also to alcoholic beverages, substances such as sulphites for example have to be mandatorily labelled where they are present. In view of the failure of EU harmonisation to materialise, some Member States have adopted national rules requesting partial indication of ingredients for certain alcoholic drinks. Obviously this causes potential problems for the free circulation of products within the internal market.

There have been consumer studies on attitudes to ingredients listing in alcoholic beverages, indicating some degree of consumer demand for this issue. However, the studies in question are inconsistent (see box below).

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**Consumer studies about ingredient listing on alcoholic beverages**

The focus group based study by OPTEM found little consumer demand for ingredient listing on wine and beer. Most of the consumers point out the pleasure product characteristics of beer and wine and see no additional value in disclosing composition. In contrast, a study conducted by the Food Standard Agency U.K. reports on a majority of consumers (64 percent) to support ingredient labelling for alcoholic beverages and half of the respondents answered they would make use of such information. In the 2003 evaluation conducted on behalf of DG SANCO, consumer representatives identified “extending basic labelling to all food and drink” as one of the four most important issues not sufficiently met by the current legislation.

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17 OPTEM (2005), *The European consumers’ attitudes regarding product labelling: qualitative study in 28 European countries*, produced for European Commission DG SANCO.
3.6. **Regulatory Approach**

Certain basic approaches considered as a means of finding solutions to the main problems, as well as the option of no intervention are considered below.

3.6.1. **No intervention - No EU action**

The baseline of doing nothing would maintain the current situation with scattered legislation perpetuating the following negative effects:

- Piecemeal and confusing rules undermining the effective implementation;
- Unjustified burdens on food business because of outdated, redundant or unclear requirements;
- Inconsistent consumer use of labels;
- Ineffectiveness of labelling as a communication tool;
- Failure of the legislation to adapt to changing markets and consumers' legitimate demands.

3.6.2. **Intervention was considered in the context of deregulation, national legislation, non-statutory approach or updating Community legislation.**

3.6.2.1. Deregulation

The option of deregulation would entail the **abolition of the basic policy instruments** concerning horizontal food labelling rules with a direct impact on vertical labelling rules that make reference to the general horizontal labelling legislation.

Although food manufacturers would continue to apply the current rules for a short period of time, given the costs of changing labels, they would progressively tend to remove information considered as imposing burdens. Non harmonised rules would impair the functioning of internal market, lead to poor information and reduce the level of consumer protection. Existing rules have proven their merits in allowing free circulation of goods and the protection of consumers. Dismantling them would meet strong resistance from the majority of Member States and consumers given that consumers and enforcement authorities have been used to the current requirements and any change to the present status could be seen as an abandonment and removal of a valuable "acquis". Therefore, deregulation would be a "regulatory failure" and as such it cannot be considered as a viable approach.
3.6.2.2. National legislation

The repeal of the harmonised rules would certainly result in creation of national rules for all areas of general food labelling legislation which would have the following consequences:

– different national rules would impede the internal market;
– distortion of fair competition;
– increased administrative burden for industry;
– inconsistent approach in content and availability of information creating confusion for consumers;
– different level of protection for EU citizens.

3.6.2.3. Alternative non-statutory approach (self-regulation, co-regulation, guidance)

The different features of consumer information and food labelling on the one hand and the current trends towards the development of a "new legislative culture" call for the assessment of a new approach that could strike the balance between flexibility and prescription and between action at the national and action at the EU level.

The manner in which information is presented on labels is a good example of a rapidly changing feature of modern commercial practices. Similarly, consumers' needs and attitudes constantly evolve. Therefore labelling rules should be able to keep pace with technological innovation and change in consumer's behaviour.

Having recourse to a **multi-level bottom-up governance** (local/national/community) based on the principle of formal **commitment to measurable best practice and data sharing** between involved stakeholders could be a relevant and viable alternative in the area of food labelling.

Moving the already harmonised detailed requirements to such a flexible approach would present no added value given that such requirements have proven their merits in allowing free circulation of goods and the protection of consumers. The use of an alternative mechanism as far as the regulatory labelling "acquis" is concerned would unnecessarily complicate current understanding among stakeholders and could be perceived as a deregulation. On the contrary, as far as any new policy issues are concerned, the introduction of a more elaborate and sustainable approach to consumer information emerging from best practices and from a constant dialogue with stakeholders has the potential to achieve beneficial results both for industry and consumers. Therefore, this new governance model would be included in the new proposal as a stand-alone system with the vocation to be developed and used further. In the context of each of the main issues it is appropriate to consider the effectiveness of this alternative approaches in achieving the objectives pursued.
3.6.2.4. Statutory EU Action

Given that uniform rules and legal certainty have proven their value at the EU level, the statutory approach is considered the most appropriate means to address the current problems in the area of food labelling. A level of prescription is frequently asked even by economic operators because detailed rules save industry from the trouble of developing its own policy under its own responsibility and ensure a level playing field for all.

Besides, the new governance system (as described above) would need to have a framework of operation established in the legislation so that it has legitimacy for all the stakeholders.

3.6.3. Form of act: Regulation

The preferred option on the form of the EU measure would be to change the legal act from a Directive to a Regulation. The reason being that, in their majority, the existing rules are prescriptive with little flexibility for Member States in how the rules should be applied.

A Regulation would give a more consistent approach for the industry to follow, it would reduce the administrative burden on the industry as they would not need to familiarise themselves with the individual regulations in the Member States.

In addition, a Regulation would ensure that the rules became applicable at the same time across the EU avoiding problems with delayed transpositions by Member States and consequent infringement procedures by the Commission to assure the free circulation of goods.

According to the Simplification Communication COM(2005)535 (part d) modification of the regulatory approach), the use of Regulations supports generally the objective of simplification because it guarantees that all actors have to follow at the same time the same rules. Considering the fact of the complexity, missing clarity and rationality of the current situation combined with the need to ensure free trade within EU and fair competition a vast majority of stakeholders pleaded for choosing as a legal act one single Regulation.

A Regulation would also eliminate administrative burden of transposition into national law for Member States.

In terms of simplification of the structure of the legislation,

(a) in order to address the problems resulting from the piecemeal legislation the new proposal will amend, recast and replace provisions already in place under the current horizontal food labelling legislation, meaning the following texts:

- Directive 2000/13/EC as amended by Directives 2001/101/EC (category name “meat”) and 2003/89/EC (allergenic ingredients);
Directive 87/250/EEC (indication of alcoholic strength);

Directive 89/396/EC (lot);

Directive 94/54/EEC (additional indications on labelling provided for in cases where certain ingredients are present) as last amended by Directive 2004/77/EC (glycyrrhizinic acid);

Directive 1999/10/EC (indication of the quantity of volatile ingredients);


(b) an option that is being considered is the combination of the Directive 2000/13/EC of the European Parliament and of the Council on the general food labelling and nutrition labelling legislation into one measure which would also simplify the regulatory framework.

On the contrary, bringing together all horizontal and vertical legislation (over 100 measures) would not be a helpful approach since this would create an even more complex document difficult to use and potentially difficult both to agree and to amend, especially since vertical legislation includes composition or marketing standards to which the labelling requirements relate.

3.7. **The right of the Union to act – Subsidiarity test**

The proposal is to revise existing legislation so the problem at issue and the objectives pursued by the Union have been already defined. Article 95 of the Treaty, functioning of the internal market, provided the legal basis for the EU legislative measures on general food labelling. Although the internal market is a central aspect of legislative harmonisation in the field of food labelling, there are several aspects in the new proposal related to consumers' right to information (Article 153) and protection of human health (Article 152).

Food labelling protects consumers and informs their decision making. It is considered that action at the EU level would deliver better results than a series of individual actions by Member States because i) a harmonised approach across Member States may simplify administrative burden on any food companies operating either trans-nationally or Community wide, and ii) uniform action will ensure Community wide minimum standards for consumers and thereby reduce inequity for citizens across the EU. A proliferation of different labelling requirements could undermine the current single market opportunities for the food chain which could have a major impact on trade given the high volume of intra-Community trade which in 2003 accounted for over 75% of all trade with flows of around € 120 billion. The SME Panel survey indicates that 65% of companies exported their products to other Member States and in this survey over 60% of the respondents favoured harmonisation of general food labelling through European legislation.

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Community competence is used taking full account of the principles of subsidiarity and proportionality acknowledging that total uniformity of labels throughout the EU is not necessarily the only and desired way to reach the objectives sought. It would, on the contrary, dismantle the potential for rapid adjustment to changing needs and circumstances of the applicable rules.

The core of the Community action is setting the conditions for the labelling of food within the EU which can not be appropriately addressed by Member States alone if the common internal market is to function smoothly. As to the details of the regulation applicable, a more participative and flexible way of designing and enforcing it will be offered by a new multi-level governance model intended to introduce a more elaborate and sustainable approach to consumer information emerging from best practices and from a constant dialogue with stakeholders.

In the light of the different elements outlined EU action is justified as experience shows that Member States cannot achieve a harmonised common market satisfactorily and that the EU can do better and more efficiently for the provision of information to help consumers make informed choices. EU action in the new proposal provides also space for softer intervention mechanism at national and/or EU level.

4. **Objectives**

The project is included in the rolling programme of simplification. Thus, the general objectives are linked to the Commission's strategic objectives and the initiative Better Regulation, improving the implementation of regulations, facilitating innovation, social equity, environmental protection and international responsibilities while maintaining high level of public health protection. The simplification needs that emerged from the consultation of Member States and stakeholders in relation to general food labelling was to make the labelling easier and clearer for operators and consumers.

The main objectives of the legislation on food labelling are:

- to enable consumers to make informed, safe, healthy and sustainable choices;
- to provide consumers with relevant, useful and legitimately expected information;
- to ensure the smooth functioning of the internal market;
- to foster a pro-competitive market environment.
Taking this objective into account, the broad scope of the revision should meet the needs of consumers and industry, and reflect the following specific objectives:

- ensure consistency and clarity in the provision of information;
- protect consumers' health and address specific consumer demands for information;
- avoid misleading indications and eliminate existing inconsistencies;
- enable and reward industry innovation on food labelling allowing them to make full use of the power of labelling to sell their products;

A schematic illustrating the hierarchy of the objectives for the general food labelling revision is presented in Annex 2.

5. MAJOR POLICY ISSUES

With a view to achieving the objectives and in line with the simplification process a number of measures have been considered. Taking full account of the simplification needs that emerged from the consultation of Member States and stakeholders those measures have been divided into two categories:

(1) General simplification tools to bring the legal text into line with other EU policies (including Better Regulation) and legislation and to modernise, simplify and clarify the current food labelling scene. As they mostly relate to legal updating and clarification these simplification elements do not require detailed analysis:

- Setting-up of a flexible bottom-up mechanism (new labelling governance) that would enable the industry to innovate on food labelling, and the labelling rules to adapt to different and continuously changing markets and consumer demands. The approach of the labelling provisions that have existed for decades has been carefully questioned as required by the Commission Simplification Communication and the Impact Assessment Guidelines;

- Recasting of the different horizontal provisions on labelling. The merging of the horizontal texts will maximize synergies, minimize overlaps and redundancies and increase the clarity, and consistency of Community rules. This is a powerful simplification method that should provide economic operators and enforcement authorities with a clearer and more streamlined regulatory framework. Consideration was given to bring all labelling legislation, including requirements from vertical legislation, into one text but this would have been complicated and resulted in an even more complex approach;
• Introduction of clear principles to draw a clearer borderline between mandatory and voluntary information;

• Elimination of inconsistencies between horizontal and vertical rules, where possible;

• Rationalisation (update, clarification, removal of redundancies) of the compulsory information required by Article 3.1 of Directive 2000/13/EC.

(2) Measures that during the consultations were identified as having more important impacts, e.g. major policy actions with potential economic, social or environmental impact and for which a more detailed analysis has been carried out. Addressing the following issues would contribute towards simplification in terms of easier compliance and greater clarity for stakeholders:

• How to improve legibility of the labels – the objective is to simplify the way information is made available to the consumers, improve the legibility of information for the average consumer and make it easier for operators to comply with the general requirement for readable and clear labels;

• How to deal with the lack of information on allergenic ingredients on non-pre-packaged food – the objective is to protect consumers' health and to ensure consistency in the provision of information;

• Origin labelling – the objective is to simplify the current situation where due to uncertainty there is a proliferation of misleading voluntary indications of origin and a non-ending debate on how to address recurrent consumer demand for information on food origin. Addressing this issue would provide clarity in the legislation, facilitate compliance for operators and improve consumer understanding of origin indications;

• Inconsistent information on ingredients and in particular ingredient listing for alcoholic beverages – the objective is to rationalise the current situation by clarifying the existing legal limbo.

Most recent developments have shown that there is an increasing demand to make use of labelling schemes in order to inform consumers about issues of public interest in relation to the production methods concerned. The discussion on animal welfare labelling as tool to improve the farming methods applied is an example of a trend which could also extend to other elements of sustainability, such as environmental protection and climate change (“carbon footprint”) or social questions as decent working conditions and child labour.
Following the conference “Animal Welfare – Improving by labelling?” jointly organised by the German Presidency, the EESC and the Commission, the Council adopted in May 2007 “Council Conclusions on Animal Welfare Labelling”. In these conclusions, the Council recognises that animal welfare is of concern and that labelling could be one important element in the provision of information to consumers and could allow producers to capitalise on high animal welfare standards. The Council invites the Commission to conduct an in-depth study into the effects of introducing animal welfare labelling.

