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COMMISSION STAFF WORKING DOCUMENT

A FITNESS CHECK OF THE FOOD CHAIN

State of play and next steps

COMMISSION STAFF WORKING DOCUMENT

A FITNESS CHECK OF THE FOOD CHAIN

State of play and next steps

EXECUTIVE SUMMARY

In October 2010, the Commission initiated the 'fitness check' exercise which aims to review an entire body of legislation in a certain policy area with the purpose of identifying excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures. The food chain was identified as one of four pilot projects. This fitness check provides the groundwork for the Regulatory Fitness and Performance Programme (REFIT) which was introduced at the end of 2012. It serves as both an overall assessment by establishing the state of play and, at the same time, as initial mapping exercise outlining the next steps. Laying this groundwork was challenging given the complexity and heterogeneity of the food chain policy area. The first step was to assess the impact of smart regulation objectives on the main policy areas. The second step was to map the whole body of legislation on the basis of four priority objectives and to identify how well it delivers smart regulation objectives. This forms the substance of this document. The results of this mapping exercise lead to the next step, which includes extensive consultation with the interested public and stakeholders. It will focus on the basic legislative framework as part of the REFIT programme.

The food chain is distinct from other European policy areas. Firstly, European legislation is very important for the actual food sector, which is one of the most comprehensively regulated sectors, with almost 98% of all laws harmonised at EU level. Secondly, the sector is a crucial player in the EU economy, employing almost 50 million people (including agriculture) and generating approximately 6% of total EU GDP. Finally, the principles of risk analysis are used to provide a systematic methodology to determine effective, proportionate and targeted measures to protect health and ensure the functioning of the single market.

In the food chain, the Commission Directorate-General for Health and Consumers (DG SANCO) has already delivered very substantially on the smart regulation agenda during the process of assessment and revision of the relevant legislation in recent years, with a view to making it 'fit for purpose'.

In particular, Commission proposals elaborated by DG SANCO have been based on quantifying impact, allowing the costs and benefits of concrete policy options to be identified. While the public policy objective of food chain legislation makes it necessary to set up a legal framework to prevent risks regardless of the size of the operator involved, the specific situation of SMEs has systematically been assessed. As a consequence, a number of special rules for those enterprises have been developed, especially where it is possible to reduce the administrative burden without compromising safety. At the same time, the consistency of the legal framework is safeguarded in order to maintain the competitive advantage of the EU sector in the global market, drawing on the high quality and safety standards and the possibility to promote the EU regulatory model worldwide. In this single area, more than 75 legal acts have been abolished, repealed or replaced. In addition, as part of wider Commission efforts to reduce the administrative burden, savings of approximately EUR 260 million have been delivered in the food chain.

This Staff Working Document, while demonstrating past achievements, also reinforces DG SANCO's commitment to the future. Mapping the whole body of legislation provides the basis for further work ensuring a simple, efficient and relevant legislative framework, now and in the future.

Contents

1. CONTEXT

As part of its smart regulation policy, the European Commission announced in its Work Programme for 2010 that, 'to keep current regulation fit for purpose, the Commission will begin reviewing, from this year onwards, the entire body of legislation in selected policy fields through "fitness checks". The purpose is to identify excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures which may have appeared over time.'[1]

The main objective of this exercise is to assess whether EU legislation in a certain policy area, covering several legal acts, is 'fit for purpose' in addressing the original objective for which it was intended. The main tools for this exercise are stakeholder feedback and information gathered throughout the policy design and implementation process, including the results of monitoring and evaluation.

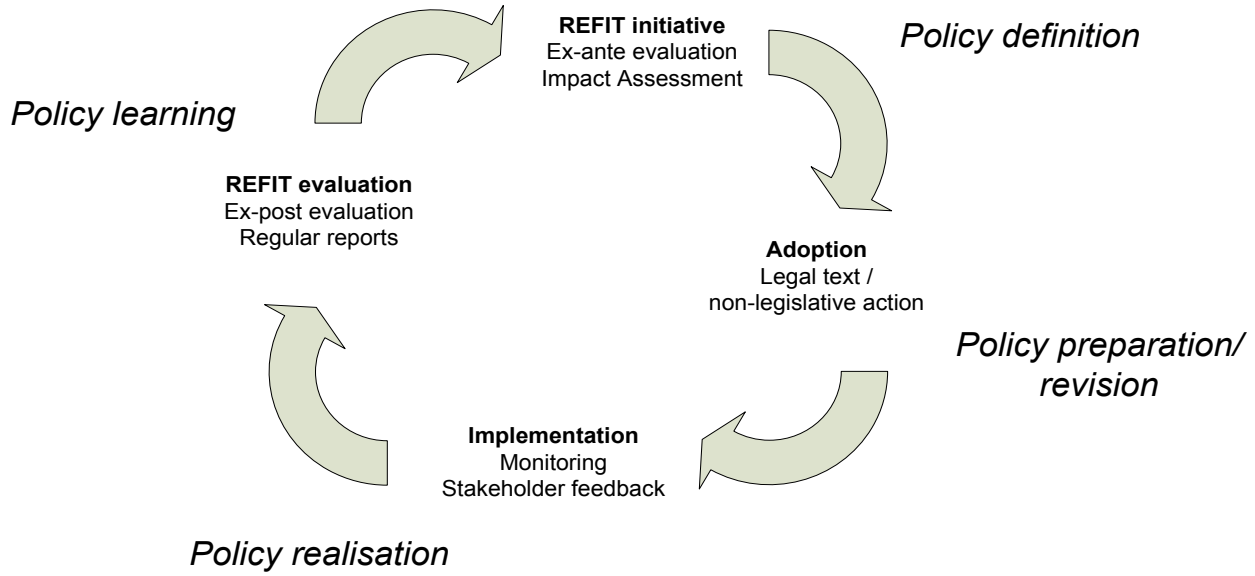

Figure 1: Policy cycle

The food chain was identified as a pilot project for a fitness check. These checks form an important component of the Commission's Regulatory Fitness programme as announced in December 2012 in the communication *EU Regulatory Fitness*.[2] The communication confirms the Commission's commitment to '[meeting] policy goals at minimum cost, achieving the benefits that only EU legislation can bring and eliminating possible unnecessary regulatory burden.' In the course of the Regulatory Fitness and Performance Programme (REFIT), regulatory tools will be assessed, as well as implementation and enforcement of EU legislation, in close cooperation with other European institutions and with Member States.

This Staff Working Document aims to deliver on the objectives of the fitness check while contributing to the REFIT exercise. It provides the state of play based on an overall assessment of

[1] Communication *Commission Work Programme 2010: Time to act*, COM(2010) 135 final.
[2] Communication 2012 *EU Regulatory Fitness*, COM(2012) 746 final.

the food chain policy area. Drawing on this assessment, recommendations are made for follow-up action in the context of the next steps in the REFIT exercise.

2. SCOPE OF THE EUROPEAN FOOD CHAIN

The term **food (supply) chain** describes a concept which is wide, yet rather linear:[3] it comprises all actors and activities from primary production (agriculture and inputs), food processing (all four stages from e.g. animal slaughter to ready-to-eat products, including industrial and craft-based enterprises), distribution and retailing (supermarkets and farmers' markets), and finally consumption by citizens/consumers. For a schematic overview, see Figure 2.

On the other hand, **food sector** is a more narrowly defined term, focusing on the main economic actors from primary processing to the final point of sale. Thus, it mainly includes the food and drink industry, but also retailers, food crafts and wholesalers, as well as trade and distribution. These actors and their economic activities are the focus of this assessment.

2.1. Economic dimension

The **food and drink sector** (including agriculture) plays a crucial role in the EU economy. Employing over 48 million people, it represents more than one fifth of the EU's total workforce. It generates added value of EUR 751 billion, which is equivalent to almost 6% of the EU's total GDP. Close to 17 million different holdings/enterprises operate in the food chain. At the same time, the sector enjoys significant benefits from the opportunities the single market offers. Cross-border trade among EU Member States has risen by 72% in value over the last decade, and accounts for about 20% of the EU's food and beverage production.

The **food and beverages processing** sector accounts for just 1.6% of the total number of enterprises in the EU's food chain in 2008; however, it contributes 26% to the total added value. With a turnover close to EUR 1 trillion, it is the largest manufacturing sector in the EU economy. This amount corresponds to 16%[4] of the total turnover of the manufacturing sector. Also, the sector is the leading employer in the EU, with 4.1 million staff, representing 15% of the total employment in the sector.[5]

Regarding the **economic relevance** for Member States, in 2011, Germany had the largest workforce in food and beverage manufacturing (845 400 persons, 17.9% of the EU-27 total). Spain had the largest number of persons employed in food and beverage wholesaling (350 600, or 17.5%) and specialised food and beverage retailing (254 700, or 18.0%); the latter accounted for more than one third (37.9%) of those employed in Spanish food and beverage retailing. No other Member State reported a proportion above 30%.[6]

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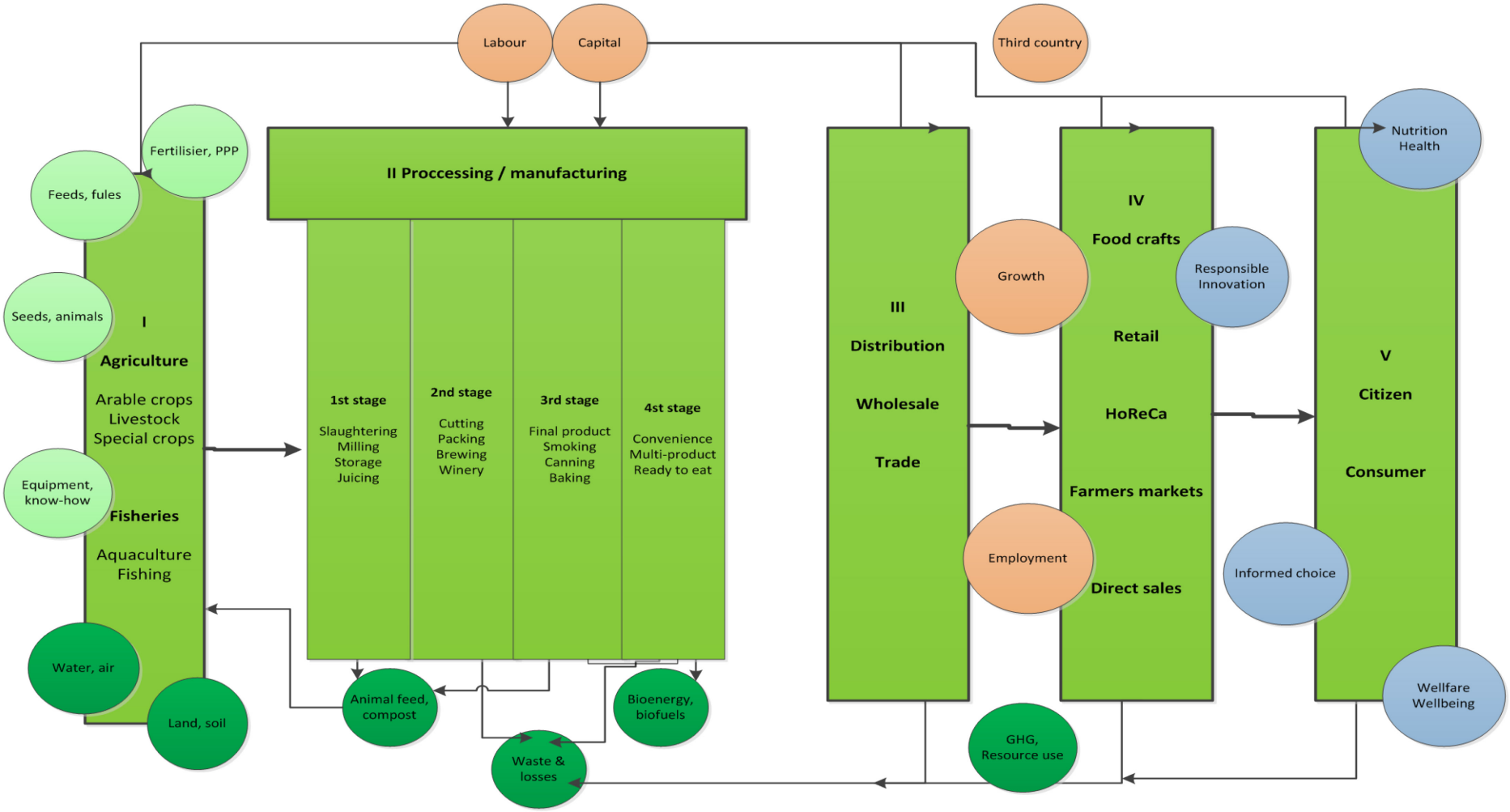
[3] The term 'food system' stands for a broader concept, allowing other approaches to food production and consumption, such as community-supported agriculture or subsistence farming.

[4] Sources: FoodDrinkEurope, Eurostat 2011.

[5] Sources: FoodDrinkEurope, Eurostat 2011.

[6] Eurostat:, *From farm to fork – a statistical journey along the EU's food chain*, 2011, http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-SF-11-027/EN/KS-SF-11-027-EN.PDF.

Figure 2: EU food chain – actors and impact (authors' compilation)



Key: Inputs/outputs by colour (circles): light green (primary production), dark green (environment), red (socio-economic), blue (public health and consumer welfare).

Small and medium-sized enterprises (SMEs, including micro-businesses) represent 99% of food and beverage manufacturing enterprises and account for 49% of the turnover and 63% of total employment.[7] The number of SMEs as a percentage of the total number of enterprises in the major food industries (processing and preserving of meat and production of meat products; processing and preserving of fish, crustaceans and molluscs; manufacture of dairy products; manufacture of prepared animal feeds) shows that the large majority of these are micro-enterprises. Indeed, for 16 of the 23 Member States,[8] micro-enterprises represent more than half of all food business operators (FBOs) in the four major industries (for 9 of the 23,[9] this figure rises to two thirds or more of all enterprises). Actually, the average number of employees per company in the food sector is 15 across EU Member States, which is just above the threshold for micro-enterprises of 10 employees.[10]

The EU is the biggest **global exporter and importer** of food and drink, with total annual exports of EUR 85 billion and imports of EUR 89 billion.[11] The main items imported into the EU are animal feed, exotic products, wine, sugar and tobacco, as well as fruit and vegetables. The main exports are alcoholic drinks, animal products, animal feed preparations and smoking products. The main recipient countries of EU exports are the USA, Russia, Japan, Norway, Canada and Switzerland, while the main countries from which the EU imports are Brazil, Argentina, the USA, Norway and the People's Republic of China.

Once the effects of the **financial and economic crisis** took hold in 2008, there was an abrupt downturn in that year also in the manufacture of many different foods and beverages. Nevertheless, the food and beverages output of the EU fell by a relatively small amount compared with the manufacturing average, likely due to many of these products being basic consumer necessities.[12] Industrial output actually grew in food manufacturing, by around 1.3% for the period from 2008 to 2011, while textiles, for example, decreased by almost 20% over the same period.[13]

Research and development investment in food and drink manufacturing has traditionally been low compared to other industries, averaging in the EU around 2.2% of the total investment, while in non-EU countries it is 2.1%.[14] However, food and drink companies, both within the EU and outside it, have continued to withstand the economic crisis to a certain extent, maintaining similar levels of R&D investment.[15] The EU is supporting the food sector in research and development through the 7th Research Framework Programme[16] in the areas of consumers, nutrition, food safety, food processing and the environmental impact of the food chain. A total of approximately

[7] Sources: FoodDrinkEurope, Eurostat 2009.
[8] For which data are available.
[9] AT, BE, CY, FI, IT, NL, PL, SE, SI.
[10] ESTAT: *European business: Facts and figures*, 'Food, beverages and tobacco', 2008.
[11] Comext 2011 (Trade since 1988 by SITC, Food and live animals + beverages).
[12] http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-32-11-743/EN/KS-32-11-743-EN.PDF (pg. 81).
[13] European Commission: *European Competitiveness Report 2012: Reaping the benefits of globalisation*, Commission Staff Working Document SWD(2012)299 final.
[14] European Commission 2011: *The 2012 EU Industrial R&D Investment Scoreboard*, JRC and DG R&I 2011.
[15] FoodDrinkEurope: *Data & Trends of the European Food and Drink Industry 2011* (http://www.fooddrinkeurope.eu/uploads/publications_documents/Data_Trends_2011.pdf).
[16] FP7's Theme 2: Food, Agriculture and Fisheries, and Biotechnology (FAFB) – 'Fork to farm: Food (including seafood), health and well-being'.

EUR 500 million has been invested, with SMEs being specifically targeted. In addition, two Joint Programming Initiatives (JPIs) contribute to improving cooperation between Member States.[17]

Household expenditure on food, beverages and catering services accounted for 21.5% of EU household expenditure in 2009; this share ranged from 17.4% in the Netherlands to 34.1% in Romania. Since 2007, the development in the volume of expenditure on food has been similar to that for total household consumption expenditure.[18] For the EU, private expenditure only on food and beverages represents 15% of the total expenditure of EU households (including alcoholic beverages).

