Council of the European Union

Brussels, 17 January 2018
(OR. en)

5447/18
ADD 1

AGRILEG 8
MI 33
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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	15 January 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2018) 38 final PART 2/2
Subject:	COMMISSION STAFF WORKING DOCUMENT THE REFIT EVALUATION of the General Food Law (Regulation (EC) No 178/2002)

Delegations will find attached document SWD(2018) 38 final PART 2/2.

Encl.: SWD(2018) 38 final PART 2/2

EUROPEAN
COMMISSION

Brussels, 15.1.2018
SWD(2018) 38 final

PART 2/2

COMMISSION STAFF WORKING DOCUMENT

THE REFIT EVALUATION

of the

General Food Law (Regulation (EC) No 178/2002)

{SWD(2018) 37 final}

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4 Appendix 1 – Other EU secondary Food legislation implementing the common definitions, general principles and requirements of the GFL Regulation

A. List of other EU secondary Food legislation implementing the Common Definitions, General Principles and Requirements of the GFL Regulation

Legislative acts in the area of food law, **pre-existing the GFL Regulation**, which were automatically aligned to the new system of scientific advice by EFSA or amended accordingly after the adoption of the GFL Regulation:

1) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1);

2) 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 (OJ L 125, 23.5.1996, p. 10);

3) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1);

4) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) – This act was adopted very soon after the GFL Regulation;

5) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183,12.7.2002, p. 51) – This act was also adopted very soon after the GFL Regulation;

6) Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (OJ L 262, 14.10.2003, p. 17);

7) Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJ L 308, 25.11.2003, p. 15).

Legislative acts in the area of food law **adopted after the GFL Regulation** and implementing the common definitions and the general principles and requirements, where relevant:

1) Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other food-borne zoonotic agents, (OJ L 325, 12.12.2003, p. 1);

2) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1);

3) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24);

4) Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29);

5) Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1);

6) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1);

7) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55. Corrected version in OJ L 226, 25.6.2004, p. 22);

8) Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206);

9) Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1);

10) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food (OJ L 338, 13.11.2004, p. 4);

11) Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1);

12) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (OJ L 70, 16.3.2005, p. 1);

13) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 12, 18.1.2007, p. 3. Corrected version in OJ L 12, 18.1.2007, p. 3);

14) Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26);

15) Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1);

16) Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7);

17) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16);

18) Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34);

19) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (OJ L 152, 16.6.2009, p. 11);

20) Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (recast), (OJ L 141, 6.6.2009, p. 3);

21) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (recast) (OJ L 124, 20.5.2009, p. 21);

22) Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters (recast) (OJ L 164, 26.6.2009, p. 45);

23) 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 (OJ L 229, 1.9.2009, p. 1);

24) Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption (Animal by-products Regulation), (OJ L 300, 14.11.2009, p. 1);

25) 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 (OJ L 309, 24.11.2009, p. 1)**;**

26) 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, (OJ L 304, 22.11.2011, p. 18);

27) 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, (OJ L 181, 29.6.2013, p. 35);

28) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1);

29) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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 and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and

Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, (OJ L 95, 7.4.2017, p. 1).

B. Table depicting the elements of the GFL legislative framework that are implemented in other EU secondary food legislation

Implementation of the GFL legislative framework in other EU secondary food legislation	
Common definitions	**'food', 'food law', 'food business', 'food business operator', 'feed', 'feed business', 'feed business operator', 'retail', 'placing on the market', 'risk', 'risk analysis', 'risk assessment', 'risk management', 'risk communication', 'hazard', 'traceability'.** *The common definitions of the GFL Regulation **have consistently been incorporated** in other EU secondary food legislation, adopted after the introduction of the GFL Regulation, where relevant, i.e. in 25 out of the 29 other legislative acts which have been identified as relevant for this fitness check.* *1) Regulation (EC) No 2160/2003 on the control of salmonella and other food-borne zoonotic agents;* *2) Regulation (EC) No 1829/2003 on genetically modified food and feed;* *3) Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;* *4) Regulation (EC) No 1831/2003 on additives for use in animal nutrition;* *5) Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods;* *6) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;* *7) Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;* *8) Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;* *9) Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;*

	10) Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food; *11) Regulation (EC) No 183/2005 laying down requirements for feed hygiene;* *12) Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal;* *13) Regulation (EC) No 1924/2006 on nutrition and health claims made on foods;* *14) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods;* *15) Regulation (EC) No 1332/2008 on food enzymes;* *16) Regulation (EC) No 1333/2008 on food additives;* *17) Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on;* *18) Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin;* *19) Regulation (EC) No 767/2009 on the placing on the market and use of feed;* *20) Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;* *21) Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market;* *22) Regulation (EU) No 1169/2011 on the provision of food information to consumers;* *23) Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control;* *24) Regulation (EU) 2015/2283 on novel foods;* *25) Regulation (EU) 2017/625 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 and plant protection products.* *The four acts that did not include a reference to the GFL definitions were Regulation (EC) No 1331/2008 establishing a common authorisation procedure and three recast Directives, i.e. Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used*

	in the production of foodstuffs and food ingredients, Directive 2009/39/EC on foodstuffs intended for particular nutritional uses, and Directive 2009/54/EC on the exploitation and marketing of natural mineral waters. Regulation (EC) No 1331/2008 does not include any definitions given its subject matter. The three recast Directives were not substantially changed,m due to the nature of the recast exercise.
General principles	**A. Risk analysis principle (including establishment of EFSA)** *As required by the GFL, all EU food related legislation was required to incorporate the risk analysis principle.* *Accordingly, and following the creation of EFSA, EU food legislation that **predated the GFL Regulation** was aligned to/reviewed in line with the risk analysis principle. Indeed, where pre-existing legislation referred to scientific opinions by the previous Scientific Committees, the GFL Regulation made provision for the automatic alignment to the new regulatory system of scientific assessment (EFSA) by means of Article 62 thereof **(automatic alignment)**. The automatic alignment concerned the following legislative acts:* *8) Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food* *9) Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products;* *10) Regulation (EC) No 258/97 concerning novel foods and novel food ingredients;* *11) Directive 2002/32/EC on undesirable substances in animal feed– This act was adopted very soon after the GFL Regulation;* *12) Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements – This act was also adopted very soon after the GFL Regulation;* *13) Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists – This act also takes into account the precautionary principle as laid down in the GFL Regulation (recital 10);* *14) Directive 2003/89/EC amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (OJ L 308, 25.11.2003, p. 15). The pre-existing Directive 2000/13/EC did refer to scientific assessment; this act adapted Directive 2000/13/EC to ensure compliance with the risk analysis principle.* *In addition, **all subsequent EU legislation, adopted after the GFL Regulation**, which, amongst others, manages microbiological, chemical and physical risk linked to food/feed has consistently incorporated the risk*

	analysis principle, providing the consultation of EFSA prior to risk management decisions. In that respect, the following acts have been identified as relevant: *1) Regulation (EC) No 2160/2003 on the control of salmonella and other food-borne zoonotic agents;* *2) Regulation (EC) No 1829/2003 on genetically modified food and feed;* *3) Regulation (EC) No 1831/2003 on additives for use in animal nutrition;* *4) Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods;* *5) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;* *6) Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;* *7) Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;* *8) Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food;* *9) Regulation (EC) No 183/2005 laying down requirements for feed hygiene;* *10) Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal;* *11) Regulation (EC) No 1924/2006 on nutrition and health claims made on foods;* *12) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods;* *13) Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings;* *14) Regulation (EC) No 1332/2008 on food enzymes;* *15) Regulation (EC) No 1333/2008 on food additives;* *16) Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on;* *17) Directive 2009/39/EC on foodstuffs intended for particular nutritional uses;* *18) Directive 2009/54/EC on the exploitation and marketing of natural mineral waters;*

19) *Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin;*

20) *Regulation (EC) No 767/2009 on the placing on the market and use of feed;*

21) *Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;*

22) *Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market;*

23) *Regulation (EU) No 1169/2011 on the provision of food information to consumers;*

24) *Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control;*

25) *Regulation (EU) 2015/2283 on novel foods.*

B. Principle of protection of consumers' interests

This principle has been implemented through the adoption of the following EU food legislation in order to prevent misleading labelling practices and to ensure the consumers' right to food information:

1) *Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements;*

2) *Regulation (EC) No 1829/2003 on genetically modified food and feed;*

3) *Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;*

4) *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods;*

5) *Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods;*

6) *Regulation (EU) No 1169/2011 on the provision of food information to consumers;*

7) *Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control;*

8) *Regulation (EU) 2015/2283 on novel foods.*

C. Principles of transparency: Public consultation and public information

The principle of transparency in terms of public consultation throughout the decision-making cycle and the right of the public to be informed where there are reasonable grounds to suspect that a food may present a risk to health was not required to be implemented as such to other EU secondary food legislation. Public consultation is a requirement whenever EU and national food law is adopted or revised. Similarly, whenever there is a risk to health regardless of the EU secondary food legislation applicable, the public authorities are required to inform the public by means of the GFL Regulation.