However, while the issue of animal welfare has been recognized as important for the consumers, it cannot form part of this impact assessment, as the discussion is at a too early stage to produce specific policy options which could be assessed. But the revision should already now provide for flexible tools to respond to future emerging, justifiable demands to use food labelling as communication tool on issues of public concern.

5.1. Baseline projection

If the legislation is not changed then it is anticipated that there would be a continual confusion among stakeholders concerning food labelling rules and that the labels would lose progressively their added value as the food business operators would continue to increase voluntary commercial information to the detriment of mandatory information that is important to enable safe, healthy informed and sustainable choices.

5.2. Policy Issue 1 - Legibility of the information

Options

5.2.1. Option 1: no EU action

No change to the present legislation would mean leaving the interpretation of the provisions of the legislation to the enforcement competent authorities in Member States possibly through case-law.

5.2.2. Option 2: Non statutory approach

– Sub-option 2a): New food labelling governance for all aspects of labelling presentation

Stakeholders and public authorities at national and community level could set a common framework for the development and exchange of best practices covering all aspects of labelling presentation to guarantee a certain level of clarity of labels.

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21 www.animal-welfare-labelling.de
Ibid.
– **Sub-option 2b): New food labelling governance for all aspects of labelling presentation apart minimum font size**

Stakeholders and public authorities at national and community level could set a common framework for the development and exchange of best practices covering all aspects of labelling presentation to guarantee a certain level of clarity of labels apart minimum font size.

5.2.3. **Option 3: Statutory approach**

– **Sub-option 3a): standardise the presentation of all aspects of labelling**

To set up in detail the way mandatory information should be presented: its place on the label, as well as the minimum character size, the spacing of words, the type-face and colour.

– **Sub-option 3b): establish a minimum font size**

Whilst only directly addressing one issue of presentation (text size) this would provide a basis for control of this aspect).

5.3. **Policy Issue 2 - Lack of information on allergenic ingredients on non-prepacked food**

**Options**

5.3.1. **Option 1: No EU action**

No change to the present legislation would mean leaving it to the Member States to adopt detailed rules concerning which pieces of information should be given to the consumer for unpacked food and in which manner. More precisely, although unpacked food would not be excluded from the legislation, Member States may decide not to require the provision of all those requirements or some of these, provided that the purchaser receives sufficient information.

5.3.2. **Option 2: Non statutory approach**

– **New food labelling governance**

Stakeholders and public authorities at national and community level could set a common framework for the adoption of standards related to the provision of information concerning non-pre-packed food and the details of these standards would be addressed in codes of best practice or national Guidance to encourage and help industry to provide information concerning non-prepacked.
5.3.3. **Option 3: Statutory approach**

- **To extend mandatory allergens labelling to non-pre-packaged food**

Allergens labelling would be mandatory for non-pre-packaged food and Member States would have to adopt detailed rules concerning the manner in which this information should be provided.

5.4. **Policy issue 3 - Clarification of the use of origin labelling on foods**

**Options**

5.4.1. **Option 1: No EU action**

This would mean that origin or provenance of foodstuffs is not mandatory information, unless its omission could mislead the purchaser and that the rules for the use of origin labelling would remain unclear.

5.4.2. **Option 2: Non statutory approach**

- **New food labelling governance to encourage non misleading origin labelling**

Stakeholders and public authorities at national and community level could set a common framework for the adoption of standards related to the provision of information on origin and the details of these standards would be addressed in codes of best practice or national guidance to encourage and help industry to provide information on origin.

5.4.3. **Option 3: Statutory approach**

- **Sub-option 3a): To require mandatory origin labelling for all unprocessed food**

All unprocessed food, meaning raw products would have to provide information on origin. Origin information of such products would have to be provided even when they are included in a processed food.

- **Sub-option 3b): To address specific justified demands of origin labelling**

This option would imply setting out a procedure whereby requests for mandatory origin labelling were looked at on the basis of a clearer requirement for proof that final consumers really want such labelling. If such proof were provided, there would still be a need for detailed technical rules for implementation.
– **Sub-option 3c): To lay down criteria to frame the voluntary use of origin labelling**

This option can be combined with any of the previous sub-options (3a and 3b) or stand alone. It would provide for criteria to be taken into account when origin labelling appears voluntarily. These criteria would then need to be further detailed in implementing measures or guidance.

5.5. **Policy Issue 4 - Consistent application of ingredients listing rules**

**Options**

5.5.1. **Option 1: No EU action**

This option would maintain the current legal limbo whereby although there is in the legislation a theoretical obligation for labelling of ingredients of alcoholic beverages, it is not operational due to the lack of specific rules.

5.5.2. **Option 2: Non statutory approach**

– **New food labelling governance**

Stakeholders and public authorities at national and community level could set a common framework for the adoption of standards related to the provision of information on the ingredients of alcoholic beverages and the details of these standards would be addressed in codes of best practice or national guidance to encourage and help industry to provide this information.

5.5.3. **Option 3: Statutory approach**

– **Sub-option 3a): exempting all alcoholic beverages from compulsory ingredient listing**

This option would put an end to the current legal inconsistency by changing the legislation to bring it in line with the current reality that has existed, without apparent problems, for nearly 30 years, where alcoholic drinks do not list their ingredients.

– **Sub-option 3b): exempting alcoholic beverages in general from compulsory ingredient listing but creating and making operational a labelling requirement for beverages resulting from a mixture of alcoholic beverages with non alcoholic beverages.**

This option would mean that only ready to drink pre-mixed alcoholic beverages (commonly called alcopops), would be required to label their ingredients.
– **Sub-option 3c): creating and making operational a labelling requirement of ingredient listing for alcoholic beverages on basis of specific characteristics of the products and consumers' expectations.**

This option would imply that alcoholic beverages would have to label substances or ingredients that are likely to influence the consumer's choice, such as sweeteners, flavourings, colouring agents.

6. **ANALYSIS OF IMPACTS**

This Impact Assessment combines quantitative and qualitative approaches so that adequate consideration is given to a broad range of direct and indirect as well as social, environmental and economic impacts. The impact analysis is based on the evidence obtained through a review of the literature (published in peer reviewed journals and non-peer reviewed publications), reports prepared by Member States, semi-structured interviews with relevant public and private actors, the SME Panel on Food Labelling in 2006 and the online questionnaire organised in 2007 by the external consultant RAND Europe. In addition, the impact assessment results were scrutinised by the experts from different Commission Directorate-Generals' represented in the Inter-Service Steering Group on Impact Assessment.

**Data limitations:** There is not sufficient cost information available on the impact of general food labelling which makes it difficult to apply the Standard Cost Model. The online survey conducted by the RAND EUROPE included questions on the costs associated with specific aspects of the food labelling process (*see Annex 3*), however, it was not possible to derive reliable estimates of time spent or costs associated with labelling of products that could be applied in a Standard Cost Model.

Based on these data limitations and according to the proportionality principle, the assessment of the options has not been undertaken using the Standard Cost Model. Consequently in order to quantify the impacts, calculations for concrete options have been based on assumptions where appropriate.

**Probable reasons for non delivery of information:** Given that there was proper advance notice and adequate time for the stakeholders to reply, the poor delivery could be attributed to some methodological limitations of the survey and other attributes linked to the nature of a web-base survey as well as to lack of responses from the part of the industry.
6.1. **Approach taken in assessing the impacts**

The current legislation covers prepacked foods i.e. foods that are not packed at the request of the consumer or that are packed on the same premises of manufacture for immediate sale. The approach in assessing the impacts has been to consider the proportion of labels on prepacked products that might need to change. Although this is potentially a crude measure, it is practically impossible to examine in detail the impacts because of the sheer range of products and labels that exist. Therefore this section starts by providing general information about the labelling process so that the potential impacts can be more readily understood.

6.2. **Food Labelling Process**

In considering the economic impacts that might occur due to changes to the food labelling legislation it is important and useful to understand the food labelling process. Including recognition that even in the absence of labelling legislation, prepacked food would still be labelled. Therefore, whilst changes in food labelling legislation may mean some additional costs associated with including the information required, companies producing prepacked foods will always have costs of labelling that are not due to legislative requirements.

The costs of labelling legislation, and changes to labelling legislation, fall primarily at company level. Generally on the food manufacturer (for branded products), but increasingly on the retailer as well with the increase of ‘own brand’ products in many EU markets. To be able to understand the potential impact of changes to the legislation of specific aspects of food labelling on the industry, it is useful to try to consider the various steps that comprise the food labelling process. These are set out in the table below with information on costs also provided. Further information on the origin of these costs is then provided in the main text.
There is a wide variety of means of labelling pre-packaged foods such as labelling information printed directly on the packaging material or labels stuck on to the package. For example, tins can have paper labels stuck onto the tin or can have the labelling information printed directly on the tin (as is often the case for soft drinks). In surveys of producers of pre-packaged foods when asked about costs of implementing changes the responses range from a negligible impact to a substantial cost if there is a need to invest in new equipment. The different packaging materials and methods of labelling have an impact on the labelling costs making it difficult to give a representative cost of labelling.
6.2.1. Drivers for labelling changes

A label change can be triggered by various reasons: the most common ones are changes in regulation, marketing reasons, product reformulation and recipe changes and adding additional information to the label. Food manufacturers have indicated that changes in regulation is the most common reason for labelling changes but changes in the recipe or updating the label are also considered important reasons. Labels are usually changed by producers at regular intervals. These life cycles of a label may range from a few months for branded products with a high turnover such as cereals or soft drinks, or they might be a few years for niche products and commodity products such as sugar, salt or flour. According to the results of the surveys of the industry most manufacturers change the product labels at least every 3 years with around 20% of manufacturers changing their labels less frequently.

![Figure 2: Reasons for modification of labels: “What is the main reason for changing a product label?”](image)

SOURCE: EICN (2006); Question 11

24. RAND report.
25. SME Panel and RAND survey.
26. RAND report.
6.2.2. **Familiarisation with the regulations and information to be provided**

After the need for changing a label has been established, the company has to become familiar with the legislation to establish the legal requirements for the new label. A UK administrative burden exercise estimated the costs attributed to familiarisation and understanding the General Food Labelling regulations as 13% of all administrative costs across all the regulation. An administrative measurement exercise conducted in Denmark estimates the costs associated with familiarisation with food labelling legislation to account for 5% of the total administrative burden.

If the information to be provided on the label is not readily available within the company, additional costs are associated with the collection of this data.

6.2.3. **Design and printing costs**

After the food-business has collected all the necessary information to be presented the design of the label is the next step. The design costs vary with the extent of the overhaul of the label, with a complete overhaul being the most expensive option. The report from RAND shows that a small change would cost €2000-4000 whilst full resign of a label would cost an additional €7000-9000.

Labels are printed by various methods the costs of which vary. There are US estimates of costs associated with preparing the printing plates ranging from $380 for a minor change up to $16,600 for a full redesign. Another cost impacts of labelling changes is the write off of existing stocks of labels. Data on the typical stock of labels available for the UK indicates that 69% of companies use their labels within 12 months, and only 11% need more than 24 months to use their labels.

<table>
<thead>
<tr>
<th></th>
<th>Percentage of labels changed</th>
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<tbody>
<tr>
<td></td>
<td>Once a year</td>
</tr>
<tr>
<td>RAND Survey</td>
<td>37%</td>
</tr>
<tr>
<td>SME Panel Survey</td>
<td>29%</td>
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The potential impact of labelling changes on businesses can be reduced if the changes are incorporated into the usual lifecycle of a label that is through adequate transitional periods.

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On the basis of the available information it is estimated that over a 3 year period 80% of companies would introduce labelling changes as a normal part of their business operation. In fact on average 35% of labels would be changed within one year with a further 25% within 2 years. Normally the implementation of new labelling requirements are not imposed immediately and generally there is a period of transposition included in the legislation with some flexibility with products that had been labelled and placed on the market before a certain date being able to continue to be sold. Therefore, an extended period during which products that does not comply with the requirements can continue to be placed on the market would have an impact on the ability of companies to adapt to the new requirements by minimising costs. Therefore in the assessment of the impacts the effect of different transition times on food business operators is estimated.

6.3. Administrative burden

Standard Cost Modelling measures the administrative burden to industry of complying with regulations. The burden refers to the provision of information to third parties, the regulator and the public. In the case of food labelling, the administrative burden of providing information to regulators will be minimal as the regulator does not require the provision of information from those regulated. In the case of the cost of providing information to the public, the cost of compliance is part of the overall cost of labelling and difficult to disaggregate. The calculations presented in Annex 4 do not apply Standard Cost Model as required by Impact Assessment Guidelines. It draws from the SCM analysis of Member States, and then combines these data with data collected by the external consultants. It enabled only a rough estimation of overall costs, but this is already useful for the analysis of options.

The administrative burden exercises in the different Member States have tried to establish the current costs of compliance to industry and show that it is not possible to anticipate what the costs to industry related to revisions in labelling regulations might be and in which type of industry specifically these costs will be incurred.

Is should be borne in mind that a food manufacturer would label his food product to be able to distinguish it from his competitors products. Therefore, there is an ongoing underlying costs associated with producing and labelling products even in absence of mandatory labelling legal provisions. Where regulation can have an impact is in the requirements on the information that must be included on the label and the costs associated with providing the specified information. There is an ongoing project to assess the administrative burden associated with the food labelling legislation. The Directorate Generals Enterprise and Industry, and Health and Consumer Protection are working closely together on this project.
6.4. Other impacts

6.4.1. Impact on innovation and research

It is considered that innovation and research will not be affected by the revision of the legislation so these aspects are not considered separately during the analysis of each of the policy issues.