In terms of **public health**, food safety legislation has a threefold impact. Firstly, outbreaks of animal disease, notably zoonoses which may put human lives at risk and may result also in economic costs – e.g. the BSE crisis originating in the UK in 1988, which had around 170 direct victims and interrupted a trade worth more than EUR 800 million per year, and food-borne illnesses such as the *E. coli* incident in 2011 with the loss of more than 50 human lives and economic costs estimated at EUR 800 million, in addition to EU-funded emergency payments of around EUR 200 million.[19] Secondly, the fact that six of the seven biggest risk factors for premature death in Europe relate to how we eat, drink and move demonstrates the impact of nutrition and lifestyles on health. In addition, currently more than half of adults in the EU are overweight or obese; this means a doubling of the obesity rate over the past 20 years. Severely obese people lose 8–10 years from their life and incur 25% higher health expenditures in any given year.[20]

2.2. Legislative dimension

The provision of **safe, nutritious, high quality and affordable food** to Europe's consumers is the central objective of the extensive EU policy and legislative framework which covers all stages of the supply chain (see Figure 3).

Apart from the legislative framework directly linked to the food sector, the actors throughout the food supply chain are also subject to legislation stemming from other policy areas. This includes agriculture (DG Agriculture and Rural Development) and more specifically the Single Common Market Organisation (sCMO), including marketing standards. Other relevant areas are internal market legislation (DG Internal Market and Services), international obligations such as in agreements and standards (DG Trade), environmental protection and sustainability (DG Environment), industrial policy and SMEs (DG Enterprise and Industry), competition and its impact on choice and innovation (DG Competition) and the research and innovation agenda (DG Research and Innovation and the Joint Research Centres).

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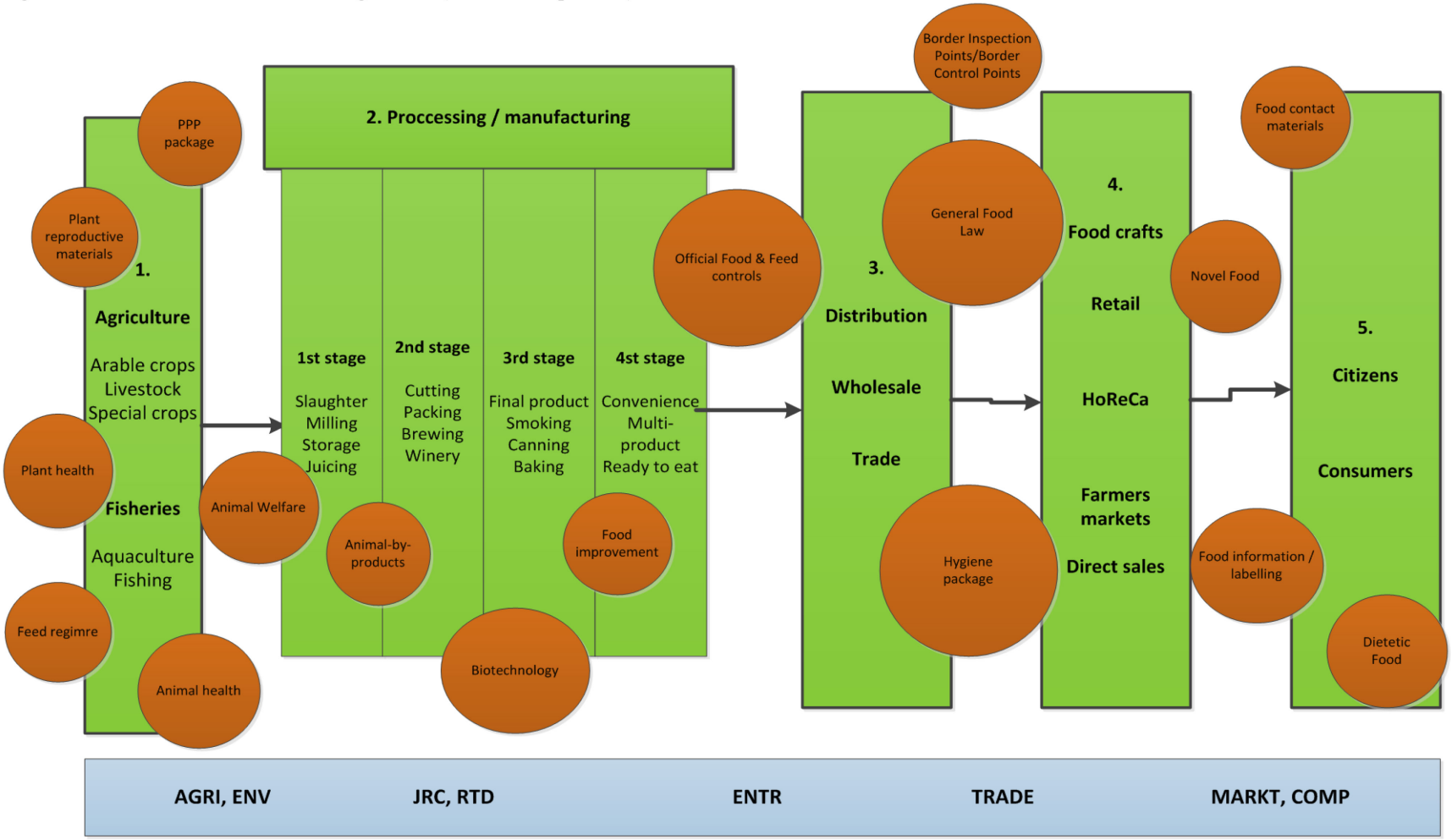
[17] Joint Programming Initiative on Agriculture, Food Security and Climate Change (http://www.faccejpi.com/); Joint Programming Initiative 'A Healthy Diet for a Healthy Life' (https://www.healthydietforhealthylife.eu/).
[18] Eurostat 2011: *Food: from farm to fork statistics*, http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-32-11-743/EN/KS-32-11-743-EN.PDF.
[19] European Commission Staff Working Document 2011: *Lessons learned from the 2011 outbreak of Shiga toxin-producing Escherichia coli (STEC) O104:H4 in sprouted seeds*; SANCO/13004/2011.
[20] OECD 2012: *Health at a Glance*, 2012.

Figure 3: EU food chain – actors and legislation (authors compilation)



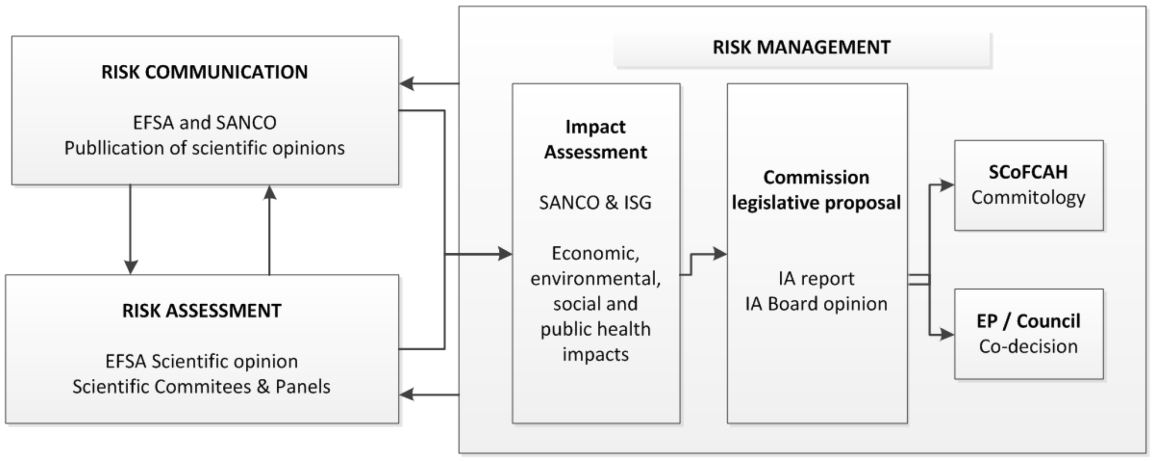
Key: The size of the circles reflects the scope of the respective legal act – Commission legislation under chief responsibility of DG SANCO (red circles), other Commission services (blue) in charge of relevant legislation for the food chain.

This **EU regulatory framework** is based on the principles of good law-making such as impact assessment, stakeholder consultation and full and consistent implementation. The food sector is one of the most regulated sectors in the EU, with a particularly high degree of legislation harmonised at EU level.[21] These EU standards and requirements aim to ensure that consumers can avail themselves of **efficient, competitive and innovative markets** in which high levels of safety prevail.

Within the European Commission, the respective legislation is almost exclusively within the competence of the Directorate General for Health and Consumers (DG SANCO). The foundation of this framework was established in EU law by the General Food Law,[22] which defines general concepts and principles such as 'the high level of protection of human life and health', and the precautionary principle. It also establishes the central role of risk analysis for all legislation and policies aimed at the provision of safe and healthy food to EU citizens and consumers.

Food law is based on science. The General Food Law established the European Food Safety Authority (EFSA) as an independent agency responsible for providing scientific opinions (risk assessment) as a basis for legislative actions (risk management) of the EU institutions. In particular, EFSA is responsible for the safety evaluations of dossiers put forward for the approval of substances/products/claims in the food/feed sectors, and delivers the scientific opinions upon which EU authorisations are based. EFSA's tasks also include collection and analysis of data related to the safety of the food chain, including emerging risks, scientific support of the Commission in crisis situations, and communicating the results of its scientific work. The graph below depicts a simplified approach to the process of placing the principles of risk analysis in the wider context of policy design.

Graph 4: Risk analysis (Compilation on basis of Regulation (EC) No 178/2002, OJ L 031, 1 February 2002)



The principles of risk analysis as a basis for all policy measures entails three interconnected components: risk assessment, risk management, and risk communication, which provide a

[21] European Commission 2007: *Competitiveness of the European Food Industry: An economic and legal assessment 2007*, (J.H.M. Wijnands, B.M.J. van der Meulen, K.J. Poppe (eds.), 2006.
[22] Regulation (EC) No 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (the General Food Law), OJ L 031, 1 February 2002.

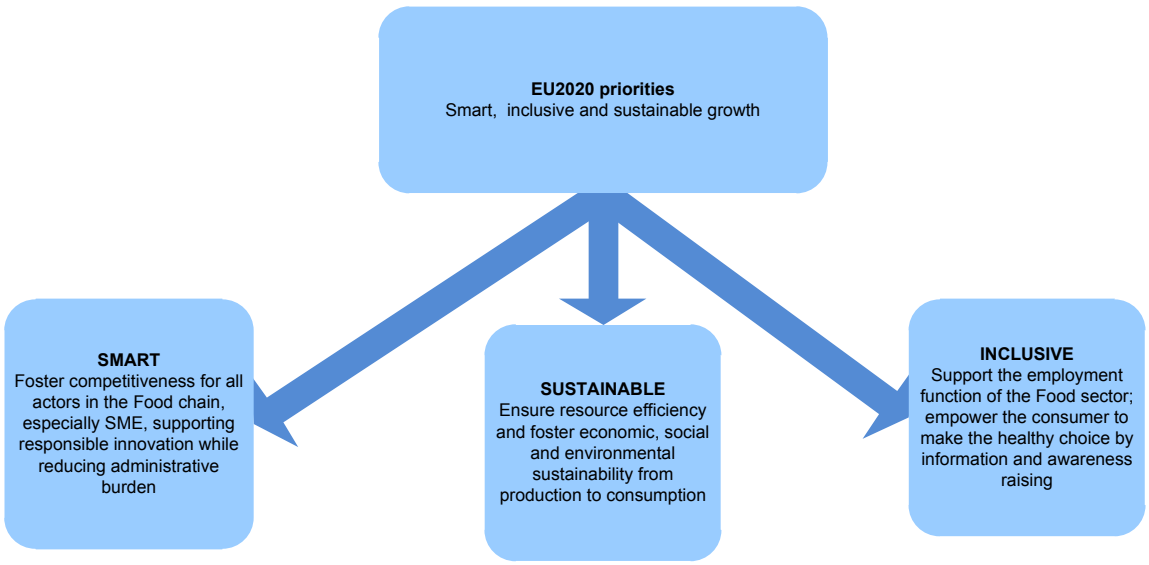
systematic methodology for determining effective, proportionate and targeted measures or other actions to protect health.

In addition to legislative measures, a series of non-legislative initiatives are in place in the food chain. This includes the High Level Group on Nutrition and Physical Activity[23] which reunites Member States and Commission services, and the EU platform for action on diet, physical activity and health,[24] which is composed of representatives of the social and economic sectors under the chairmanship of the Commission. Another relevant initiative is the High Level Forum for a Better Functioning Food Supply Chain[25] which between 2010 and 2012 implemented a roadmap of key initiatives to improve competitiveness in the food sector. Its mandate has been renewed for 2013–2014, thus allowing it to continue to provide a high-level consultation forum, comprising key Commission services, Member States and social and economic partners.

3. THE FOOD CHAIN POLICY AREA AND SMART REGULATION

Food chain policy and legislation makes an important contribution to the ambitious objectives of the Europe 2020 strategy for smart, sustainable and inclusive growth.[26]

Figure 5: EU2020 priorities for Health and Consumers (DG SANCO compilation)



The contribution of the food sector is most significant to three of the **flagship initiatives of Europe 2020.** First of all, to industrial policy,[27] which sets out the objective of reindustrialising Europe. By

[23] European Commission 2011: *Strategy for Europe on nutrition, overweight and obesity related health issues: Implementation progress report 2011*.
[24] EU Platform for Action on Diet, Physical Activity and Health, 15 March 2005, *Diet, Physical Activity and Health: A European Platform for Action*.
[25] European Commission decision of 30 July 2010 establishing the High Level Forum for a Better Functioning Food Supply Chain (2010/C 210/03), amended by Commission Decision of 19 December 2012 (2012/C 396/06).
[26] European Commission 2010: *Europe 2020: A strategy for smart, sustainable and inclusive growth*, COM(2010)2020.
[27] European Commission 2010: Communication *An Integrated Industrial Policy for the Globalisation Era: Putting Competitiveness and Sustainability at Centre Stage* (2010).

2020, the share of industry should increase from 16% to 20%. As the first EU manufacturing sector in terms of employment and added value, the food sector naturally has a role to play to reach this target. The second area is the flagship initiative 'A resource-efficient Europe',[28] which calls for incentives for healthier and more sustainable production and consumption of food, including the aim of halving the amount of edible food waste disposed of in the EU by 2020. Thirdly, the flagship initiative 'Innovation Union' which is closely linked to the Horizon 2020 integrated research programme, and finally, through European Innovation Partnerships (EIPs), notably on 'agricultural productivity and sustainability'.[29]

It has to be highlighted that consumers' and public health concerns are to be reflected in all policies addressing the food supply chain.

The most important example is the **Common Agricultural Policy (CAP),** in which the safety of the primary production of food is part of the system of cross compliance (CC), linking support payments to 13 specific legislative acts concerning food safety and the health and welfare of animals. The Rural Development Programme also includes measures where on-farm investments provide incentives for food safety and animal health and welfare. Furthermore, various measures under the Common Market Organisation (CMO) contribute to this issue, such as standards for public intervention, marketing standards, quality policy, and the School Fruit Scheme (SFS).[30]

Drawing from the Commission's commitment to the principles of **smart regulation,**[31] the following tools and approaches have been applied in the food chain policy:

Firstly, there is the need to **reduce the administrative burden,**[32] both for Member States' competent authorities and for food business operators.

Secondly, the **simplification of the regulatory environment**[33] by repealing, revising or replacing existing legal acts with the aim of fostering compliance and enforcement.

Thirdly, **special consideration is given to micro-, small and medium-sized enterprises**[34] by applying the principle of 'reverse burden of proof', according to which micro-entities could be excluded from the scope of legislative proposals unless their being covered can be demonstrated to be proportionate.

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[28] European Commission 2011: *Roadmap to a Resource Efficient Europe*, COM(2011)571 final.
[29] European Commission 2012: *Communication on the European Innovation Partnership 'Agricultural Productivity and Sustainability'*, COM(2012)79 final.
[30] European Commission Regulation (EU) No 34/2011 of 18 January 2011 amending Regulation (EC) No 288/2009 laying down detailed rules for applying Council Regulation (EC) No 1234/2007 as regards Community aid for supplying fruit and vegetables, processed fruit and vegetables, and banana products to children in educational establishments, in the framework of a School Fruit Scheme.
[31] European Commission 2010: Communication *Smart Regulation in the European Union*, COM(2010)543 final.
[32] European Commission 2012: *Action Programme for Reducing Administrative Burdens in the EU Final Report*, SWD(2012) 423 final.
[33] European Commission 2009: Communication *Third strategic review of Better Regulation in the European Union*, COM(2009)15 final.
[34] European Commission 2011: Communication *Minimizing regulatory burden for SMEs: Adapting EU regulation to the needs of micro-enterprises*, COM(2011) 803 final.