D. International standards to be taken into account in the development of EU food law

Certain EU food secondary legislation makes specific reference to international standards in the development of food law, although this is not strictly speaking required, given that this is a general principle of the GFL Regulation that underpins all EU and national food legislation. Where this has been included, it was to give more emphasis to this specific requirement. Indicatively, the following EU food-related acts make an explicit reference to international standards:

1) *Regulation (EC) No 1829/2003 on genetically modified food and feed;*

2) *Regulation (EC) No 183/2005 on feed hygiene;*

3) *Regulation (EC) No 396/2005 on maximum levels of pesticides in or on food and feed of plant and animal origin;*

4) *Regulation (EC) No 852/2004 on the hygiene of foodstuffs;*

5) *Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;*

6) *Regulation (EC) No 882/2004 on official controls;*

7) *Regulation (EC) No 396/2005 on maximum levels of pesticides in or on food and feed of plant and animal origin and subsequent amendments of annexes thereto;*

8) *Regulation (EC) No 1924/2006 on nutrition and health claims made on foods;*

9) *Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods;*

10) *Regulation (EC) No 1333/2008 on food additives and amendments to annexes thereto;*

11) *Regulation (EC) No 470/2009 on the establishment of residue limits of*

		pharmacologically active substances in foodstuffs of animal origin; Regulation (EU) 2015/2283 on novel foods; *12) R**egulation (EU) 2017/625 on official controls and other official activities**.*
General requirements	On FBOs	**1. Primary responsibility of FBOs (compliance and own controls)** *This principle is further implemented in the EU food and feed hygiene legislation:* *1) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;* *2) Regulation (EC) No 853/2004 on the hygiene of food of animal origin;* *3) Regulation (EC) No 183/2005 laying down requirements for feed hygiene.* *4) A specific regime governing the repartition of responsibilities in the area of food information was introduced in Regulation (EU) 1169/2011 (Article 8) reflecting the general requirement as laid down in the GFL.* **2. Safety requirements of food and feed** *The GFL sets out a general requirement that food and feed placed on the market must be safe (food/feed safety requirement). It also provides that food and feed that complies with specific EU food legislation governing food safety is deemed to be safe insofar as the aspects covered by the specific EU food legislation is concerned. Nevertheless, conformity of a food and feed with specific provisions applicable to that food and feed does not prevent the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food or feed is unsafe (Article 14 of the GFL Regulation).* **3. Withdrawal of unsafe food and feed** *This requirement applies directly to all food business operators, which are required to withdraw from the market food that does not meet the food/feed that does not meet the food/feed safety requirements and notify this to competent authorities. Where the product may have reached the consumer, the operator must inform the consumer and if necessary recall from consumer products already supplied to them. This obligation must be read together with EU food sectorial legislation that sets out food safety requirements.*

		Indicatively: *1) Regulation (EC) No 2160/2003 on the control of salmonella and other food-borne zoonotic agents;* *2) Regulation (EC) No 1829/2003 on genetically modified food and feed;* *3) Regulation (EC) No 1831/2003 on additives for use in animal nutrition;* *4) Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods;* *5) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;* *6) Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;* *7) Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food;* *8) Regulation (EC) No 183/2005 laying down requirements for feed hygiene;* *9) Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal;* *10) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods;* *11) Regulation (EC) No 1332/2008 on food enzymes;* *12) Regulation (EC) No 1333/2008 on food additives;* *13) Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on;* *14) Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin;* *15) Regulation (EC) No 767/2009 on the placing on the market and use of feed;* *16) Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;* *17) Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market;*

18) *Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control;*

19) *Regulation (EU) 2015/2283 on novel foods;*

4. Traceability for food safety purposes

This is a general requirement that applies directly across the food chain, including feed.

5. Imported food and feed to comply with EU food law and exported food and feed to comply with EU law or requirements set up by the Non-EU importing Country

These are general requirements that apply in conjunction with all EU food sectorial legislation setting out requirements for the placing on the market of food and feed in the EU. That covers all food legislation that predates the GFL:

- *Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food;*
- *Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products;*
- *Regulation (EC) No 258/97 concerning novel foods and novel food ingredients;*
- *Directive 2002/32/EC on undesirable substances in animal feed (this act was adopted very soon after the GFL Regulation);*
- *Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements (this act was also adopted very soon after the GFL Regulation); and,*
- *Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists.*

It is also applied in conjunction with all sectorial EU food legislation adopted after the GFL:

1) *Regulation (EC) No 2160/2003 on the control of salmonella and other food-borne zoonotic agents;*

2) *Regulation (EC) No 1829/2003 on genetically modified food and feed;*

3) *Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from*

		genetically modified organisms; *4) Regulation (EC) No 1831/2003 on additives for use in animal nutrition;* *5) Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods (;* *6) Regulation (EC) No 852/2004 on the hygiene of foodstuffs;* *7) Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin;* *8) Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption;* *9) Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;* *10) Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food;* *11) Regulation (EC) No 183/2005 laying down requirements for feed hygiene;* *12) Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin;* *13) Regulation (EC) No 1924/2006 on nutrition and health claims made on foods;* *14) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods;* *15) Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ;* *16) Regulation (EC) No 1332/2008 on food enzymes;* *17) Regulation (EC) No 1333/2008 on food additives;* *18) Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods;* *19) Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of*

		animal origin; *20) Directive 2009/32/EC on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients (recast)* *21) Directive 2009/39/EC on foodstuffs intended for particular nutritional uses (recast);* *22) Directive 2009/54/EC on the exploitation and marketing of natural mineral waters (recast);* *23) Regulation (EC) No 767/2009 on the placing on the market and use of feed;* *24) Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption;* *25) Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market;* *26) Regulation (EU) No 1169/2011 on the provision of food information to consumers;* *27) Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control;* *28) Regulation (EU) 2015/2283 on novel foods.*
	On MS CAs	**Carry out official controls** *This requirement is further elaborated upon on specific EU food legislation:* *1) Regulation (EC) No 882/2004 on official controls;* 2) ***Regulation (EU) 2017/625 on official controls and other official activities.***
Tools for the prevention and management of food crises	1. **RASFF**: *This is established in the GFL framework.* 2. **EU or national emergency measures**: *This article applies directly in conjunction with all EU secondary food legislation that regulates food safety (see above under withdrawals).* 3. **General plan for crisis management**: *This is established by means of Commission Decision 2004/478/EC.* 4. **Crisis Unit:** *The modalities are established by means of Commission Decision 2004/478/EC.*	

5 Appendix 2 – Procedural information

1 Identification of the lead Directorate General ('DG')

DG SANTE is the lead DG for the Fitness Check of the GFL.

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.[1] On 2 October 2013, the Commission decided to carry out a 'Fitness Check on Regulation (EC) No 178/2002 on General Food Law' under the Regulatory Fitness and Performance Programme (REFIT) in order to evaluate whether the latter legislation is 'fit for purpose'.[2]

The GFL Regulation was adopted in 2002 and entered into force in 2005. It was not accompanied by an impact assessment and it has never undergone a comprehensive evaluation since its adoption.

The Fitness Check on the GFL was validated in the Agenda Planning by the Vice President of the Commission Jyrki Katainen on 13 March 2015 under reference no. 2015/SANTE/427.

2 Organisation and timing

For the purposes of this Fitness Check, a mandate was published, outlining the scope, aim and the evaluation questions ('EQs') of this evaluation exercise.[3]

In order to build upon the findings of the 2013 'Fitness check of the Food chain' ('SWD 2013'),[4] two studies were carried out in parallel by the FCEC consortium, from September 2014 until December 2015, on:

a) the general part of the GFL Regulation, outlining the common definitions, general principles and requirements of EU food law (Articles 1-21 of the GFL) – 'the General GFL study';[5] and,
b) the RASFF/emergencies/crisis management provisions (Articles 50-57 of the GFL) – 'the RASFF study').[6]

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[1] Commission Staff Working Document, '*Regulatory Fitness and Performance Programme (REFIT): Initial Results of the Mapping of the Acquis*', SWD(2013)401.
[2] Annex to Commission Communication *"Regulatory Fitness and Performance (REFIT): Results and next steps"*, COM(2013)685.
[3] To be found at: http://ec.europa.eu/smart-regulation/evaluation/docs/fitness_check_of_general_food_law.pdf. As this exercise began before the application of the Better Regulation Package, no formal roadmap was published.
[4] Commission Staff Working Document, 'A fitness check of the Food Chain – State of play and next steps', SWD(2013)516, dated 5.12.2013.
[5] See Appendix 5.
[6] See Appendix 6.

EFSA's operation is subject to a mandatory external evaluation every 6 years, under the GFL Regulation. The last external evaluation of EFSA dates back to 2012, which covered the period January 2006 to December 2010 ('EFSA 2012 evaluation').[7] As time had elapsed since 2010 and since the next external evaluation was scheduled for 2018, the Commission proceeded to an internal intermediary report of EFSA covering the period up to 2013-2014 to support this Fitness Check; where significant, more recent data have also been taken into account.[8] The intermediary report updates the EFSA 2012 evaluation, on the basis of input received from EFSA and MSs, taking into account the results of the Impact Assessment on the establishment of fees for EFSA.[9] The views of stakeholders and MSs, contained in the intermediary report, mainly stem from the surveys performed in the context of the EFSA 2012 evaluation; where more recent views were expressed, these have been taken into account.

In February 2014, an Intra-SANTE Task force was established bringing together all relevant units across the DG: Unit A1 (formerly 01 and 03) responsible for evaluations and relations with SG, Unit D1 (formerly 03) responsible for EFSA, Unit E1 (formerly E4), Unit G5 (formerly G4) responsible for RASFF and Unit G4 responsible for crisis management.

In parallel, to ensure the quality assessment of the external studies and of the overall process, an Inter-Service Steering Group ('ISG') was set up comprising 8 Directorate-Generals ('DGs') of the Commission: Secretariat-General ('SG'), Legal Service ('SJ'), DG for Research and Innovation ('RTD'), DG for Internal Market, Industry and Entrepreneurship and SMEs ('GROW', formerly known as 'ENTER'), DG for Trade ('TRADE), DG for the Environment ('ENV'), DG for Agriculture and Rural Development ('AGRI'), and DG for Competition ('COMP'). The ISG held 8 meetings.

ISG meetings on the Fitness Check on the GFL	
28 April 2014	Agreement in principle on the mandate and discussion on the draft Terms of Reference ('ToRs') of the General GFL study and the RASFF study
2 December 2014	Discussion on the inception report of the RASFF study – final endorsement through email consultation on 11 February 2015
10 December 2014	1) Final endorsement of the mandate 2) Discussion on the inception report of the General GFL study – final endorsement through email consultation on 24 March 2015

[7] To be found at http://www.efsa.europa.eu/en/keydocs/docs/efsafinalreport.pdf.
[8] See Appendix 7.
[9] Commission Staff Working Document, '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, dated 11.2.2013.

23 April 2015	Interim report of the RASFF study – final endorsement through email consultation on 18 June 2015
7 May 2015	Interim report of the General GFL study – final endorsement through email consultation on 5 June 2015
9 September 2015	Draft final report of the RASFF study – final endorsement through email consultation on 7 December 2015
11 September 2015	Draft final report of the General GFL study – final endorsement through email consultation on 8 December 2015
5 July 2017	Endorsement of the draft CSWD on the Fitness Check of the GFL[10]

In the context of the two external studies and the intermediary report on EFSA, the Commission has been assisted by the Expert Group on the General Food Law and the Working Group on the RASFF, both composed of experts from the MS CAs. The following tables provide an overview of the meetings held and subject matters discussed.