6.4.2. Employment, equality, private life and access to social welfare systems

It is considered that social aspects relating to employment, equal opportunities, private life and access to social welfare systems will not be affected by the revision of the legislation so these aspects are not considered separately during the analysis of each of the policy issues.

6.4.3. Environmental impacts

The potential environmental impacts could be that the requirements for the provision of certain information on food labels would mean that the manufacturer would have to increase the size of the packaging to provide the information in a legible format.

This would lead to increased use of material resources and energy, and of waste. Under the existing General Food Labelling legislation small packages may be exempt from certain requirements. No significant environmental impacts would be expected from the new proposal on general food labelling.

6.5. Policy Issue 1 - Legibility of the information

Option 1: No EU action

Option 2: Non-statutory approach

– Sub-option 2a): a new governance system for all aspects of labelling presentation

– Sub-option 2b): a new governance system for all aspects of labelling presentation apart minimum font size

Option 3: Statutory approach

– Sub-option 3a): standardize the presentation of all aspects of labelling

– Sub-option 3b): establish a minimum font size

6.5.1. Economic Impacts

Impact on competitiveness, markets, trade

No significant impacts are foreseen. Under option 2, it is more likely that the large firms would have the resources to participate in voluntary collaborative approaches and the competitiveness of SMEs might be affected.
Operating costs and conduct of business

Option 1 would oppose no additional costs on food producers and retailers. Under option 2 the total costs for the industry depend on the degree of uptake of the voluntary agreements and commitments. For individual companies applying voluntarily the standards, the cost would be identical to those resulted from a statutory approach (option 3). However, these costs might be reduced if the mechanism framing the voluntary agreements produced input savings, i.e.: enhancing reputation of companies that comply voluntarily with standards. In addition, option 2 might produce regulatory gains -- that is, savings through the avoidance of public regulations: in the form of reduced compliance costs given that a voluntary approach may set the same target as option (3) but may allow companies greater flexibility in achieving those targets. This would allow industry to find more cost-effective solutions adapted to its specific situation.

There is little evidence about the impact of options 3a) and 3b). The three options reduce the producers’ and retailers’ flexibility in the design of the label and have the potential to increase costs.

Respondents to the survey conducted by RAND reported that increasing font sizes (option 3b)) could lead both to the need for larger packages, and to an increase in costs for redesigning labels. The problem aggravates if the products have multiple ingredients and have multi lingual labels. Depending on the degree of pre-compliance, labels might have to be slightly re-designed and potentially some adjustments to printing equipment would have to be made. To identify the range of potential costs, the model described in detail in Annex 5 was used. Assuming that familiarisation with the legislation that would concern only a limited number of requirements should be inexpensive, the main burden of costs lies with potential need for labels' re-designing.

Based on the findings of a UK survey on the uptake of voluntary guidance on clear food labelling in the UK\(^2^9\) it is expected that introduction of a minimum font size of 10pt or (8pt the absolute minimum) would require label changes for 87% of products given that only 13% of products use 8pt as a minimum font size. Hence, assuming average illegibility of 87% of labels, and one-off cost of € 225 per label for small re-design, the costs of these modifications in the option without transition period reach € 5.2 billion. The actual incurred or marginal costs of providing a minimum font size, or meeting other requirement, will be however much lower if they can be integrated into the labelling cycle. With application of transition period they reduce to € 1.7 billions with 2-year grace period being granted, and to only € 250 million with 3-year grace period. Costs will however increase if multi lingual space limitations lead to major adjustments of the food labels and if the number of Stock keeping units (SKUs) to be produced increases due to less multilingual labelling.

Option 3a) has prospectively the highest potential of increasing cost of food producers across the policy options discussed here. In some cases it can even require an extensive redesign, and as a consequence the cost could be situated at the upper margin of the cost estimates described above (on average €2,000 - €13,000 per label). Standardised mandatory information is the most space consuming of the discussed policy options. This might also have an impact for companies which market their products in several countries if this had knock-on effects on the number of stock-keeping units (i.e. basic label design for products within a range of products), warehousing, and distribution operations (from the survey of SMEs around 65% of companies exported their products). In this context the use of multilingual labelling may be affected. One study shows that 74% of companies with a turnover in excess of €50 million use multilingual labelling. This figure drops to 14% for companies with a turnover below €50 million. Data from the survey conducted by RAND Europe suggests that large firms are more likely to produce multilingual labels with 40% of large, 25% of medium, 25% of small and 9% of micro businesses producing multilingual labels varying from maximum 2 languages (35%) to 9 languages (10%). (In some Member States due to the language requirements companies may be obliged to label their products with more than one language).

To illustrate the impact of a label's legibility on the overall benefits of labelling, we have used the example of nutrition labelling. Graph below depicts the potential impacts – in case of front-of-pack labelling it is assumed label is read by 80% of the customers (if not every time, at least during first purchase), in case of easily legible back-of-pack label the ratio goes down to 40%, while in case of illegible back-of-pack label it further decreases to 10%, as only the most tenacious customers will read them. The way reading a label then transforms into action, and changing behaviour was assumed equal in all 3 cases.

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30 SME Panel results.
31 SME Panel results.
33 RAND nutrition labelling report.
Figure 3: Estimated potential costs and benefits of labelling of 5 nutritional elements either on front or back of pack being associated with a 1% reduction in salt intake and placement of information

Impact on SMEs

No impacts are expected with option 1 on SMEs. As with other policy issues it is expected that the impact of the different options under Option 3a) and 3b) would be greater on SMEs than on large companies as cost for implementing changes are generally proportionally greater for SMEs but there would not be any special costs for SMEs.

Impact on administrative burden

Depending on the different elements of the system supporting the voluntary agreements and best practices, option 2 would create some burdens to industry and enforcement authorities related to the monitoring of the voluntary schemes, reporting, publicity of the scheme. Options 3a) and 3b) might be considered as increasing the administrative burdens for the companies to familiarise with the regulation. This should be small for option 3b) because only the font size is concerned. Standardisation of information (option 3a) requires a considerable number of single prescriptions which have to be understood and followed by the food companies, which imposes information costs on the food producer and increase the risk of accidental non-compliance due to more complicated regulation.
Third countries and international relations

No negative impacts are expected with option 1. Options 3a) and 3b) could have impacts although some companies that might be affected by changes in the EU legislation would have to already take account of legislation in third countries that include specification of minimum font size or other aspects of presentation. As far as international standards are concerned, the CODEX standard for the labelling of pre-packaged foods does not provide any details concerning the presentation of labelling. The current standard is very much similar to the present EU legislation (broad requirement for the label to be understandable).

6.5.2. Social Impacts

Impact on public health, safety and consumers' right to information

Option 1 would mean that consumers continue to be clearly dissatisfied with the legibility of food labels.

Option 1 is not expected to have any impact on public health. Options 3a) and 3b) should make it easier for consumers to read the information, especially information which is related to the safety of the product, such as durability date or to health aspects, such as allergens. Avoidance of products that can cause anaphylactic shock is expected to be helped by the quality and legibility of the allergen risk labelling.

Option 2 may lead to a certain harmonisation of approach of the voluntary agreements, if exchange of practices was effective. The social benefits of this approach may vary from zero to the total benefits achieved by a prescriptive statutory option (3). However, on the basis of evidence from the UK that in one survey that on 87% of packages the minimum font size was not in line with the best practise guidance, it is considered that option 2 would not address the basic legibility problem frequently raised by consumers. A minimum font size as proposed under Option 3b) is likely to have a positive impact in helping consumers read labelling information. This is fundamental to help consumers make better informed food choices, which is the central aim of food labelling. These positive impacts could reasonably be expected to be even greater if all aspects of legibility were provided for in the legislation as proposed under option 3a).

6.5.3. Impacts on Member States

No significant negative impacts are expected. Options 3a) and 3b) might make it easier for Member States to implement legislation.
6.6. Policy issue 2 – Lack of information on allergenic ingredients on non-prepacked food

Option 1: No EU action

Option 2: Non-regulatory approach
   – a new food labelling governance to encourage allergens labelling non-prepacked food

Option 3: Regulatory approach
   – To extend mandatory allergens labelling to non-pr-packed food

6.6.1. Economic Impacts

Impact on competitiveness, markets, trade

No impacts are foreseen, given the local characteristics of selling non-prepacked food.

Operating Costs and conduct of business

"Non-pre-packaged’ foods are foods which are sold loose i.e. non-wrapped. In a retail environment, this would apply to any foods that are sold loose from a delicatessen counter, as well as to nuts and vegetables sold loose. In a catering environment this would apply to foods which are sold non-wrapped, for example, from a canteen or meals served in a restaurant/takeaway. Foods sold ‘pre-packaged for direct sale’ generally means those foods that have been packed on the same premises as that from which they are being sold. Consequently, the business sectors affected will be all those selling foods not prepacked i.e. ‘non-prepacked’ and ‘pre-packaged for direct sale’ via catering establishments or through retail outlets. In terms of number of businesses affected the overall cost is likely to be significant. According to EUROSTAT data there are currently in the European Union about 500,000 retail companies, employing some 4.7 million staff and around 1.4 million restaurants, caterers and canteens employing some 6.4 million staff.34

Typical retailers of food sold loose range from the butcher’s shop and bakeries to medium and large retailers offering fresh products and unpacked food at deli counters.

34 NACE classification h553 to h555.
Option 1 would lead to no additional costs. However, there would continue to be costs in terms of the health effects for a consumer with food allergies or food intolerances in respect of ill health, and, in extreme cases, death occurring as a result of eating allergenic foods. Food businesses will not be sufficiently well informed about food allergy in order for them to know how to respond to food allergic consumers, when asked about the ingredient content of their foods, which may also enable them to be less efficient. There could also be costs to businesses if they knowingly provide inaccurate information about the allergen content of their foods.

Under option 2 the total costs for the industry depend on the degree of uptake of the voluntary agreements and commitments. For individual companies applying voluntarily the standards, the cost would be identical to those resulted from a statutory approach (option 3). In addition, option 2 might produce regulatory gains -- that is, savings through the avoidance of public regulations: in the form of reduced compliance costs given that a voluntary approach may set the same target as option 3 but may allow companies greater flexibility in achieving those targets. This would allow industry to find more cost-effective solutions adapted to its specific situation.

The operational costs of option 3 are difficult to quantify. Unlike the extensive literature on labelling of prepacked food, there is little literature available on the costs of labelling food sold loose. In addition, businesses may choose different ways of providing the information to the customer, such as product labelling, or point of sale notices (on e.g. menu’s, posters, point of sale displays etc.)

Although the actual production of a physical label for food sold loose seems to be a rather unproblematic feature of extending labelling requirements to food sold loose, there might be more important issues with generating and updating the information to be provided on the labels. However, any difficulties for the seller to have the information available could be mitigated if the responsibility of the food chain for ensuring the transmission of information was to be reinforced.

Cost of actual production of a "physical labelling"

If retailers provide information on products sold loose, this is typically done by adhesive labels printed in stores and then attached to the food or by displays at the point of sale, which has been considered by RAND interviewees as a cheap and flexible solution. Taking the example of fish sold at wet counters, which can be considered similar to food sold loose, there are only marginal costs in changing labels for food sold loose. On wet fish counters, labelling information is often given on pre-printed tickets displayed with the fish. Changing one of these tickets was estimated to be around € 4.50. Depending on the number of different products sold at the respective retailer, one off re-labelling costs could thus be between around € 45 for ten product lines or up to € 450, if hundred products have to be re-labelled.35

On a daily basis, the time needed for printing and apply "labels" for food sold loose can be estimated as on average half an hour\textsuperscript{36}.

Restaurants would have to provide information on their food products at the point of sale. There is a number of ways to provide such information, it could be for example be included in the written menus or be put on clearly visible displays at the point of sale (specific booklets or displays with additional information). No systematic research has however answered the question of how much such a provision would cost.

**Information costs**

Food sold loose prepared by the retailer and sold at deli counters, such as sandwiches or pizzas or roasted chicken, might be based on recipes that change frequently, depending on available ingredients etc. If e.g. full allergen and ingredient labelling is required, labels have to be changed frequently and, especially for allergens, accuracy of the information must be secured. This involves requiring information from the food producers as well as training the own staff. For other foodstuff the required information should be readily available to the retailer from the producer of the foodstuff (in accordance with the current legal requirements), however this will impose information costs on the retailers\textsuperscript{37}. The survey conducted by RAND Europe contained a set of questions on food sold loose. Out of 117 respondents 32 companies were selling loose food. Of these, 22 provided information that would usually be included on a label. However, due to severe limitations in the responses, no data on the costs involved in providing this information could be generated.

As far as restaurants are concerned most of the information to be provided should be readily available to the catering outlets, such as ingredients used etc. (in accordance with the current legal requirements). Some training for the staff would probably be required for the staff to be able to provide accurate and reliable allergen information. The nature of the products offered at catering outlets, with frequently changing recipes and ingredients, makes it however difficult to keep information up to date.

Option 3 would allow the European Union to set a certain “benefit level”, while allowing the Member States flexibility in implementing the requirements.

\textsuperscript{36} Internal documents based on a Dutch pilot study on labelling in the trade and craft sector provided to RAND by the Dutch Ministry of Health, Welfare and Sport.

\textsuperscript{37} Evidence obtained through interviews.
Impact on SMEs

Option 3 clearly impacts on SMEs, as most of specialized food retailers and restaurants are small or even micro companies. There is however no specific evidence, that SMEs would be disadvantaged by such a regulation, besides the general observation that SMEs usually have fewer and less specialized resources at hand to handle labelling related issues. Guidance on the presentation of information could help SMEs to comply with any new requirements.

