



Framework conditions for sectorial Research and Innovation

1) What specific EU legal/ regulatory instruments (hard and/or soft) stifle or threaten to stifle innovation in your sectors? What underpinning evidence is available?

We think that it is worth mentioning the **lack of coherence between different policies and regulatory requirements**. In the case of the food sector, quite often environmental and agricultural policies and the food safety legislation are not aligned. An example of this inconsistency is the use of mineral oil in paper and board: For ecological purposes, cardboard packaging material is largely produced using recycled paper, which can contain significant quantities of mineral oils that might migrate from the cardboard to the foodstuff and therefore this material is not suitable for food packaging. There are also inconsistent expectations in agricultural practices: Minimum tillage is promoted by DG Environment as an environment and biodiversity friendly practice, but this growing technique is contrary to the advice of DG Agriculture as it can lead to a highly undesirable increase of *Fusarium* toxins (Don1 for example in wheat or other crops). And even within the same area of legislation we can find some examples of non-aligned rules, which lead often to a non-compliance issues in the food industry (e.g. dual use substances when the default pesticide MRLs are applied to active substances which are not used as pesticides).

At the European level, novel foods are an excellent example of the **administrative burden to innovation**. Before being placed on the EU market, novel foods must undergo an authorisation procedure, including a safety assessment. If we analyse the time frame of such authorisation procedures in different regions across the world, we can clearly see that the approval procedures are extremely long in the EU. This, added to the **uncertainty in decision making** prevents the food industry from making use of its research and bringing novel foods to the market in a timely fashion. In some cases, despite a positive risk assessment by EFSA and the suggestion of the Commission to approve the use of a certain substance/material, the European Parliament rejects this approval. The same can be applied to other politically-sensitive issues such as GMO regulation, with a great impact for the food industry in terms of access to raw material. We cannot emphasise strong enough that decision-making must be science-based, politics has no role to play; if this is not the case, there is little or no incentive to invest in innovation.

Thus, and in the light of growing regulation based on the concept of positive listing in the food sector (e.g. health claims, enzymes, REACH etc.) it is of key importance to **establish good functioning, science-based and fast procedures** to enable innovation and renovation of food products. The Commission shall be empowered to adopt delegated acts at this regard and based its position upon relevant technical and scientific progress, including data provided by interested parties in relation to innovative products.

Another problem that is stifling innovation especially in the food sector is the **misuse of the precautionary principle and risk analysis**. The precautionary principle articulates a basis for taking action in cases with insufficient scientific understanding, including extreme complexity, especially when outcomes are irreversible and/or widespread. The connection among environmental issues and issues such as health and societal infrastructure extends the application to a broader field. Today European citizens are intolerant to any type of risk that somehow could threaten the quality of life achieved in the last few years. Consequently preventing and managing risks, either perceived or real, play a central role in modern society. It is therefore necessary to continue to make proper use of the notification procedure according to Directive 98/34/EC to avoid unjustified national draft technical regulations even if they are based on alleged urgent reasons. However, this is not always the case. For instance, Denmark has banned food fortification in most foods, which leads to the development of specific recipes with a higher cost for the consumer. For some products a separate recipe has not been marketed as the Danish consumer market is too small to justify the additional complexity in terms of manufacturing and logistics, thus limiting consumers' choice. Another example is the national legislative proposals on breast milk substitute products that have been presented in Romania and other Member States although these areas are currently under revision by the Commission. A non-exhaustive list of other misuses of the precautionary principle and risk analysis is presented in Table 1.

Jurisdiction	Action	Rationale	Additional information
Norway	Banned cornflakes fortified with vitamins.	Vitamins may harm susceptible individuals.	The aim was to ban Kellogg's Corn Flakes®. The ban was struck down by EFTA court.
France	Banned caffeinated energy drinks.	Pregnant women may consume too much caffeine.	The ban was struck down by European Court of Justice.
Denmark	Banned cranberry juice drinks with extra vitamin C	Some individuals may be susceptible to vitamin C	The aim was to ban Ocean Spray Cranberry®. The ban was struck down by European Court of Justice.
Europe	In Europe foods and drinks that contain six artificial food colours, which are all approved, are required to have a warning label.	Colourings were linked to hyperactivity in children based on a study of the UK FSA, the evidence of which was challenged by EFSA.	So-called azo colours are in the spotlight and the warning labels are considered a means to indirectly restrict their use. The measure is still in place.