Expert Group on General Food Law Fitness Check of the GFL	
3 March 2014	Preparation of the ToRs for the two external studies
16 January 2015	Presentation of the objective, context and timeline of the Fitness check; Workshop on two case-studies in the context of the General GFL study: (a) Risk analysis and precautionary principle and (b) transparency*
27 April 2015	Updates on the state of play of the two external studies; presentation of preliminary findings of the two external studies followed by discussion (workshop)
29 June 2015	Discussion on the intermediary EFSA report with the participation of EFSA (special workshop on EFSA)
16-17 September 2015	Presentation of the final findings of the two external studies and of the intermediary EFSA report
** The details for this Workshop are provided in Appendix 3.*	

[10] The minutes of the last ISG meeting, that took place on 5 July 2017, are attached in Appendix 2a.

All relevant documentation about these meetings (*e.g.* agenda, working documents and summary reports) is to be found at: http://ec.europa.eu/food/safety/generalalviz_food_law/expert_group/index_en.htm.

Working Group on the RASFF Fitness Check of the GFL	
3 March 2014	Preparation of the ToRs for the two external studies*
13 October 2015	Presentation of the objective and timeline of the RASFF study
23 February 2015	Update on the state of play of the RASFF study
5 October 2015	Presentation of the final findings of the RASFF study
** Joint meeting with the Expert Group on the General Food Law*	

As the Fitness Check was conceived as a joint evaluation with the MSs, the evaluation was also followed by the High Level Group on Better Regulation ('HLG'), containing national regulatory experts. The HLG was tasked to oversee the steps taken in the Fitness Check to ensure a robust evidence-base. To this end, the Commission had encouraged the HLG early on in the process to complement the work in collaboration with their colleagues from the relevant Ministries, by carrying out their own case studies and consultations of FBOs, and SMEs in particular. Nevertheless, no additional input was provided. The members of the HLG had been invited in all meetings of the Expert Group on the General Food Law that took place in 2015; some of them participated in the meetings held on 16 January 2015, 27 April 2015 and 16-17 September 2015.

Discussions involving stakeholders (*i.e.* industry, NGOs and consumer organisations) played also a very important part in the Fitness Check exercise. These have taken place mostly in the context of a special Working Group of the Advisory Group on the Food Chain and Animal and Plant Health. The participation to this Working Group was expanded to include stakeholders that are not formally members of the Advisory Group precisely to ensure the broader representation of the interests concerned possible. An overview of the meetings held is provided below:

Working Group of the Advisory Group on the Food Chain and Animal and Plant Health Fitness Check of the GFL	
4 March 2014	Preparation of the ToRs for the two external studies
19 December 2014	Presentation of the objective, context and timeline of the Fitness check; Workshop on two case-studies in the context of the General GFL study: (a) traceability and (b) distribution of responsibilities of food and feed business operators*

6 May 2015	Updates on the state of play of the two external studies; presentation of preliminary findings of the two external studies followed by discussion (workshop)
21-22 September 2015	Presentation of the final findings of the two external studies and of the intermediary EFSA report
** The details for this Workshop are provided in Appendix 3.* All relevant documentation about these meetings (*e.g.* agenda, working documents and summary reports) is to be found at: http://ec.europa.eu/dgs/health_food-safety/advisory_groups_action_platforms/advisory_group_en.htm.	

The evidence base of the present evaluation exercise is further complemented by relevant reports from the audit and inspection service of the Commission Directorate General for Health and Food Safety ('DG SANTE'), formerly known as the 'Food and Veterinary Office' ('FVO'), other Commission Staff Working Documents and Communications, EFSA outputs, a recent study on the competitive position of the European food and drink industry commissioned on behalf of the Commission ('Competitiveness study'),[11] Court of Auditors reports, case-law of the Court of Justice of the European Union as well as other studies and available literature.

The Regulatory Scrutiny Board was consulted on 11 October 2017 and provided a positive opinion on 13 October 2017.

[11] The competitive position of the European food and drink industry, ECSIP consortium, Rotterdam, February 2016, published at http://ec.europa.eu/growth/sectors/food/competitiveness/studies/index_en.htm.

6 Appendix 2a – Minutes of ISG group of 05.07.2017

INTER-SERVICE STEERING GROUP (ISG) MEETING ON THE FITNESS CHECK ON GENERAL FOOD LAW –

PRESENTATION AND DISCUSSION ON THE DRAFT COMMISSION STAFF WORKING DOCUMENT

Wednesday, 5 July 2017

Participants:

DG SANTE: Alexandra Nikolakopoulou (E1), Anastasia Alvizou (E1), Jeannie Vergnettes (D1), Katarzyna Kielar (A1), Enrique Beltran Poveda (G5)

DG AGRI: Gebhard Seiwald (D2)

SG: Annette Schäfer (C1)

DG GROW: Annalisa La Rovere (D3)

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The objective of this meeting was to collect the views of the ISG on the draft Commission Staff Working Document (CSWD), the Executive Summary and the accompanied appendices with a view to the final endorsement of these documents by the ISG before final submission to the Regulatory Scrutiny Board (RSB) in September 2017.

DG SANTE E1 (A. Nikolakopoulou) introduced the draft CSWD on the Fitness Check on General Food Law (GFL) to the ISG. DG SANTE explained that the project has experienced delays mainly due to the maternity leave of the main case-handler (A. Alvizou) and underlined the fact that such long-term projects cannot easily been assigned to other colleagues to take over. This Fitness Check exercise was a particularly difficult one given its subject matter but also because it was initiated before the Better Regulation Guidelines, which raised considerably the standards of evaluations. As it was not possible to launch additional studies for the collection of new data, DG SANTE faced the challenge to complete this evaluation with the data collected thus far while meeting the new requirements of the Better Regulation Guidelines. In addition, colleagues from the relevant services have been consulted in previous drafts of the CSWD and their input has been taken into account (*e.g.* SG, DG AGRI).

DG SANTE informed the ISG that a preliminary meeting with the RSB had taken place on 14 February 2017 to discuss the Fitness Check and get early guidance from the RSB on its main expectations from this exercise. The minutes of that meeting reflect the points that were of particular interest to the RSB (see Annex).

DG SANTE, therefore, suggested, on the basis of those minutes (which were distributed to the participants), to focus the discussion of the ISG on whether the issues that, according to the RSB

require particular attention, have been properly and adequately addressed in the draft CSWD. The participants agreed to this approach.

Point 1: Scope of Fitness Check – consider secondary legislation and implementation – upfront warnings on potentially problematic issues e.g. difficulties faced by SMEs

DG SANTE explained in that the Fitness Check also assesses the implementation of the GFL through 29 secondary acts in the area of food law, a list of which is attached as Appendix 1 (similarly to the FC OSH example). However, the scope (Section 1.2) does not explicitly refer to that list, which is only further analysed in another section. **DG SANTE will amend Section 1.2 to better reflect the scope of the Fitness Check and explicitly mention the reference to the 29 legislative acts that were evaluated to the extent they were implementing the GFL. The executive summary will be amended accordingly.**

All ISG participants agreed to these modifications, as it would enhance the clarity of the scope.

As regards SMEs, DG SANTE explained that a particular attention has been given to the position of SMEs in this evaluation exercise. A specific survey has been carried out targeting individual SMEs including small and micro enterprises. The findings have been included in the CSWD, in the context of an evaluation question under efficiency on the challenges faced by SMES as well as in Appendix 4 to the CSWD providing a summary of consultations where a specific section is added on the position of small and micro enterprises. The CSWD has also included the response of the Commission to some of the concerns raised by SMEs. For example, SMEs have pointed out that one of the most burdensome Information Obligations is labelling requirements. In that respect and to ensure the familiarisation of FBOs, and particularly SMEs, with labelling requirements, the Commission is currently setting up a Food Labelling Information System which is intended to provide a comprehensive and reliable overview of all applicable EU and MS requirements for food labelling per food product. **The ISG participants welcomed this clarification and it was agreed that the scope will be further amended to also make a specific reference to SMEs both in the CSWD and in the Executive summary.**

DG SANTE also drew the attention of the ISG to the temporal scope of the CSWD. According to the CSWD, the main data collection tools cover the period 2002-2013 in the EU 28 Member States ('MS'). Where significant, more recent data available has also been taken into account. SG suggested clarifying that the original temporal scope stems from the timing of the external studies carried out in 2014-2015. **DG SANTE agreed to make this clarification.**

Point 2: Quantification of regulatory burden – Potential for simplification as an explicit objective

DG SANTE explained that the main data collection tools, namely the two external studies underpinning the fitness check were initiated in the period prior to the adoption of the Better Regulation package. An effort has been made to meet the new requirements with the available data. The replies to the specific evaluation questions on efficiency address the quantification of costs, where feasible based on the information that could be gathered within the studies. On the basis of the data available within the EU a cost-benefit analysis was not feasible. Therefore, the CSWD illustrates the cost-benefit of the traceability requirement through a cost-benefit analysis carried out in the US on traceability. Moreover, the CSWD also indicates that some of the general requirements imposed on the FBOs either cover business as usual (*e.g.* for a FBO to be commercially viable in the

food and drink sector, it must ensure the safety of its products or compliance with the food law requirements applicable in the relevant markets) or consist of a codification of practices that were already applied – albeit not in a systematic manner – by FBOs prior to the GFL (*e.g.* traceability). Furthermore, the fitness check has revealed that adherence to standards has become a common practice and very often, these standards go beyond regulatory requirements adding to the burden of FBOs. The potential for simplification has also been included as an explicit objective of the exercise (scope) and it has been explored mainly through the General GFL study. The latter external study did not reveal any potential for simplification as regards the GFL as such.

SG proposed to make clearer in the CSWD the unintended effects of the GFL, such as the proliferation of standards. DG SANTE pointed out the specific parts where this aspect has been addressed and especially the power that retailers have gained over their suppliers, which are often SMEs. DG SANTE further added that the goal-oriented structure of GFL and its limited regulatory requirements has advantages and disadvantages: in terms of advantages, the current structure of the GFL has been praised by all consulted parties for providing the necessary flexibility to fit all actors in the food supply chain, however, it has provided a fertile ground for the proliferation of standards developed by the industry. These standards, as they go beyond the minimum regulatory requirements enhance even further the objectives of the GFL – especially in terms of high level of protection of public health and consumers' interests, but on the other hand it adds to the burden of the FBOs. DG SANTE mentioned that DG GROW is addressing this issue in the context of the High Level Forum. DG GROW will provide some text on the work that is taking place in that respect.