Impact on administrative burdens

Depending on the different elements of the system supporting the voluntary agreements and best practices, option 2 would create some burdens to industry and enforcement authorities related to the monitoring of the voluntary schemes, reporting, publicity of the scheme. Option 3 could result in certain information costs for companies in collating the required information from different sources and staff training costs to guarantee the accuracy and the currency of the information.

From a Member State’s enforcement agency perspective, extending the mandatory allergen labelling to all food business would increase the number of businesses which have to be supervised and monitored for labelling reasons.

6.6.2. Social Impact

Impact on public health and consumers' right to information

Option 1 would result in no benefits for food allergic consumers. The risks to food allergic consumers purchasing food sold loose or prepacked for direct sale containing an allergic ingredient about which they were unaware, will continue to exist and may continue to restrict their choice of foods unnecessarily.

A UK allergen survey that was carried out in 2004 on foods which are exempt from providing an indication of allergenic ingredients and which were purchased with a special request that they should be free from a number of specified allergens revealed that 9.3% of the samples from the foods which were analysed, indicated the presence of these allergens, indicating either a breakdown in communication in these instances and/or lack of knowledge by serving staff of the ingredients in the foods they are selling.

Between \( \leq 20-30 \) percent of the general population perceive themselves to have a food allergy or some other form of adverse reaction to food, however estimates of the true prevalence of food allergy range between 1-2 percent for adults and 5-8 percent for children.\(^{40}\) At least 1 in 100 people need to avoid gluten, because they have coeliac disease.

There is evidence from clinical records to suggest that foods sold not pre-packaged present a greater risk to food allergic consumers than pre-packed foods, in terms of the numbers of fatal and near-fatal allergic reactions occurring. Current estimates indicate that around 10 people die per year in the UK alone as a result of allergic reactions to food. The Anaphylaxis Campaign suggest that around 75\% of these deaths occur when people are eating outside the home (where food is sold loose, for example in restaurants or take-aways). In 2004/5 there were 990 hospital admissions in the UK caused by anaphylactic reactions to food. There is a cost to the person concerned and to the National Health Service for every anaphylactic shock reaction, which can result in a stay in hospital. In 2005 the average cost for (non-elective) treatments of shock and anaphylaxis was £471 per treatment.

Option 2 may lead to a certain harmonisation of approach if the voluntary agreements, exchange of practices were effective. The social benefits of this approach may vary from zero to the total benefits achieved by a prescriptive statutory option (3). As it is the case for each voluntary approach, depending on the mechanisms put in place to monitor the voluntary agreements, option 2 has the potential to lead to a trade-off between flexibility on the one hand, and effectiveness of the label and consumer information on the other.

Option 3 would ensure especially that food allergic consumers receive sufficient and accurate information about the ingredient content of foods purchased. There would be health benefits and reduction of the number of allergic reactions as a consequence of allergic consumers not realising that a food contains an ingredient to which they are allergic. These options would possibly reduce costs to the Public Health Services in relation to the number of people suffering anaphylactic shock reactions.

6.6.3. Impact on Member States

Option 1 would have no impact on Member States. Option 3 means an increase in the number of companies to be controlled for complying with labelling regulation, in particular restaurants as a British regulatory impact assessment states\(^{41}\), and time spent following up on issues if non-compliant. However, this policy option gives the Member States more flexibility in implementing mandatory requirements. This flexibility can be used to tailor any legislative measure to the domestic characteristics of each Member States food retail and food catering business. While the general cost considerations still apply, this might be an opportunity for a more cost effective regime.


\(^{41}\) Ibid.
6.7. Policy issue 3 - Clarification of the use of origin labelling on foods

**Option 1:** No EU action

**Option 2:** Non-statutory approach

- New labelling governance

**Option 3:** Regulatory approach

- **Sub-option 3a):** to require mandatory origin labelling for all unprocessed food.
- **Sub-option 3b):** to address specific justified demands of origin labelling.
- **Sub-option 3c):** to lay down criteria to frame the voluntary use of origin labelling

6.7.1. Economic Impacts

*Impact on competitiveness, markets, trade*

As consumers tend to prefer products from their own countries, options 3a) and 3b) (mandatory origin labelling) have the potential to increase entrance barriers to markets in other Member States, except for products which have a strong connotation of origin and quality. Option 3c) could increase the competitive situation of some producers given that in the market place a reliable and trusted country of origin label might constitute a valuable marketing asset.

Option 3b) could allow the Member States to enact national regulation on origin labelling, if they can provide sufficient evidence, that their consumers demand origin labels for specific food products. Leaving aside the difficult questions what would constitute sufficient evidence to support the introduction of origin labelling and how such decisions could be taken, this policy option has the potential to lead to the proliferation of national country of origin labelling requirements across the European Union. The result could be a scattered regulatory landscape across Europe, and across different food products.

However, as long as only some countries opt or manage to provide the required evidence for origin labelling for some products, option 3b) is likely to entail less costs that option 3a).
Operating costs and conduct of business

Costs implications of country of origin labelling on the firms are related to the following:

• First, the company needs to collate the country of origin information of its products. The cost in acquiring this information depend on the actual definition of country of origin used and the extent, to which country of origin information of single and compound ingredients has to be traced back. If place of production would be a label of origin, this information is readily available at no cost. If the regulations require labelling the origin according to the origin of the ingredients, information costs are likely to rise, depending on whether the information is already available using established information systems or whether these have to be established. RAND Interviews with two small food producers indicated that information on the country of origin of their food products could easily be included on their products.

• Secondly, firms would incur one off costs for changing their labels to include the information. If there are extensive, i.e. space consuming labelling requirements, and if labels are already crowded, these might be higher as labels might have to be redesigned or even new stock keeping units have to created.

• Thirdly, country of origin labelling might have a cost driving effect by requiring an increased frequency of labelling changes. If country of origin labelling is extended to cover single ingredients, changes in recipes and sourcing require changes on the label to adequately cover the origin of the product.

Under option 2 (best practices) the total costs for the industry depend on the degree of uptake of the voluntary agreements and commitments. For individual companies applying voluntarily the standards, the cost would be identical to those resulted from a statutory approach (option 3). However the costs could be reduced given that option 2 can produce regulatory gains -- that is, savings through the avoidance of public regulations: in the form of reduced compliance costs given that a voluntary approach may set the same target as option 3 but may allow companies greater flexibility in achieving those targets. This would allow industry to find more cost-effective solutions adapted to its specific situation.
Option 3a), providing origin information of single ingredient, unprocessed food requires a certain degree of tracking and tracing of the products, but does not seem to substantially increase the cost of food producers. An impact assessment conducted in the US\textsuperscript{42} which basically covers raw food, and is similar to this option and which is considered to considerably overestimate the costs of labelling calculates cost increases in the range of 0.01 percent for chicken meat and 0.64 percent for fish. Labelling different raw products within processed food however has the potential to lead to an increase of production costs on average of 1.4 percent for the implementation of extensive labelling requirements, as an Australian study shows.\textsuperscript{43} However, taking account of existing tracking and tracing systems which would allow generating country of origin information, cost increase could be estimated in between 0.11 percent of food turnover and 0.86 percent with a medium estimate of 0.48 percent, as a study from New Zealand shows”.\textsuperscript{44}

Seasonal sourcing of raw products might require several different labels a year and thus multiplies labelling costs. These potential costs for the whole industry are however reduced through the number of companies that already use such labels. Evidence from the SME Panel\textsuperscript{45} suggests that a majority of companies (70 percent) indicate the country of origin on at least some of their products already, and that around half of these companies provide country of origin information on a voluntary basis. Apparently, the decision to voluntary label the origin is accompanied by the perception that the label provides them with a commercial advantage).\textsuperscript{46}

\textsuperscript{43} CIE (2006) \textit{Feasibility of extending COOL. A benefit cost analysis}, prepared for Food Standards Australia and New Zealand, Australia.
\textsuperscript{44} NZIER (2005) \textit{COOL revisited. Benefit cost analysis of country Origin Labelling}. Prepared for Food Standards Australia and New Zealand.
\textsuperscript{45} EICN (2006), SME Panel, data collection on possible impacts of labelling changes. Euro Info Centre Network, Belgium.
\textsuperscript{46} These results however have to be interpreted with care, as there is some misfit between the number of respondents answering the sub questions. One possible explanation for this is, that companies with a range of products ticked boxes if for example they had both products which had to be labelled mandatory and some they labelled on a voluntary basis.
Do you include information on the origin of the product on your labelling?

If yes, why is it included? If included on a voluntary basis, does this information represent a commercial advantage for your products?

SOURCE: EICN (2006); Question 11

**Figure 4: Country of origin labelling**

More than half of the companies expect a significant or moderate positive impact on the company, while only 14 percent expect a significant or moderate negative impact on their products.47

If mandatory origin labelling is to be considered, could you evaluate the impact on your products?

SOURCE: EICN (2006); Question 21

**Figure 5: Impacts of mandatory origin labelling on food industry**

This policy option (3a) would thus tackle a prime concern of consumers and constitute a major benefit to them. However, a label indicating a number of countries of origin of a processed food might not convey a specific message to the consumer.

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47 Again, these results have to be treated with care. As the total number of responses exceeds the number of respondents of the survey, companies might have estimated different impacts across their product ranges.
Impact on SMEs

While general reasoning to the capacity of SMEs to implement labelling changes apply, there seem to be no special costs for SMEs with the introduction of any mandatory origin labelling. Assuming a more regional and national focus of SMEs activities in the food sector, burdens might be even less compared to large companies. A demand based approach (option 3b)) entails the possibilities of more targeted regulation, which can decrease the burden on SMEs. Frequent label changes magnify the disadvantaged position of SMEs in producing labels; option 3a) might thus put an additional burden on SMEs.

Option 3c) might have the potential to decrease some of the information costs and encourage the voluntary use of country of origin labels. No significant impact is expected. Option 3c) would require familiarisation with the criteria framing the way information on origin is provided. Option 2 might lead to some burdens to industry and Member States related to the monitoring of the voluntary schemes reporting of outcomes publicity of the schemes.

Third countries and international relations

Mandatory country of origin labelling has the potential to conflict with international trade rules when it becomes a practical barrier for trade inside the European Union.

In 2004 the Codex Committee on Food Labelling (CCFL) discussed the need for further work on origin labelling but no consensus could be reached. The European Community will continue to support the need for harmonised standards at the level of Codex Alimentarius but it would not be appropriate to refrain from any initiative aiming to improve consumer information, prevent misleading label and introduce greater homogeneity and clarity across the EU internal market until any work at Codex level is undertaken and completed.

Negotiations are taking place currently with in the WTO Committee on Rules of Origin, in order to find agreement on what "substantial transformation" is, on a product by product basis. Final agreement is not expected for some time. The scope of any agreed definitions should not be expected to cover food labelling for purposes of consumer information. Therefore, work at Community level should be initiated and international developments should be monitored.

In the context of developments in third countries it should be noted that there is a more increase interest in and a move towards the introduction of mandatory origin labelling that was led by Australia. USA has introduced mandatory origin labelling for fish and is currently considering mandatory labelling for meat and agricultural commodities.

However, there is a more increase interest in origin labelling for food internationally. However only Australia has introduced an extensive regime on country of origin labelling and any further prescription at EU level in this field could generate a short of ‘first-mover’ advantage with other countries likely to follow. In terms of international standard, the CODEX General Food Labelling standard is similar to the present EU legislation.
6.7.2. Social Impacts

Impact on public health, safety and consumers’ right to information

Health and food safety are not improved by the introduction of any degree mandatory origin labelling. More efficient systems already exist to deal with these issues.

Option 3a) would tackle a prime concern of consumers and constitute a major benefit to them given that raw products, such as red meat and vegetables are among the products for which country or origin information is most sought-after. However a label indicating a number of countries of origin of a processed food might not convey a specific message to the consumer.

Option 3b) would allow for the introduction of different degrees of origin labelling for different food products, modelled after the different consumer demands for labelling, thus potentially increasing benefits for consumers. Theoretically, this policy option would allow for the best matching of national demand for origin information and mandatory requirements to provide such information.

While there is a fairly clear support of origin labelling from consumers, the benefits and the effects of origin labelling are less clear. The idea of providing country of origin information is firmly grounded in the principle of allowing an informed choice to the consumer, and constitutes a benefit to the society as such, although it might be difficult to quantify such benefits to the public.48 Following a study in USA49 the total willingness to pay for origin labelled beef by consumers was calculated at $ 2.7 billion. (a premium of 11 and 24 percent for steak and hamburgers respectively). Food quality ranks among the most important associations with country of origin, French wine and cheese, Italian pasta and olive oil etc. are associated with certain qualities that the same food products from other countries are not perceived to have.50

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Often, country of origin is linked to food safety, especially in connections to certain health crises such as BSE or avian flu. Consumers however fail to take into account, that food safety and hygiene issues are already addressed in other legislation and that these standards do not differ between domestic and imported food.51 Further aspects derived from the country of origin label are for example ethical considerations such as animal welfare or environmental impacts of buying food locally or regionally.52

Option 3c) has the potential to improve some of consumers understanding of country of origin information. Guidance to frame the voluntary use of origin labelling might reduce the number of misleading information on labels, such as “British sausages”, if the meat actually was imported. Harmonisation of labelling between producers might also increase the value of the information to the consumer, if it is presented in an easy to read and recognisable way.

In UK a desk-based examination of information on food labels could not determine the actual place of origin of a food or its primary ingredients, beyond that which was declared. A Survey of Uptake of Food Standards Agency Guidance on Country of Origin found that for 260 of 358 samples of origin labelling the assessors had insufficient information to determine the origin. Often a product origin statement such as “produced in the UK” was given, but no reference was made as to the origin of the ingredients.

