REFIT Fitness Check of Regulation (EC) No 178/2002

Directorate General/Unit: DG SANCO/Directorate E, unit E4

 Planned start date:
 03/2014

 Planned completion date:
 12/2015

 Date/version:
 01/06/2014/V-09

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1. Introduction

The Commission's 2010 Communication on Smart Regulation¹ introduced '*Fitness checks*' as comprehensive policy evaluations assessing whether the regulatory framework for an entire policy sector is fit for purpose. The Fitness Checks' aim is to identify excessive regulatory burdens, overlaps, gaps, inconsistencies and/or obsolete measures which may have appeared over time, and to help to identify the cumulative impact of legislation.

Between November 2011 and July 2013, the Directorate-General Health and Consumers (DG SANCO) carried out one of the four Pilot projects '*Fitness check of the Food chain: State-of-play and next steps*¹².

In December 2012, the Commission's Communication on Regulatory Fitness³ stipulated that Union legislation *'is essential to ... set the conditions for smart, sustainable and inclusive growth, benefitting citizens, businesses and workers ...'.* In addition, it underlines the Commission's commitment to *'meet policy goals at minimum cost, achieving the benefits that only [Union] legislation can bring and eliminating all unnecessary regulatory burdens.'*

In August 2013, the Commission Staff Working document '*Regulatory Fitness and Performance Programme (REFIT): Initial Results of the Mapping of the Acquis'* was published defining the key critical issues across policies, including Health and Consumer and food safety.⁴ On 2 October 2013, the Commission decided to carry out a Fitness Check of Regulation (EC) 178/2002 (General Food Law)⁵ under the Regulatory Fitness and Performance Programme (REFIT) in order to evaluate whether legislation in this area is '*fit for purpose*', this includes a focus on simplification and the reduction of regulatory costs and burdens.⁶

¹ Commission Communication 'Smart Regulation in the European Union', COM(2010)543.

² Commission Staff Working document: 'A Fitness check of the Food chain – state-of-play and next steps', SWD(2013)f516.

³ Commission Communication '*EU Regulatory Fitness*' COM(2012)746.

⁴ Commission Staff Working document: '*Regulatory Fitness and Performance Programme (REFIT)*: Initial Results of the Mapping of the Acquis', SWD(2013)401.

⁵ 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 (General Food Law), (OJ L 31, 1.2.2002, p.1).

⁶ Annex to Commission Communication 'Regulatory Fitness and Performance (REFIT): Results and next steps' COM(2013)685.

This mandate outlines the key elements and assessment criteria for the REFIT Fitness check of Regulation (EC) N° 178/2002. It will be updated during the exercise, when relevant changes occur. Also, it will be published on the Commission's website in order to keep stakeholders and the interested public informed about the process, its contents and timing as well as on the opportunity to participate.

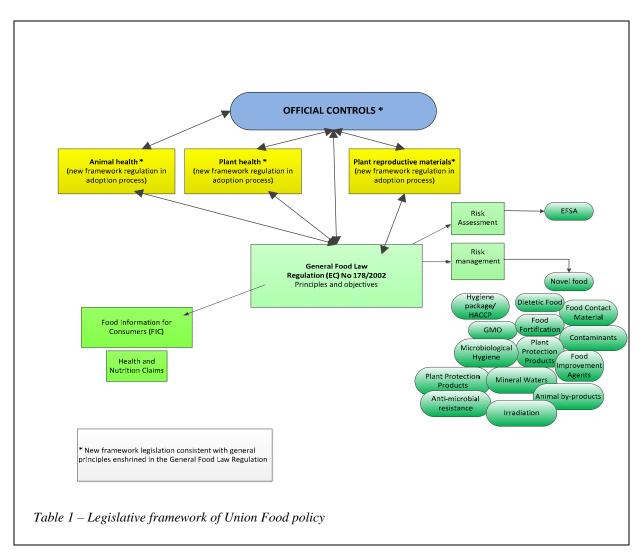
1.1. Justification and purpose

From November 2011 to July 2013, DG SANCO performed a first phase of the 'Fitness check of the Food chain' as one of four Fitness Check Pilot projects. The food chain was chosen due to its economic and social importance as well as its extensive European legislative framework. The main objective of this exercise was to map and describe the legislation in question, covering 16 major legislative acts, with a view to assessing if Union legislation of the Food chain is 'fit for purpose' in addressing the original objective it was initially intended for.