It was agreed to take on board SG's suggestion to make the aspect on proliferation of standards clearer with the additional contribution of DG GROW and mention this aspect both in the conclusions and in the executive summary.

Point 3: Relationship of this fitness check with other ongoing-pending evaluations

DG SANTE indicated that this is explained in Section 1.1 where a reference is made to the cascade approach of evaluations in the area of food law with the present fitness check being the second phase. **A third phase will consist of sectorial evaluations, a list of which is provided in an endnote as well as in the conclusions and in the executive summary.**

Point 4: Comprehensiveness of the fitness check – e.g. attention paid to the consumer perspective

DG SANTE explained that the consumer perspective is taken into account in the evaluation exercise. Nevertheless, even the consumer associations have indicated that it is difficult for them to quantify benefits.

It was agreed however to add a specific reference in the conclusions (and potentially in the executive summary) of the ongoing SANTE reflection on how to measure or quantify benefits in future evaluations.

SG also asked whether there is any new Eurobarometer study concerning consumers' attitude to food. DG SANTE replied that the latest Eurobarometer dates back to 2010.

SG also asked about the intentions of DG SANTE with respect to an open public consultation, as an exemption was granted for the open public consultation with an invitation to perform the OPC after the fitness check to verify its findings. DG SANTE replied that the findings of the Fitness Check will feed into other ongoing and future evaluations and they will be submitted for public consultation in the context of those sectorial evaluations.

Point 5: 'Fit for purpose' claims must be substantiated by examples – comparison of EU system vs. non EU countries' systems

DG SANTE explained how this point is addressed mainly in the context of the replies to the efficiency-related evaluation questions (*e.g.* figure on the crises pre- and post-GFL, OECD study on traceability where EU scores the highest amongst 21 OECD countries).

The ISG participants had no comment on this point.

Point 6: Potential weaknesses to be explored and described – thorough analysis also of problems relating to implementation – public debate issues should be addressed

DG SANTE explained how this point has been addressed in the CSWD. Indicatively, problems have been identified on the implementation at national level of the risk analysis principle. The reasons behind the need for national risk assessments are elaborated in Section 4.2.2.1.2. Moreover, issues which are part of the current public debate are also being addressed: issues relating to trust in scientific expertise, glyphosate case, dual quality issue, new Comitology regulation.

The ISG participants had no comment on this point.

Point 7: Historical context of the GFL and the achievements since the GFL adoption

This point has been addressed with the inclusion of the Baseline and the replies to the effectiveness-related evaluation questions. The ISG participants had no further comments.

NEXT STEPS:

DG SANTE described the next steps as follows:

- ISG members are to provide additional comments by 11 July 2017 COB.
- A revised draft CSWD and a revised Executive Summary on the basis of the ISG comments will be circulated by 14 July 2017 COB.
- The draft documents will be submitted to the SANTE Cabinet for additional comments.
- Should any additional comments be made by SANTE Cabinet, the draft documents will be resubmitted to the ISG for final approval in early September. To this effect, a provisional meeting of the ISG is foreseen for 6 September 2017.
- The formal submission of the documents to the RSB is planned for 13 September 2017 and the discussion will take place on 11 October 2017.
- A formal CIS will be launched after the delivery of the RSB's opinion – most likely at the end of October – early November 2017.

- The final adoption of the CSWD and of the Executive Summary is expected by end of December 2017.

7 Appendix 3 – Methodology

The present fitness check relied mainly on the findings of two targeted external studies commissioned by the Commission, *i.e.* the General GFL study and the RASFF study. In terms of temporal scope, both the GFL study and the RASFF study covered the period 2002-2013. The General GFL study covered EU-28 MS, while the RASFF study covered in addition Switzerland and the EEA countries (Norway, Liechtenstein and Iceland). As stated in Appendix 2, the Commission has also completed an internal intermediary report, updating the EFSA 2012 external evaluation to cover the period up to 2013-2014, while, where significant, more recent data available have also been taken into account. This intermediary report and the methodology followed is provided in Appendix 6.

This evidence base was further complemented by literature and other external studies, including reports from the audit and inspection service of the Commission Directorate General for Health and Food Safety ('DG SANTE'), formerly known as the 'Food and Veterinary Office' ('FVO'), a recent external study on the competitive position of the European food and drink industry commissioned by the Commission ('Competitiveness study'),[12] other relevant studies, Court of Auditors reports and case-law of the Court of Justice of the European Union.

8 General GFL study – Data collection strategy

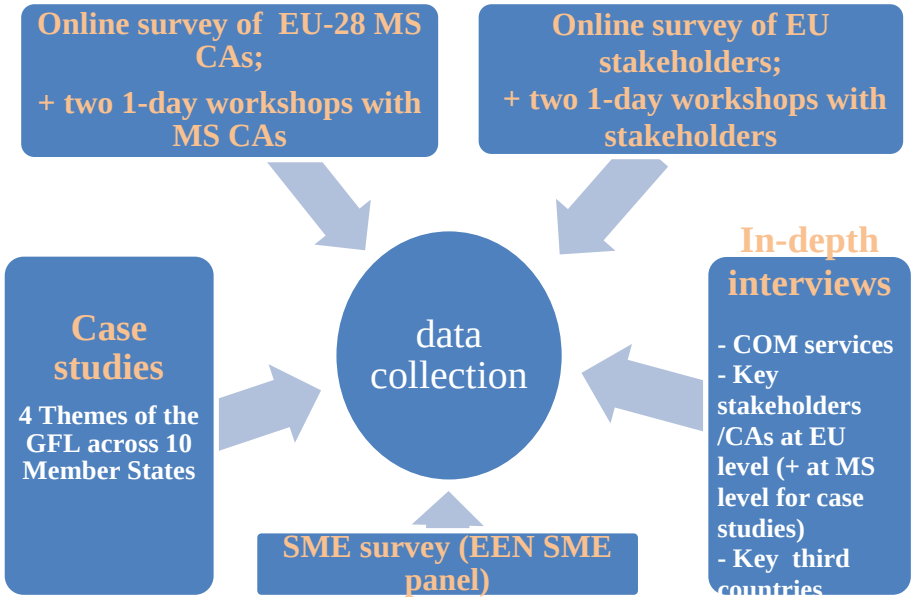
The purpose of the General GFL study was to assess (a) the implementation of the fundamental principles and definitions of the GFL by all public authorities, (b) whether the general requirements for the FBOs were fit for purpose and, (c) the cumulative impact of, and potential overlaps with, other EU secondary food legislation implementing the GFL provisions.[13]

The General GFL study was carried out on the basis of 34 evaluation questions ('EQs'), focusing on the following evaluation themes: relevance, EU added value, effectiveness, efficiency, internal coherence, external coherence and complementarity.[14] The judgment criteria and indicators that were used to address these 34 EQs were set out in a detailed matrix.[15]

The data collection strategy of the General GFL study is depicted in Figure 2.

[12] The competitive position of the European food and drink industry, ECSIP consortium, Rotterdam, February 2016, published at http://ec.europa.eu/growth/sectors/food/competitiveness/studies/index_en.htm.
[13] Terms of Reference of "Study on the Evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation"), dated 6.6.2014, to be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_fitc_tor_ev_regulation_en.pdf. The draft ToRs were discussed with both MSs and stakeholders and were validated by the ISG. See also Appendix 2.
[14] *Id.*
[15] See Appendix 5 (Annex 2b to the General GFL study).

Figure 2: Data collection strategy



Agra CEAS Consulting (FCEC)

The data collection strategy followed a stepwise approach:

- *1st step:* Workshops and taregeted surveys were the first step of the evidence gathering process, before proceeding to examine in-depth issues at a later step. The working documents supporting the workshops and the surveys were designed to collect an essential set of perceptions and other qualitative, as well as quantitative, data from the highest possible number of participants.
- *2nd step:* Interviews and case-studies were aimed at deepening the evidence base and focusing on (qualitative/quantitative) data collection in specific areas that merited further investigation/analysis.

Each of the data collection tools played a distinct role. For example, the targeted survey for the stakeholders was targeting stakeholder organisations representing FBOs in the various segments of the food chain[16] as well as organisations representing consumers and NGOs active on food chain issues. The targeted survey of MS CAs was addressed to the EU 28. The SME consultation through the EEN SME Panel targeted individual SMEs, including micro-enterprises.

1.1 Stakeholder and MS CA workshops

Two one-day workshops with stakeholders and MS CAs were held on 19 December 2014 and 16 January 2015 in the context of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health (stakeholders) and the Expert Group on General Food Law (MS CAs) respectively. Both workshops opened with a general presentation of the evaluation study context

[16] Individual companies were also indirectly consulted through their umbrella organisations/associations representing their sector (*e.g.* some of the larger companies are direct members of such organisations at MS level and/or at EU level; the SME sector is broadly represented by UEAPME).

and methodology. This was followed by specific sessions focusing on two thematic case studies per work shop on the basis of detailed working documents:[17] The selection of the thematic case studies was determined by the relevance of the themes to each workshop, as follows:

- The workshop of stakeholders focused on case studies on traceability (case study 1) and distribution of FBO responsibilities (case study 2);
- The workshop of MS CAs focused on case studies on risk analysis (case study 3) and transparency (case study 4).

For both stakeholders and MS CAs, the deadline for providing a response to the working documents was ultimately set on 27 March 2015, to allow them sufficient time to perform internal consultations and to contribute with verified, quality inputs and data. The inputs provided in the written feedbacks have fed into the data collection and provided the basis for the interviews carried out in the context of the case studies, as outlined in paragraph 1.4 below.

The benefits of these two workshops were two-fold:

- First, the workshops informed participants of the evaluation process, and provided further clarifications and explanations to allow them to develop better targeted, quality inputs in the context of the data collection tools used (*e.g.* targeted surveys, case studies, interviews) for the study. This was important as, typically, EU-level stakeholders needed to hold internal discussions with their members, and MS CAs internally within their services and/or with other authorities involved, in order to perform their evidence gathering and data collection.
- Second, early involvement in the process enabled stakeholders to feel ownership of the evaluation process thus improving the validity of the results ultimately obtained. The approach has been to consider stakeholders as partners in the evaluation process, while always being mindful that their job is to protect the interests of their members, hence a wider stakeholder involvement and triangulation of evidence provided has been an important element our methodology. Conducting the workshops has facilitated working relations, while it has improved the transparency/visibility of the evaluation with the different actors consulted, and provided for a balanced exchange of information and analysis on the issues covered by the evaluation.