Fourthly, the (quantitative) **assessment of socio-economic impact**, notably the impact on cost competiveness[35] across actors in the food chain, but also the impact on public health and consumer welfare.

Finally, the **evaluation** that delivers concrete input for redesigning initiatives by providing evidence-based data and information from policy implementation.

3.1. Reducing the administrative burden

Reducing administrative burden has been identified as a Commission priority, also by the High Level Group on Administrative Burden (the 'Stoiber Group').[36] Subsequently, the Commission's approach, including the Standard Cost Model and the Administrative Burden Calculator, have been used for impact assessments (e.g. on the Regulation on Animal Health[37]).[38]

The original Sector Reduction Plan 2009 identified 11 measures in the policy area of food safety.[39]

The recent final report of the Commission provides an assessment of what has been achieved since then in the area of food safety. It also spells out the continuing commitment to searching for further reductions in reporting requirements, as well as to achieving a broader and deeper overall reduction in the regulatory burden at EU level, to be conducted under ABR+.[40]

An extended overview of recent contributions in administrative burden reduction in the food chain is provided below, totalling approx. EUR 260 million.

	Legal act	**Administrative burden reduction (ABR)**
1	Simplifying **bovine identification** procedures and repealing provisions on voluntary beef labelling	ABR of **EUR 0.4 million** to be achieved according to the Commission's proposal, which is based on an IA performed in 2011.
2	Reducing paperwork for transporters thanks to satellite tracking of **animal transport**	Although the Regulation has been in force for four years, most Member States neither ensure compliance of newly-installed systems nor systematically use the data collected for checks and controls. The identified **ABR of more than EUR 1 billion** has therefore not yet been realised.

[35] European Commission 2012: *Operational guidance for assessing impacts on sectoral competitiveness within the Commission Impact Assessment System: A "Competitiveness Proofing" Toolkit for use in Impact Assessments*, SEC(2012)91final.

[36] Commission decision of 5.12.2012 amending Commission Decision 2007/623/EC setting up the High Level Group of Independent Stakeholders on Administrative Burdens, as amended by Commission Decision of 17 August 2010, C(2012) 8881 final.

[37] Proposal for a Regulation of the European Parliament and of the Council on Animal Health, COM(2013)260 final of 6.5.2013

[38] European Commission 2007: *Action Programme for Reducing Administrative Burdens in the European Union* COM(2007) 23 final

[39] European Commission 2009: *Action Programme for Reducing Administrative Burdens in the EU: Sectoral Reduction Plans and 2009 Actions*, Annex C, COM(2009) 544 final.

[40] European Commission 2012: *Action Programme for Reducing Administrative Burdens in the EU Final Report* accompanying the Communication *EU Regulatory Fitness*, SWD(2012) 423 final.

3	Eliminating **veterinary border inspection** posts between the EU and Switzerland	ABR achieved of **EUR 1.3 million.**
4	Streamlining legislation on the production, marketing and use of **animal by-products**	Potential ABR impact of **EUR 21.2 million** (estimated; yet to be confirmed).
5	Abolishing authorisation procedures and simplifying labelling requirements for **feed materials**	ABR of **EUR 2.0 million** achieved by abolishing the pre-market authorisation procedure for bio-proteins while shifting responsibility to FBOs.
6	Setting a common and shorter authorisation procedure for **food improvement agents**	ABR achieved of **EUR 0.1 million.**
7	Modernising the general **food labelling** and nutritional labelling regime	The Commission proposal in 2008 included the **deletion of several IOs**; since then, Council and EP have introduced significant changes which will have a potentially negative impact on ABR.
8	Simplifying and modernising the **EU Animal health regime**	The Commission proposal allows for derogations for intra-EU movement of animals which would provide **annual ABR of up to EUR 79 million** for FBOs and farmers.
9	Simplifying and modernising the **EU Plant health regime**	The Commission proposes the **transfer of the Plant passport requirements** to the operators, which would allow them to fully integrate this IO into their standard business practices, which is expected to have a significant ABR impact.
10	Simplifying **the EU Plant Reproductive Materials law**	The DG SANCO proposal includes **transferring inspection tasks** for varieties registration to the private sector (current costs: **EUR 55 to 60 million a year**) which is expected to have a significant ABR impact.
11	Simplifying and extending the regulation on **Official controls** along the food chain	The DG SANCO proposal includes repealing annual submissions and approvals of MS residue plans and redundant specific reporting obligations which lead to an **ABR of approx. EUR 0.6 million a year** for the Commission and EU MS. In the area of residues of veterinary medicines, up to **EUR 98.5 million** could be saved by Member States if control activities were organised according to the risk to human health.
12	Revision of the **Hygiene package**	A focus of the currently on-going IA is the impact on retailers, and food crafts (notably SMEs and micro-businesses) with a view to allowing MS flexibility in defining exceptions on MS level for **ABR impact**.

3.2. Simplification

During the preparation of recent initiatives, simplification gains to existing legislation are consistently being realised. These have historically grown into a dispersed set of rules and are now being transformed into regulations which set directly applicable rules across the EU. This process allows for the rules to be streamlined and clarified in order to foster compliance and enforcement within the EU. It also helps to promote the EU regulatory model in third countries, with direct benefits for EU operators. Any such changes are explained in dedicated overview tables of the current and future legal architecture as part of every IA.

The total amount of the these simplification gains alone for the recent package of legislative proposals in the area of animal and plant health, plant reproductive materials and official controls, has identified around 75 repealed legal acts; this does not include simplification gains achieved within the legal acts which remain.

The table below depicts the legislation on **Plant Health** as an example of a successful simplification exercise:

	Plant Health Law	Repealed	Replaced	Remains
1.	Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community		x	
2.	Commission Regulation (EC) No 690/2008 recognising protected zones exposed to particular plant health risks in the Community.	x	x	
3–6.	Four Council Directives (69/464/EEC, 93/85/EEC, 98/57/EC and 2007/33/EC) concerning the control of specific organisms harmful to potatoes.		x	x
7–8.	Council Directives 74/647EEC and 2006/91/EC concerning the control of carnation leaf-rollers and of San José scale.	x		

3.3. Impact on SMEs

The recently published Communication on smart regulation[41] and related documents[42] list two SME priority files in the Commission Work programme 2013 within the food chain: official controls on food and feed (a Commission proposal for new legislation was adopted on 6 May 2013) and the hygiene package (revision on-going). In the survey of the top ten most burdensome legislative acts for SMEs, no item from the food chain was listed. However, in the replies from organisations on the policy areas which, in their view, lead to burdens, both food hygiene[43] and food information for consumers[44] are listed.

In order to facilitate and further substantiate consultation with SMEs, the Commission has been cooperating with the Enterprise Europe Network (EEN) to test legislation and get feedback through the permanent online SME feedback database and ad hoc specific SME panels. A more elaborated assessment was performed in the context of the IA on plant reproductive materials (PRM) which

[41] European Commission 2013: Communication *Smart regulation: Responding to the needs of small and medium - sized enterprises*, COM(2013) 122 final

[42] European Commission 2013: Staff Working Document *Monitoring and Consultation on Smart Regulation for SMEs*

[43] Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs (OJ L 139/1), 29 April 2004, and Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for the hygiene of foodstuffs (OJ L 139), 30 April 2004.

[44] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC, and Commission Regulation (EC) No 608/2004, (OJ, L 304/18), 22 November 2011.

included a sector questionnaire that was developed with input from the EEN. Other initiatives, such as official controls, have addressed in a specific exercise the potential impact on SMEs in terms of contributing to cost recovery. This was also the case for the revision of the General Food Law concerning the possible introduction of fees for EFSA, where an EEN survey of SMEs was performed.

SME test: Case study – 'Plant reproductive material'

The plant reproductive material (PRM) sector in the EU is the largest global exporter of seeds, with a total export value of EUR 4.4 billion (more than 60 % of global exports). The sector is concentrated (the 10 largest companies represent nearly 67 % of the global seed market), but SMEs play a crucial role in the internal market, notably in niche markets such as organic crops. The largest amounts of SME are in Hungary, Poland and Romania, with about 4 900 companies, more than 90 % of which are SMEs.

Benefits: Micro-enterprises and SMEs mainly need to have equal access to the internal market for the varieties they have developed by maintaining registration rules. Therefore, official inspection services shall always be made available by competent authorities to conduct work that SMEs or micro-enterprises cannot conduct themselves. The possibility to have a variety description provided by the operator increases the opportunities for specific markets (e.g. conservation varieties) which are of particular interest for SMEs and micro-enterprises. Moreover, introducing more relaxed rules on marketing PRM in small quantities without variety registration by micro-enterprises will benefit small local operators in particular by reducing the administrative burden and improving their business opportunities.

Costs: The current provisions on variety registration only allow examinations by competent authorities; they do not allow private operators to carry out examinations. As regards certification, the current legislation permits part of the work related to certification of lots of PRM to be transferred in certain cases to industry through a system of certification under official supervision. However, limitations to the legislation do not allow certain plant species (e.g. potatoes) and categories of seeds to fully benefit from such officially supervised examination. This will have an impact on large companies and competitive, innovative SMEs in particular, which are currently restricted in their entrepreneurial freedom. Furthermore, the rules on fees foresee an exemption to variety registration fees for micro-enterprises.

Conclusions: With a view to ensuring the proportionality of measures, notably reducing the administrative burden for Member States and private actors, the future system of pre-market control will take into consideration freedom of choice and the economic viability of agricultural stakeholders as well as SMEs and micro-entities regarding the more specific parts of the PRM market. Access of all growers, including amateur gardeners, to varieties of common knowledge, conservation or amateur varieties must be ensured, even if they do not pass modern variety evaluations. Conservation varieties can play an important role in maintaining resilient systems in agricultural production and genetic diversity at the field level. Smart growth is fostered by specifically focusing on niche markets (e.g. old varieties or other types of material), such as by allowing simplified market access for specific varieties and types of PRM.

In addition, the Commission has recently launched a dedicated study on the 'cost of the cumulative effects of compliance with EU law for SMEs'.[45] It will consider all EU legislation affecting small and medium-sized enterprises in certain economic sectors. The precise scope has not yet been decided, but food manufacturing and food retail are two candidates. Any relevant findings of this study will be used in the follow-up to this fitness check.

3.4. Economic impact on operators and competent authorities

In order to assess the impact not only on economic operators, but also on competent authorities in Member States, the impact is quantified whenever this is possible. This is either achieved with internal resources (e.g. in the case of the Regulation on Animal Health), or external contractors are used (e.g. for the new Plant Health rules). The results of this quantification exercise may lead to a decision on whether or not to include a certain element in the legislative proposal: For example, in the plant health regime the possibility of including invasive alien species was considered during the review, but finally rejected, also in view of a separate proposal of the Commissions department for Environment on this issue. It may also lead to a proposal to address the pertinent issue via a voluntary scheme, as was the case in the Regulation on Animal Health when it came to biosecurity measures.

Cost and benefit analysis: Case study – 'Biosecurity in the Regulation on Animal Health'

One possible measure which was considered in the early stages of the impact assessment process was to lay the down the obligation to adopt biosecurity measures for all EU farms by means of minimum criteria. This would allow Member States some flexibility in adapting them to local circumstances. Guidelines at EU/national level would be drafted to facilitate compliance with this obligation.

Benefits. This would likely reduce the risk of spreading animal diseases (assuming widespread compliance with the legislation), while at the same time requiring a relatively high level of biosecurity, given the fact that every farm/holding would have to draft its own biosecurity plan. Different production systems in different geographical contexts lead to very different levels of biosecurity risk, and therefore an appropriate level of biosecurity for a particular farm or holding can vary significantly.

Risks. This would impose very significant costs and a high administrative burden on some sectors, particularly for those who do not currently have widespread biosecurity measures or self-regulated guidelines or plans. It is difficult to extrapolate exactly the administrative burden associated with implementing this option EU-wide. Leaving aside the need for competent authorities to develop guidance, the average time they need to assess and verify each plan would be 29 working hours. If the number of agricultural holdings across the EU is 7 310 000,[46] this amounts to 212 000 000 working hours (which equals more than 24 000 years).

[45] Request for services 2012/07 under framework contract JUST/2011/EVAL/01.

[46] Eurostat Pocketbooks: *Agricultural Statistics: Main results — 2008–09*, http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-ED-10-001/EN/KS-ED-10-001-EN.PDF.

The cost to operators is more difficult to assess, as some operators will already have quite significant measures in place, while others would need to introduce considerable changes. Taking the average cost of drafting and implementing a plan as EUR 12 750, this would represent a total cost of EUR 93.2 billion across the EU farming sector. In 2008, the gross value added (GVA) at producer prices of all EU farming amounted to EUR 190 billion.[47] So, the estimated costs of introducing biosecurity plans would represent approx. 50 % of the total annual GVA of agricultural output. It would be extremely hard to demonstrate that the benefits of introducing universal biosecurity plans would generate a similar value to the total cost involved, which leads to the conclusion that these measures can be considered to be completely disproportionate.

Another element to consider when setting a very high regulatory bar is the serious risk of non-compliance. The potentially large cost involved in implementing biosecurity plans across the board increases the probability of non-compliance, thus undermining the objective of the legislation and the credibility of the EU.

As a consequence, the Commission proposal introduces the prevention tool of biosecurity plans in a more proportionate way, i.e. as a farm-level voluntary measure linked to incentives (e.g. to easier cross-border animal movement, movement during disease outbreaks, etc.).

The Europe 2020 Flagship initiative 'industrial policy for the globalisation era' aims to support the preservation of a strong, diversified and competitive industrial base in Europe.[48] Therefore, all policy proposals will be subject to a thorough and explicit analysis of their impact on the competitiveness of industry by a comprehensive **'competitiveness proofing'**. This includes cost competitiveness, the capacity to innovate and also international competitiveness. It complements existing IA guidelines.

Competitiveness proofing: Case study – the food chain

The objective of 'competitiveness proofing' is to identify and, wherever possible, to quantify the likely impact of any new policy proposal on the competitiveness of enterprises. Three main dimensions are relevant for the food sector:

Cost competitiveness: the cost of doing business, which includes the cost of factors of production (labour and capital) and costs which may be a direct consequence of the policy proposal (compliance costs).

Capacity to innovate: the capacity of the business to produce more and/or higher-quality products and services that better meet customers' preferences (innovative competitiveness) including the cost of bringing new products to market (authorisation).

International competitiveness: assessing innovation and cost competitiveness in an international comparison, including undistorted access to external markets and adequate import regimes (international standards).

[47] European Commission 2011: *Food: from farm to fork statistics*, ESTAT 2011.
[48] Communication on new industrial policy (COM(2010) 614).

In general, quantitative evidence should be used to estimate impacts, especially if they are expected to be particularly significant. The final input into the IA report from the qualitative screening leads to a short analysis with the four following elements: (1) the sectors affected; (2) the identified (direct and indirect) impacts on these sectors; (3) qualitative (quantitative) estimates of the size, time and duration (permanent) of impacts; and (4) the probability that the impact will materialise, including possible critical assumptions.

The analysis could benefit substantially from a consultation on the results of the qualitative screening both internally (in an IA steering group) and externally (with business associations and other stakeholders). The Commission developed internal guidance[49] to carry out competitiveness proofing, which is being used as a standard tool in impact assessments.

Recent examples in the food sector are the ongoing report and impact assessment respectively on country of origin labelling for food stuffs (voluntary) and meat as an ingredient (mandatory). Both comprise a dedicated annex on competitiveness proofing, reflecting these principles and tools.

3.5. Public health and consumer welfare

A tool for fostering the integration of public health in all policies is the **Health Impact Assessment** (HIA),[50] developed by the European Observatory for Health Systems and Policies of the World Health Organisation, with support from Commission services including DG SANCO. Its application and use in designing policy proposals, however, still needs to be pursued on a regular basis. At the same time, methodological approaches such as cost-effectiveness analysis (CEA) allow the comparison of costs with outcomes in quantitative, non-monetary units. This offers a possibility to define the cost of illness and societal costs resulting from food-borne diseases, as well as zoonoses.

Also, a better alignment with the **demands of consumers** is being sought across all policy areas. Of particular interest in this context is how consumers access, interpret and use information to make an informed choice. This in turn should help to identify the optimal way to present information. In order to allow for this, however, robust evidence of consumers' literacy, information needs, and response to information has to be generated. Economic models of consumer behaviour together with experimental assessments should provide recommendations with respect to the feasibility and appropriateness of possible policy options.