In the next step, the Commission will assess the effectiveness and efficiency of the legislation in question, the relevance, EU-added value, the coherence with Union wider policy priorities (synergies/trade-offs) as well as a focus on simplification and the reduction of regulatory costs and burdens.

This Fitness Check will cover Regulation (EC) N° 178/2002 setting up general principles and requirements, definitions and basic objectives of food law, establishing the European Food Safety Authority (EFSA) and providing for the management of emergencies and crises.

Regulation (EC) N° 178/2002 was adopted in 2002. It entered fully into force in 2005 but existing national and Union food principles and procedures had to be adapted at the latest by January 2007 to comply with the general principles (Articles 5 to 10) of the Regulation. Since its adoption, it has never undergone a comprehensive evaluation.



The fundamental principles to be followed by public authorities enshrined in this Regulation are reflected in other horizontal and sectorial food legislation that was adopted or revised following the adoption of the General Food Law.

Therefore, this Fitness check cannot be performed in isolation. It implies checking whether the fundamental principles and definitions (that are to be applied by all public authorities through the entire spectrum of food law) were effectively and efficiently implemented taking into account potential for simplification and for the reduction of regulatory costs and burdens. It also implies checking whether the new responsibilities/requirements for operators as well as the new procedures and tools that were created in order to better prevent and manage emergencies and crisis are fit for purpose. This exercise should take into account the rules and standards established by the subsequent legislation, in particular to assess the cumulative effects and potential overlaps that could have been created by the general framework enacted by Regulation (EC) N° 178/2002.

The overall purpose of the Fitness check of the General Food law can be summarised as follows: it is a comprehensive policy evaluation assessing whether the regulatory framework for an entire policy sector is '*fit for purpose*'. Thus, this Fitness check is designed to broaden and strengthen the way the Commission critically reviews the performance of Union policy and regulation, providing a solid platform for the consideration of any proposals for new or revised legislation. It can lead to the identification of issues and possible recommendations on the concerned legislation with a long term time horizon.

2. Regulatory framework subjected to the Fitness Check

2.1. Context

Food Law in the Union has evolved in several stages. Originally food law was principally directed towards the creation of an internal market for foods. The outbreak of the 'Mad cow diseases' (BSE crisis) and other scares that followed brought to light many shortcomings in the existing body of European food law and it became clear that radical reforms were needed. In particular:

- Most technical rules governing the safety of food had been harmonised (probably around 90%) but the harmonisation process had been performed according to different policies and objectives such as the Common Agriculture Policy (CAP) and the Single market. The fragmentation of the legal and administrative system (at Union and national level) was considered as one of the causes for the underestimation of the BSE outbreak, the system lacking a global approach on the safety of the whole chain⁷.
- Food law had to be risk based but the system did not provide for a systematic scientific assessment of the risk and when it did the instruments at stake (Commission scientific committees) lacked the capacity to provide the necessary scientific advice.⁸
- The crises also demonstrated that the tools in place for preventing and managing crisis were not adequate (absence of traceability led to huge withdrawals and recalls making the crisis worse; RASFF system not sufficiently performing)⁹.

The General Food Law (Regulation (EC) No 178/2002) was established as a re-foundation of the food law legal system after two big food crisis at the end of the 90s. It establishes that the main focus of the new system is the protection of human health and consumer's interests. It takes a comprehensive and integrated approach to the safety of food and feed while also providing a basis for consumers to make informed choices. It provides a harmonised framework to ensure a coherent approach to the development and implementation of food legislation at Union and national level. It finally creates tools and procedures to better prevent and manage crisis.

2.2. Objectives

Regulation (EC) N° 178/2002 defines food law as "laws, regulations and administrative provisions governing food in general, and food safety in particular, at Union or national level". It therefore takes a broad view on the scope of food law looking at the wide variety of fields that must actually be regulated in order to ensure the production, trade and handling of safe food. In other words, everything having to do with food at Union or national level, whether directly or indirectly would come within the ambit of food law.