Towards the completion of the data collection phase, two additional one-day workshops took place with both MS CAs and stakeholders on 27 April 2015 and 6 May 2015 respectively. The two workshops constituted important follow-up steps to the consultation and validation process. In addition to the benefits indicated above, these workshops have contributed to two objectives:

- To update MS CAs and stakeholders on the progress of the evaluation, timeline and next steps;
- To share preliminary findings of the evaluation, in particular the aggregate results of the targeted survey, and to stimulate some further discussions/exchange on some points.

These workshops contributed to the Commission's commitment to transparency during the process of the evaluation.

[17] See Appendix 5. The working documents presented in those workshops are attached as Annexes 5d and 5e to the General GFL study.

1.2 Targeted surveys

Two targeted (web-based) surveys were carried out in the period February-March 2015 (8 weeks). One survey was directed at MS CAs; the other at stakeholders of the food chain, *i.e.* associations representing the interests of various business operators along the food and feed supply chains, NGOs (e.g. environmental NGOs) and consumer associations.

MS CAs targeted survey

As for the responding MS CAs, a total of 25 out of targeted 28 MS CAs replied to the online survey. Thus, most of the MS CA survey results are based on N=25 respondents (apart from questions that were not mandatory or that allowed more than one response).[18]

Stakeholders' targeted survey

There have been 67 complete replies to the targeted survey of stakeholders (of 105 total replies) therefore the stakeholder survey results are based on N=67 respondents. Of those 67 complete replies, 14 were received from consumer groups and NGOs. For some of the questions, in particular those relating to costs, the overall findings were limited only to replies received from operators, *i.e.* excluding consumers and NGOs (N=53).

Stakeholders that have responded to this survey were for the most part active in the food sector (63%) while 21% were active in the feed sector and 16% in other activities, which also include consumer organisations and other NGOs. As regards their position in the food chain, responding stakeholders were for the most part (39%) involved in processing (primary: 16%; secondary and further processing stages: 23%). Wholesale/trading/brokers/distribution represents the second most represented business activity (12%), retail the third (10%), followed by feed production (8%), consumers (7%). Other sectors included agriculture input production, agricultural production, transport and other interest/NGOs. Several respondents have indicated that they are involved in more than one stages of the supply chain. An overview of the geographical coverage of the responded stakeholders is provided in Annex 3 to the General GFL study (Appendix 5).

1.3 SME Panel

SMEs dominate the food and drink manufacturing sector in the EU. It was therefore considered essential to consider the impact of the GFL on SMEs, particularly on micro- and small-enterprises, as these FBOs are likely to have a different capacity to interact with legislation. To this end, a SME survey was launched using the Europe Enterprise Network (EEN) SME Panel. The SME survey was carried out in April-June (9 weeks) 2015 and received 925 replies.

Profile of SME respondents

[18] The MSs that did not provide input within the time frame were Bulgaria, Denmark and Portugal. Any input received after the online survey was closed as well as input received from Norway, although not reflected in the aggregated results, has been taken into account in the final report of the General GFL study.

The main target of the Panel was individual SMEs (up to 250 employees; 94% of the respondents). Of these, 37% were micro-enterprises (from self employed – 9 employees), 34% were small-enterprises (10-49 employees) and 24% were medium-enterprises (50-250 employees). The large-enterprises that participated in the survey were estimated at 6%.[19]

Nearly two thirds of the respondents were processors/manufacturers of food products, followed by food retailers, caterers/restaurants and wholesalers of food and feed products, as depicted below:

	Answers	Ratio
Processor/manufacturer of feed products	79	8.54 %
Processor/manufacturer of food products	623	67.35%
Manufacturer of agricultural inputs, other than food/feed (e.g. plant protection products)	11	1.19%
Wholesaler of food/feed products (including import/export)	136	14.7%
Retailer (mainly selling food/feed, specialised or non-specialised)	155	16.76%
Caterer/restaurant	155	16.76%
Transport/storage/packaging (mainly for the food/feed sector, specialised or non-specialised)	60	6.49%

The vast majority of the SME respondents buys from, or sells to their national markets (89%). More than half indicated to trade in the EU market (57%), one third in markets outside the EU (36%).

[19] Percentages may not total 100% due to rounding.

1.4 Case studies

Given the framework structure of the GFL, four thematic case studies were carried out to allow a more in-depth collection of data and evidence with respect to key GFL areas, to complement the findings of the targeted surveys, as depicted below.

Theme	Scope (GFL)	Focus sectors/issues
Case study 1: Traceability	Art. 18	• Adequacy of '*one step forward – one step back*' approach (Art. 18), along the extended supply chain • Application in practice: is it enforced at the level required by Art. 18? Or, does it go beyond (e.g. due to contractual obligations)? Implementation of internal traceability? • EU added value • Impact on SMEs • How has it applied in food safety situations (in particular for withdrawals/recalls) and the outcomes positive/negative • Whether it is fit for purpose • Costs of traceability vs broader benefits
Case study 2: FBO responsibilities	*Art. 17.1;* Art. 19 to 21; Article 8	• Distribution of FBO responsibilities/liability along the chain, including retailers, brokers and where food/feed is manufactured outside the EU (importers) • Application in practice: implementation for withdrawals/recalls (Art. 19 to 21) • Own-controls – verification of food law requirements • Whether it is fit for purpose • Impact on SMEs • Costs vs benefits • EU added value • Sanctions applied in case of infringements of food law more generally (intended or unintended) (adequacy of Art. 8)

Theme	Scope (GFL)	Focus sectors/issues
Case study 3: Risk analysis and precautionary principle	Art. 6 and 7	• Whether it is fit for purpose • Comparative assessment on how the risk analysis principle of GFL has been applied in other secondary legislation: Food additives; Feed additives; Contaminants; Food contact materials • Assessment whether the 3 components of risk analysis (risk assessment, risk management and risk communication) are clearly defined and have been consistently, efficiently and effectively applied. • Separation of risk assessment from risk management • EU added value of risk analysis • Science vs other legitimate factors in risk management • Application of precautionary principle
Case study 4: Transparency	Section 2 of the GFL (Articles 9 and 10)	• Public consultation during the preparation/evaluation/revision of food law at EU/national level (Art 9) • Public information (Art 10) • EU added value • How it is applied in practice • Whether it is fit for purpose

The case studies were carried out on the basis of detailed questions set out in Working Documents.[20] The implementation of the GFL through other EU secondary food legislation was also addressed in those thematic cases, where relevant, *e.g.* the implementation of the risk analysis principle in the areas of food additives, feed additives, contaminants and food contact materials.

Ten MS CAs were interviewed in the context of the thematic case studies: Austria, Estonia, Finland, France, Germany, Hungary, Italy, Netherlands, Slovakia, and the UK. The selection of the MSs was made taking into account a) the appropriate geographical coverage, b) the appropriate mix of old and new MS as

[20] See Appendix 5 (Annex 5 to General GFL study).

well as large and small and c) the MS CAs' interest to actively participate and provide data and information to these case studies. The MS coverage as well as the selected themes were approved by the ISG at the end of the inception phase.

1.5 Interviews

Extensive interviews were conducted with EU-level stakeholders (*e.g.* EU associations of FBOs at the different stages of the supply chain[21] and EU consumer associations), officials form the Commission and EFSA, MS stakeholders in the context of the case studies (*e.g.* representatives of national food industry associations), officials of MS CAs in the selected MS covered by the case studies and five selected non EU countries in May-June 2015 (*i.e.* US, Chile, Brazil, Canada and China).

9 RASFF study – Data collection strategy

The purpose of the RASFF study was to assess whether the regulatory framework established by Articles 50 to 57 of the GFL Regulation is effective and efficiently working and providing added value to its stakeholders (RASFF and crisis management provisions).

The RASFF study was carried out on the basis of a number of EQs set out in the relevant Terms of Reference.[22] The judgement criteria and indicators that were sued to address these EQs were set out in a detailed matrix.[23]

The main data collection tools for the RASFF study were the following: document review, on-line surveys, three case studies of serious food safety incidents and interviews.

1.6 Targeted surveys

Two targeted surveys were conducted in the framework of the RASFF study, targeting (1) RASFF national contact points and other stakeholders involved in the RASFF; and (2) relevant competent authorities in the field of food/feed crisis management and relevant stakeholders. Stakeholders that were consulted, in addition to the RASFF National Contact Points (NCPs) and the relevant competent authorities in the field of food/feed crisis management, included the Administrative Assistance and Cooperation (AAC) contact points in Member States, EU and international organisations, relevant government bodies in non EU countries as well as organisations of FBOs and consumer organisations in the EU.

The surveys were launched on 19 December 2014 and closed on 27 February 2015. In total, 75 NCPs and other stakeholders participated in the RASFF survey and 47 MS CAs and relevant stakeholders participated in the survey on crisis management (see also Appendix 4b).

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[21] EU level organisations were encouraged to invite their most active national members to join the interviews and express their national viewpoints.

[22] Terms of Reference of the "Evaluation of the Rapid Alert System for Food and Feed and of crisis management procedure", dated 23.5.2014, to be found at: https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_fitc_tor_rasff_en.pdf . The draft ToRs were discussed with both MSs and stakeholders and were validated by the ISG. See also Appendix 2.

[23] See Appendix 6 (Annex 10 to the RASFF study).

1.7 Case studies

Three case studies focusing on serious food safety incidents were carried out in the context of the RASFF study. These concerned the melamine crisis of 2008, an incident involving glass fragments in instant coffee in 2010 and the outbreak of Shiga toxin producing Escherichia coli – STEC – serotype O104:H4 - *E.coli* incident in sprouts – in 2011. The three case studies covered different hazard categories (chemical, foreign body, pathogenic micro-organism) and different geographical areas (within the EU/globally).

The case studies consisted of a review of relevant documents as well as interviews at EU level and in at least three countries affected by the incident. Key stakeholders consulted for the case studies included the RASFF NCPs and MS CAs involved in the management of the incidents. All interviews were based on semi-structured questionnaires which were developed for the different stakeholder groups.

1.8 Interviews

The interviews conducted during the case studies were complemented by additional interviews, including with EFSA, the European Centre for Disease Prevention and Control (ECDC), INFOSAN, the US and New Zealand.