And finally, the Commission's Directorate-General for Health and Consumers aims to provide for a **consistent approach** in order to ensure that EU food policy contributes to delivering sufficient, affordable, safe, healthy, high-quality food and feed, and healthy plants and animals produced in a sustainable manner with good animal welfare, including in the future. A close link to the EU research programmes with a view to fostering resilient systems in animal and plant production and

[49] Commission Staff Working Document *Operational guidance for assessing impacts on sectoral competitiveness within the Commission impact assessment system: A "Competitiveness Proofing" Toolkit for use in Impact Assessments*, SEC(2012) 91 final.

[50] WHO 2008: *The Effectiveness of Health Impact Assessments: Scope and limitations of supporting decision-making in Europe*; http://www.euro.who.int/__data/assets/pdf_file/0003/98283/E90794.pdf.

along the food chain is one way forward. Coherent enforcement and consistent compliance across all actors of the food chain, access to innovation for all stakeholders in the food chain, and information for citizens and consumers to allow for an informed and healthy choice are other key elements. All of these are framed within research and foresight activities, supported or commissioned by the Directorate-General for Health and Consumers.

3.6. Evaluation

As part of the policy learning component of the policy cycle, all major pieces of legislation within the food chain are systematically **evaluated**. In order to allow for best possible use by the line units which are designing and implementing food chain legislation, the evaluations are planned and performed according to the following requirements: Firstly, legal acts requiring an evaluation including all proposals with budget expenditure exceeding EUR 5 million should be the subject of an interim and/or ex post evaluation.

Secondly, management decisions according to political priorities and operational need for information can also lead to evaluations as well as all activities addressed to external parties.[51] Thirdly, evaluations have to be available before any significant new initiatives, including IAs, are undertaken.[52]

Within DG SANCO, these combined requirements following the 'evaluation first' principle find their reflection in an exhaustive list of evaluations over recent years:

Evaluation	**Completion date**	**Accountability purpose / legal basis**	**Web-link**
Community Animal Health Policy (CAHP) 1995–2004	Completed 07/2006	Management decision	http://ec.europa.eu/food/animal/diseases/strategy/final_report_en.htm
Phytosanitary: Harmful Organisms - Financial Aspects	Completed 11/2007	Evaluation of the Community's financial support in the context of 'phytosanitary solidarity'	http://ec.europa.eu/dgs/secretariat_general/evaluation/search/download.do?documentId=5030
Community *acquis* on the marketing of seed and plant propagating material (S&PM)	Completed 10/2008	Management decision	http://ec.europa.eu/food/plant/plant_propagation_material/review_eu_rules/index_en.htm
Better Training for Safer Food training activities 2006–2010	Completed 04/2009	Commission SWD on 'Challenges and strategies for the BTSF programme' of 10/2010	http://ec.europa.eu/dgs/secretariat_general/evaluation/search/download.do?documentId=4718
Community Reference Laboratories in the field of animal health and live animals	Completed 11/2009	Action Plan for the implementation of Community Animal Health Strategy	http://ec.europa.eu/dgs/secretariat_general/evaluation/search/download.do?documentId=4756
EU legal framework in the field of GM food and feed	Completed 07/2010	Regulation 882/2004/EC	http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm

[51] European Commission 2007: *Responding to Strategic Needs: Reinforcing the use of evaluation*, SEC(2007) 213.
[52] Communication *Commission Work Programme 2010*: *Time to act*, COM(2010) 135 final.

EU legal framework of cultivation of GMOs	Completed 10/2010	Management decision	http://ec.europa.eu/food/plant/gmo/evaluation/index_en.htm
Plant Health Strategic Evaluation	Completed 05/2010	Management decision	http://ec.europa.eu/food/plant/plant_health_biosafety/rules/
Community Policy on Animal Welfare (C-PAW) and possible policy options for the future	Completed 05/2011	Management decision	http://ec.europa.eu/dgs/secretariat_general/evaluation/search/download.do?documentId=4630
Community Plant Variety Right Regime	Completed 04/2011	Management decision	http://ec.europa.eu/food/plant/plant_property_rights/evaluation/index_en.htm
EU Reference Laboratories in the field of food and feed safety and animal health	Completed 04/2011	Management decision, and Financial Regulation Article 27	http://ec.europa.eu/dgs/secretariat_general/evaluation/search/download.do?documentId=4753
EU rapid response network, regarding certain transmissible animal diseases	Completed 08/2012	Action Plan implementing Animal Health Strategy – action number 22	http://ec.europa.eu/dgs/secretariat_general/evaluation/search/download.do?documentId=6336096
Expenditure in the veterinary field	completed 07/2013	Council Decision 2009/470/EC, Article 27 Financial Regulation, Article 21 Implementing Rules	
Veterinary Week campaign	completed 09/2013	Article 27 Financial Regulation	

4. RESULTS OF MAPPING THE FOOD CHAIN

The food chain is regulated by a comprehensive set of legislative acts. These rules and regulations have been substantially revised since 2002, on the basis of the principles of 'smart regulation' and of the wider Commission strategy (Europe 2020). This chapter aims to establish the state of play of all relevant legislative acts and policy areas and whether they are still 'fit for purpose'. They can be categorised according to four broader objectives: safety, consumer choice, competitiveness and innovation. However, these categories are not exclusive; rather, they reflect the main focus of the respective policy area.

	Policy area / Legal act	State of play
Food safety	Hygiene package	IA elaborated , proposal at the end of 2013
	Plant Protection Products (PPP)	Applicable since June 2011
	Food contact material	Framework regulation applicable since 2004, implementation of rules under assessment
	Food Improvement Agents package	Applicable since January 2011
Consumer choice	Food Information for Consumers (labelling, health claims)	Applicable as of the end of 2014, implementing rules for Country of Origin Labelling (COOL) in preparation (IA) for 2013 Implementation of rules for health claims on-going.
	Dietetic Food Regime (Food for special groups)	Commission proposal adopted on 12 June 2013
	Animal Welfare	Impact assessment on a possible legislative framework expected in2015
Competitiveness	Animal Health regulation	Commission proposal adopted on 6 May 2013
	Plant Health regime	
	Plant reproductive material	
	Official controls in the food chain	
	Feed regime	Applicable since 2010
	Animal by-products	Applicable since March 2011
Innovation	General Food Law – EFSA fees	Staff Working Document published 2012
	Biotechnology (GMO)	Measures proposed for GM-free labelling & Low-Level Presence (LLP) feed are under consideration
	Novel Food Food from Clones	New proposals for Novel Food and for Cloning (IA on-going) are planned for 2013

4.1. Food safety

Reflecting the core objective of the European Union's legislation on the food chain – the provision of safe food to the consumer/citizen – these policies safeguard the physical, biological and chemical safety of all products placed on the market in the EU. While setting standards and obligations for accessing the single market requires significant efforts in compliance and enforcement, they also ensure consumer confidence and legal security for food business operators, both in the EU and in third countries, and thus, ultimately, the successful functioning of the single market.

4.1.1. Hygiene package

The Commission reported in 2009 on the implementation of the hygiene package.[53] The recommendations included the need for a strengthened focus on SMEs, the clarification and simplification of the legal framework, market access for third-country imports, and finally, a level playing field in the single market. Particularly the first issue, the impact on SMEs, is of significant importance given that approximately 99 % of the 275 000 enterprises active in the food sector are SMEs.[54]

Objectives and results

It is noteworthy, however, that the EU hygiene legislation currently in force provides for a proportionate approach for SMEs. This approach reflects the major importance of SMEs while ensuring public health, in particular against food-borne infections. Already in 2010,[55] the Commission established guidelines on 'flexibility provisions' (exclusions, derogations and adaptations) for both competent authorities and FBOs. Measures which provide exemptions for SMEs include the possibility to adapt specific requirements, such as for direct supply and retail, or to exclude certain activities completely. Simplified reporting obligations (e.g. document records of HACCP-based procedures) and for the use of guides (EU guides, national guides or stakeholder guides) are also in place. In addition, the Hygiene Regulations allow for the granting of derogations/exemptions from certain requirements, such as for slaughterhouses or for premises handling foods with traditional characteristics. Member States also have the possibility to adapt the requirements of the hygiene regulations to enable the continued use of traditional methods of production, to accommodate the needs of food businesses in regions subject to special geographic constraints, or to adapt requirements on the construction, layout and equipment of establishments.

The initiative aims to improve food hygiene and to increase food safety by introducing simplified procedures and an enhanced risk-based approach. It will introduce more legal flexibility concerning the category of staff allowed to perform official controls related to meat inspection, which would allow for a reattribution of resources based on actual risks.

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[53] Report on implementation of the Hygiene package 2006–2008: http://ec.europa.eu/food/food/biosafety/hygienelegislation/dvd/index.html.

[54] Sources: FoodDrinkEurope, Eurostat 2011.

[55] http://ec.europa.eu/food/food/biosafety/hygienelegislation/index_en.htm.

Another goal is to enhance the harmonised application of EU provisions (e.g. import conditions) in order to facilitate trade without jeopardizing public health. The initiative intends to introduce a more proportionate, risk-based approach for the provisions of the hygiene package concerning import conditions for composite products produced from ingredients of animal and non-animal origin.

Simplified procedures for notifying the application of flexibility provisions will allow Member States to apply such flexibility more easily and thus more frequently, with a corresponding benefit regarding the reduction of the administrative burden and compliance costs of food business operators.

Next steps

Commission services lead by DG SANCO are currently conducting an impact assessment of simplified risk-based procedures and SME exemptions as appropriate to reduce impact and increase flexibility for SMEs.

As a follow-up to the FVO's report on the application of flexibility provisions in certain Member States,[56] dedicated workshops will be organised for authorities and food business operators in Member States in 2013 to explain the implementation options available.

In 2014, in the framework of the Better Training for Safer Food (BTSF)[57] programme, specific training for competent authorities of Member States on the correct application of flexibility provisions is expected.

4.1.2. Plant protection products (PPPs)

In 2002, the Commission adopted the Strategy on the Sustainable Use of Pesticides.[58] Subsequently, the Commission organised meetings and workshops with Member States, the European Parliament and NGOs, as well as stakeholder conferences between 2002 and 2005. In 2008, an impact assessment[59] was performed and stakeholders and the general public were consulted. The new regulation was adopted in 2009, repealing two Directives, and entered into force in 2011.[60]

[56] European Commission 2010: *General report of a mission series carried out in six member states in the period November 2009 to March 2010 in order to gather information regarding the application of the hygiene regulations in small establishments producing meat and meat products of mammals and dairy products*, DG(SANCO)/2010-6150 - MR FINAL.

[57] http://ec.europa.eu/food/training_strategy/index_en.htm

[58] Communication *Towards a Thematic Strategy on the Sustainable Use of Pesticides*, COM(2002) 349, 2002. http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21288_en.htm.

[59] IA on the Directive on plant protection products. http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2006/sec_2006_0931_en.pdf.

[60] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, OJ L 309/1, 24 November 2009.

Objectives and results

The major aim of the 2009 regulation is to address three elements of a strategy into action: firstly, placing products on the market; secondly, the sustainable use of plant protection products (PPPs); and thirdly, monitoring and reporting.[61]

The objective of this strategy is to reinforce the high level of protection of human health and the environment with a more prudent, sustainable and transparent use of PPPs. Also, it aims to improve the functioning of the internal market by addressing the key issues of provisional authorisation, mutual recognition and comparative assessment of PPPs, facilitating market access for innovative products, and establishing rules for more efficient use of inputs. This is intended for the overall competitiveness of the sector, especially the EU chemical industry. Farmers in different Member States should benefit from the same availability of PPPs, while data protection and the information of neighbours on PPP use foster transparency. And finally, the repetition of animal testing for PPPs is avoided and the specific role of the European Food Safety Authority as a risk assessor is strengthened.

Next steps

Since the entry into force of this regulation, the development and commercialisation of products for specific uses remains an issue requiring continuing attention. These are PPPs that are used only for a small market ('minor uses'); several examples exist in the fruit and vegetable sector. Limited commercial interest of companies leads to insufficient investment and thus to a lack of availability of PPPs for such minor uses. This in turn puts the commercial production of certain agricultural products at risk.

The creation of a specific tool to support investment in these areas is currently under consideration. One of the proposals is to set-up a coordination platform supported by the EU budget, as advocated by the economic sector.

A second issue is the mutual recognition of authorisations for placing PPPs on the market by Member States. The full implementation of this mutual recognition is hampered by different approaches to risk assessment and risk management due to different derogations existing in Member States. This is addressed by a series of dedicated working groups of the Standing Committee of the Food Chain and Animal Health (SCoFCAH) aiming to establish harmonised risk assessment guidelines, with the support of the European Food Safety Authority. At the same time, Better Training for Safer Food (BTSF) is offering workshops for training and experience exchange between the competent authorities of Member States. Stakeholders from the economic sector are also invited to specific advisory group meetings whenever it is relevant. Finally, the Commission has elaborated specific guidelines.[62]

[61] Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides, OJ L 324/1, 10 December 2009.

[62] http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm.

A third issue is the entry into force of the Sustainable Use Directive (SUD) by 1 January 2014.[63] Notably, the issue of integrated pest management (IPM) is a core issue closely linked to the Common Agriculture Policy (CAP) and the system of cross-compliance. Currently, several Member States are facing challenges in drawing up national strategies, while at the same time the level of obligation required in the framework of the CAP is still under discussion.

4.1.3. Food contact material

In 2004, a first simplification exercise of the general rules on food contact materials resulted in the replacement of two Directives with one framework regulation and two implementing regulations (recycled plastics and intelligent materials). In 2011, a second simplification exercise led to the revision of the implementing rules (Directives on plastics) and their transformation into a single Regulation. In addition, a series of guidance documents have been published on these materials, as well as on the specific import rules, including question and answer documents, covering the most pertinent issues with a focus both on private and public actors in the food chain.[64]

Problems and objectives

In 2012, an initiative for the revision of food contact materials other than plastic was launched, on the basis of a roadmap.[65] According to the roadmap, recent food scares linked to substances originating from food packaging (materials other than plastics) were due to a lack of knowledge of substances used in these materials at EU and at national level.

In a significant number of cases, the safety of the materials used has not been assessed at EU or at national level or by industry itself. A recent report[66] by the European Food Safety Authority on risk assessment at national level has shown that, for non-EU harmonised materials, the use of 3 000 substances is regulated at national level, while only 320 of these regulated substances have received adequate risk assessments. This lack of knowledge of the risks posed by substances led to a withdrawal from the market of large amounts of food and packaging when some of the substances were detected in food. In addition, lack of knowledge results in reduced consumer trust in the safety of food packaging.

The enforceability of current rules is limited by the lack of specific parameters, criteria or limits against which compliance can be assessed. In combination with limitations on resources and the lack of awareness of the competent authorities of Member States, this might lead to gaps in enforcement. In addition, the lack of full application of risk assessments and good manufacturing practice at manufacturer/user level leads to unsafe products being put on the market.

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[63] Directive 2009/128/EC on Community action to achieve the sustainable use of pesticides (SUD) of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, Official Journal of the European Union L 309/71, 24 November 2009.

[64] Link to webpage on legislation authorisations, guidance documents, registers and lists: http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm.

[65] Roadmap http://ec.europa.eu/governance/impact/planned_ia/docs/2014_sanco_005_fcm_specific_provisions_for_materials_other_than_plastics_en.pdf.

[66] EFSA report 2012: *Report of ESCO WG on non-plastic Food Contact Materials*. Supporting Publications 2012:139 http://www.efsa.europa.eu/en/supporting/doc/139e.pdf.

Limitations in the functioning of the internal market have also been observed**.** Demonstrating the safety of the materials to customers becomes more difficult when the criteria for safety are not established. In the absence of harmonised limits and divergent national rules on how to assess safety, more and more certification and accreditation systems are being set up at industrial level. Certification and accreditation schemes have varying requirements and different forms to be filled in by food business operators. National provisions often differ between Member States, e.g. the migration level limits set for metals are different in Italy than they are in the Netherlands. Industry operators situated in third countries misunderstand the absence of EU-harmonised specific requirements as no obligation on the safety of food contact materials.

Results

The main issues addressed throughout the systematic renewal and update of the legislative framework are simplification and improving the functioning of the single market – for example by way of a harmonised list of substances used in plastics and common requirements for the use of recycled plastic throughout the EU. One EU application and authorisation replacing several national authorisation schemes reduces the administrative burden for industry, results in legal certainty for the EU-wide marketing of plastic materials, and ensures a high level of consumer protection throughout the EU. This general acceptance of the EU system is thus of significant advantage to the sector.

Next steps

Deficits remain for materials for which no specific measures are established at EU level, as indicated in the problems section. The necessity of further implementing provisions is under investigation, with an impact assessment and a supporting external study currently being prepared.[67]

EU legislation only requires that a declaration of compliance is available for plastic food contact materials. It does not need to be provided with every delivery of the same article; it only needs to be renewed when substantive changes are made in the manufacture or the legislative requirements have changed.

[67] IA Roadmap for a forthcoming Impact assessment http://ec.europa.eu/governance/impact/planned_ia/docs/2014_sanco_005_fcm_specific_provisions_for_materials_other_than_plastics_en.pdf.