Regulation (EC) N° 178/2002 pursued the following main objectives:

1) To ensure a high level of protection of consumers in particular of their health

A fundamental_objective of high level of protection of human health was established while taking account of animal and welfare, plant health and environment. Strong guarantees are established on safety: the separation of risk assessment and risk management (independent assessment of risk), the creation of a general safety obligation and of a general requirement of verification (for all actors in the food/feed chain), specific requirements provide for the

⁷ European Commission 2000: 'White paper on Food safety' COM (1999)719.

 $^{^{8}}$ Id.

Id. Also, see recitals (28) and (59) of Regulation (EC) No 178/2002.

withdrawal and recall of unsafe food and restrict the export of unsafe food. The protection of consumers against misleading information and frauds is also foreseen.

2) To ensure a comprehensive and integrated approach of the food/feed chain as well as a common field for the free movement of foods by creating a harmonised framework for the development of all food law (Union and national)

Harmonised scope (all steps of the food/feed chain), definitions, principles and procedures should form a common basis for measures governing food and feed taken at national and Union level. Public authorities have to primarily pursue the objectives of high level of protection of health and the protection of consumers' interests; they have to apply the risk analysis approach (risk assessment, risk management and risk communication). Risk management shall be based on the results of risk assessment taking into account other legitimate factors. In order to eliminate barriers to the free movement of food and feed due to the application of precautionary principle, a uniform basis for the use of this principle is adopted. Public authorities have to apply general procedures ensuring the transparency of their decision-making process (consultation of stakeholders) and the information of the public on risks to health. The Regulation recognises the EU's commitment to its international obligations. Food law will be developed and adapted taking international standards into consideration, except where this might undermine the high level of consumer protection pursued by the EU.

3) To ensure that Food Law is supported by high quality, independent and efficient scientific and technical support and to secure a science based approach of the risks

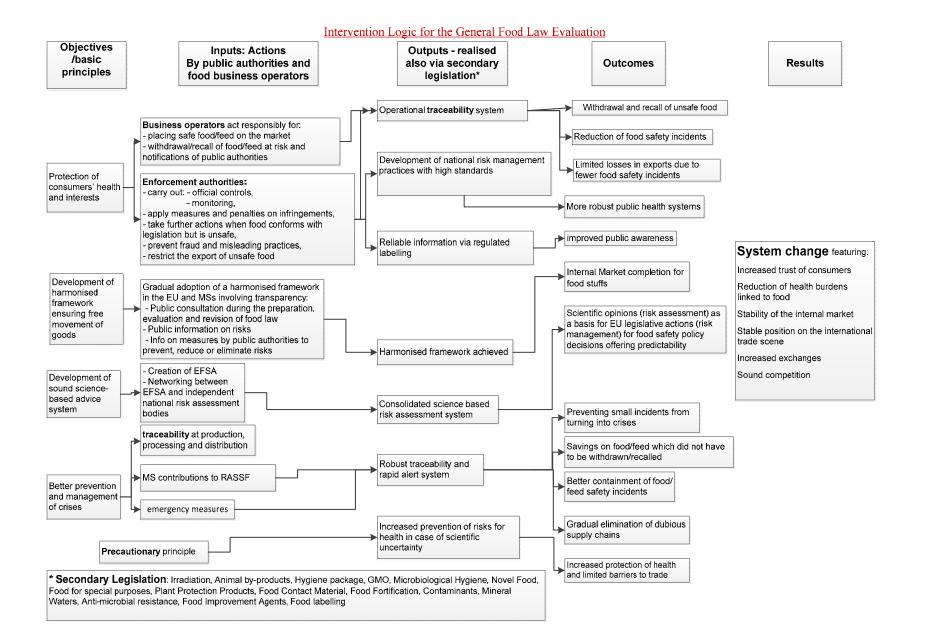
Food law must be science-based. The General Food Law establishes the European Food Safety Authority (EFSA) as an independent agency with sufficient scientific capacity responsible for providing the scientific opinions (risk assessment) as a basis for legislative actions (risk management) of the Union institutions.