10 Appendix 4 – Stakeholder consultation

1 Stakeholder strategy

Stakeholder involvement was crucial in collecting evidence with respect to the implementation of the GFL and in identifying possible systemic failures of the GFL provisions and problems with the implementation of the GFL general principles and requirements in other EU secondary food legislation.

The consultations carried out in the context of the present Fitness Check predated or coincided with the publication of the Better Regulation Guidelines in May 2015. Nevertheless, the consultation processes have respected the Commission's minimum standards, *i.e.* clarity of the consultation documents, appropriate consultations of target groups to ensure the widest possible representation of the relevant interests, appropriate consultation periods to ensure that stakeholders had sufficient time to respond to invitations and written contributions, and regular updates of stakeholders concerning the consultant's work through the Expert Group on General Food Law (MSs) and the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health (FBO associations, NGOs and consumer groups), as stated in Appendix 2.

1.1 General GFL study - Relevant stakeholders

The General GFL study was relevant to a wide and varied range of stakeholders,[24] as depicted in Figure 1 below:

Figure 1: Overview of stakeholder groups

Stakeholder group	***Reason for consultation***
1. Consumer organisations	One of the two core objectives of the GFL is a "*high level of protection of human health and consumers' interests in relation to food*". It was therefore important to collect any relevant evidence as to what extent this core objective has been achieved through the GFL framework and its implementation in other EU secondary food legislation addressing, amongst others, EU consumers' trust in food.
2. Organisations/associations representing food and feed businesses, at European and national/regional level, active in	The second core objective of the GFL is *"the effective functioning of the internal market",* including the creation of equal conditions of competition, avoiding the potential for unnecessary wider market disruptions in the event of food safety problems. This objective relates directly to food and feed business operators along the

[24] The list includes external stakeholders only. In addition, consultations have taken place with the Commission services and EFSA.

Stakeholder group	*Reason for consultation*
the entire food chain	entire food chain, including SMEs. The GFL imposes certain, though, few direct obligations on food and feed businesses. In addition, the implementation of the GFL principles and common definitions in other EU secondary food legislation also has had an impact on food and feed businesses. This fitness check falls under the Commission's Better Regulation initiative, hence the need to understand the effects of the GFL framework on businesses and whether there is need and/or potential for simplification and reduction of regulatory burden.
3. SMEs (in particular the small- and micro-enterprises, given their relative importance in this sector)	The food supply chain is dominated by SMEs (almost 99%). It was therefore important to assess the effects of food legislation on the relevant SMEs, including micro-enterprises.
4. Member States' competent authorities (MS CAs) (the relevant ministries and enforcement authorities in the food chain)	MS CAs have broad experience on the implementation and enforcement of the GFL framework and other relevant EU secondary food legislation.
5. NGOs and other associations representing interests other than those listed above	The associations listed above may not cover the whole range of stakeholders with an interest on the GFL framework and the agri-food chain in general. Such stakeholders are captured by this group.
6. International dimension: selected non EU countries	The consultation of this stakeholder group is of particular importance to assess the impact of the GFL on international trade in relation to the main EU trading partners.

A detailed mapping of the EU-level stakeholders in the food chain including consumer groups and NGOs that were identified as being most relevant to consult for this study (except MS CAs, non-EU and international organisations) is set out in Appendix 4a.

1.2 RASFF study – Relevant stakeholders

The RASFF study was relevant mostly to the MS CAs, who are the main users of RASFF pursuant to the GFL. The same applies also to the crisis management provisions to some extent, although the latter is also relevant for other stakeholders such as FBOs and consumer organisations. A detailed mapping of all stakeholders in the food chain including MS CAs, agencies, industry, and consumer associations that were identified as being most relevant to consult for this is set out in Appendix 2a.

2 Summary of the consultation process and results

2.1 Overview of consultations

As elaborated in detail in Appendix 3 for the General GFL study and the RASFF study and in Appendix 7 for the EFSA intermediary report, consultations took place through different methodological tools:

- *Stakeholder and MS CA workshops:* In the context of the General GFL study, two one-day workshops with stakeholders and MS CAs were held on 19 December 2014 and 16 January 2015 in the context of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health (stakeholders) and the Expert Group on General Food Law (MS CAs) respectively. These two workshops focused on two thematic case studies each on the basis of detailed working documents, as follows: (a) the workshop of stakeholders focused on case studies on traceability (case study 1) and distribution of FBO responsibilities (case study 2) and (b) the workshop of MS CAs focused on case studies on risk analysis (case study 3) and transparency (case study 4). For both stakeholders and MS CAs, the deadline for providing a response to the working documents was ultimately set on 27 March 2015, to allow them sufficient time to perform internal consultations and to contribute with verified, quality inputs and data. Towards the completion of the data collection phase, two additional one-day workshops took place with both MS CAs and stakeholders on 27 April 2015 and 6 May 2015 respectively, to share preliminary findings of the evaluation, in particular the aggregate results of the targeted surveys, and to stimulate some further discussions/exchange on specific points of interest. In the context of the update for the intermediary report of EFSA, a special workshop on EFSA took place on 29 June 2017 in the context of the Expert Group on General Food Law with the participation of EFSA. The aim of this workshop was to update the findings of the EFSA 2012 evaluation on the cooperation between EFSA and MS on the basis of a working document.[25]
- *Targeted surveys:*
    - General GFL study: Two targeted surveys for the stakeholders and the MS CAs took place in in the period February-March 2015 (8 weeks).
        - The targeted survey for the stakeholders was targeting stakeholder organisations representing FBOs in the various segments of the food chain as well as organisations representing consumers and NGOs active on food chain issues. Individual companies were also indirectly consulted through their umbrella organisations/associations representing their sector (*e.g.* some of the larger companies are direct members of such organisations at MS level and/or at EU level; the SME sector is broadly represented by the association UEAPME). As stated in Appendix 3, there have been 67 complete replies to the targeted survey of stakeholders (of 105 total replies) therefore the stakeholder survey results are based on N=67 respondents. Of those 67 complete replies, 14 were received from consumer groups and NGOs. For some of the questions, in particular those relating to costs, the overall findings were limited only to replies received from operators, *i.e.* excluding consumers and NGOs (N=53). Stakeholders that have responded to this survey were for the most part active in the food sector (63%) while 21% were active in the feed sector and 16% in other activities, which also include consumer organisations and other NGOs. As regards their position in the

[25] All relevant documentation about the meetings of the Expert Group on General Food Law (MS), *e.g.* agenda, working documents and summary reports, is to be found at: http://ec.europa.eu/food/safety/general_food_law/expert_group/index_en.htm. All relevant documentation about the meetings of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health (stakeholders), *e.g.* agenda, working documents and summary reports), is to be found at: http://ec.europa.eu/dgs/health_food-safety/advisory_groups_action_platforms/advisory_group_en.htm.

food chain, responding stakeholders were for the most part (39%) involved in processing (primary: 16%; secondary and further processing stages: 23%). Wholesale/trading/brokers/distribution represents the second most represented business activity (12%), retail the third (10%), followed by feed production (8%), consumers (7%). Other sectors included agriculture input production, agricultural production, transport and other interest/NGOs. Several respondents have indicated that they are involved in more than one stages of the supply chain. An overview of the geographical coverage of the responded stakeholders is provided in Annex 3 to the General GFL study (Appendix 5).

    - The targeted survey of MS CAs was addressed to the EU 28. A total of 25 out of targeted 28 MS CAs replied to the targeted survey.

- RASFF study: Two targeted surveys were conducted in the framework of the RASFF study, targeting (1) RASFF national contact points and other stakeholders involved in the RASFF; and (2) relevant competent authorities in the field of food/feed crisis management and relevant stakeholders. Stakeholders that were consulted, in addition to the RASFF National Contact Points (NCPs) and the relevant competent authorities in the field of food/feed crisis management, included the Administrative Assistance and Cooperation (AAC) contact points in Member States, EU and international organisations, relevant government bodies in non EU countries as well as organisations of FBOs and consumer organisations in the EU. The surveys were launched on 19 December 2014 and closed on 27 February 2015. As stated in Appendix 3, in total, 75 NCPs and other stakeholders participated in the RASFF survey and 47 MS CAs and relevant stakeholders participated in the survey on crisis management (see also Appendix 4b).

- *SME consultation:* SMEs were consulted in the context of the GFL study through the EEN SME Panel by means of EU survey. The EU survey targeted individual SMEs, including micro-enterprises and took place in the period April-June 2015 (9 weeks). It received 925 replies. As elaborated in Appendix 3, 37% of the respondents were micro-enterprises (from self employed – 9 employees), 34% were small-enterprises (10-49 employees) and 24% were medium-enterprises (50-250 employees). The large-enterprises that participated in the survey were estimated at 6%.[26] Nearly two thirds of the respondents were processors/manufacturers of food products, followed by food retailers, caterers/restaurants and wholesalers of food and feed products.
- *Interviews:* In the context of the General GFL study, extensive interviews were conducted with EU-level stakeholders (*e.g.* EU associations of FBOs at the different stages of the supply chain[27] and EU consumer associations), officials form the Commission and EFSA, MS stakeholders in the context of the case studies (*e.g.* representatives of national food industry associations), officials of MS CAs in the selected MS covered by the case studies and five selected non EU countries in May-June 2015 (*i.e.* US, Chile, Brazil, Canada and China). Similarly, in the context of the RASFF study, interviews took place in the context of the case studies conducted at EU level and in at least three countries affected by the incident, including the RASFF NCPs and MS CAs involved in

[26] Percentages may not total 100% due to rounding.

[27] EU level organisations were encouraged to invite their most active national members to join the interviews and express their national viewpoints.

the management of the incidents. Additional interviews were also carried out EFSA, the European Centre for Disease Prevention and Control (ECDC), INFOSAN, the US and New Zealand.

2.2 Consultation results

In the following paragraphs, a summary of the consultation results per subject matter is provided. Nevertheless, as the food and drink industry is dominated in numbers by SMEs, particular attention has been paid to the concerns of SMEs and in particular to those of small- and micro-enterprises. To this end, a dedicated section on the small- and micro-enterprises sets out the specific viewpoints of the latter to the overall GFL framework and its implementation in other EU secondary food legislation.