4.1.4. Food Improvement Agent package

On 16 December 2008, the European Parliament and the Council adopted a legislative package on food improvement agents based on several impact assessments.[68] This package refers to regulations on food additives, food enzymes and flavourings. It contributes to the Commission's simplification programme and provides for harmonisation, and not only in their respective fields – it also promotes consistency between these three related areas. An additional fourth regulation within the package establishes a single common authorisation procedure for the evaluation and approval of these substances.

Objectives and results

The main improvements of the regulation on food additives were to recast and simplify the existing legislation by creating a single instrument for both its principles and approvals. In addition, implementing powers have been conferred upon the Commission to update the EU list of approved food additives (the introduction of comitology). This greatly facilitates the process of placing new products on the single market and thus fosters innovation. The single EU list which comprises the use of additives according to the food to which they may be added is accessible on-line.[69]

For food enzymes, the objective of the new EU rules is the full harmonisation of the authorisation and use of all food enzymes.

For food flavourings, the existing legislation has been modernised and adapted to technological and scientific developments, and clear evaluation and authorisation requirements have been established. Finally, the procedural aspects of the three sectoral Regulations (such as handling applications before well-defined deadlines, their evaluation by EFSA and the subsequent risk management decision by the Commission) have been combined into one single regulation. This will increase consistency in common areas and accelerate procedures.

Next steps

Since its adoption in November 2011, the EU list of authorised food additives has been updated 14 times in response to applications from the food industry and taking into account the advice of EFSA.

This demonstrates that the EU legislation on food additives is an effective instrument to protect the safety of consumers and that it ensures the efficient functioning of the internal market, for example

[68] IA for the Proposal for a Regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, and Council Directive 2001/112/EC.
IA for the Proposal for a Regulation of the European Parliament and of the Council on food additives.
IA for the Proposal for a Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods amending Council Regulation (EEC) No 1576/89, Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2006/sec_2006_1040_en.pdf.
[69] https://webgate.ec.europa.eu/sanco_foods/main/?event=display.

by allowing industry to gain access to the market with new innovative uses of food additives that may benefit consumers.

4.2. Consumer choice

This category brings together policies and legislation that are intended to reflect consumers' expectations and perceptions, allowing them to make an informed choice. In some cases requiring compliance costs, these policies also ensure a high level of consumer choice and welfare. At the same time, they offer the European food sector a unique selling proposition for products and services delivered in the single market and potentially, global export markets.

4.2.1. Food information for consumers

In 2003, DG SANCO launched an evaluation[70] of food labelling to reassess the effectiveness of its policy and to identify consumer needs and expectations, taking into account the technical constraints on implementation by industry. A public consultation took place in early 2006, based on a comprehensive document,[71] and focusing on the strategic goal of labelling. Groups consulted in several Expert Working Group meetings in 2006–2007 included the Advisory Group on the Food Chain and Animal and Plant Health, the European Consumer Consultative Group (ECCG), the Consumer Policy Network of senior officials, and the Health Policy Forum, as well as Member State authorities. A qualitative study of labelling was carried out by an external contractor in 2005[72] in order to assess consumers' attitudes to labels. This study also provided the basis for the impact assessment,[73] notably including the specific focus on administrative burden reduction and the combined economic impact.

The new EU Regulation (EU) No 1169/2011 on the provision of food information to consumers[74] considerably changes existing rules on food labelling by introducing mandatory nutrition information, better legibility (a minimum font size), mandatory origin labelling of several kinds of fresh meat (in addition to beef), strengthening rules for voluntary origin labelling, highlighting allergens (e.g. peanuts or milk) in the list of ingredients, including in food sold in restaurants and cafés. It will become fully applicable from December 2014, except nutrition information, which will be required from December 2016.

[70] Evaluation report 2004, http://europa.eu.int/comm/food/food/labellingnutrition/foodlabelling/effl_conclu.pdf.
[71] Consultation Document 2006, *Labelling: competitiveness, consumer information and better regulation for the EU*, http://ec.europa.eu/food/food/labellingnutrition/betterregulation/competitiveness_consumer_info.pdf.
[72] External study 2005, http://europa.eu.int/comm/consumers/topics/product_labelling_en.htm.
[73] *Impact Assessment Report on General Labelling Issues*, SEC(2008) 92.
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/ia_general_food_labelling.pdf;
Impact Assessment Report on Nutrition Labelling Issues, SEC(2008) 94.
http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/publications/ia_nutrition_labelling.pdf.
[74] *OJ L 304, 22.11.2011, p. 18–63*

Objectives

The main challenge was to streamline and simplify the food labelling regime without undermining the high level of consumer protection, while improving the competitiveness of the EU sector by reducing the administrative burden.

The major driver, as identified in the evaluation report, was the basic contradiction between the complexities of the rules and the completeness of the issues covered. The approach chosen was to recast different horizontal labelling rules, to simplify the legal framework, to modernise the specific requirements of enforcement and compliance, and to clarify the actual implementation. This was also achieved by repealing the two existing Directives (labelling of food and nutrition labelling) and integrating them into one regulation.

However, given the novelty of the legislation and the scope and complexity of the issues covered, Member States and food business operators across the food chain are challenged to ensure adequate enforcement and compliance, respectively. Therefore, as follow-up to the Food Information to Consumers (FIC) Regulation, a series of meetings in the context of the Advisory group for the food chain are on-going with Member States and the sector concerned to ensure consistent implementation. In addition, only recently, a Question & Answer document[75] was published in all EU languages aiming to assist all actors in the food chain as well as the competent national authorities to better understand and correctly apply the FIC Regulation when it enters into force. This is a dynamic document which will be updated regularly in order to address new issues, where appropriate.

Different mandatory labelling requirements can hinder operators from freely sourcing across the EU when looking for a better price. The existing EU regulatory regime allows for the introduction of additional mandatory labelling requirements at national level for certain specific reasons. Thus, even though the rules applied in the Member States are similar, in some cases product marketing requires country-by-country compliance assessment. The resulting legal complexity can hamper cross-border sourcing and make it difficult to reap the benefits of economies of scale. Increased transparency in this area would bring benefits to all stakeholders. A feasibility study for a pilot database bringing together both EU and national labelling requirements in the food sector will be launched in order to make information on labelling rules accessible to all.

Next steps

In addition, the FIC Regulation identifies two more issues which need to be addressed by means of implementing rules on origin labelling: the voluntary indication of origin for all foodstuffs, and the mandatory indication of origin for fresh meat and for meat used as an ingredient.

First, regarding voluntary origin indications for all foodstuffs, an Impact Assessment process has been launched which will form the basis of a Commission implementing measure on voluntary labelling, to be delivered by the end of 2013. This exercise is supported by an external study[76]

[75] DG SANCO: *Questions and Answers on the application of the Regulation (EU) No 1169/2011 on the provision of food information to consumers*, 31 January 2013, http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm.

[76] External study on the application of rules on 'voluntary origin' labelling of foods and on the mandatory indication of country of origin or place of provenance of meat used as an ingredient, http://ec.europa.eu/food/food/labellingnutrition/foodlabelling/proposed_legislation_en.htm.

which aims to assess the impact of several policy options on SMEs, allowing the constraints and specificities of the different sectors to be taken into account and to provide advice on possible flexibility in the implementation of the new rules.

Second, regarding the mandatory origin labelling of meat and meat ingredients, a report to examine the need for and feasibility of any such measures is foreseen to be adopted in December 2013. It will also draw on the external study on voluntary labelling and will address the administrative burden, impact on SMEs and competiveness aspects. At the same time, a major study to collect and assess data and information on consumer behaviour in the context of implementing rules on food information in the future has been launched.

At the end of 2006, Regulation 1924/2006 on **'nutrition and health claims made on food'**[77] was adopted, laying down harmonised EU rules for the use of terms such as 'low fat', 'high in fibre' or 'reduces blood cholesterol' and ensuring that such claims are clear, accurate and based on scientific evidence.

Furthermore, this Regulation ensures fair competition and protects innovation in the area of food. It also facilitates the free circulation of foods bearing claims, as any food company will be able to use the same claims on its products everywhere in Europe. In order to ensure the necessary transparency, guidance documents have been elaborated.[78] While the list of permitted nutrition claims is applicable since 2006, the setting of the list of authorised health claims is still on-going. A database[79] and public website have been set up and are attracting significant traffic from all over the world.

In parallel, the issue of nutrient profiles included in the FIC Regulation as an obligatory follow-up measure to the health claims is being considered further.

4.2.2. Revision of the legislation concerning dietetic food (Food for special groups)

In 2007, DG SANCO initiated a consultation about elaborating on two Commission reports on Member States' experiences in the implementation of the Framework Directive on foods for particular nutritional uses ('dietetic foods'). These are foods that are defined as different from 'normal' foods for the general public, since they target particular groups of the population with specific nutritional requirements. Working groups with Member States were organised from 2007 to 2009 to discuss the draft Commission reports and to consider the need for a complete revision of the legislation. In addition, questionnaires were sent to Member States enquiring about their experiences and in order to identify problems. The two reports were published in June 2008.[80]

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[77] *OJ L 404, 30.12.2006, p. 9–25*

[78] European Commission 2007: Guidance on the implementation of regulation 1924/2006 on nutrition and health claims made on food, 14 December 2007.

[79] Health claims database: http://ec.europa.eu/nuhclaims/.

[80] Commission of the European Communities: *Report from the Commission to the European Parliament and the Council on the implementation of Article 9 of Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses*, COM(2008) 393.
Commission of the European Communities: *Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes)*, COM(2008) 392.

The impact assessment, launched in 2008, was supported by an external study of the economic, social and environmental impact of potential policy options, providing an ex-ante assessment of the economic and wider social implications. Focused meetings were organised with the dietetic food industry (IDACE) and the European Consumer Consultative Group (ECCG). The impact assessment was finalised in late 2010.[81]

In June 2011, the Commission adopted a proposal for a new framework Regulation applying to dietetic foods[82]. The European Parliament, Council and Commission agreed on the new rules in November 2012 and the new text was adopted on 12 June2013.[83]

Problems and Objectives

The existing Framework Directive is based on the broad concept of 'foodstuffs for particular nutritional uses', which dates back to 1977. The consultations, reports and IA revealed that, in an evolved market and legal regime, this concept is out of date and creates distortions of trade in the internal market due to uneven interpretation and enforcement across Member States.

Indeed, the evolution of the food market, in which more and more normal foods target specific sub-groups of the population, and the corresponding evolution of the EU legal framework, in which several horizontal measures set specific and more up-to-date rules for these normal foods, bring into question the need to maintain the entire concept of 'foodstuffs for particular nutritional uses'.

In addition, problems have emerged with classifying foods as normal foods or dietetic foods, and the different requirements applicable to normal foods and dietetic foods have led, in turn, to legal uncertainty for operators, conditions of unfair competition and uneven levels of consumer protection in the internal market.

Therefore the Commission's proposal (and the subsequent Regulation) abolishes the concept of food for particular nutritional uses and provides for a framework establishing general provisions only for a limited number of categories of foods that are considered essential for certain vulnerable groups of the population. The proposal (and the subsequent Regulation) also foresees the establishment of a single EU list of certain categories of substances that may be added to the categories of food it covers, consolidating different pre-existing lists.

The proposal (and the subsequent Regulation) pursues the objectives of better regulation by maintaining specific rules for products only where these are necessary to protect vulnerable groups of the population. It also simplifies the current legislation by removing rules that have become

[81] Commission Staff Working Paper *Impact Assessment Accompanying the document* Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes, SEC(2011) 762 final.

[82] *Proposal for a Regulation of the European Parliament and of the Council on food intended for infants and young children and on food for special medical purposes*, COM(2011) 353 final, 2011/0156 (COD).

[83] Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, p. 35–56.

unnecessary or contradictory, and by bringing together the different lists of substances that may be added to these foods.

Next steps

Based on the framework Regulation, specific rules for four different categories of foods (infant formula and follow-on formula, processed cereal-based foods and baby foods, food for special medical purposes and total diet replacements for weight control) have to be adopted by delegated acts. These will transfer existing rules and update them, taking into account recent scientific developments and new requirements requested by the co-legislators.

In addition, rules on the use of the statements 'gluten-free' and 'very low in gluten' will be transferred under the Regulation on the provision of food information to consumers. Under the same Regulation, the Commission will establish rules on the use of statements on the absence of lactose. In the context of adopting these measures, experts from Member States will be consulted, as well as other experts in the field. The co-legislators will have the right to examine the delegated acts.

Finally, the Commission is required to adopt two reports assessing whether it will be necessary to propose specific rules for two categories of foods not covered by the Regulation ('growing up milk' and foods for sportsmen). In the process of drafting the reports, EFSA will be consulted. Consideration is being given to the opportunity to carry out an external study reflecting the market situation for at least some of these products. Relevant stakeholders will be consulted and relevant developments at international level (e.g. the *Codex Alimentarius*) will be considered.

4.2.3. Animal welfare

Within the publication of the communication on the EU strategy for the protection and welfare of animals 2012–2015[84] in 2012, the Commission stated that it will consider the need for a revised EU legislative framework based on a holistic approach to animal welfare legislation. Support was expressed by a resolution of the European Parliament in July 2012.[85]

Problem and objectives

The main problems are the lack of enforcement of EU legislation on animal welfare, as identified by an external evaluation of the EU policy on animal welfare in 2010.[86] EU animal welfare legislation is considerably prescriptive: it does not allow food business operators to obtain similar animal welfare outcomes with more economically viable solutions. The absence of a common methodology to assess compliance for qualitative requirements also poses a problem, since it leaves

[84] *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the European Union Strategy for the Protection and Welfare of Animals 2012–2015*, COM(2012) 6 final/2.

[85] European Parliament 2012: *Report on the European Union Strategy for the Protection and Welfare of Animals 2012–2015* (2012/2043(INI)), Committee on Agriculture and Rural Development (Rapporteur: Marit Paulsen MEP).

[86] Food Policy Evaluation Consortium 2010, *Evaluation of the EU Policy on Animal Welfare and Possible Policy Options for the Future*, Final report, GHK in association with ADAS UK.

open a wide range of interpretations for national or regional authorities. In consequence, enforcement by the competent authorities of Member States and compliance by FBOs does not allow the objectives of the legislation in place to be fully achieved.

Another issue is the lack of incentives for farmers who are proactive in developing good animal welfare practices or anticipating legal deadlines. A suitable instrument in this respect may be offered from within the Rural Development measures of the Common Agriculture Policy (CAP).

Next steps

Further action has to be taken here. As already indicated in the **2012–2015 EU strategy** for the protection and welfare of animals in 2012, the Commission will consider introducing a simplified legislative framework, with a view to reconciling animal welfare principles with the need to simplify and optimise enforcement of existing laws, reduce the administrative burden and valorise welfare standards to enhance EU food industry competitiveness. This will be the subject of an impact assessment expected in 2015.

4.3. Competitiveness

The legislative proposals regarding animal health, plant health, plant reproductive material and official controls were adopted by the Commission on 6 May 2013,[87] *accompanied by a Communication.*[88] *An additional proposal relating to financial aspects, simplifying, streamlining and improving management of the financial expenditure programs of the EU will be adopted at a later stage.*

The objective of the entire package is to strengthen, modernise and streamline the current legal environment in order to ensure a high level of food and feed safety. A special focus of the four underlying impact assessments was on simplification gains, administrative burden reduction and economic impacts, such as on SMEs.

In addition, the feed regime and animal by-products (not for human consumption) are covered in this section, as their primary role is to safeguard food safety while ensuring, as in the recent legislative package, a competitive European food sector.

[87] European Commission: *Proposal for a Regulation on the production and making available on the market of plant reproductive material (plant reproductive material law)*, COM(2013) 262, 6 May 2013.
European Commission: *Proposal for a Regulation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products*, COM(2013) 265, 6 May 2013.
European Commission: *Proposal for a Regulation on animal health*, COM(2013) 260, 6 May 2013.
European Commission: *Proposal for a Regulation on protective measures against pests of plants*, COM(2013) 267, 6 May 2013.

[88] Communication from the Commission to the Council and the European Parliament: *Healthier Animals and Plants and a Safer Agri-Food Chain: A modernised legal framework for a more competitive EU*, COM(2013) 264 final.

4.3.1. Animal Health

A comprehensive evaluation of the Community Animal Health Policy (CAHP) 1995–2004 took place in 2005–2006, including wide-ranging consultation with stakeholders. Based on its results, the Animal Health Strategy 'Prevention is better than cure' was developed (2007) followed by an Action Plan for its implementation (2008).[89] In 2009, an impact assessment began, which was supported by two extensive stakeholder consultations in 2009 and 2010 (covering Member States, sectors relevant to animal health and the general public). The final impact assessment, including the opinion of the IA Board, was published together with the legislative proposal adopted on 6 May 2013.[90]

Problems and objectives

The current EU animal health policy is complex due to the large number of legal acts (over 40 Council or Council and Parliament acts as the basis for around 400 Commission acts). Furthermore, the responsibilities of animal keepers and other stakeholders in preventing and fighting epidemics are not always clear.