Table 1. Examples of misuse of the precautionary principle and risk analysis.



In order to allow full **traceability** of suspect foods and prevent food fraud in certain sectors it is not necessary to amend to amend the General Food Law Regulation 178/2002/EC itself. Article 18(5) already allows the adoption of additional provisions for the purpose of applying the requirements of this Article in respect of specific sectors. In addition, the application of a risk-based and harmonized enforcement of the EU food law by amending the subordinate law e.g. on official food controls can be an appropriate measure (as already proposed by the Commission in the pending Revision of Regulation 882/2004/EC).

Reformulation is asked by the Commission, National Authorities and other stakeholders, in order to reduce the content of salt, sugars and fat in foods. However, this is not always feasible due to the regulation and standard of identities. The components and ingredients that could be used to replace salt, sugars and fat are not always authorised for the products as modified. In addition, some additives could be needed for technological or organoleptic reasons in some reformulated products, in order to propose an acceptable product, but they are not authorised for these applications. We also think that a flexible approach should be the preferred option in terms of labelling, since some of the potential components and ingredients in the reformulated products could be alien for consumers (as these are not really known as such) and therefore not accepted by the public opinion.

Nutrition claims criteria don't offer to the food industry the possibility to inform consumers, especially in case of small reduction of sugars, salt and fat. The Nutrition and Health Claims regulation should be modified in order to favour better information to the consumer and to allow the food industry to propose some new products: without any communication, consumers will not accept these products.

Furthermore, the standards set for **health claims substantiation** by the Commission are prohibitively high, and will eventually stop European investments into the development of new health claims (and hence health benefits), to the disadvantage of European public health.

In the case of **specialised nutrition**, it is necessary to develop a European legislation that stimulates innovation and that creates a competitive environment for innovative technologies and processes and fruitful collaborations between academia and industry (including SMEs). This would enable the EU to remain a key player on the global innovation market in the infant food category. The importance of innovation is stated in Regulation (EU) 609/2013 on Foods for Specific Groups. The European Commission has been mandated to adopt delegated acts with respect to laying specific provisions for compositional and information requirements for (inter alia) infant formula and follow-on formula. The provisions and especially the proposed process by which modifications that lead to changes in composition beyond the essential criteria in infant and follow-on formulae on the basis of scientific progress should support and encourage innovation. Thus, a process that ensures a standard of certainty, transparency, consistency, efficiency and credibility would support innovation and investment in research in the EU and ensure that infants may be provided the most suitable and safe formulae to meet their nutritional needs. As an example, choline and inositol were both considered unnecessary nutrients before 2006 and are now regarded as essential in infant formulae. In addition, EFSA recognized in its last opinion (July 2014) the fact that docosahexaenoic acid



(DHA) is now a key ingredient to be added in infant formulae and follow-on formulae while in the past the benefits were questioned – this recognition would not have been possible without industry innovation. An abundance of scientific evidence, including 32 years of expertise by the FAO and WHO, backed by many clinical trials, confirm that arachidonic acid (ARA, a nutrient present in breast milk) and DHA together are essential to brain development and vision. EFSA stated in its 2013 report on the requirements and intakes of infants and young children that infants of 0-6 months require 140 mg ARA per day. However, the 2014 EFSA Scientific Opinion² classified ARA as an ‘unnecessary’ nutrient, not considering sufficiently that the vast majority of studies have been done with infant formula with a balanced ratio of DHA and ARA. If EFSA’s opinion would be reflected in the upcoming Delegated Act pertaining to infant and follow-on formulae, this, in addition to overturning current legislation and contradicting years of internationally recognised standards, could also impede European innovation.