6.7.3. Impact on Member States

No particular effects could be identified on Member States. Option 3b) would enable them to better respond to consumer pressure for origin labelling. In enforcing the origin labelling requirements, it might however be difficult for Member States administrations to actually verify origin claims, depending on the complexity of the regulation.

6.7.4. Environmental impact

No particular environmental effects could be identified, regional shopping by consumers could benefit the environment through reducing transport, however these effects are less likely for country of origin, rather than regional, labelling and would need further scientific enquiry.

51 Mori (2000), Importance and Impact of Country of Origin of Food, Research study conducted for the Ministry of Agriculture, Fisheries and Food, United Kingdom, also: OPTEM (2005), The European consumers’ attitudes regarding product labelling: qualitative study in 28 European countries, produced for European Commission DG SANCO.

52 See e.g. Mori (2000), Importance and Impact of Country of Origin of Food, Research study conducted for the Ministry of Agriculture, Fisheries and Food, United Kingdom.
6.8. Policy issue 4 – Consistent application of ingredients listing rules

Option 1: No EU action

Option 2: Non-statutory approach

– New labelling governance to encourage labelling of ingredients of alcoholic beverages

Option 3: Statutory approach

Sub-option 3a): exempting alcoholic beverages from compulsory ingredient listing

Sub-option 3b): exempting alcoholic beverages in general from compulsory ingredient listing but creating and making operational a labelling requirement for beverages resulting from a mixture of alcoholic beverages with non alcoholic beverages

Sub-option 3c): creating and making operational a labelling requirement of ingredient listing for alcoholic beverages on basis of specific characteristics of the products and consumers' expectations

6.8.1. Economic Impacts

The alcohol industry represents 23% of the food industry’s contribution to GDP, and 0.4% of EU-25 GDP and it employs a total of around 1.2 million workers in the EU25.

Table 3. Contribution of the alcoholic beverages industry to Gross Domestic Product, c. 2004 (€millions)

<table>
<thead>
<tr>
<th>Type</th>
<th>Sub-type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>beer</td>
<td>breweries</td>
<td>12,000</td>
</tr>
<tr>
<td></td>
<td>supplying industries</td>
<td>11,500</td>
</tr>
<tr>
<td></td>
<td>retail</td>
<td>1,700</td>
</tr>
<tr>
<td></td>
<td><strong>total</strong></td>
<td><strong>25,200</strong></td>
</tr>
<tr>
<td>wine</td>
<td><strong>total</strong></td>
<td><strong>8,700</strong></td>
</tr>
<tr>
<td>spirits</td>
<td>Spirit industry</td>
<td>3,659</td>
</tr>
<tr>
<td></td>
<td>Supplying industries</td>
<td>8,041</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>11,700</strong></td>
</tr>
<tr>
<td>alcohol industry</td>
<td></td>
<td>45,600</td>
</tr>
<tr>
<td>food industry</td>
<td></td>
<td>199,048</td>
</tr>
<tr>
<td>total employment</td>
<td></td>
<td>10,421,644</td>
</tr>
</tbody>
</table>

Source: Eurostat online database. DG Agriculture.
Table 4. Employment in the alcoholic beverages industry, c. 2004 (thousands of persons)

<table>
<thead>
<tr>
<th></th>
<th>breweries:</th>
<th>supplying industries:</th>
<th>total:</th>
</tr>
</thead>
<tbody>
<tr>
<td>beer</td>
<td>164</td>
<td>342</td>
<td>506</td>
</tr>
<tr>
<td>wine</td>
<td></td>
<td></td>
<td>c. 385</td>
</tr>
<tr>
<td>spirits</td>
<td>distilleries: 50</td>
<td>supplying industries: 250</td>
<td>300</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>11.1% of food industry</th>
<th>0.3% of total employment</th>
</tr>
</thead>
<tbody>
<tr>
<td>alcohol industry</td>
<td>1,191</td>
<td></td>
</tr>
<tr>
<td>food industry</td>
<td>4,553</td>
<td></td>
</tr>
<tr>
<td>total employment</td>
<td>200,125</td>
<td></td>
</tr>
</tbody>
</table>

Source: Eurostat online database. ICAP 2006.

Impact on competitiveness, markets, trade

No significant impact expected. Taking into account the value consumers put into beverages prepared according to traditional principles, if alcoholic beverages were to label their ingredients, this might lead to favourable market positions for some producers. A typical example would be beer brewed according to the German “Reinheitsgebot” (German purity law), without using additives beyond the traditional ingredients. If there is a consumer demand for such products, ingredient labelling, even if it is on a voluntary basis, would make the characteristics of such products more visible to the consumer. Under option 2, it is more likely that the large firms would have the resources to participate in voluntary collaborative approaches and the competitiveness of SMEs might be affected.

Operating costs and conduct of business

Option 1 (maintaining the status-quo) would imply no additional costs for business, as long as the legal limbo remains. The costs entailed by a non-statutory approach (option 2) are difficult to measure. Given that the costs depend on level of uptake of any guidance or code of best practice, these could vary from zero to the costs entailed by a regulatory approach. For individual companies applying voluntarily the standards, the cost would be identical to those that would result from a statutory approach. However, these costs might be reduced if the mechanism framing the voluntary agreements produced input savings, i.e.: enhancing reputation of companies that comply voluntarily with standards. In addition, option 2 might produce regulatory gains - that is, savings through the avoidance of public regulations: in the form of reduced compliance costs given that a voluntary approach may allow companies flexibility that would enable industry to find more cost-effective solutions adapted to its specific situation.
As regards options 3b) and 3c) there are no independent and plausible estimates of the costs of ingredient listing of alcoholic beverages available. The estimate put forward by the international federation of wine and spirits (FIVS) of annual costs of €297.2 million was considered by RAND to grossly overestimate the additional cost for labelling, and thus does not accurately reflect the costs for industry.53 In addition no cost information on the labelling of alcoholic beverages could be obtained through the survey.

Given this scarcity of specific evidence, the assessment has to rely on the information on the general costs of food labelling. For this estimation, the model described in detail in Annex 6 was applied. For companies which did not label the ingredients before, certain one off cost of familiarising with the regulation can occur, however as it concerns only one requirement it is unlikely it will demand significant effort from the companies. Nevertheless as described in the model an average cost of €1,408 per company was applied, giving the overall cost of familiarisation for the whole alcohol-producing industry of €23,5 millions.

Secondly, the information to be put on the label, i.e. the ingredients of the products, should be readily available to the producers. It can be expected that producers keep records of the ingredients they use, however some ingredient information, particularly for mixed alcoholic beverages, or for must in the wine production, must be required from suppliers. In any case the costs are expected to be on average insignificant, henceforth zero cost was attributed to data collection.

Finally, including a list of ingredients appears to be overall a small change to the product label which does not need a major redesign of the labels. To calculate the final costs, it was assumed that 16.7 thousands of alcohol producers produces around 5 million labels at one point in time. Multiplying the number of labels' estimate by average costs of minor label's modification (€225), the cost of immediate imposition of ingredients labelling rule can reach up to €1,115 billion. However taking into account regular periodical re-design of labels, when the introduction of the rule is equipped with transition period rules, the final cost can be largely decreased (by 70% in case of 2-year grace period, and almost reduced to zero if 3 of more years is considered).

If including ingredient information leads to a reduction of multi lingual labelling due to space limitations, this might impact on the number of necessary SKUs. 17 out of the RAND surveyed 24 producers of alcoholic beverages use multi-lingual labels on their products, and out of these seventeen, use bi- or tri-lingual labels. Given these answers, a slight increase in SKUs might not be avoidable for producers who have to label the ingredients of alcoholic beverages.

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53 The calculations are based on a cost increase per label of €0.20. If you compare this data to the average price of an adhesive label for a bottle of carbonated beverages of between €0.011 and €0.025 as used in the FDA’s labelling cost model, these assumptions seem to overestimate the effect of alcohol labelling considerably.
Option 3b) would impose only a small cost to the industry as a whole given that products concerned represent less than 4,5 percent of the total alcoholic beverage industry. Using the above calculations, only in case of requirements being imposed without transition period, the costs could be substantial (€ 46 million). However, given a sufficient transition time, it is likely that no additional costs for the design and printing of the labels have to be incurred, when changes can be done within the normal labelling cycle.

**Figure 6: Manufacture of beverages (NACE Group 15.9) Breakdown of sectorial value added, EU-25, 2003 (%)**

**Impact on SMEs**

There is no evidence on special costs for SMEs available for policy option 3b) and 3c).

**Impacts on administrative burden**

Depending on the different elements of the system supporting the voluntary agreements and best practices, option 2 (voluntary approach) might create some burdens to industry and enforcement authorities related to the monitoring of the voluntary schemes, reporting, publicity of the scheme.
6.8.2. **Social Impacts**

**Impact on public health, safety and consumers’ right to information**

No impact is expected on public health. Options 3b) and 3c) support the consumer’s right to informed choice. The share of consumers’ beverage consumption is substantial (see table below).

<table>
<thead>
<tr>
<th>Consumption of beverages per capita (litres per year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE</td>
</tr>
<tr>
<td>CZ</td>
</tr>
<tr>
<td>DK</td>
</tr>
<tr>
<td>DE</td>
</tr>
<tr>
<td>EE</td>
</tr>
<tr>
<td>EL</td>
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<tr>
<td>ES</td>
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<tr>
<td>FR</td>
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<tr>
<td>IE</td>
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<tr>
<td>IT</td>
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<tr>
<td>CY</td>
</tr>
<tr>
<td>LV</td>
</tr>
<tr>
<td>LT</td>
</tr>
<tr>
<td>LU</td>
</tr>
<tr>
<td>HU</td>
</tr>
<tr>
<td>MT</td>
</tr>
<tr>
<td>NL</td>
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<tr>
<td>AT</td>
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<tr>
<td>PL</td>
</tr>
<tr>
<td>PT</td>
</tr>
<tr>
<td>SI</td>
</tr>
<tr>
<td>SK</td>
</tr>
<tr>
<td>FI</td>
</tr>
<tr>
<td>SE</td>
</tr>
<tr>
<td>UK</td>
</tr>
</tbody>
</table>

(1) Estimated amount of pure ethanol, as calculated from official statistics on local production, sales, imports and exports, taking into account stocks and home production.
(2) Apparent consumption based on sales.
(3) Greece, Spain and Luxembourg, 2003.


*Table 5: Consumption of beverages per capita (litres per year)*
However, the current understanding of consumer demand for labelling of alcoholic beverages is not detailed enough to judge how the consumers would value such information.

6.8.3. Impact on Member States

No particular effects could be identified on Member States.

7. COMPARING THE OPTIONS

7.1. Approach taken

For the comparison of the options examined in the context of this Impact Assessment it was considered more appropriate to compare the options for each policy issue separately instead of carrying out a comparison of the so-called ‘basic approaches’ (as identified in the IA Guidelines) as a whole. However, in the draft impact assessment report there is a broad analysis of these approaches.

An analysis of approaches rather than specific options is likely to create confusion that would make analysis of impacts more difficult, and hence would complicate the presentation of choices to be made by policy makers. Identification of policy options for each of the policy issues clearly presents suggestions of possible delivery mechanisms (regulatory or non-regulatory approaches). In addition, during the consultation process the policy issues were discussed separately as this was preferred by stakeholders.

Given that the four policy issues to be addressed in the context of the revision of the general labelling legislation are standalone and do not interrelate, it would be certainly easier for policy-makers and stakeholders who are familiar with considering the issues related to the legislation this way, to compare the expected costs and benefits and have a clear picture of the different impacts.

7.2. Optimising the statutory options

For each option ways to optimise the statutory approach have been considered. A mechanism to ease adaptation to new legal requirements is allowing firms a suitable amount of time to respond to the regulation; it costs less for firms to have to comply over the medium term than if they had to comply immediately, because there is a natural cycle in product lines and labels, into which changes to labels can be incorporated.