In addition, the CAHP evaluation revealed: a lack of objective categorisation and prioritisation of animal disease policy measures; poor co-ordination of animal disease surveillance with various surveillance systems and actors not working together in the most effective ways possible; insufficient harmonisation with agreed international standards (e.g. the World Organisation for Animal Health (OIE)); and an insufficient long-term view of emerging, re-emerging and exotic diseases. Overall, there is an insufficient focus on disease prevention in favour of fighting diseases once they occur. As the EU provides co-financing for Member States both for emergency measures and planned disease prevention and control measures, large outbreaks of disease can cause a great deal of uncertainty in budget planning and distract from the need to prevent diseases in favour of 'putting out fires'.[91] The intra-EU movements of certain animals are not as simple and flexible as they could be, given the lower risk they pose. For example, transport of animals destined for direct slaughter, and transport between certain establishments that can guarantee a higher health status, which pose a lower risk of spreading disease, should have their administrative burden reduced.

The objectives of the intended clearer regulatory structure for animal health in the EU are manifold. The existing legislation, composed of interrelated policy actions (e.g. on intra-EU trade, imports and animal disease control), will be replaced with a single and comprehensive regulatory framework. This will not only lead to easier familiarisation with the rights and obligations of different actors and stakeholders, assisting implementation and lessening administrative burden, but will also encourage the competitiveness and sustainability of the European livestock sector by reducing the occurrence of economically damaging animal diseases. The framework will converge,

[89] Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, *A new Animal Health Strategy for the European Union (2007–2013) where "Prevention is better than cure"*, COM(2007) 539 final.
[90] *Proposal for a Regulation of the European Parliament and of the Council on Animal Health*, COM(2013) 260 final, 2013/0136 (COD).
[91] Council Decision of 25 May 2009 on expenditure in the veterinary field (2009/470/EC), Official Journal of the European Union, L 155/30.

as far as possible, on the international recommendations, standards and guidelines of the OIE and the Codex Alimentarius Commission, the food standard-setting body created by the UN,[92] which is intended to provide a streamlined context for the international trade of animals and their products (e.g. meat and milk) and possibly reduce the number of trade disputes. Another important objective is more coherent and integrated regulation, and cooperation between various electronic information systems and databases: this is intended to reduce the administrative burden for disease notification, trade certification, animal identification and registration.

Next steps

The Commission proposal is subject to the ordinary legislative procedure and has been transmitted to the European Parliament and the Council.

The AHL clearly sets out the overarching principles and objectives which are necessary to achieve further reduction in animal diseases while retaining the EU's economic competiveness. On the other hand, detailed provisions — such as specific disease control measures, identification and registration rules for certain species or specific measures on movements within the EU for particular species or uses — are to be dealt with by means of subsequent delegated or implementing acts. These changes will be informed by the Commission's own inspection reports and from data supplied by the competent authorities of Member States.[93]

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[92] The EU's relationship with the OIE: exchange of letters between the Commission of the European Communities and the Office international des epizooties (2004/C 215/03), Official Journal of the European Union C 215/3, 27 August 2004; Exchange of letters between the Commission of the European Communities and the Office international des epizooties (2004/C 215/04), Official Journal of the European Union C 215/5, 27 August 2004.
Common OIE negotiating positions: http://ec.europa.eu/food/international/organisations/EU_comments_position_papers_en.htm.

[93] Recent EU–third country trade agreements for sanitary and phytosanitary matters: http://ec.europa.eu/food/international/trade/agreements_en.htm.
Added value of the EU budget (animal health, welfare and food safety references on P36) http://ec.europa.eu/budget/library/biblio/documents/fin_fwk1420/working_paper_added_value_EU_budget_SEC-867_en.pdf.
Report on the outcome of the EU co-financed animal disease eradication and monitoring programmes in the MS and the EU (FCEC 2011):
http://ec.europa.eu/food/animal/diseases/eradication/docs/fcec_report_ah_eradication_and_monitoring_programmes.pdf
Annual Reports on the monitoring and testing of ruminants for the presence of Transmissible Spongiform Encephalopathies (TSEs) in the EU.
http://ec.europa.eu/food/food/biosafety/tse_bse/monitoring_annual_reports_en.htm**.**
European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks (elaborated by EFSA in cooperation with ECDC), http://www.efsa.europa.eu/en/efsajournal/doc/2090.pdf.
Annual Report on notifiable diseases of bovine animals and swine (Article 8 of Directive 64/432/EEC), http://ec.europa.eu/food/animal/liveanimals/bovine/intra_trade_en.htm.
Annual report on certain animal diseases that were notified by Member States to the animal disease notification system, http://ec.europa.eu/food/animal/diseases/adns/index_en.htm.
Annual report on surveillance for avian influenza in poultry and wild birds, http://ec.europa.eu/food/animal/diseases/controlmeasures/avian/eu_resp_surveillance_en.htm.

4.3.2. Plant Health

An evaluation of the EU Plant Health regime (2009–2010)[94] revealed the need to strengthen the regime, to better protect EU agriculture, forestry, landscape and public and private green spaces, and modernise it *inter alia* by developing partnerships with the private sector and minimising the administrative burden.

The subsequently launched IA exercise[95] thus focused on establishing a transparent framework regulation and streamlining requirements with linked legislation (e.g. plant reproductive material and official controls). In 2011, a supporting study for the IA focusing on the economic impact of a revised scheme was finalised; a legislative proposal was published as part of the package adopted on 6 May 2013.[96]

Problems and objectives

In the evaluation and during regular stakeholder consultation, the main issues raised for improvement were better risk targeting (prioritization) and more joint EU action to tackle risks of high significance. Given the complexity of the legislation, simplification and improved transparency of the legal text were also considered necessary.

The Commission is strengthening and modernising the EU Plant Health Regime in line with the recommendations of the evaluation. The existing seven individual Directives will be repealed and replaced by one single Regulation.

Apart from ensuring better protection against any influx of new harmful organisms from third countries through harmonised surveillance and outbreak eradication rules, the Commission proposes a further transfer of responsibilities to professional operators who are authorised to issue plant passports. This will allow those food business operators to fully integrate the certification process and the corresponding traceability and information obligations into their usual business practices, which is expected to positively impact the administrative burden.

Next steps

One outcome of the extensive consultation process with stakeholders and Member States is that the private sector will assume more responsibility for plant health, e.g. for traceability and certification for intra-Union movements of plant material requiring a plant passport. This modernisation accommodates requests from the private sector to minimise costs, while increasing the level of safety and harmonising rules for a level playing field.

The Commission proposal for a new plant health regime[97] sets out the overarching principles and objectives which are necessary to achieve better protection against plant pests while retaining the

[94] Evaluation and review of the EU Plant Health Regime, http://ec.europa.eu/food/plant/plant_health_biosafety/rules/index_en.htm.
[95] Roadmap for Impact assessment, http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_002_eu_plant_health_law_en.pdf.
[96] http://ec.europa.eu/dgs/health_consumer/pressroom/animal-plant-health_en.htm.
[97] Proposal for a Regulation of the European Parliament and of the Council on protective measures against pest of plants, COM(2013)267 final of 6.5.2013

EU's economic competiveness. The detailed provisions — such as specific pest survey and eradication measures, and prohibitions and special requirements regarding importing plants and plant products into and their movement within the Union — are to be dealt with by means of subsequent delegated or implementing acts. The Commission proposal is subject to the ordinary legislative procedure and has been transmitted to the European Parliament and the Council.

4.3.3. Plant reproductive materials

An evaluation of the Plant Reproductive Material (PRM) legal framework took place in 2009; it identified the complexity of the legislation and the need to streamline, modernise and harmonise it as the main issues.[98] In 2011–2012, an IA was performed, with public consultations carried out in 2011.[99] A legislative proposal[100] was adopted as part of the package on 6 May 2013.[101]

Objectives

Reflecting the results of the evaluation, the IA included a special focus on increasing flexibility in the legislation to allow for faster reactions to technical and scientific developments. It also attributes more responsibilities to operators in order to reduce the administrative burden and to enhance competitiveness, notably with a view to increased innovation. In addition, the simplification of the legislative framework will help the EU industry to further expand its role as the largest seed exporter in the world. The legislation also reflects better the importance of PRM not only for productivity, but also for food security and safety, the nutritional value of food, the environment, biodiversity and climate change.

Next steps

The creation of a framework law delivering simplification gains faces requests for specific sector-related rulings due to the considerable heterogeneity of the plant reproductive sector. Competitiveness in external markets, a major factor for providing input to conventional, large-scale agriculture, is in certain contradiction with the needs of a highly diverse segment of small operators and civil society organisations active in the preservation of traditional varieties, mostly of vegetables and fruit. These latter stakeholders consider compulsory variety registration to be an undue administrative and financial burden and a factor contributing to the decline in agricultural biodiversity. The Commission proposal itself is subject to the ordinary legislative procedure and has been transmitted to the European Parliament and the Council.

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[98] European Commission, DG SANCO, Final Report 2008: *Evaluation of the Community* acquis *on the marketing of seed and plant propagating material (S&PM)*.
Assignment 5 of the Framework Contract for evaluation and evaluation related services – Lot 3: Food Chain (awarded through tender no 2004/S 243-208899)

[99] Roadmap for Impact assessment:
http://ec.europa.eu/governance/impact/planned_ia/docs/2011_sanco_008_marketing_of_seed_en.pdf.

[100] Proposal for a Regulation of the European Parliament and of the Council on the promotion and making available on the market of plant reproductive material, COM(2013)262 final of 6.5.2013

[101] http://ec.europa.eu/dgs/health_consumer/pressroom/animal-plant-health_en.htm.

4.3.4. Regulation on official controls along the food chain

The current legislative regime has introduced important improvements to the way competent authorities organise and carry out official controls along the food chain, laying the foundations for a more integrated and horizontal approach. However, evidence gathered over the last five years (feedback from the competent authorities of Member States and stakeholders, and DG SANCO's Food Veterinary Office (FVO) audits[102,103,104]) has shown shortcomings stemming from the incomplete implementation/achievement of certain principles/objectives, and from the fact that the integrated approach to official controls is consolidated only partly. With regard to inspection fees, a first external study (2008)[105] developed several policy options, followed by another study (2011),[106] focusing on the impacts of these options. A legislative proposal was adopted as part of the package on 6 May 2013.[107] It is subject to the ordinary legislative procedure and has been transmitted to the European Parliament and the Council.

Problems and objectives

Although Member States ensure a good level of implementation of official controls across the food supply chain,[108] and progress can be measured in the use of the enforcement tools established by the Regulation,[109] shortcomings have been identified due to both the design of the official controls framework and uncertainties as to the availability of sufficient resources to adequately finance official controls. From these problems flow a series of objectives which, when achieved, will: ensure a comprehensive and consistent approach to official controls along the food chain, while allowing for the efficient use of national control resources; reduce the administrative burden and remove it where unnecessary; deliver the benefits of improved transparency; and foster cooperation between Member States to improve official control delivery. With regard to the financing of official controls, the objectives are: to ensure the availability of adequate resources; ensure equity and fairness in the financing of official controls; and improve transparency of the system of financing official controls.

Next steps

The proposal for a revised legislative regime for official controls across the agri-food chain[110] (supported by the Impact Assessment) brings a number of important improvements with the:

[102] Annual reports: http://ec.europa.eu/food/fvo/annualreports/index_en.htm.
[103] Inspection reports: http://ec.europa.eu/food/fvo/ir_search_en.cfm.
[104] Country profiles: http://ec.europa.eu/food/fvo/country_profiles_en.cfm.
[105] Study to assess the fees or charges collected by Member States for official controls 2009: http://ec.europa.eu/food/food/controls/inspection_fees/docs/external_study_en.pdf.
[106] To be published in 2013.
[107] http://ec.europa.eu/dgs/health_consumer/pressroom/animal-plant-health_en.htm.
[108] Multi-Annual Control Plans (MANCP) and reports are available at: https://circa.europa.eu/Public/irc/sanco/Home/main?f=login&referer=http%3A%2F%2Fcirca.europa.eu%2FMembers%2Firc%2Fsanco%2Fcountprof%2Flibrary%3Fcookie%3D1
[109] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

[110] COM(2013)265 final of 6.5.2013

- simplification of the legal framework by removing fragmentation, overlaps and gaps, and therefore differences of interpretation and implementation at national level;
- consistent use of 'risk-based controls';
- systematic and consistent use of administrative cooperation tools and of computerised information systems (e.g. the TRAde Control and Expert System, a trans-European network to monitor trade in animals for FBOs and MS CA globally);
- repeal of unnecessary administrative requirements, including for third-country imports, whereby a single Border Control Post will replace the current three sector-specific control points, uniform rules for all commodities, and a Common Health Entry Document, replacing the current sector specific documents.

As regards the financing of official controls, revisions will achieve:

- steady and consistent funding of the work of the competent authorities through full recovery of the costs of performing official controls based on common principles;
- fairness to all operators through a common approach across all sectors of the food chain; Member States have to fully exempt micro-enterprises from fees;
- greater compliance driven by the recognition of good performance leading to a lower frequency of official controls;
- a drive towards more efficient and effective controls regimes through high levels of transparency by the publication of enforcement activities of the competent authorities of Member States.

4.3.5. Feed regime

In its *White Paper on Food Safety*,[111] the Commission announced its intention to modernise and simplify the existing legislation concerning feed additives. The evaluation of the regime of feed additives, established in 1970, identified the need to establish a state-of-the-art procedure for authorising new feed additives (innovation) and the phasing out of antibiotic growth promoters, which were both addressed in a Regulation in 2003.[112]

An evaluation of feed marketing rules (manufacture, labelling, and use) was undertaken in 2004,[113] including consultations with stakeholders. Based on its result, an impact assessment started in 2006, again with extensive consultation. The regulation was adopted in 2009.[114]

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[111] http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf.

[112] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, Official Journal of the European Union L 268/29, 18 October 2003.

[113] http://ec.europa.eu/food/consultations/study_civic_consulting.pdf.

[114] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, Official Journal of the European Union L 229/1, 1 September 2009: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:229:0001:0028:EN:PDF.

In one small remaining sector, the legislation regarding medicated feed was addressed beginning in 2010 by a comprehensive impact assessment exercise,[115] based on an external study,[116] in close coordination with the parallel on-going revision of the veterinary medicinal products (VMPs) legislation, thus ensuring a holistic approach. Together with VMP legislation, access of livestock farmers to medicated feedstuffs produced according to safe standards and at competitive prices is being addressed. Furthermore, barriers to innovation should be removed, e.g. to also allow medicated feed for pets.

The Commission plans to table a legislative proposal regarding medicated feed, closely linked to the revised framework legislation on VMPs, in the second half of 2013.

Problems and objectives

All three reviews identified a similar set of problems and underlying drivers, including: an outdated and over-complex legislative framework which may lead to differences in implementation across Member States, thus hampering the single market and increasing enforcement and compliance costs for public and private actors; non-transparent and over-exhaustive approval procedures for new products affecting market access and the speed of innovation; and requirements and obligations for compliance limiting the choice of inputs for farmers/producers and thus decreasing the competitiveness of the sector.

The objective of the proposal regarding feed marketing was to introduce modernised and simplified labelling rules aiming to improve market transparency and accountability across the supply chain. At the same time, market access for new products should be facilitated, thus encouraging innovation, while fostering cross-border trade through harmonisation of Member State legislation at EU level.

Next steps

The EU action for both feed marketing and feed additives resulted in the legal framework being modernised, which allows for faster commercialisation of innovative products, and internationally competitive standards for the approval of feed additives guaranteeing marketing based on one single application, not only throughout the EU, but also in many third countries. The removal of marketing barriers (such as national labelling requirements for compound feed) within the EU has led to the creation of a genuine single market in the feed industry, which again improves the competitiveness of EU livestock farming. Another concrete improvement for the sector was the removal of the burdensome pre-market authorisation procedure for 'bio-proteins' (specific feed materials); this reduced the administrative burden and increased the availability of scarce feed materials without compromising food safety. Finally, the modern marketing rules limit the potential to mislead regarding labelling, including via the internet.

The only remaining non-harmonised sector is medicated feed, which will be the subject of a proposal in 2013. Much emphasis is placed on the interface between medicated feed and veterinary medicines, which are also being revised. The new framework for medicated feed should allow this

[115] Roadmap: http://ec.europa.eu/governance/impact/planned_ia/docs/2010_sanco_055_medicated_feed_en.pdf.
[116] http://ec.europa.eu/food/food/animalnutrition/labelling/medicated_feed_report_20100224.pdf.

area to benefit from the rules already applicable to the EU feed industry rather than the current system of disparate national approvals and markets.