2) Does the non-uniform implementation of EU regulations between and/or in Member States hinder innovation in the single market? What underpinning evidence is available?

One of the main problems for the food sector faces is indeed the non-function of the internal market. There is a need for harmonization to avoid discrepancies within Member States, which will prevent barriers to trade and will help companies to innovate. Nowadays, there are **non-harmonised interpretations of EU Food Law**. For example, when analysing the Interpretation of the Nutrition and Health Claims Regulation 1924/2006/EC, only some of the Member States agreed on an unofficial guidance and leaved room for additional national guidelines about the wording of authorised health claims. Those Member States having introduced such guidance are not all directly comparable. There are also **non-harmonised legislations** across the Member States of the European Union, such as the actions initiated by several countries which regulate food contact materials at national level and thus resulting in various regulations rather than moving towards harmonisation. These actions create a distortion of the free movement of goods in the European market and cause disproportionate costs for businesses. The main example are the actions concerning bisphenol-A (BPA) taking place since 2011 in Belgium, Denmark, Sweden and France, all applying different rules. Lately, France has issued a national legislation banning BPA in all food contact materials in France with a date of enforcement as of 1st January 2015. The French authorities took this decision despite the fact that the final Scientific Opinion on the safety of BPA is not yet published by the European Food Safety Authority.

Barriers to internal trade should also be eliminated by reviewing the application of the **Mutual Recognition Principle** in Member States and considering a revision of Regulation 764/2008/EC. For instance, under the UK Bread and Flour Regulations 1998 (FLR) industry is required to add certain nutrients (i.e. iron, calcium, thiamin and niacin) to all British milled wheat flour (except whole meal flour). Although the mentioned regulation foresees the application of the Mutual Recognition Principle by exempting flour lawfully produced in another Member State and brought into Great Britain from a Member State in which it was



lawfully sold, it does not allow using domestic unfortified flour for food products intended for other Member State. By contrast, food products manufactured with fortified flour under the UK Bread and Flour Regulations may contain the respective nutrients in non-significant amounts and if they are marketed outside the UK it could be questionable whether their fortification is complying with EU Regulation.

3) What specific gaps, if any, do you think exist that would need to be covered by EU legal/regulatory instruments (hard and/or soft) in the sectors covered by your ETP?

In the food area, many innovations cannot be protected by patents. For instance, innovations that have been granted generic approvals are not protected if there is no applicant-linked approval and can therefore be freely used in the public domain. If everyone can benefit from such an approval, and can copy the innovation because sufficient information is available, the data protection given to the applicant will not give him sufficient advantage in the marketing of his product. In order to provide greater incentives to innovate we need to establish **advantageous rules for intellectual property rights**.

It is also necessary to **facilitate market access** for strategic technologies, products and materials and to increase science and risk-benefit communication and education by competent public authorities to **improve public understanding** of the safety of assessed products.

Given that the 98% of the total of the EU food and drink industries are SMEs, the obstacles they face to innovate need to be overcome by initiating an all-inclusive innovation dialogue in order to discuss the **real possibilities for technology transfer**. The main bottlenecks for SMEs relate to the lack of the resources needed to innovate (skills, information, infrastructures, etc.), which explains the low participation rate in publicly-funded R&D activities. The analysis of these challenges is an on-going process and, as such, deserves further investigation.

R&D activities in the food sector are a **collaborative process between in-house activities and external research cooperation**. Both learning and innovation are interactive processes relying on productive and social networks. Segregated actions of researchers, which are focused on occasional, one-phase, short periods of a project, have limited chance of success. The uncertainty of success in the field of innovation can be reduced by regular feedback from market testing and other disciplines involved in the process of development. It is important to note that large companies have internal resources to collect and combine the knowledge of different disciplines including R&D, management, production, engineering, finance, legal, marketing, etc., and have capacities and structures for steering the entire process. SMEs, on the other hand, do not have such capacities and resources. They usually need external support and services provided to them at all stages in the innovation process, from idea generation to market launch in order to cope with these issues. These services can be provided by clusters, networks, food federations, industry and project management organisations.