In the absence of legislation companies would still label their products otherwise consumers would not be able to distinguish the products from one another. Therefore, there will always be a cost to industry associated with labelling. Industry can minimise the costs associated with any changes in requirements for labelling by incorporating labelling changes within the normal timetable for label changes.
7.3. Tables and scoring system

The following scoring system is used to compare the options:

++ Evidence of substantial increase in benefit/reduction of costs in a particular area (e.g. for consumers, individual producers or market competitiveness) compared to the status quo

+ Evidence of some benefit increase/reduction of costs in a particular area compared to the status quo

≈ Evidence of no change in a particular area compared to the status quo OR evidence of no net cost or benefit

- Evidence of some reduction of benefits/increases in cost in a particular area compared to the status quo

-- Evidence of substantial reduction of benefits/increases in a particular area compared to the status quo

7.4. Policy issue 1 – Legibility of the information

<table>
<thead>
<tr>
<th>Impact category</th>
<th>Option 1 Non EU action</th>
<th>Option 2 Non-statutory approach</th>
<th>Option 3 Statutory approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic</td>
<td>- No significant impact</td>
<td>- No significant impact</td>
<td>- No significant impact</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- No significant impact</td>
</tr>
<tr>
<td>Competitiveness, trade and competition in the internal market</td>
<td>- No significant impact</td>
<td>- No significant impact</td>
<td>- This option is the most expensive option for companies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- The policy option might lead to some cost increases for companies with multi-lingual and small labels.</td>
</tr>
<tr>
<td>Operating costs and conduct of business</td>
<td>- No significant impact</td>
<td>- No significant impact</td>
<td>- Coordination with other label change might make costs marginal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Coordination with other label changes might make costs marginal.</td>
</tr>
<tr>
<td>Administrative burden</td>
<td>- No additional burden</td>
<td>- No significant impact</td>
<td>- Increase of administrative burden for the companies to familiarise with the regulation. Information costs and increase of accidental non-compliance due to complicated regulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- No significant impact</td>
</tr>
<tr>
<td>SMEs</td>
<td>- There is no evidence on how the current regulation impacts on SME</td>
<td>- No significant impact</td>
<td>- There is no evidence of impact on SMEs different than on large firms.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- There is no evidence of impact on SMEs different than on large firms.</td>
</tr>
<tr>
<td>International Trade</td>
<td>- No significant impact</td>
<td>- No significant impact</td>
<td>- No significant impact</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- No significant impact</td>
</tr>
<tr>
<td>Social</td>
<td>- Consumers are dissatisfied with the current situation as labels are difficult to understand and read</td>
<td>- Consumers not satisfied with current label – if voluntary agreements do not work, the labels will continue to be difficult to read and understand</td>
<td>- Depending on the precise requirements, standardisation allows the best consumer information. And informs the consumers in an optimal way</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- improve consumers understanding of labels</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Lack of standardisation on other issues might prevent labels from becoming optimal information tools for consumers.</td>
</tr>
</tbody>
</table>

Sub-option 3a Standardise the presentation of all aspects of labelling

Sub-option 3b Establish a minimum font size
<table>
<thead>
<tr>
<th>Impact category</th>
<th>Option 1 Non EU action</th>
<th>Option 2 Non-statutory approach</th>
<th>Option 3 Statutory approach</th>
<th>Sub-option 3a</th>
<th>Sub-option 3b</th>
</tr>
</thead>
</table>
| Member States   | - No change in costs of enforcement and control  
|                 | - Some Member States find it difficult to implement the current regulation as it allows for too much interpretation | - Need for participation and monitoring voluntary schemes | - Some Member States might find it easier to implement detailed regulation | +            | +            |
| Environment     | - No evidence on impact | - No evidence on impact | - An increase in packaging size might have a negative environmental impact, there is however no evidence on such an effect | +            | +            |

### 7.4.1. Potential for optimising options

The specification of a minimum font size would tackle the most frequent complaint of consumers about the legibility of labels. A suitable transition period that enabled in the majority of cases for any labelling changes that might be required to be incorporated into the usual labelling cycle would help to reduce any direct costs associated with changes in the legislation. Guidance on the presentation of information might help SMEs to develop better labels.

### 7.4.2. Analysis of current situation and justification

Although the framework directive requires that the mandatory requirements be easy to understand, marked in a conspicuous place and in such a way as to be easily visible, clearly legible and indelible, there is widespread complaint that labels are neither legible nor understandable. The most frequent complaint in particular is the size of the type face.
A UK survey\textsuperscript{54} of the labelling of products noted that "A large number of products were found to have given undue emphasis to information on branding, claims, pictures and the like, and to have done so at the expense of the essential information specified in the Food Standards Agency’s Guidance. In a majority of these cases, it would seem to have been possible to avoid doing so, in one or more of the ways recommended in the Guidance.". Therefore, it appears that the problem of use of a small type face is not solely due to the size of the packaging. In addition, in the case of the UK report it was noted that the guidance on minimum font was not being followed by the majority of manufacturers. It appears that voluntary mechanisms alone would not lead to a change in the approach of manufacturers.

Specific rules on typeface size would address one of the fundamental issues related to legibility of information. However, it is recognised that this is not the only aspect. If other aspects of legibility are seen to be creating a significant problem for consumers then the desirability of harmonisation on these factors may need to be addressed in the future.

There is inadequate information to assess the impact of the change in the legislation to include a minimum font size however manufacturers already have to follow the principle that their labels should be legible so the inclusion of specific requirements related to legibility in the legislation would provide a framework through which it could be expected that the label would be legible for the average consumer.

Further prescription on the legibility of food labels has been opposed by the business stakeholders so far, as they fear it will increase the costs of food labelling and reduce their flexibility. This is one of the key issues of the revision, since it does not make sense to set obligations as to the information to be provided to the consumer if the latter cannot make use of it. Therefore, it is considered that there will be no benefit from any review of the labelling legislation if it does not lead to more readable labels.

### 7.5. Policy issue 2 – Provision of information on non-prepacked food

<table>
<thead>
<tr>
<th>Impact category</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Competitiveness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>trade and</td>
<td>- No impact expected given the local</td>
<td>- No significant impact</td>
<td>- No impact expected given the local</td>
</tr>
<tr>
<td>competition in</td>
<td>characteristics of non-pre-packed</td>
<td>potential for undermining SME's</td>
<td>characteristics of selling non-pre-packed</td>
</tr>
<tr>
<td>the internal</td>
<td>food,</td>
<td>competitiveness</td>
<td>food</td>
</tr>
<tr>
<td>market</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating costs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and conduct of</td>
<td>- No additional costs</td>
<td>- No significant impact</td>
<td>- Specialized food</td>
</tr>
<tr>
<td>business</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMEs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No particular</td>
<td></td>
<td></td>
<td>- Although most of the</td>
</tr>
<tr>
<td>impact</td>
<td></td>
<td></td>
<td>affected companies</td>
</tr>
<tr>
<td></td>
<td>=</td>
<td></td>
<td>will be SMEs, no</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>particular</td>
</tr>
<tr>
<td>Administrative</td>
<td></td>
<td></td>
<td>disadvantages for these</td>
</tr>
<tr>
<td>burden</td>
<td>- No additional</td>
<td>- Reporting Monitoring,</td>
<td>companies could be</td>
</tr>
<tr>
<td></td>
<td>burden</td>
<td>- Publicising system</td>
<td>identified</td>
</tr>
<tr>
<td></td>
<td>=</td>
<td></td>
<td></td>
</tr>
<tr>
<td>International</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Trade</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>- Given the local</td>
<td>- No impact</td>
<td>- Given the local</td>
<td></td>
</tr>
<tr>
<td>characteristics of</td>
<td></td>
<td>characteristics of</td>
<td></td>
</tr>
<tr>
<td>selling non-pre-</td>
<td></td>
<td>selling loose food</td>
<td></td>
</tr>
<tr>
<td>packed food.</td>
<td></td>
<td>and selling food</td>
<td></td>
</tr>
<tr>
<td>- No effects on</td>
<td></td>
<td>in restaurants, no</td>
<td></td>
</tr>
<tr>
<td>the international</td>
<td></td>
<td>effects on the</td>
<td></td>
</tr>
<tr>
<td>trade are</td>
<td></td>
<td>international</td>
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</tr>
<tr>
<td>perceived</td>
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<td>trade is perceived</td>
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<td></td>
<td>=</td>
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</tr>
<tr>
<td>Social</td>
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</tr>
<tr>
<td>Public health,</td>
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<tr>
<td>safety and</td>
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<tr>
<td>consumers’</td>
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<tr>
<td>right to</td>
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<td></td>
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<tr>
<td>information</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Consumers</td>
<td></td>
<td>- If voluntary agreements</td>
<td></td>
</tr>
<tr>
<td>currently get</td>
<td></td>
<td>don't work consumer</td>
<td></td>
</tr>
<tr>
<td>not necessary</td>
<td></td>
<td>health is undermined</td>
<td></td>
</tr>
<tr>
<td>information for</td>
<td></td>
<td></td>
<td>++</td>
</tr>
<tr>
<td>health (allergens)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Member States</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No particular</td>
<td></td>
<td>- No significant impact</td>
<td>- A number of businesses have to be</td>
</tr>
<tr>
<td>costs are</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>currently</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>associated with</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>implementing the</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>labelling of non-</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pre-packed food</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>=</td>
<td></td>
<td>=</td>
</tr>
<tr>
<td>Environment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- There are no</td>
<td></td>
<td>There are no reported</td>
<td></td>
</tr>
<tr>
<td>reported</td>
<td></td>
<td>environmental impacts</td>
<td></td>
</tr>
<tr>
<td>environmental</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>impacts</td>
<td>=</td>
<td></td>
<td>=</td>
</tr>
</tbody>
</table>
7.5.1. **Potential for optimising options**

Providing information about the presence of allergens would respond to a safety and health concern expressed by consumers. Ensuring that the required information is readily available to retailers selling non-prepacked food from the producers and wholesalers and to restaurants from their suppliers would reduce the information costs. Flexibility for Member States with the implementation should allow tailoring any legislative measure to the domestic characteristics of each Member State’s food retail and food catering business and might enable a more cost effective regime.

7.5.2. **Analysis of current situation and justification**

Concerning food non-prepacked (catering/restaurants/retailers) information on potential allergens is considered very important by consumers and some Members States alike. Evidence suggests that most food allergy incidents happen outside the home and can be traced back to non-prepacked food. The provision of such information for non-prepacked food imposes cost on the food industry for tracing the relevant information and keeping it up to date. The most likely way to presenting information is on the menu in restaurants and on displays for food sold loose at counters, which require trained staff for daily updates. Due to the nature of transactions the provision of labelling information for food sold loose has no single market impact, thus different national legislations would not pose additional burdens on the food industry. There are no reliable cost estimates for labelling non-prepacked food, but they are expected to be reasonably small. Under a voluntary approach there is less likely to be consistency in the provision of reliable and accurate information. The requirement for provision of information on aspects of non-prepacked food related to health and in particular allergens would constitute a clear benefit.
### Impact category

<table>
<thead>
<tr>
<th>Impact category</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Economic</strong></td>
<td>Status quo</td>
<td>Non statutory</td>
<td>Statutory approach</td>
</tr>
<tr>
<td><strong>Competitiveness</strong> trade and competition in internal market**</td>
<td>- No level playing field</td>
<td>- No significant impact</td>
<td>- Ethnocentric consumption pattern might lead to a fragmentation of food markets and create virtual trade barriers</td>
</tr>
<tr>
<td><strong>Operating costs and conduct of business</strong></td>
<td>No impact</td>
<td>- Cost depends on actual definition of origin</td>
<td>- Tracking and tracing can increases information costs but normally operators have already such systems in place</td>
</tr>
<tr>
<td><strong>Administrative burden</strong></td>
<td>No impact</td>
<td>- No significant impact</td>
<td>Familiarisation with new rules</td>
</tr>
<tr>
<td><strong>SMEs</strong></td>
<td>No effect</td>
<td>- No particular effect for SMEs discernible</td>
<td>- Higher frequency of label changes disadvantages SMEs</td>
</tr>
<tr>
<td><strong>International Trade</strong></td>
<td>No impact</td>
<td>- No significant impact</td>
<td>- Depending on the concrete rule, there might be conflicts with WTO rules</td>
</tr>
<tr>
<td><strong>Social</strong></td>
<td>- Regional consumption patterns might benefit small producers</td>
<td>- Regional consumption patterns might benefit small producers</td>
<td>- Regional consumption patterns might benefit small producers</td>
</tr>
<tr>
<td><strong>Member States</strong></td>
<td>Member States unable to deal effectively with consumers demands</td>
<td>- No significant effect on Member States public administrations</td>
<td>- No significant impact</td>
</tr>
<tr>
<td><strong>Impact on public health, safety and consumers’ right to information</strong></td>
<td>- Validity of country of origin information might be difficult to verify</td>
<td>- Validity of country of origin information might be difficult to verify</td>
<td>- Validity of country of origin information might be difficult to verify</td>
</tr>
</tbody>
</table>
7.6.1. Potential for optimising options

The potential costs for the whole industry entailed by origin labelling are reduced through the number of companies that already use of such labels. Evidence from the SME Panel\textsuperscript{55} suggests that a majority of companies (70 percent) indicate the country of origin on at least some of their products already, and that around half of these companies provide country of origin information on a voluntary basis. A suitable transition period that enabled in the majority of cases for any labelling changes that might be required to be incorporated into the usual labelling cycle would help to reduce any direct costs associated with changes in the legislation.

7.6.2. Analysis of current situation and justification

Consumers across the European Union not only demand but also value country of origin information on foodstuff. Mandatory country of origin labelling can increase labelling costs for food producers and these costs are variable and dependent on the extent of the requirement. In meeting consumers demands and contributing to an informed choice the introduction of different degrees of origin labelling for different food products, modelled after the different consumer demands for labelling would constitute a benefit compared to the current situation. However, to secure these benefits, the country of origin label has to be clear, and understandable and not misleading to the consumer. Current labelling practices are poorly understood by consumers and are sometimes even misleading. Clarification about the use of origin labelling would thus be a benefit to the consumers but also to industry and enforcement authorities.