4) To ensure the prevention of crises (adequate prevention and management of emergencies in order to prevent that they develop into crises)

The prevention and better management of crisis involved the creation of new tools, in particular the obligation of traceability, the requirement that food/feed business operators withdraw/recall food/feed at risk and notify public authorities, an improved and broader RASFF allowing for adequate management of emergencies (to avoid that small incidents turn to crises) and the establishment of procedures for emergencies/crises.

2.3. Intervention logic

The following diagram shows how the various components of Regulation (EC) No 178/2002 and other relevant secondary legislation were expected to interact and achieve the set objectives.



3. Fitness Check of the General Food law (Regulation (EC) No 178/2002)

3.1. Scope

The General Food Law (GFL) consists of several chapters establishing common definitions and laying down overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection and the effective functioning of the internal market. It seeks to harmonise at Union level general food law principles and requirements, already existing in Member States' legal history, placing them in the European context and providing the basic framework of definitions, principles and requirements for future European food law. It applies to all stages of the production, processing and distribution of food and feed. An important attribute of the Regulation is that it assigns to food business operators the primary responsibility for food safety. The Regulation also establishes the European Food Safety Authority (EFSA) and procedures and tools on the management of emergencies and crises.

The chapters establishing the European Food Safety Authority (ESFA) are subject to a regular evaluation every five years (next one in 2017). The results of the last evaluation in 2012¹⁰ forms part of the data and information bases of the present Fitness Check.

The procedures and tools on the management of emergencies and crises, in particular the Rapid Alert System for Food and Feed (RASFF), are included in the Fitness Check on the General Food Law.

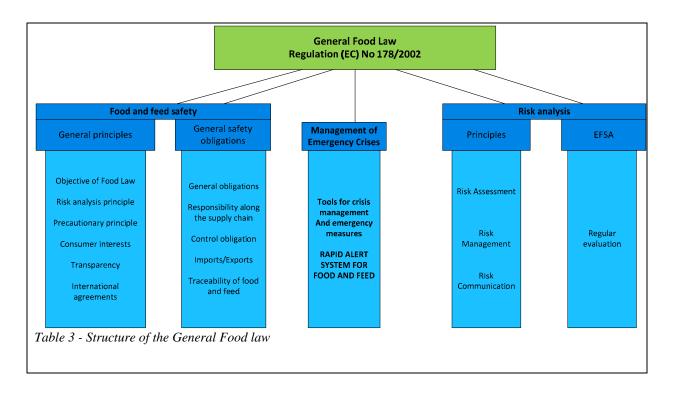
All other legal acts of the Food chain regulatory system are subject to the full Policy Cycle according to the rules of Smart regulation¹¹, which includes Impact assessments, evaluations and a wealth of reporting obligations. The detailed overview of this permanent assessment is outlined in the 'SWD Fitness check – State of play and next steps'¹².

The Fitness Check on GFL covers the period 2002-2013 in all Member States.

¹⁰ European Food Safety Authority (EFSA) 2012: 'External evaluation of EFSA – Final report', Ernst & Young 2012.

¹¹ See footnote 1.

¹² See footnote 2.



3.2. Overall aim of the Fitness Check

The overall aim of the Fitness Check is to analyse the effectiveness, efficiency, coherence, relevance and EU added value of the legislative framework introduced by Regulation (EC) No 178/2002 on general food law.

In doing so, the Fitness Check should take into account previous evaluations already performed in this policy area as well as the results of the two external evaluations that have been commissioned to support the Fitness check: one on the RASSF and management of emergencies/crisis and the other on the General Food Law. Broad stakeholder consultations should be performed during the whole Fitness Check exercise to collect the views of relevant actors in the Food chain and to gather information and evidence.

The focus of the Fitness Check should be to assess whether the fundamental objectives of the General Food law have been efficiently achieved and whether the provided tools have been consistently implemented via secondary legislation and have fully delivered. In addition, the assessment should focus on potential for simplification in the regulation and on the reduction of regulatory costs and burdens. For this purpose, consultation with Member states authorities and stakeholders will be organised. The exercise should also examine whether Regulation (EC) No 178/2002 captures and reflects policy trends of today, taking into account developments at Union and international level, and to what extent it fits the Union's institutional, legal, economic and political landscape.