2.2.1 General remarks

There is overall consensus amongst all consulted parties (MS CAs, FBOs, consumer organisations and NGOs) that the GFL has made a positive contribution, as a framework, to the EU legislative *acquis* of relevance to the entire food chain by raising the level of food safety across the EU and strengthening the internal market. From the perspective of MS CAs, the GFL has brought a relatively pioneering application of a global safety approach to the food chain at national level. From the FBOs' perspective, the harmonisation of requirements has been particularly beneficial for companies located in multiple MS. Nonetheless, the full reaping of the benefits is to some extent hampered by discrepancies/ inconsistencies in implementation in the different MS, and lack of full harmonisation in some fields. From a consumers' perspective, the focus on consumer interest is considered to be one of the key improvements introduced by the GFL in the field of consumer protection.

As far as the interaction between FBOs and MS CAs is concerned, more than half of the SME respondents indicated that national authorities always/usually or sometimes help them meet food and feed law requirements (e.g. by providing information on food/feed rules specific to small/medium businesses, or guidelines). Over one third have indicated, however, that authorities rarely/never help.

2.2.2 Objectives of GFL – current trends and needs

There is consensus amongst all consulted parties (MS CAs, FBOs including SMEs), consumer organisations, environmental NGOs that the GFL has achieved a high standard harmonisation across the EU to ensure the safety of food and feed placed on the market and to protect consumers' health and interests, while facilitating the free movement of goods. Generally, the GFL is considered more adequate to address other objectives/needs, such as consuming healthier foods and the competiveness of the supply chain, than current trends such as distance selling or sustainability/food waste.

2.2.3 Common definitions and scope

MS CAs, FBOs and NGOs overall considered that the scope and general definitions of the GFL have been sufficiently broad to ensure an integrated approach to food/feed safety management and relevant to address the main objectives of food law (EU/national). All consulted parties considered that the alignment of the GFL definitions to those at international level enhances the international

orientation and objectives of the GFL. FBOs expressed some concerns over the different interpretations of some of these definitions by MS CAs and the borderline cases: 'food' vs. medicinal products/medical devices, 'food' vs. 'feed'. Some definitions were also considered missing according to some MS CAs and FBOs, *e.g.* local/craft, e-commerce/distance selling.

2.2.4 Risk analysis principle

Overall, all consulted parties considered that the risk analysis principle, including the consideration of other legitimate factors had had a substantial positive impact on consumers' health and protection and has improved the scientific basis and transparency of EU/national food-related measures.

- *Risk assessment at EU level (EFSA)*

According to the 2012 external EFSA Evaluation, 89% of the respondents, which included institutional stakeholders (Commission, European Parliament, national risk assessors and national risk managers), external stakeholders (scientific organisations of Art. 36 of the GFL, food industry/applicants, NGOs, consumer organisations, international institutions, media) and EFSA's bodies (Management Board and Scientific Committee), considered that EFSA scientific outputs were reliable and the most reliable if compared with other EU agencies, *i.e.* EMA and ECHA.

All MS CAs highly valued the cooperation between EFSA and national risk assessors. They have, however, raised certain concerns with respect to future trends in EFSA's scientific expertise: EFSA is becoming increasingly deprived from valuable expertise, as there is a rising trend for private-public partnerships in science, which is not in line with EFSA's strict independence rules. For MS CAs, other disincentives for experts to participate in EFSA's activities include: the insufficient recognition of the experts' contribution to EFSA for the scientists' career, the amount of time required, the fact that in some cases experts do too much routine work, the high workload, the low financial compensation for experts (or their employers) as well as the location of EFSA in Parma. Several MS CAs have also raised the fact that they are not consulted on the mandate drafting for EFSA setting out the subject matter of the risk assessment, although called to vote for the final decision at the Standing Committee (PAFF) at risk management level.

FBOs have raised the following concerns with respect to EFSA: a) deficiencies in communication between EFSA and industry, leading to unpredictability, lack of clarity in terms of *e.g.* data requirements, delays and additional regulatory costs; and, b) the relevance of the mandates developed by the Commission as this has an impact on the outcome of EFSA opinions. FBOs have noted the limited opportunities to interact with EFSA. FBOs also consider that EFSA is progressively losing expertise because of its strict independence rules for participation to its Panels.

Some NGOs criticise EFSA's independence rules. They perceive the existence of links between EFSA's experts and industry and the level of conflict of interests as too high, due to the fact that the responsibility for completing and updating DoIs rests only with the holder. In their view, any link with industry must be considered as a conflict of interest. The use of data and studies coming from industry in EFSA risk assessments is also questioned from few NGOs that cannot have access to them because of the use of confidentiality clauses. They consider that EFSA makes use of 'industry science' to judge whether products are safe. They therefore advocate a stronger cooperation with research

institutions and universities in order to better deal with the most controversial risk assessment and to commission independent safety testing.

- *Risk assessment at MS level*

According to MS CAs, national measures on feed and food have been adopted on the basis of risk analysis. For the most part, the non systematic application of risk analysis as the basis for national measures is attributed by MS CAs to the difficulties and constraints associated with the implementation of fully fledged risk analysis.

According to FBOs, certain national MS measures are not adopted on the basis of risk analysis, leading in some cases to an excessive application of the precautionary principle by MSs.

- *Risk management at EU level*

Pursuant to the MS CAs, 'other legitimate factors' have been taken into account mostly on a case by case basis when EU measures on feed and food have been adopted. MS CAs considered that the precautionary principle has been applied correctly mostly for measures taken at national level and to a lesser extent for measures taken at EU level.

Overall, FBOs, consumer associations and NGOs welcomed the application of the risk analysis principle. Nevertheless, FBOs, while for the most part accept the arguments in favour of the consideration of other legitimate factors, have also highlighted that, in practice, this is also a major source of uncertainty for businesses. Generally, all stakeholders of the food chain considered that the precautionary principle had been applied correctly mostly for measures taken at EU level and to a lesser extent for measures taken at national level.

- *Risk management of MS level*

Pursuant to the MS CAs, 'other legitimate factors' (i.e. factors other than scientific opinions assessing the risk to health) have also been taken into account mostly on a case by case basis when national measures on feed and food have been adopted. MS have provided examples of national measures (23) taken on the basis of the precautionary principle; the main driver for their adoption was the identification of the possibility of harmful effects on health (15 measures), with persisting scientific uncertainly raised only for few (3) measures; other factors were raised for few (5) measures e.g. environmental reasons.

- *Risk communication*

According to FBOs, information on the rationale of EU risk management decisions can only be found in recitals of EU food regulations, but these only give some brief explanations of how the decision was taken and what were the factors, other than science, that were into account; and/or, the minutes of the PAFF committee meetings, but these are very concise and do not usually contain any explanation. Consumer organisations indicated that, where national measures differ from or even contradict EU legislation, it is particularly important to understand better the political choices and possible trade-offs behind any decision.

- *Separation of risk assessment – risk management*

All consulted parties (MS CAs, FBOs, NGOs and consumer associations) considered that the separation of the risk assessment and risk management has improved considerably over time and generally functions well in practice.

- *Impact of measures taken on the basis of risk analysis*

All consulted parties (MS CAs, FBOs, NGOs and consumer associations) considered that the application of risk analysis has achieved positive outcomes, *i.e.* effective and proportionate EU/national measures, increased level of consumer protection and elimination of unjustified barriers to trade.

- *Commission response to the concerns/criticisms raised*

EFSA has addressed some of the concerns raised by the MS CAs. For instance, the publication of its scientific outputs in a scientific journal contributes to having the scientific work of EFSA's experts published and thus better recognised by the scientific community. As regards the drafting of mandates, the comment of MS CAs does not take into account the fact that in the area of regulated products, the existing legal provisions provide that it is the Commission or the MS that may send a mandate to EFSA requesting the latter to assess whether a substance is in conformity with the applicable legal criteria. In the area of general scientific opinions, however, the experts groups managed by the Commission may discuss some important mandates.

To remedy delays in the risk assessment phase, EFSA has initiated since 2012 a series of actions, *e.g.* introduction of a single entry point for applicants (application desk unit), dialogue with industry in particular through info sessions and work shop helping applicants for the submission of their dossiers and better involvement of stakeholders in the guidance on authorisations. In addition, a new Regulation on novel foods with simplified centralised authorisation procedure at EU level has also been recently adopted, which sets out specific deadlines for risk assessment and for the Commission to propose a draft risk management measure to the PAFF committee. Furthermore, the Commission and EFSA are currently setting up electronic systems to manage the authorisation process in the area of regulated products to support innovation by FBOs, and in particular SMEs. EFSA is already trying to ensure greater involvement of its stakeholders in the risk assessment phase in the context of the most important self-tasking mandates.

All the above-mentioned criticisms relating to EFSA will be further analysed in the context of its specific mandatory external evaluation, launched in 2017. The latter evaluation will focus on the EFSA's operation and governance structure and it will address, amongst others, the trends for the future of EFSA in particular the reduced attractiveness of EFSA for national experts, the relevance of the EFSA governance model, EFSA's effectiveness and efficiency in particular for the delivery of scientific opinions as well as its capacity to minimise administrative burdens, the cooperation with Member States and the link between citizens' trust and the scientific excellence, independence and transparency of EFSA.

2.2.5 Distribution of responsibilities (primary responsibility and official controls – general safety requirement)

All consulted stakeholders (MS CAs, FBOs, NGOs and consumer associations), considered that the primary responsibility imposed on FBOs and the official controls to be carried out by MS have ensured an efficient allocation of responsibilities, have created a level playing field for all feed/food business operators in the EU, have reduced administrative burden and, have freed up resources at MS CA level to focus on the enforcement of food law. In addition, there is consensus amongst all consulted stakeholders that FBOs at all stages of production, processing and distribution verify (e.g. via their own internal controls) that the core feed/food law requirements (set out at EU and national level) which are relevant to their activities are met.

Several of the consulted MS CAs have acknowledged differences in the implementation of controls between MS which are due to different approaches followed rather than the legal provisions of the GFL as such. According to MS CAs, overall, operators have complied with all the actions foreseen in the context of withdrawals/recalls of unsafe food/feed.

According to FBOs, a key obstacle to delivering a fully efficient system is that the own check systems in place by them are not recognised by authorities in most MS, even when independent third party auditing/certification is performed. FBOs have also noted differences in the implementation of controls carried out by national authorities between MS but even within MS (at regional/local level). This variable approach of the MS CAs can, however, also reflect to some extent differences in the **reliability of own controls**.