4.3.6. Animal by-Products (not intended for human consumption)

A complete review of the legislation regarding animal by-products was performed in recent years, replacing previous legislation with new, improved basic rules (in 2009); this process was completed in early 2011 with the publication of a single implementing Regulation.[117]

This was achieved following extensive consultations with Member States and stakeholders, based on a report to the European Parliament and the Council (2005). The new proposal was accompanied by an impact assessment (2008),[118] which specifically took on board experiences with the application of this legislation.

Results and objectives

The new legal framework establishes the basic principles for categorising animal by-products according to the risk they pose. Subsequently, it determines how they should be produced, collected, transported, stored, processed, used and disposed of, and which official controls the competent authorities of Member States have to carry out in order to ensure compliance. It also lays down the conditions for imports from third countries.

The Implementing Regulation laying down more specific requirements and technical standards for animal by-products has been prepared on the basis of extensive consultation with operators, interest groups, experts from Member States, major trading partners of the EU and in close contact with the European Parliament.

The main improvements are less burdensome rules concerning finished products produced on the basis of animal by-products and regarding official controls over premises, better traceability of imported products, and the implementation of a more risk-based approach to the categorisation of products in order to allow for a greater valorisation of materials under safe conditions, particularly for innovative uses and for generating energy, while maintaining safeguards proportionate to the risk posed by such materials.

In order to simplify existing legislation and to reduce the administrative burden, the new implementing rules consolidate approximately 30 separate measures into a single, more coherent legal act. An end point in the manufacturing chain has been fixed for processed and packaged pet food, biodiesel, tanned hides and skins, and for a number of other products. Since these products

[117] Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, Official Journal of the European Union L 54/1, 26 February 2011.

[118] Commission Staff Working Document *Impact Assessment accompanying the Draft proposal for a Regulation of the European Parliament and of the Council laying down health rules as regards animal by-products not intended for human consumption (Animal by-products Regulation)*, SEC(2008) 1994.

have been subject to treatment which ensures that the health risks are mitigated, it is justified to exempt them from veterinary controls. As a result, operators handling or selling such products do not have to be approved or registered by the competent authorities. This should allow controls to focus on major health risks, without bringing the current high level of protection of public and animal health into question.

The administrative burden for economic operators producing medicines and diagnostics from animal by-products has also been reduced. This facilitates the use of blood fractions, enzymes and tissues from animals in products which are used in human and veterinary medicine. Moreover, the new rules facilitate official controls of laboratories at processing plants and biogas plants in which animal by-products are handled. The new traceability rules for animal by-products make it easier to follow materials coming from food production and destined for non-food uses.

Next steps

Currently, the implementing rules for the legislation are being further elaborated. These focus on the issue of using animal by-products for energy, notably in combustion for use as fuel and regarding imports of rendered fats for biodiesel and renewable fuel production. These efforts are undertaken in close cooperation with other Commission services. Also, Member States and stakeholders are regularly consulted, the latter through the Advisory Group for the Food Chain.

Recently, the use of processed animal protein (PAP) in livestock feeding has re-entered the debate in the context of the revision of the current total feed ban provisions. These have been in place for over 10 years. They can be considered to be disproportionate today, as the scientific opinion indicates that the risk of BSE transmission between non-ruminant animals is negligible, provided that intra-species recycling (cannibalism) is prevented. Due to the considerable size of the animal production sector in the EU, a review of the current feeding restrictions will reduce dependency on imported, and currently expensive, feed materials of plant origin, and produce economic benefits for EU farmers.

A Commission Regulation lifting the ban on pig and poultry PAP in feed for aquaculture animals entered into force on 1 June 2013, improving overall sustainability in the aquaculture sector, as those PAPs could be a valuable substitute to fishmeal, which is currently used for feeding fish and which is a scarce resource. The reauthorisation of pig and poultry PAP for pigs and poultry will be discussed further in 2013.

4.4. Innovation

The legislative acts listed within this category are closely linked to the three components of risk analysis, notably risk management. By bringing together both EFSA scientific opinions and pre-market authorisation, they determine the market access of innovative products.

4.4.1. General Food Law – rules on EFSA fees

A Roadmap providing for the launch of an impact assessment was published in November 2011,[119] reflecting the requirement of Regulation (EC) No 178/2002 to verify the possibility of introducing fees with regard to the processing of authorisation dossiers presented to the European Food Safety Authority. Related aspects aimed at improving the efficiency of the functioning of EFSA were also included.

In September 2012, the external evaluation of EFSA's organisation and functioning (foreseen in Article 61 of Regulation 178/2002) was published.[120]

The impact assessment on the possibility to establish fees for EFSA was published in February 2013 as a Commission Staff Working Document.[121]

Problems and objectives

The external evaluation gave a positive opinion of EFSA overall, but put forward some recommendations to further improve its performance. As a follow-up to the external evaluation, the EFSA Management Board issued its recommendations aimed at ensuring the long-term sustainability of EFSA's operations (in particular in relation to new modalities of sharing work between experts of the Panels, EFSA's staff and national scientific bodies), enhancing transparency and EU risk assessment capacity, and strengthening the clarity and accessibility of communications from EFSA.[122]

Next steps

The recommendations of the EFSA Management Board are focused on an improved internal organisation of EFSA; they will be implemented in the next EFSA management plans (starting in 2013). Stakeholders, EU institutions and Member States have been consulted in order to gather views and suggestions.

According to the General Food Law, every six years EFSA shall undergo an independent external evaluation of its achievements, working practices and its impact, taking into account the views of the stakeholders, and eventually issuing recommendations. The next evaluation will be commissioned in 2017.

4.4.2. Biotechnology

Several highly complex matters are covered within the legal framework for biotechnology, for which certain adaptations are reflected upon within the existing set of rules. These are now being

[119] http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2012_en.htm#SANCO.
[120] http://www.efsa.europa.eu/en/keydocs/docs/efsafinalreport.pdf.
[121] European Commission 2013: *Impact Assessment on the Revision of Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety on the establishment of fees for EFSA*, SWD(2013) 45 final.
[122] http://www.efsa.europa.eu/en/events/event/130313.htm

implemented step by step, from the low-level presence (LLP) of genetically-modified organisms (GMOs) to GMO cultivation. In this context, studies and consultation are being carried out which aim to address the relevant health and safety, socio-economic and consumer perspectives.

Problems and objectives

The evaluation of the GMO legislation issued in October 2011[123] concluded that the main objectives of the legislation are broadly supported by stakeholders and Member States, but that some adjustments are necessary to better implement the existing legislation. Also, reflecting the findings of the report, the Commission has launched several initiatives to address existing gaps and deficits, some of them prior to the publication of the report.

Among these initiatives is the Commission package on GMO cultivation adopted in July 2010,[124] which responds to the needs of Member States. The package includes recommendations on the co-existence of GM and non-GM plants that grant more flexibility to Member States, allowing them to take into account their specific local, regional and national conditions and requirements when adopting their respective national legislation. The other element of the package — a proposal for a regulation allowing Member States to restrict or prohibit the cultivation of GMOs in their territory — is currently under discussion in the Council and the Parliament.

The Commission also advanced on tackling the technical problem of the LLP of unauthorised GMOs in imported feed products with new legal rules[125] which entered into force in July 2011. Furthermore, the Commission is currently monitoring its implementation. In April 2011, the Commission published a report on the socio-economic implications of GMO cultivation,[126] based on contributions from Member States as requested by the 2008 Environment Council Conclusions. A conference was organised in October 2011 to discuss the findings of this study. A European GMO Socio-Economic Bureau (ESEB)[127] was set up in January 2013 to organise and facilitate the exchange of technical and scientific information regarding the socio-economic implications of the cultivation and use of GMOs between Member States and the Commission. The ESEB will develop consensus documents that will enable a science-based assessment of these impacts in Member States and across the EU.

Next steps

In early 2013, the Commission adopted a Regulation[128] on requirements for companies submitting applications for the authorisation of new GMOs for food and feed. The key objectives of the Regulation are to reinforce and improve the authorisation process for genetically modified food and

[123] Evaluation of the legislative framework on GMO cultivation and of GM food and feed (SANCO 2011): http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm.
[124] New approach to GMO cultivation: http://ec.europa.eu/food/food/biotechnology/index_en.htm.
[125] Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired, Official Journal of the European Union L 166/9, 25 June 2011.
[126] Report on the socio-economic implications of GMO cultivation (SANCO 2011): http://ec.europa.eu/food/plant/gmo/reports_studies/index_en.htm.
[127] http://ec.europa.eu/dgs/jrc/index.cfm?id=1410&dt_code=NWS&obj_id=15030&ori=RSS.
[128] Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired Official Journal of the European Union L 166/9, 25 June 2011.

feed, to clarify the requirements for submitting a request, and to have these requirements formally endorsed by the Member States.

The Commission is also revising the guidelines on environmental risk assessment to make them more detailed and precise, and is already discussing them with Member States and stakeholders. The final document will have legal status and will be endorsed by Member States. This is an important step towards a better implementation of the strict environmental risk assessment requirements of the GMO legislation.

In order to ensure the broadest possible sound scientific base, the Commission's Joint Research Centre (JRC) is also working on this issue by providing data and scientific evidence, as illustrated by the organisation of a workshop on the 'Market for non-GM identity preserved crops and derived products' in June 2012.[129]

Consumer choice and perception regarding GMOs is also addressed by commissioning an external study on GMO-free labelling.[130] The aim of this study is to map existing and developing GMO-free labels in the EU, and to assess the need for harmonisation in this field. The study should be published early 2014.

4.4.3. Novel food and cloning

Between 2002 and 2006, stakeholder consultations (2002), a Commission discussion paper and an evaluation identified the need to update the existing regulatory act on novel food. An impact assessment, including a public consultation (2006), was finalised in 2008.[131] The proposal on the revision of Novel Food Regulation, which in practice covers newly developed innovative foods (since 2004 genetically-modified foods are dealt with separately), was transmitted to the European Parliament and the Council in January 2008. The main issue addressed the assessment and authorisation procedures, streamlining the rules and imposing time limits. In order to support innovation, an applicant-linked authorisation for really innovative food was introduced.

Problems and objectives

The main objective remains to ensure that innovative products can be developed and commercialised on the single market under safe conditions.

With regard to novel foods, a centralized authorisation procedure based on individual EFSA risk assessments should facilitate access to the market for innovative products. In general, generic authorisations should be granted instead of applicant-linked authorisations. Such individual authorisations will only be granted for really innovative foods for a period of five years. A simplified procedure for the placing traditional food from third countries on the market in the EU will also be introduced.

[129] Proceedings of an international workshop on the socioeconomic impacts of genetically modified crops co-organised by JRC-IPTS and FAO: http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=5019.
[130] Study on GMO free labelling: http://www.gm-free.eu/.
[131] Commission Staff Working Document *Draft report on impact assessment for a regulation replacing regulation (EC) No 258/97 on novel foods and novel food ingredients*, SEC(2008) 12.

With regard to cloning, the Commission has only recently engaged in an impact assessment on the 'use of cloning for food production' in order to publish a separate legislative proposal from the Novel Food Regulation on this issue.[132] The impact assessment is to cover all issues linked to cloning for food production, namely: the use of the cloning technique, the use of clones, of their reproductive materials (semen, embryo and ova), of their progeny and of their food. Its scope covers all farm species it is possible to clone: cattle, pigs, sheep and goats, and horses. Cloning of animals for research purposes, for producing medicinal products, for preserving endangered species or for sport purposes are excluded.

Also this exercise comprises a public (online) consultation, an assessment of the administrative burden and a specific SME test. The most recent EFSA statements in 2012, as well as previous statements and opinions,[133] are also being used to assess impacts on animal health and welfare and food safety. Information from two Eurobarometers from 2008 (Europeans' attitudes towards animal cloning)[134] and 2010 (Biotechnology)[135] have been also used.

Another major aspect is the economic and social impacts, including on third-country partners, of a possible suspension of the cloning technique, and the imposition of traceability and labelling requirements. In order to allow for an in-depth assessment, including the performance of competiveness proofing, an external study of the economic and environmental impact and feasibility aspects has been commissioned[136] and the JRC has provided a supporting research report[137] on the specific impact on trade flows of the possible policy options considered in the impact assessment.

Next steps

A legislative proposal on novel food based on the outcome of the conciliation procedure will be adopted in parallel to a proposal on the use of the cloning technique for food production. Both proposals are expected at the end of 2013.

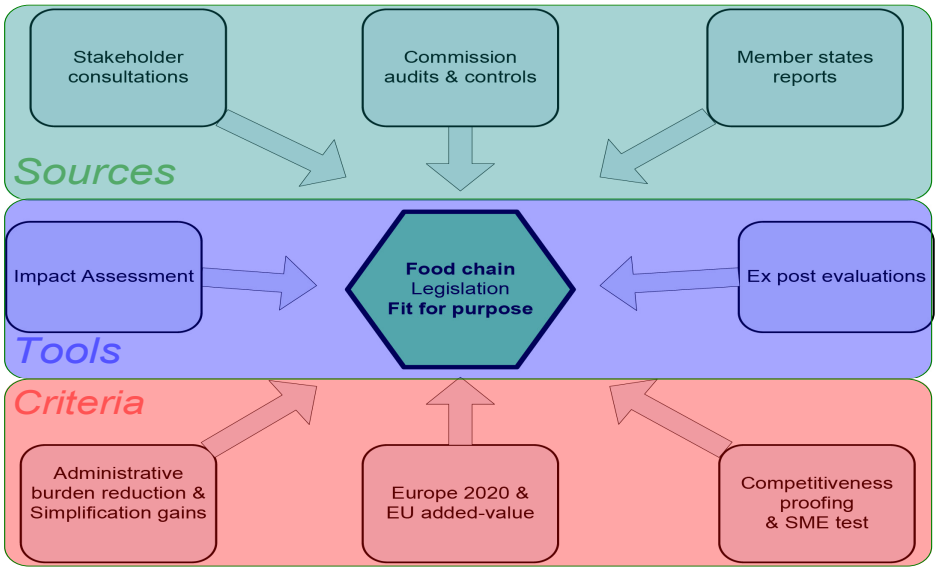
[132] Cloning roadmap:
http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_007_use_of_cloning_technique_for_food_production_en.pdf.
[133] EFSA Food safety, animal health and welfare and environmental impact of animals derived from cloning by SNCT and their offspring and product obtained from those animals (Opinion and Statements):
http://www.efsa.europa.eu/en/efsajournal/doc/767.pdf; http://www.efsa.europa.eu/en/efsajournal/doc/319r.pdf;
http://www.efsa.europa.eu/en/efsajournal/doc/1784.pdf; http://www.efsa.europa.eu/en/efsajournal/doc/2794.pdf.
[134] Eurobarometer *Europeans' attitudes towards animal cloning*, October 2008:
http://ec.europa.eu/food/food/resources/docs/eurobarometer_cloning_en.pdf.
[135] Special Eurobarometer Biotechnology October 2010:
http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf.
[136] ICF GHK 2012: *Impact in the EU and third countries of EU measures on animal cloning for food production*, 2012.
[137] JRC 2012: Contribution to the economic impact assessment of policy options to regulate animal cloning for food production with an economic simulation model, 2012, JRC Scientific report EUR 25856 Publication Office of the European Union; 2013 N° JRC 79995.

5. CONCLUSIONS AND PERSPECTIVE

This Staff Working document delivers an overview of the state of play of EU food chain policy, comprising 16 main legislative acts classified according to four objectives: food safety, consumer choice, competiveness and innovation. At the same time, the entire legislative framework is assessed according to the six main smart regulation tools: reducing the administrative burden, simplification, impacts on SMEs, public health, and consumer welfare and evaluation. This overview demonstrates that DG SANCO is drawing on the full range of smart regulation principles and tools to assess and, if necessary, revise the relevant legislation.

These tools notably include all relevant information sources, both internal — stemming from the Commission's own reports — and external studies; the main tools of policy learning and design, impact assessments and evaluations, as well as the actual smart regulation principles, as criteria for assessment, including EU added value, reducing the administrative burden and competiveness proofing.