\textsuperscript{55} EICN (2006), SME Panel, data collection on possible impacts of labelling changes. Euro Info Centre Network, Belgium.
### 7.7. Policy issue 4 – Ingredients listing for alcoholic beverages

<table>
<thead>
<tr>
<th>Impact category</th>
<th>Option 1</th>
<th>Option 2</th>
<th>Option 3</th>
<th>Statutory approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic</td>
<td>- No impact expected</td>
<td>= No significant impact</td>
<td>= - No impact expected</td>
<td>= - No impact expected</td>
</tr>
<tr>
<td>Competitiveness trade and competition in the internal market</td>
<td>- Requires labelling changes of € 2,000 to 4,000 per SKU</td>
<td>= Individual companies voluntarily labelling ingredients would be opposed to some costs of 2,000 to 4,000 per SKU</td>
<td>= - No costs for exempt types of producers</td>
<td>= For individual companies costs would be at the lower estimate of labelling costs (2,000 to 4,000 per SKU)</td>
</tr>
<tr>
<td>Operating costs and conduct of business</td>
<td>- Might lead to a small increase in SKU for companies that label voluntarily</td>
<td>= - No costs</td>
<td>= Labelling costs are expected to be marginal if transition periods are long enough</td>
<td></td>
</tr>
<tr>
<td>Administrative burden</td>
<td>No impact</td>
<td>= Some impact in terms of monitoring outcomes, reporting, information to consumers</td>
<td>= No impact</td>
<td>= Familiarisation with new rules</td>
</tr>
<tr>
<td>SMEs</td>
<td>No impact</td>
<td>= General reasoning to the capacity of SMEs to implement labelling changes applies</td>
<td>= If SMEs are overrepresented in traditional alcoholic beverage sectors they would benefit from the exemption</td>
<td></td>
</tr>
<tr>
<td>International Trade</td>
<td>- No impact expected</td>
<td>= No significant impact</td>
<td>= - No impact expected</td>
<td>= No significant impact</td>
</tr>
<tr>
<td>Social</td>
<td>No impact</td>
<td>= No significant impact</td>
<td>= No impact</td>
<td>= Ingredient listing increases consumers’ opportunity for informed choice</td>
</tr>
<tr>
<td>Impact on public health, safety and consumers’ right to information</td>
<td>= No particular effects could be identified on Member States</td>
<td>= No particular effects could be identified on Member States</td>
<td>= No particular effects could be identified on Member States</td>
<td></td>
</tr>
<tr>
<td>Member States</td>
<td>- No impact expected, no evidence</td>
<td>= No impact expected, no evidence</td>
<td>= - No impact</td>
<td>= No impact expected, no evidence</td>
</tr>
<tr>
<td>Environment</td>
<td>- No impact expected, no evidence</td>
<td>= No impact expected, no evidence</td>
<td>= - No impact</td>
<td>= No impact expected, no evidence</td>
</tr>
</tbody>
</table>

#### 7.7.1. Potential for optimising options

A suitable transition period that enabled in the majority of cases for any labelling changes that might be required to be incorporated into the usual labelling cycle would help to reduce any direct costs associated with any changes in the legislation that might result in ingredient listing of any alcoholic beverage.
7.7.2. Analysis of current situation and justification

There is little evidence on the impacts of extending horizontal, mandatory ingredient listing requirements to alcoholic beverages, which so far have been exempt from regulation and the level of consumer interest in ingredient labelling of alcoholic beverages is unclear.

Although significant progress has been made in relation to the labelling of allergens, the situation is still unchanged for other ingredients which may be present in alcoholic drinks and not labelled, such as food additives and flavours that are used in many of these drinks, including ready-to-drink beverages, without any information for consumers. Consumers should be provided with information that is useful and vital to enable them to make an informed decision and often to prevent them from being misled. Therefore, the use of substances that are likely to influence the consumer's choice because of their presence or technological effect on the finished product should normally be expected to result in compulsory labelling.

Introducing ingredient listings would impose some small costs on the producers to change and print new labels, while the actual ingredient listing should be readily available to the company. The value consumers put into beverages prepared according to traditional principles might lead to a favourable market positions for producers which can differentiate their products via the ingredient listing as adhering to such principles.

8. Monitoring and evaluation

The general monitoring of the legislation on general food labelling is included in the Regulation 882/2004 on official controls of food and feed. This Regulation foresees that the Member States implement efficiently the requirements of the food legislation. The Commission (Food and Veterinary Office) controls the correct enforcement of the Member States.

The monitoring would be done by the Commission and Member States for example through reports from Member States, NGOs and self monitoring activities of the industry.

- To assess the availability of information to the consumer monitoring could be done through surveys of the products on the market by organisations such as NGOs, Member State Authorities and self monitoring by the industry.

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56 OJ L 165, 30.4.2004, p. 1–141
• The monitoring of the presentation of the information, and consumer understanding and use, including its legibility could be done through consumer surveys by various organisations and enforcement activities of Member State Authorities.

• Any change in the functioning of the internal market could be assessed through the feedback at national or European level through the governance system for the exchange of best practice on national schemes that is foreseen as part of the revision of the legislation.

In order to keep the evaluation proportionate to the resources allocated and in line with the impact of the programme and activity concerned, an evaluation should apply under the evaluation programme as planned by DG SANCO. The Commission should carry out an evaluation of the new legislation as from 5 to 7 years after the date of application of the legislation in order to assess its relevance to stakeholders' needs. In particular, such evaluation should focus on the uptake and efficiency of the voluntary national schemes foreseen in the draft proposal in view of assessing the need for Community rules on aspects for which such schemes have been adopted.
ANNEX 1- Structure of the European food and drink industry

Food manufacturing

In 2005 the food and beverage manufacturing industry within the EU25 had a turnover of €836 billion, employing 3.8 million people. In 2003, there were 282,600 businesses 99.1% of which had less than 250 employees and generated 47.8% of total turnover and employed 61.3% of the workforce within the food and drink sector. In contrast, the large companies, constituting just 0.9% of businesses provided 53.8% to the turnover and employed 38.7% of the respective workforce

Structure of the European food and drink industry

![Graph showing breakdown of number of enterprises, turnover and value added by size of companies.]

![Graph showing turnover of the food and drink industry by size of companies.]

Comparison between turnover, value added and number of employees of the food and drink industry and the manufacturing industry by size of companies (%)

<table>
<thead>
<tr>
<th></th>
<th>Micro comp. 1 to 9</th>
<th>Small comp. 10 to 49</th>
<th>Medium comp. 50 to 249</th>
<th>Large comp. + 250</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover</td>
<td>6.8</td>
<td>13.3</td>
<td>20.8</td>
<td>59.1</td>
</tr>
<tr>
<td>Value added</td>
<td>6.8</td>
<td>15.1</td>
<td>26.0</td>
<td>52.2</td>
</tr>
<tr>
<td>Number of employees</td>
<td>7.3</td>
<td>15.8</td>
<td>22.3</td>
<td>54.6</td>
</tr>
<tr>
<td>Manufacturing ind.</td>
<td>8.7</td>
<td>15.0</td>
<td>22.5</td>
<td>53.8</td>
</tr>
<tr>
<td>F&amp;D ind.</td>
<td>9.5</td>
<td>21.8</td>
<td>25.2</td>
<td>43.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Micro comp. 1 to 9</th>
<th>Small comp. 10 to 49</th>
<th>Medium comp. 50 to 249</th>
<th>Large comp. + 250</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turnover</td>
<td>16.4</td>
<td>20.7</td>
<td>24.3</td>
<td>38.7</td>
</tr>
</tbody>
</table>


57 Based on EUROSTAT data, as presented in: CIAA (2006): Data & trends of the European Food and Drink Industry, CIAA, Brussels.
Food retail

In the sector of food retailers, specialised food retailers are generally relatively small outlets such as fruit and vegetable shops, bakers, butchers and fishmongers which do not belong to a larger chain. In 2004 there were 889,284 food retailing businesses with specialised food retailing companies representing 56% of the sector and the non-specialised were 44%. Specialised retailers accounted for around 14% of the €888 billion total turnover and employed 23% of the 6.2 billion workforce.

Structure of retail sale of food, beverages and tobacco in specialised stores, 2004 data

Due to data limitations and the confidential character of some of the statistics, no European average data (EU-27 or EU-25) can be provided and results are only shown for countries with complete data sets.
Structure of European food retail industry, 2004 data

SOURCE: EUROSTAT Database
ANNEX 2 – Horizontal Labelling Objectives

Overarching Commission's strategic objective: Better Regulation and simplification

General objectives
- Provide consumers with relevant information
- Enable informed, safe and healthy consumer choices
- Ensure smooth functioning of the Internal Market
- Foster a pro-competitive market environment

Specific objectives
- Ensure consistency and clarity in the provision of information
- Protect consumers' health and address consumer demands
- Avoid misleading indications and eliminate existing inconsistencies
- Enable/reward industry innovation on food labelling

Policy issues/measures
- Legibility of information (policy issue 1)
- Allergenic ingredients on non-pre-packaged food (policy issue 2)
- Clarification on use of origin labelling (policy issue 3)
- Ingredients listing rules for alcohol beverages (policy issue 4)

New labelling governance (bottom-up mechanism)
**ANNEX 3 - Extract of RAND Questionnaire – Questions on labelling costs**

**Costs of food labelling**

We would like to understand the costs associated with making a label and the activity that is associated with the costs.

1. What is the per-unit average cost of production in euro across your range of stock-keeping units?

2. What is the average cost per stock-keeping unit of labelling (i.e. designing and applying the label)
   - in euros and
   - as a percentage of the total on average cost of production of a stock-keeping unit?

3. When you produce a new label, what is the average cost (direct and indirect), associated with the following tasks (outsourced or not)? Please estimate this cost as a percentage of the total cost of the production of the label.
   - Identification of the information legally required on the label (identifying and understanding the regulations that apply; obtaining relevant information to comply with labelling regulations; obtaining data for the label through analysis etc.)
   - Translation for labelling in different languages
   - Redesign of the label and packaging
   - Production of the printing plate
     - Printing of the label
     - Audit and inspection associated with compliance with the labelling regulations
     - Other (please specify)

4. How many times in the last 10 years have you changed labels, solely as a result of a change in labelling regulations? (Options given: None, once, twice, three times, other (please specify [tick box]))

5. What was the average cost per stock-keeping unit of changing the labels specifically due to a past change in the labelling legislation?
   - (1) no costs specifically due to changes in legislation
   - (2) average cost in euros, and
   - (3) as a percentage of the average total cost of a stock-keeping unit,
Administrative costs of labelling

How much time (in man-hours, including work of external consultants) on average per year do you estimate your company spends on the following tasks?

- Determination of the information legally required on the label (identifying and understanding the regulations that apply; obtaining relevant information to comply with labelling regulations; obtaining data for the label through analysis etc.)
- Translation for labelling in different languages
- Redesign of the label and packaging
- Production of the printing plate
- Printing of the label
- Audit and inspection associated with compliance
- Submitting information to the regulator
- Other (please specify)
- Total

What is the average cost per hour of staff (across grades) working on these tasks (as above)?

What is the main reason for the amount of time spent on these tasks (please rank them: 1=main reason; 5=least important reason)?

- Part of the usual labelling cycle (launch of new products, normal changes of labels)
- It takes time to familiarise ourselves with the relevant regulations
- There is a large number of regulations to comply with
- Adapting to changes in the regulations
- Other (please specify)
**ANNEX 4 - Summary of results of assessment of Administrative Burdens associated with food labelling in Denmark, the Netherlands, Sweden and the United Kingdom**

<table>
<thead>
<tr>
<th>Definition of administrative burden used</th>
<th>Denmark</th>
<th>The Netherlands&lt;sup&gt;59&lt;/sup&gt;</th>
<th>Sweden</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Administrative activities (e.g. collection of information within the company) to meet data requirements, consisting of internal resource use in the form of employees’ time consumption and occasionally an external resource use in the form of costs to accountants, external experts etc. In total, these administrative costs constitute the costs that are related to the performance of different administrative activities.</td>
<td>The costs to Dutch industry of complying with the information requirements of government regulation. These concern the collection, processing, registering, storage, and provision of information</td>
<td>Administrative costs are defined as costs born by business to gather, store or transmit information which is required in regulation.</td>
<td>UK calculates the sum of internal, external and overhead costs to meet an information obligation and adjusts it for the business as usual costs (costs that would have been incurred in the normal business process), which gives a net administrative costs</td>
<td></td>
</tr>
</tbody>
</table>

| Total amount of administrative burden associated with all food regulations identified | € 554.9 million (current exchange rate) per year as of 2005 (all regulation within the Danish Veterinary and Food Agency) | €940 million per year as of January 2006 | € 913 million (current exchange rate) per year as of 2006 | €180 million (current exchange rate) as of May 2005 over 53 regulations |

<table>
<thead>
<tr>
<th>Total amount of administrative burden associated with European regulations</th>
<th>(all regulation within the Danish Veterinary and Food Agency)</th>
<th>Horizontal Labelling regulations</th>
<th>Category A: € 900.1 million</th>
<th>Category A: 49%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A: 45 %</td>
<td>Category A: 95 %</td>
<td>Category B: 26 %</td>
<td>Category B: 0 %</td>
<td>Category C: 5 %</td>
</tr>
<tr>
<td>Category C: 30 %</td>
<td>Category C: 5 %</td>
<td>Category C: 30 %</td>
<td>Category C: 5 %</td>
<td>Category C: 5 %</td>
</tr>
<tr>
<td>€535 million per year</td>
<td></td>
<td>Category B: € 12.5 million</td>
<td>Category B: 49%</td>
<td></td>
</tr>
<tr>
<td>Category C € 0.005 million</td>
<td>Category C: 2%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---


60 Category A is the European regulation with no discretion in implementation. Category B is European with domestic discretion, which accounts for 49%. Category C is domestic regulation with full discretion.
### Total amount of administrative burden associated with food labelling

<table>
<thead>
<tr>
<th>Type of Industry</th>
<th>Horizontal labelling</th>
<th>Vertical labelling</th>
<th>Nutrition labelling</th>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>€337.5 million per year</td>
<td></td>
<td>€93.2 million per year</td>
<td>€37.9 million per year</td>
</tr>
</tbody>
</table>

- **Horizontal labelling:** €93.2 million per year
- **Vertical labelling:** €0.842 million per year
- **Nutrition labelling:** €2.8 million per year
- **Traceability:** €37.9 million per year

**UK assessed the impact of the 1996 Food Labelling Directives**

Total administrative costs were: 10.2 million (current exchange rate) or 6% of total administrative burdens.