Questions to be addressed by the Fitness Check

In the context of this Fitness Check, the following questions should be addressed:

• Effectiveness¹³

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The degree to which something is successful in producing a desired result and the degree to which objectives are achieved and the extent to which targeted problems are solved.

- What progress has been made over time towards achieving the objectives of the legislative framework introduced by Regulation (EC) No 178/2002? Is this progress in line with the initial expectations?
- Which main factors (*e.g.* implementation by Member States, action by stakeholders) have contributed to or stood in the way of achieving these objectives?
- Beyond these objectives, has the legislative framework introduced by Regulation (EC) No 178/2002 led to any other significant changes both positive and negative?
- Efficiency¹⁴
 - What are the costs and benefits (monetary and non-monetary) associated with the application of the legislative framework introduced by Regulation (EC) No 178/2002 in the Member States and in the EU?
 - What good practices in terms of cost-effective implementation of the legislative framework introduced by Regulation (EC) No 178/2202 can be identified?
 - What, if any, specific provisions in the legislative framework introduced by Regulation (EC) No 178/2002 can be identified that make a cost- effective implementation more difficult and hamper the maximisation of the benefits?
 - What are the specific challenges to SMEs with respect to the implementation of the legislative framework introduced by Regulation (EC) No 178/2002?
- Coherence¹⁵
 - To what extent have the general principles and requirements set out in Regulation (EC) No 178/2002 contributed to the coherence of food law? To what extent has the legislative framework introduced by Regulation (EC) No 178/2002 proved complementary to other Union interventions/initiatives in the field of food policy?
 - What, if any, specific inconsistencies and unjustified overlaps, obsolete provisions and/or gaps can be identified with other pieces of Union legislation? How do they affect the application/performance of Regulation (EC) No 178/2002?
- Relevance¹⁶
 - To what extent are the objectives of Regulation (EC) No 178/2002 still relevant and valid? Are there any other objectives that should be considered?
 - To what extent is the legislative framework introduced by Regulation (EC) No 178/2002 still relevant to address current needs and trends?
- EU added value

The ability to do something or produce something without wasting materials, time or energy: the quality or degree of being efficient.
 Forming a unified whole

¹⁵ Forming a unified whole.

¹⁶ To know the relevance of something is to know why it matters or how it is important.

• What has been the EU added value of the legislative framework introduced by Regulation (EC) No 178/2002 and what would be the likely situation in case of there having been no such legislative framework?

4. Data and Monitoring Provisions

4.1. Monitoring Provisions

Official Controls regulation (882/2004) OCR

Multi-Annual Control Plans (MANCP): Under the legislative framework (EC) Regulation 882/2004 (art. 41), Member States are required to draw up single, integrated Multi-Annual Control Plans (MANCP) and to implement them (from 01/01/2007) in line with some basic requirements (art. 42). The MANCP describe the strategy of the Member State (for a particular period) in order to guarantee an efficient result of controls and the preservation of the respect of food legislation by operators. They include among others a description of the competent authorities, of the general organization and of the management of official controls, and of the different control systems. Article 44 requires Member States to submit each year a report on the implementation of their MANCP to the Commission.

For both MANCP and reports guidelines have been drafted for the Member States, giving further advice on structure and contain.

MANCP and reports are available at

https://circa.europa.eu/Public/irc/sanco/Home/main?f=login&referer=http%3A%2F%2Fcirca.europa.eu%2FMem bers%2Firc%2Fsanco%2Fcountprof%2Flibrary%3Fcookie%3D1

The report draws from the results of the three rapid alert systems:

- Rapid Alert System for Feed and Food RASFF <u>http://ec.europa.eu/food/food/rapidalert/rasff_publications_en.htm</u>
- Animal Disease Notification System ADNS <u>http://ec.europa.eu/food/animal/diseases/adns/previous_table_11_en.htm</u>
 Alert system for threats to plant health – Europhyt
- Alert system for threats to plant health Europhyt <u>http://ec.europa.eu/food/plant/europhyt/interceptions_en.htm</u>