Graph 7: Smart regulation tools in the food chain (authors' compilation)



In line with the initial objectives of the fitness check, this Staff Working Document on a comprehensive fitness check throughout the entire body of the relevant legislation allowed some general trends and problems to be identified, which appear more horizontally, complicating or influencing the proper functioning and delivery of the regulation. Some of these problems seem to have a more generic character, and their identification allows for systematic checking during reviews of existing legislation or in preparation of new legislation. Recent legislative proposals from DG SANCO therefore have already taken this into account, and the proposed legislation aims to avoid such problems whenever feasible and possible. The main problems identified were as follows:

1. Overarching, and often **unnecessary complexity** of the whole legal framework. This is mostly caused by the complexity of food-related business (see Figure 2) and by long-term development of the legislation (which has been occurring since the 1960s). This problem can be addressed only by reframing the legislation as a whole, which was attempted already in several areas (ABP, animal health, plant reproductive material, etc.).
2. **Duplication and overlaps**, usually caused by independent development of particular pieces of legislation. Addressing individual problems led in the past, and still often leads, to repetition of the approaches used already in similar cases, resulting in a legal framework with several very similar regulations despite their different subjects. This problem can be avoided by the creation of framework approaches, in which one approach is applicable to any of the relevant cases, including cases which may arise in the future. As documented in this fitness check, these problems were identified in areas such as animal health and plant health, and new proposals reflected this as appropriate.
3. **Inconsistencies** in approaches, where for similar needs there are different solutions in individual regulations. Typically, that was the case with official controls, where the legal background was defined in sector legislation and consequently differed in approach. Inconsistent legislation makes it difficult to allocate resources more efficiently and make decisions based purely on real risks and needs. Another type of inconsistency was identified in the lack of a common authorisation procedure for market access of innovative products (including novel foods, GMOs, food additives and food contact materials). As a result, in the preparation of new legislative proposals, a whole family of regulations needs to be checked and any new proposal should avoid such situations. This is reflected e.g. in a new proposal on official controls, in which all types of control within animal and plant health and plant reproductive material have been placed under the same umbrella approach.
4. **Absence of some important elements in legislation**: Typically, this was the case of dealing with food fraud, which was 'left' to other legislation (criminal law, fraud, etc.) implemented by other official bodies (such as the police). Analysis of the situation and lessons learned from the recent food scandals showed clearly that effectively dealing with a problem is impossible without the participation of official authorities in the food sector, which are only capable of providing the necessary information flow to enforcement authorities. This area needs further exploration. If a need was clearly identified, it was reflected in a proposal — as in the case of official controls.
5. This fitness check shows clearly that a large part of the problems within the sector is related to difficulties in **interpretation and implementation** of the legal framework, often more than to the legal text itself. Existing flexibilities of the legal framework are therefore not used and problems may persist, despite the fact that the legal framework allows for the solution. The problem can be addressed in several manners: in principle it can be addressed by direct provision in the regulation, or by secondary legislation (delegated/implementing acts), or by guidance and a harmonised approach to interpretation. While solutions using a legislative approach may offer better legal certainty, there are significant trade-offs in terms of the flexibility of the system when it comes to developments in the particular area — which are often rapid and the average timing for amendments by the same procedure has also to be taken into account. In many cases it appears appropriate to start with official guidance instead, and to only use the legal approach if this does not deliver results. This may also contribute to a more sustainable development of the legal framework and avoid unnecessary complexity as mentioned above.

Therefore, this Staff Working Document identifies the next steps which will take place within the context of the Regulatory Fitness and Performance Programme (REFIT).[138] The mapping matrix identifies the four groups of the legislation linked to one of the main objectives. It shows the state of play in the policy cycle and makes reference to specific issues linked to implementation. Also, cross-DG aspects concerning other Commission services with a special focus on the regulatory burden and simplification aspects are included.

This comprehensive matrix of all 16 policy areas and all three criteria is provided in Annex 3.

Drawing from this mapping exercise, indications are that the General Food Law[139] is a potential candidate for the REFIT evaluation. It encompasses the entire food chain, based on the 'from farm to fork' principle. This basic regulatory framework of European food policy, notably its general principles and requirements, could be subject to such an in-depth evaluation. The Rapid Alert System for Food and Feed (RASFF) is an important tool for food safety in Europe and could also be part of a wider evaluation.

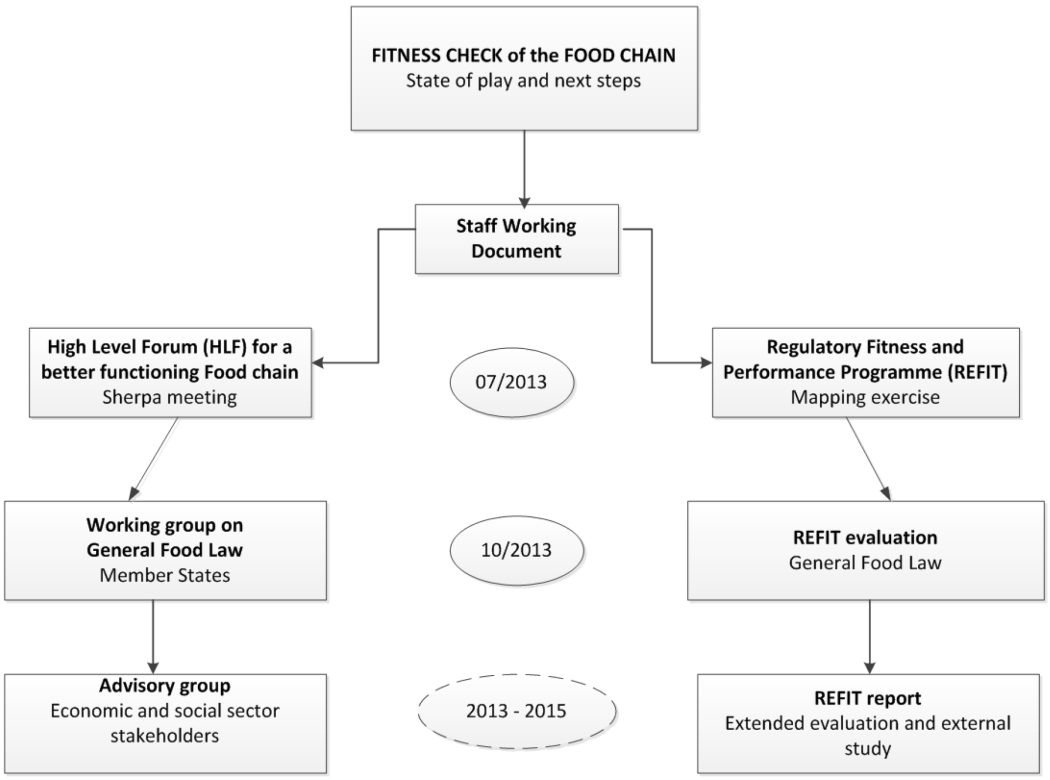
The REFIT evaluation focuses on potential simplification and regulatory cost reductions, taking into account the administrative burden, but also the impact on cost competitiveness, capacity for innovation and international competitiveness, while ensuring consumer choice and public health and safety. Issues to be considered for the evaluation include the full scope of the legal act, the application of the basic principles and the achievement of its objectives, taking into account public and private stakeholders.
The exercise will be further developed by an intra-service steering group comprising all relevant Commission services, as outlined in the Commission Communication.[140] It will be supported by DG SANCO's network of food chain economics, which brings together 20 units across the entire Directorate-General, coordinated by the Director for the safety of the food chain.

In addition, this exercise will be subject to an extensive and continuous consultation process. The main tools therein will be the two regular platforms which bring together all competent Commission services with the stakeholders in the food chain: the Standing Committee on the Food Chain and Animal Health (SCoFCAH) with its weekly meetings allowing for a regular exchange of information and experiences, dissemination of information, and also collection of data from Member States. The Advisory Group on the Food Chain and Animal and Plant Health, with stakeholders from the economic and social sectors, meets twice a year in plenary sessions and has around 15 Working Group meetings per year. Again, it allows for a continuous and interactive discussion and opinion exchange, and is thus the best placed consultation mechanism. It can and will be complemented by targeted surveys, possibly using the EEN to focus on the concerns of SMEs, where appropriate. In addition, an internet-based public consultation will be performed for a minimum period of three months.

[138] Communication *EU Regulatory Fitness*, COM(2012) 746 final.
[139] Regulation (EC) No 178/2002 of the European Parliament and the Council of 28January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (General Food Law), OJ L 031, 1 February 2002.
[140] Communication *EU Regulatory Fitness*, COM(2012) 746 final.

Other platforms include the High Level Forum for a Better Functioning Food Supply Chain for the consultation of both public and private stakeholders, and the High Level Group on Nutrition and Physical Activity, which again reunites Member States and Commission services as well as the European Consumer Consultative Group (ECCG).

Figure 8: Flowchart of the next steps in the REFIT exercise in the food chain (authors' compilation)



In addition, DG SANCO has launched a **Foresight project** with the title 'Delivering on EU Food Safety and Nutrition in 2050: Scenarios of future change and policy responses'. It comprises a scoping study which was launched at the beginning of 2013 and will also include workshops with experts, stakeholders and competent Commission services under the chairmanship of DG SANCO.

As part of the **European Commission's permanent commitment** to the principles of smart regulation, an update of this working paper will be provided in due time. It will draw on feedback from private and public stakeholders as part of the permanent consultation process, and equally, from the results of further use of smart regulation tools, specifically within the Directorate-General for Health and Consumers policy cycle in the food chain.

ANNEX 1: GLOSSARY

ABP	Animal by-products
ABR	Administrative burden reduction
AGRI	DG Agriculture and Rural development
BTSF	Better Training for Safer Food
CA	Competent authority
CAP	Common Agriculture Policy
CC	Cross compliance
DG ENTR	DG Enterprise and Industry
DG MARKT	DG Internal Market and Services
DG SANCO	DG Health and Consumers
EEN	Enterprise Europe Network
EFSA	European Food Safety Authority
FBO	Food business operator
FCM	Food contact materials
FIC	Food information for consumers
FVO	Food and Veterinary Office, Grange IE
HACCP	Hazard Analysis and Critical Control Points
HLF food chain	High Level Forum for a Better Functioning Food Supply Chain 2010–2014
HLG Administrative burden	High Level Group of Independent Stakeholders on Administrative Burdens (the 'Stoiber Group')
IA	Impact assessment
ISSG	Inter-service Steering Group
MFF	Multi-annual Financial Framework
MS	Member State
OCR	Official controls regulation for food and feed
PHR	Plant Health Regime
PPP	Plant protection products
PRM	Plant reproductive materials
RASFF	Rapid Alert System for Food and Feed
REFIT	Regulatory Fitness and Performance programme
SG	Secretariat-General
SME	Small and medium-sized enterprises
TC	Third country
WHO	World Health Organisation

ANNEX 2: CONSULTATION WITH EXTERNAL AND INTERNAL PARTNERS IN THE FOOD CHAIN

DG SANCO uses its close contact with the competent authorities of Member States in its regular meetings as well as the social and economic sectors to maintain a continuous and non-confrontational dialogue on problems encountered in the implementation of legislation, and also to gather data and information across the food chain for the design of policies.

Member States: Representatives are consulted in weekly meetings of the Standing Committee of the Food Chain and Animal Health (SCoFCAH) and monthly meetings of the Standing Committee on Plant Health (SCPH), the Commission also attends the regular meetings of Chief Veterinary Officers (CVO), Chief Plant Health Officers (COPHs) and of the heads of food agencies.

Economics and Social sector: The Advisory Group on the Food Chain and Animal and Plant Health Groups (which currently has 45 members) meets twice a year in plenary sessions and has around 15 Working Group meetings per year. Members include farmers (COPA-COGECA), industry (FDE), retail (Eurocommerce), trade (CELCAA), consumers (BEUC), health (EPHA) and other social interest organisations (Eurogroup for Animals)

The Animal Health Advisory Committee (AHAC), which is a permanent Working Group of the aforementioned Advisory Group, has three to four meetings per year with the relevant stakeholders. Further meetings with EU stakeholders on plant health as well as on official controls along the food chain currently take place on an ad hoc basis.

Broad consultative platforms: The High Level Forum (HLF) for a Better Functioning of the Food Supply Chain, which brings together Commission services (DGs SANCO, ENTR, MARKT and AGRI), some representatives of the economic sector, several Member States, as well as some non-governmental organisations. The HLF meets once a year and its work is supported by regular sherpa group meetings for the period 2013–2014.

Sources of information and data: By means of reports and audits from the Food and Veterinary Office (FVO), import control data from border inspections (BIP), Multi-annual National Controls Plans (MANCP), and national annual reports on the results of official controls and several annual reports from Member States on specific issues, DG SANCO has a profound insight into the actual implementation of EU legislation and policies in Member States. The same is true for third countries where such information helps to provide an insight into the level of equivalence. Also, data on official controls of imported animals and their products are available in TRACES,[141] which is used by all Member States to document their import controls and results. Data from EFSA on food consumption, the incidence and prevalence of biological risk, contaminants, residues and emerging risks are also available.

The **training and advice programme** (Better Training for Safer Food, BTSF) provides insight into the daily practice in Member States and third countries, thereby helping to identify weaknesses and strengths. In addition, for third countries it identifies the gaps that need to be addressed to facilitate market access through regulatory convergence.

[141] The EU system managed by DG SANCO to dispatch information set out in veterinary certificates accompanying animal and animal products traded within the EU and imported from third countries.

ANNEX 3: MAPPING

	Policy cycle Current stage (identification, adoption, implementation, evaluation)	**Implementation** Infringements, stakeholders complaints, burdens, activities	**Cross-DG aspects** Issues on which other DGs are consulted
Safety			
Hygiene package	Identification: impact assessment is ongoing, proposal expected in early 2014	Use of flexibility by MS CA through non-legislative tools for enhancing the competitiveness of the sector across the EU in line with EU safety standards	Impact on FBOs, notably SMEs, as a focus point of on-going assessment (DG ENTR)
Plant protection products (PPPs)	Implementation of framework regulation ongoing since 2011, Sustainable Use Directive (SUD) entry into force in 2014	Mutual recognition, database of authorisations for MS and operators; IPM in Member States; platform for supporting minor use	Link to CAP (DG AGRI) for integrated pest management (IPM)
Food contact materials (FCM)	Implementation since 2011, identification of possible extension to other specific materials assessed	Establishing a single reference point for market access	IA to be launched, including SME test and competitiveness proofing (DG ENTR)
Food improvement agents (food additives)	Implementation of framework regulation since 2011, adoption of implementing rules ongoing	Single and transparent authorisation procedure; practical guidance for applicants further developed (Standard Operating Procedure);	
Consumer choice			
Food information for Consumers (FIC) COOL	Implementation since entry into force in 2012 Implementing rules on Country Of Origin Labelling, IA launched 2012	Monitoring of implementation in regular meetings with stakeholders, provision of Q&A in preparation	IA on implementing measures to be launched, including SME test and competitiveness proofing (DG ENTR)
Health claims and nutrient profiles	Implementation of health claims ongoing since 2012	Monitoring of implementation on-going (dedicated website) to examine if a level playing field exists across all sectors and actor functions	-
Dietetic food (Food for special groups)	New simplified framework regulation adopted in June 2013	Specific request from the EP to prepare guidelines for implementation of the legislation by SMEs	-
Animal welfare	Possible proposal for a simplified legislative framework will be the subject of an impact assessment in 2015.	Monitoring the implementation of existing legislation by Member States in order to ensure a harmonised approach and joint standards across sectors	-

Competitiveness			
Animal Health Law	Commission proposal adopted on 6 May2013	Facilitating intra- and extra-EU trade; reducing risk of disease outbreaks; simplification of legal framework	More effective and fair cost and responsibility sharing in case of animal disease outbreaks (DG AGRI)
Plant Health Regime	Commission proposal adopted on 6 May 2013	Simplification of legal structure, incentivizing prevention while fostering competiveness	Integrative approach also ensuring complementarity with the Invasive Alien Species policy (DG ENV)
Plant reproductive material	Commission proposal adopted on 6 May 2013	Allowing innovation market access through more diversity and flexibility for seed registration and marketing	Biodiversity (DG ENV), access to genetic material (DG AGRI)
Official Controls of Food and Feed	Commission proposal adopted on 6 May 2013	Reducing the administrative burden by abolishing information obligations, risk-based approach along the chain, covering all actors	Revise and streamline Member States reporting obligations thus reducing administrative burden (DG ENTR)
Feed regime Medicated feeds Veterinary medicinal products	Implementation of simplified legislative framework since 2003 and 2009 Identification: Impact assessment is on-going, proposal expected in 2013	Facilitate implementation of market access (authorisation) and faster market access for new products	IA ongoing, including economic impacts (DG ENTR) and availability of inputs (DG AGRI)
Animal by-products (ABPs)	Implementation of a simplified legislative framework since 2011	Constant updates of implementing rules reflecting fast technological change and innovation in the sector	
Innovation			
General Food Law (incl. EFSA fees)	Implementation (including RASFF) since 2002 Next EFSA evaluation in 2017	EFSA Management Board recommendations for improved internal organisation implemented since 2013	Regular consultations in the context of risk management
Biotechnology	Evaluation finalised in 2011, specific legislation under adoption (2010, 2011 and 2013)	Consultations, assessment (EFSA), external studies, research on-going	Cooperation with EFSA and JRC on scientific evidence base
Novel Food Cloning	Adoption of revised proposal for Novel food planned by the end of 2013; Cloning, study and Impact assessment prepared, proposal expected by the end of 2013.	Assessing tools for pre-market authorisation, traceability and labelling; Special emphasis on SME impact	IA performed, including SME test and competitiveness proofing (DG ENTR) with scientific evidence from EFSA and research support from JRC