Net administrative costs adjusted for normal business practices were: €6.87 million (current exchange rate).

### Distribution of total administrative burden per type of industry

<table>
<thead>
<tr>
<th>Industry</th>
<th>Percentage of Total Administrative Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food production</td>
<td>3.3%</td>
</tr>
<tr>
<td>Packaging productions</td>
<td>0.03%</td>
</tr>
<tr>
<td>Food and drinks industry</td>
<td>33.5%</td>
</tr>
<tr>
<td>Transport</td>
<td>0.8%</td>
</tr>
<tr>
<td>Wholesale and importing</td>
<td>15.4%</td>
</tr>
<tr>
<td>Retail</td>
<td>26.5%</td>
</tr>
<tr>
<td>Hotels and restaurants</td>
<td>19.3%</td>
</tr>
</tbody>
</table>

**Not given**
<table>
<thead>
<tr>
<th>Type of administrative cost incurred</th>
<th>Horizontal labelling only:</th>
<th>n.a.</th>
<th>62% of the administrative cost associated with complying with the Food Labelling regulations of 1996 was an internal cost. The remainder (38%) was external. The main categories of administrative burdens identified for the total measurement are:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Familiarisation with requirements: 5%</td>
<td></td>
<td>- Gathering and assessing relevant information / figures (28%);</td>
</tr>
<tr>
<td></td>
<td>- Collection of information: 5%</td>
<td></td>
<td>- Familiarisation with requirements (7%); and</td>
</tr>
<tr>
<td></td>
<td>- Text description: 30%</td>
<td></td>
<td>- Reporting - including written descriptions, copying, filing, distributing or submitting information / reports (5%).</td>
</tr>
<tr>
<td></td>
<td>- Copying, distribution, archiving 60%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SOURCES:**


ANNEX 5 - Food labelling – estimation of administrative burden and labelling re-design costs

1. As described in the overview of the food labelling process, the food labelling process can be divided into five main parts:

- Familiarisation with the regulation
- Collection of necessary information
- Re-design of label (if needed)
- Printing
- Packing

As the last two processes, printing and packing, remain unchanged as a result of labelling regulations they are not analysed in this Impact Assessment.

The following describes the methodology for the calculation of administrative burdens: it is based on the example of nutrition labelling changes but it is also relevant to the calculations for general labelling issues.

Number of labels in the EU

Before the actual assessment of each cost generating process, the actual number of labels that are subject to this regulation should be analysed. Unfortunately there are no available data so one has to rely on estimation.

The estimation was done on the basis of average number of labels per company, with division into four types of companies distinguished on the basis of employment size. The average was assumed constant for all Member States.
The starting point of this estimation was the research carried out by RAND\textsuperscript{61}, which divided companies on the basis of an average number of labels / stock keeping units (SKUs - the total number of products and the different packaging sizes or types). This data enabled to roughly attribute a number of labels / SKUs per company (four groups by employment size). One has to then assume that a number of labels / SKUs per product (same ingredients formula) will increase with size of the company growing. This analysis led to the following results:

\begin{table}[h]
\centering
\begin{tabular}{|c|c|}
\hline
Number of labels / SKUs & \% of total number of companies \\
\hline
0 - 9 & 7.0\% \\
10 - 24 & 11.0\% \\
25 - 49 & 15.0\% \\
50 - 99 & 15.0\% \\
100 - 249 & 16.0\% \\
250 - 999 & 19.0\% \\
1000+ & 25.0\% \\
\hline
\end{tabular}
\end{table}

The above analysis enabled the calculation of total number of SKUs / Labels. For subsequent analysis of costs, at this stage both the \% of products with nutrition information already provided as well as \% of labels with information provided in adhesive form (as opposed to printed on pack) had to be assumed. The EAS study identified that there are already 56\% of products with nutrition information provided on the pack (the \% goes even higher for big companies), while it also identified that only 37\% of labels are printed on pack (the \% also increases with size of company). Based on the above, the number of SKUs / Labels was estimated to be the following:

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|c|}
\hline
Number for EU-27 & with no nutrition info & with nutrition info & & total \\
& adhesive & printed & total & adhesive and printed \\
\hline
Number of Labels & 10,618,585 & 4,627,965 & 15,146,550 & 11,747,700 \\
Number of Products & 7,046,459 & 2,328,149 & 9,376,608 & 5,378,850 \\
\hline
\end{tabular}
\end{table}

2. \textit{Familiarisation with the regulations and information to be provided}

After the need for changing a label has been established, the company has to become familiar with the legislation to establish the legal requirements for the new label. A UK administrative burden exercise estimated the costs attributed to familiarisation and understanding the General Food Labelling regulations as 13\% of all administrative costs across all the food regulations\textsuperscript{62}. An administrative measurement exercise conducted in Denmark estimates the costs associated with familiarisation with food labelling legislation to account for 5\% of the total administrative burden associated with the food regulations (a summary of the administrative burden survey in certain Member States is summarised on Annex 5).

\textsuperscript{61} RAND nutrition labelling report – p.109.
Table 1: Summary of administrative burdens from all food regulation and food labelling legislation

<table>
<thead>
<tr>
<th></th>
<th>Total turnover food and drink industry (2004; 2002 for DK) in mln €</th>
<th>Number of companies (2004)</th>
<th>Administrative burden associated with all food regulation in mln €</th>
<th>Administrative burden associated with food labelling in mln €</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>% of turnover per company (in thou. €)</td>
<td>% of turnover per company (in thou. €)</td>
</tr>
<tr>
<td>Denmark</td>
<td>19,809,20</td>
<td>1,773,00</td>
<td>554,90</td>
<td>2,80%</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>48,707,60</td>
<td>4,545,00</td>
<td>940,00</td>
<td>1,93%</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>108,795,80</td>
<td>7,066,00</td>
<td>180,00</td>
<td>0,17%</td>
</tr>
</tbody>
</table>

The above information clearly indicates that there is high divergence between the data. The average cost per company of familiarisation with the legislation varies from € 188 in UK to € 2,628 in Denmark. For purposes of this analysis we have assumed an average cost of € 1,408 per company. With total number of companies in EU-27 of 295,777 (ESTAT 2004) the one-off cost of familiarisation with the legislation adds up to €416.5 million.
Re-design costs

The final cost element, after the food-business has collected all the necessary information to be presented, is the design of the label is the next step. The design costs vary with the extent of the overhaul of the label, with a complete overhaul being the most expensive option. The 2004 impact assessment indicated that a small change would cost €2000-4000 whilst full extensive resign of a label would cost an additional €7000-9000 if the changes had to be implemented immediately. Although companies may have a range of different products many of the labels have the same basic layout so once the underlying design has been developed the changes to the other labels would be a minor modification and associated costs would be reduced. In this assessment we have therefore assumed that in the case of need for re-design costs concern only a type of product, while all labels / SKUs under this product line has to be only slightly modified (see below).

For the purposes of this analysis, we have assumed that all labels that already include nutritional information or when this information can be provided in adhesive form, the costs of re-design is largely reduced to €225 (taken from US FDA assessment), while in the remaining cases it is on average €7,000 (average of costs of full re-design).

However, the potential impact of labelling changes on businesses can be reduced if the changes are incorporated into the usual lifecycle of a label. Table 1 summarises the frequency of labelling changes reported in two recent surveys 63 64.

On the basis of the available information it is estimated that over a 3 year period 80% of companies would introduce labelling changes as a normal part of their business operation. Normally the implementation of new labelling requirements are not imposed immediately and generally there is a period of transposition included in the legislation with some flexibility with products that had been labelled and placed on the market before a certain date being able to continue to be sold. The period in which products that do not comply with the requirements can continue to be placed on the market will have an impact on the ability of companies to adapt to the new requirements and the associated costs.

Table 2: Frequency of labelling changes

<table>
<thead>
<tr>
<th></th>
<th>Percentage of labels changed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Once a year</td>
</tr>
<tr>
<td>RAND Survey</td>
<td>37%</td>
</tr>
<tr>
<td>SME Panel Survey</td>
<td>29%</td>
</tr>
</tbody>
</table>

63 RAND nutrition labelling report.
64 SME Panel results.
As indicated by the above table the larger the company, the more frequent is a label re-design. For the purposes of this analysis, we have therefore assumed that while it takes on average up to 5 years for micro business (1-9 employees) to re-design it labels, for bigger companies a 3-year period is on average sufficient to include the new labelling requirements in normal re-design cycle. Based on aforementioned, assuming that all companies will be exempted similarly, the following estimates of redesign costs we calculated:

<table>
<thead>
<tr>
<th>deadline of compliance with requirements</th>
<th>full re-design</th>
<th>only small modification</th>
<th>re-designed in any case</th>
<th>TOTAL COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>at once</td>
<td>2,328,749</td>
<td>24,936,101</td>
<td>10,125,200</td>
<td>21,924,416,854</td>
</tr>
<tr>
<td>grace period of 1 year</td>
<td>1,472,790</td>
<td>15,296,261</td>
<td>17,963,475</td>
<td>13,751,155,113</td>
</tr>
<tr>
<td>grace period of 2 years</td>
<td>801,945</td>
<td>8,128,830</td>
<td>25,744,250</td>
<td>7,442,600,056</td>
</tr>
<tr>
<td>grace period of 3 years</td>
<td>138,000</td>
<td>1,012,000</td>
<td></td>
<td>1,193,700,000</td>
</tr>
</tbody>
</table>

As above table indicates costs can be significantly reduced if any grace period is given, however already with lead period of 3 years the total costs reduce on average by 94%. All costs could be on average avoided if an additional 2-year grace period is granted for micro businesses.

4. Administrative burden - summary

The above analysis, despite the efforts made throughout last years, does not apply Standard Cost Model as required by Impact Assessment Guidelines. It draws from the SCM analysis of Member States, and then combines these data with data collected by the external consultants. It enabled a rough estimation of overall administrative burden, as well as analysis of options. The specific options are analysed in detail in the corresponding sections.

The number of assumptions behind this analysis does not allow drawing far-reaching conclusions on the data presented above; it nevertheless enables policy makers to assess the degree of impacts associated with various policy options.

In order to provide useful comparison of above findings with other estimates, the above findings are below compared to the analysis of administrative burdens carried out in Member States. As described in section on costs of familiarisation with legislation (see above Table), there are examples of such measurements in Denmark, the Netherlands, Sweden and the UK (further information from the studies are given in Annex 5).

The industry turnover for Sweden is not available. In terms of the overall administrative burden of € 913 million associated with all food regulations, food labelling legislation accounted for 7% of the overall burden and nutrition labelling was 0.3% of the overall burden and 4% of the burden associated with food labelling.
It is not possible to reliably extrapolate the figures for administrative burden to the EU as a whole. But to illustrate the possible costs based on the available information it may be assumed that the administrative burden associated with the food labelling legislation ranges between 0.01% and 0.69% of industry turnover. The administrative burden of food labelling legislation to the EU-27 based on the 2004 food and drink manufacturing industry turnover of € 852.1 billion would be between € 85 million and € 5880 million across 282,600 businesses. If 4% of the administrative burden associated with labelling was due to nutrition labelling the administrative burden would be between € 3 million and € 235 million.

These figures are hence well below the previous calculations which proves that assumptions taken in previous analysis are very cautious and that the costs are likely to be inflated substantially.
ANNEX 6 – Summary tables of estimated costs associated with policy issue 1 legibility and policy issue 4, ingredients listing for alcoholic beverages

**Policy Issue 1: Legibility of labels**

<table>
<thead>
<tr>
<th>Cost elements / policy options</th>
<th>number of years of grace period</th>
<th>at once</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
<th>5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarisation with the regulation</td>
<td>29,577,700,0</td>
<td>29,577,700,0</td>
<td>29,577,700,0</td>
<td>29,577,700,0</td>
<td>29,577,700,0</td>
<td></td>
</tr>
<tr>
<td>Collection of necessary information</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>(Re-)design label</td>
<td>5,143,525,312,5</td>
<td>3,207,080,812,5</td>
<td>1,708,010,718,8</td>
<td>219,937,500,0</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

**SUM (in mln €)**

| | 5,173,1 | 3,236,7 | 1,737,6 | 249,5 | 29,6 |

100€ per company to familiarize

**Policy Issue 4: Ingredients listing for alcoholic beverages**

<table>
<thead>
<tr>
<th>number of companies</th>
<th>Manufacture of beverages (total)</th>
<th>Manufacture of distilled potable alcoholic beverages</th>
<th>Production of ethyl alcohol from fermented materials</th>
<th>Manufacture of wines</th>
<th>Manufacture of cider and other fruit wines</th>
<th>Manufacture of beer</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU-27</td>
<td>21,800</td>
<td>4,553</td>
<td>876</td>
<td>8,900</td>
<td>629</td>
<td>2,100</td>
</tr>
<tr>
<td>EU-25</td>
<td>19,900</td>
<td>3,706</td>
<td>802</td>
<td>8,685</td>
<td>629</td>
<td>2,048</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>number of years of grace period</th>
<th>at once</th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarisation with the regulation</td>
<td>23,458,235,0</td>
<td>23,458,235,0</td>
<td>23,458,235,0</td>
<td>23,458,235,0</td>
</tr>
<tr>
<td>Collection of necessary information</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>(Re-)design label</td>
<td>1,124,606,645,7</td>
<td>674,763,987,4</td>
<td>337,381,993,7</td>
<td>-</td>
</tr>
</tbody>
</table>

**SUM (in mln €)**

| | 1,148,1 | 698,2 | 360,8 | 23,5 |