Better Training for Safer Food BTSF

Evaluation 2011

http://www.standardsfacility.org/Files/News/EC_Best_Practices_SPS.pdf

BTSF (2010) Communication Better training for safer food

http://ec.europa.eu/food/training/communication final report en.pdf

First report from the Commission on the overall operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health (COM(2010) 441) http://eurlex.europa.eu/Result.do?T1=V5&T2=2010&T3=441&RechType=RECH naturel&Submit=Search

Hygiene package

Report presenting factually the experiences gained in 2006, 2007 and 2008 from the implementation of the hygiene package:

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

Audit reports (Food and Veterinary Office, FVO):

- Annual reports <u>http://ec.europa.eu/food/fvo/annualreports/index_en.htm</u>
- Inspection reports <u>http://ec.europa.eu/food/fvo/ir_search_en.cfm</u>
- Country reports http://ec.europa.eu/food/fvo/country_profiles_en.cfm
- Special reports http://ec.europa.eu/food/fvo/specialreports/index en.htm

Annual Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in the EU

Article 6 (4) of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies

http://ec.europa.eu/food/biosafety/tse bse/monitoring annual reports en.htm

Summary Report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in the European Union (*Mandated to EFSA, elaborated by EFSA in cooperation with ECDC*)

Article 9 (2) of Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents

http://www.efsa.europa.eu/en/efsajournal/doc/2090.pdf

Annual Union-wide Pesticide Residues Monitoring Report (Mandated to EFSA)

Article 32 of Regulation (EC) No 396/2005 of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin

http://ec.europa.eu/food/fvo/specialreports/pesticides index en.htm

http://www.efsa.europa.eu/en/efsajournal/pub/1646.htm

Annual report on food irradiation

Article 7(3) of Directive 1999/2/EC of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising

radiationhttp://ec.europa.eu/food/food/biosafety/irradiation/index_en.htm

Commission Staff Working Paper on the Implementation of National Residue Monitoring Plans in the Member States

Article 8 of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products

http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

Annual Report on notifiable diseases of bovine animals and swine

Article 8 of Directive 64/432/EEC, details of the occurrence of diseases listed in Annex E(I) to the Directive and of any other diseases covered by the additional guarantees provided for by Union legislation in its territory. 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

4.2. Previous evaluations and other reports				
Evaluation	Completion date	Accountability purpose/ legal base	Web-link	
Community Animal Health Policy (CAHP) 1995-2004	Completed 07/2006	Management decision	http://ec.europa.eu/food/animal/di seases/strategy/final_report_en.ht m	
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/downl oad.do?documentId=5030	
Community <i>acquis</i> on the marketing of seed and plant propagating material (S&PM)	Completed 10/2008	Management decision	http://ec.europa.eu/food/plant/pla nt_propagation_material/review_e u_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 October 2010	http://ec.europa.eu/dgs/secretariat _general/evaluation/search/downl oad.do?documentId=4718	
Community Reference Laboratories in the field of animal health and live	Completed 11/2009	Action Plan for the implementation of Community Animal Health	http://ec.europa.eu/dgs/secretariat _general/evaluation/search/downl oad.do?documentId=4756	

animals		Strategy	
Union legal framework in the field of GM food and Feed	Completed 07/2010	Management decision	http://ec.europa.eu/food/food/biot echnology/evaluation/index_en.ht m
Union legal framework of cultivation of GMOs	Completed 10/2010	Management decision	http://ec.europa.eu/food/plant/gm o/evaluation/index_en.htm
Plant Health Strategic Evaluation	Completed 05/2010	Management decision	http://ec.europa.eu/food/plant/pla nt_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/downl oad.do?documentId=4630
Community Plant Variety Right Regime	Completed 04/2011	Management decision	http://ec.europa.eu/food/plant/pla nt_property_rights/evaluation/ind ex_en.htm
Union Reference Laboratories in the field of food and feed safety and animal health	Completed 04/2011	Management decision, and FR art 27	http://ec.europa.eu/dgs/secretariat _general/evaluation/search/downl oad.do?documentId=4753
Union 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/downl oad.do?documentId=6336096
Expenditure in the veterinary field	Completed 05/2014	Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC	http://eur-lex.europa.eu/legal- content/EN/TXT/PDF/?uri=CELE X:32014R0652&from=EN

4.3. Infringements, compliance and complaints

To ensure a comprehensive analysis, the Fitness Check should also take into account the nature and outcome of infringements, complaints as well as the overall compliance record relating to the application of Regulation (EC) No 178/2002.

5. Timing and consultation

5.1. Planning

1. Adoption of mandate and validation of ToRs

Meeting of the Steering Group to discuss the draft mandate and ToRs; Validation of the ToRs.

2. Launch and carrying out of external studies (September 2014 – June 2015)

External studies to be carried out in the areas of General Food Law and RASFF/emergencies procedures; Regulation involvement of the Steering Group (inception reports, interim reports, draft final reports, final reports); Regular updates on progress to the High Level Group on Better Regulation and to the High Level Forum.

3. Preparation of a draft Staff Working Document on the Fitness Check (June – November 2015)

Analysis on the effectiveness, efficiency, coherence, relevance and EU added value of Regulation (EC) No 178/2002 taking into account the rules and standards developed by subsequent legislation. The Staff Working Document will build on results of evaluations conducted under this project and any other relevant external evaluations (e.g. EFSA) and studies, so as to assess the cumulative effects of the general framework created by Regulation (EC) No 178/2002; Drafting the draft Staff Working Document on the Fitness Check.

4. Finalisation of draft Staff Working Document on the Fitness Check (December 2015)

Steering Group to agree on draft Staff Working Document on the Fitness Check including the conclusions and policy recommendations; Finalisation of the Staff Working Document, subject to an inter-service consultation.

5.2. Intra-SANCO Task Force and Inter-service Steering Group meetings

An intra-SANCO Task Force has been established which bring together all relevant units across the DG, namely: Unit 01 (evaluation function), Unit 03 (EFSA), Unit A1 (relations with SG), Unit E4 (General Food Law) and Unit G4 (Rapid Alert System for Food and Feed and emergencies/crisis procedures).

DG SANCO has also set up an Inter-Service Steering Group, including representatives of SG, LS, AGRI, MARKT, ENTR, COMP, ENV, TRADE and RTD.

Meeting 04/2014	Discussion of external evaluations (ToR)	
Meeting 12/2014	Inception report(s) of external evaluation(s)	
Meeting 03/2015	Mid-term external report(s)	
Meeting 06/2015	Final external report(s) and structure of draft Staff Working	
	Document on Fitness Check	
Meeting 12/2015	Draft Staff Working Document on Fitness Check	

An indicative timeline for the Steering Group meetings is provided below:

5.3. Consultations

Transparency and stakeholder involvement are vital for the success of the Fitness Check. An indicative overview of the planned consultations is provided in the table below.

Actors	Forum	
Member States:	Standing Committee on Plants, Animals, Food and	
	Feed (PAFF)	
Business, trade, NGOs etc.:	Advisory Group for the Food chain	
Information/exchange of	HLF Food chain	
views and contribution of	HLG Administrative burden	
MSs within the HLG	Consumer Group ECCG	
Administrative Burden		

6. Relevant documents and reports

Commission Communication 'Smart Regulation in the European Union' COM(2010)543

Commission Communication 'EU Regulatory Fitness' COM(2012)746 final

Commission Staff Working document: 'Regulatory Fitness and Performance Programme (REFIT): Initial Results of the Mapping of the Acquis', SWD (2013)401final

Commission Communication 'Regulatory Fitness and Performance (REFIT): Results and next steps' COM(2013)685 final

Commission Staff Working document 'Fitness check of the Food chain – state-of-play and next steps': Publication in 4Q 2013

European Food Safety Authority (EFSA) 2012: 'External evaluation of EFSA – Final report', Ernst and Young 2012

Foresight project 'Food safety 2050' Scoping study: Final report 4Q 2013

Competence review Netherlands and UK on Union legislation, including the Food sector: Final reports 2Q 2013

Joint study SG/ENTR on cumulative impacts of Union legislation on SMEs (case study food sector is bakery sector in three Member States): Launch 3Q 2013