The vast majority of the SME respondents were well aware of the various basic legal requirements that companies in this sector must meet. The majority of respondents have not found it hard to meet most of these legal requirements, particularly the requirement to withdraw unsafe food and feed. Carrying out their own checks to ensure compliance with food law requirements is one requirement that respondents find most hard to meet, as indicated by nearly half of respondents. Two thirds of the SME respondents have never hired an external consultant to help them comply with EU food/feed law.

A common feature of most systems in place is their integration into private certification and quality management schemes/standards. Several FBOs have indicated that they have been forced to use private tools/self-regulation to reduce legal uncertainty and unnecessary burdens resulting from diverging implementation at national level. FBOs have highlighted that while integrating legal requirements within existing quality management and certification schemes/standards, extending beyond compliance with the GFL obligations, has been an important cost-mitigating factor that has helped to accommodate the costs associated with the primary responsibility obligation of the GFL, adherence to private standards, nevertheless, adds to the sector's burden. SME respondents were also asked about certain food and feed safety requirements in their contracts with suppliers or customers. The most prevailing requirements - where half of the respondents have often/sometimes been asked to comply - are specific private standards, guidelines and codes of practice issued by industry associations and communication of results of own tests to the supplier/customer. Less common (about a third of respondents are asked to comply) is the requirement to tell the supplier/customer the results of tests carried out by public authorities and to have a more detailed

traceability system than "the one step back-one step forward traceability", with more than half of the respondents rarely/never required by suppliers or customers to do so.

FBOs were not in a position to quantify compliance costs of the primary responsibility requirement (e.g. as % of total production costs) or to estimate the cost-benefit ration in broad quantitative terms. Nevertheless, for 52% of the consulted FBOs, the benefits resulting from primary responsibility have considerably/more or less outweighed the costs of setting up the relevant operating systems (19% and 33% respectively).

2.2.6 Traceability

According to FBOs, they have been applying, for the most part, the one step back – one step forward traceability, prior to the introduction of this requirement by the GFL but not systematically.

According to all consulted parties (MS CAs, FBOs, NGOs and consumer associations), the one step back – one step forward traceability in the supply chain has provided benefits in terms of achieving the following outcomes: assisted in containing a food/feed safety problem (as well as in addressing a non-compliance problem with food/feed legislation (not safety-related)); ensured effective tracing of feed and food across the full 'farm to table' supply chain in the EU; ensured effective and efficient targeted withdrawals/recalls of unsafe food and feed; and, contributed to maintain consumer trust and confidence to the safety of a food and feed.

There is overall consensus amongst all consulted stakeholders that generally, amongst all key provisions of the GFL, traceability stands out as the area where the least differences in the interpretation and enforcement by national authorities are identified, and, overall, the identified differences are for the most part not systematic.

Most of MS CAs as well as the FBOs considered that internal traceability should remain a business decision, rather than a regulatory obligation. For MS CAs, traceability has particularly contributed to assist in containing a food/feed safety problem, assist in containing/addressing a non-compliance problem with food/feed legislation (not safety-related ensure effective and efficient targeted withdrawals/ recalls of unsafe food/feed, maintain consumer trust and confidence to the safety of a food/feed and avoid/limit unnecessary disruption of trade.

FBOs were not in a position to provide an overall estimate of the costs of providing traceability as laid down in the GFL as a % of average operational or production costs, given the diversity of the food chain as costs depend on where an operator is positioned in the food chain as well as the fact that there is no single model/system of integrating such a requirement and given the diversity of the food chain. Finally, FBOs have highlighted that integrating legal requirements within existing quality management and certification schemes/standards has been an important cost-mitigating factor that has helped to accommodate the costs associated with the traceability obligation of the GFL. FBOs, NGOs as well as consumer organisations have noted that the benefits of traceability cannot be measured.

According to FBOs, in qualitative terms, the benefits of traceability requirement have considerably outweighed the costs of setting up and operating traceability systems, as required by the GFL, for over a third (37%) of FBOs and have more or less outweighed costs for an additional 19%.

Nonetheless 22% of FBOs indicated that benefits have not for the most part outweighed costs while it is noted that 21% of them were not able to respond ('don't know').

For nearly half of the SME respondents, the one step back-one step forward traceability requirement goes beyond a normal book-keeping exercise. Around 75% of the respondents have an 'internal traceability system'[28] within the organisation. Nearly two thirds of these internal traceability systems were set up at businesses' own initiative. Moreover, three quarters of SME respondents have an internal system for withdrawing food/feed that is a safety risk, while it is still in their immediate control. A vast majority of the SME respondents indicated clear benefits of the traceability system: it makes it easier to manage risk in food/feed safety incidents (85% of respondents); helps identify which products need to be withdrawn from the market (83%); and, maintains consumer trust by providing accurate information on products affected by a food safety incident (75%). A smaller majority of respondents indicated that the system prevents unnecessary disruption to trade (54%) and improves business management (60%), although a relatively important share of respondents do not know whether the traceability system has these particular benefits (23% and 13% respectively). Only about a quarter of those businesses that have an internal traceability system in place indicated that this has provided additional benefits beyond those of having the basic traceability requirements, while a fifth of those businesses do not know.

2.2.7 Public consultation

Considerable progress towards an improved public consultation was noted by all consulted parties following the GFL, both at EU and at MS levels. Nonetheless, according to stakeholders (FBOs, consumer organisations and NGOs), the level/frequency of public consultation is generally higher in the case of EU legislation than in the case of national legislation, although this view is not shared by MS CAs. Consumer organisations have also noted that emphasis tends to be placed on the costs of legislation, and less on the benefits (or the costs of non-regulation) for the broader society, which are inevitably more difficult to demonstrate.

2.2.8 Public information

Over three quarter of stakeholders (FBOs, consumer organisations and NGOs) and nearly all MS CAs considered that the process of risk information has improved over time, in particular taking into account lessons learnt from previous food crises. For FBOs, informing the public, while providing beneficial reassurance in the short term, also carries the risk of lasting adverse impacts on business reputation and consumer trust. According to consumers, although the level and type (adequacy/ appropriateness) of the information provided to the general public has considerably improved overtime, it remains variable amongst MS and case by case.

[28] The GFL does not compel FBOs to establish a link (so-called internal traceability) between incoming and outgoing products. Nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches.

2.2.9 Trade and international aspects

The consultations with all stakeholders, including with the authorities of selected non EU countries, have found that the GFL has overall facilitated food/feed trade with non EU countries; it has influenced rather positively both imports of feed/food into the EU from non EU countries and EU exports to the latter. All consulted parties generally agree that the GFL framework is internationally recognised and, in some cases, it is a source of inspiration of non EU countries in developing their own legislation or even at Codex level, influencing the global agri-food trade.

The consulted non EU countries generally appreciate the EU harmonisation process, allowing access to a more uniform set of rules across the enlarged EU market, and the conclusion of bilateral trade agreements with the EU enhancing further trade. However, they have also noted that, in practice, MS continue to some extent to have varying interpretations of EU food law, leading to different commercial requirements for their exports across the EU.

2.2.10 RASFF

Overall, according to the consulted stakeholders including NCPs, FBOs and consumer organisations the scope of RASFF appropriately addresses needs of RASFF members. According to the RASFF NCPs and other stakeholders involved in the RASFF considered that in practice duplication with other notification systems (e.g. INFOSAN, TRACES) is not a major concern. Consulted stakeholders were split as to whether only notifications involving a risk are transmitted through RASFF: [29] 46% of respondents to this question affirmed that notifications exchanged through the RASFF are sufficiently risk based, while 44% of respondents rejected this statement. According to RASFF NCPs the costs incurred by their country for the RASFF had been appropriate when compared with the benefits of the RASFF. The main benefits identified related to the speed of information and communication exchange, the management of food/feed safety incidents, as well as the protection of consumer health and verification of product compliance that the RASFF enables.

RASFF Portal[30] and RASFF Consumers Portal[31] are considered by all consulted stakeholders (MS, consumer organisations and FBOs) as a positive step to improve transparency. There is no consensus regarding the extent to which the RASFF Portal and RASFF Consumers Portal sufficiently inform FBOs

[29] The RASFF is a system for the notification of a direct or indirect risk to human health deriving from food, food contact material or feed in accordance with the GFL or a serious risk to human health, animal health or the environment in connection to feed in accordance with Regulation (EC) No 183/2005 on animal feed.

[30] The RASFF Portal is not prescribed by the GFL but it is an initiative of the Commission to provide RASFF-related information to FBOs, subject to the professional secrecy provisions set out in the GFL. This platform enables users to find notifications using a search function, allowing them to perform queries according to e.g. the notification reference number, subject of the notification, notifying country, notification classification (i.e. alert, border rejection, etc.), hazard category, date, and others.

[31] The RASFF Consumers Portal is also not prescribed in the GFL but it is an initiative of the Commission to provide RASFF-related information to consumers. It provides information on food recall notices and public health warnings issued by MC CAs and FBOs. In this application, notifications are removed after a four-week period. It allows interested consumers to search according to the user's country, and provides a link to the country's national consumer website, where applicable. As in the RASFF Portal, the name of the company or brand producing or distributing the given product is not provided, though it may be found in the recall notice or relevant publication attached to the notification, where available.

and consumers. While on average, RASFF NCPs tend to consider that FBOs and the general public are sufficiently informed, FBOs and consumer organisations tended to disagree. The main issue appears to be the lack of detail regarding products concerned by RASFF notifications, preventing some professional operators from being able to quickly assess whether or not action should be undertaken on their side. It should be mentioned however that RASFF is established primarily for the needs of the RASFF members; the RASFF Portal and the RASFF Consumers Portal are Commission own initiatives to provide information within the confines of the RASFF system and subject to the RASFF confidentiality rules as laid down in the GFL Regulation.

2.2.11 Emergency measures and crisis management

MS CAs and other stakeholders agreed that existing crisis management arrangements have to a significant extent achieved (in order of average rating) consumer health protection, the efficient management of food/feed safety incidents and coordinated implementation of most effective measures to contain the risk in past serious food/feed safety incidents. Nine in ten respondents (MS CAs and other stakeholders) assessed emergency measures taken as having been moderately to very effective for the management of serious food/feed safety incidents.

MS CAs (and to a lesser degree also other stakeholders) consider the two layers of action, set out in the general plan (Commission Decision 2004/478/EC) to be relevant and still appropriate for food/feed crisis management. This is in spite of the fact that a crisis unit has never been set up, i.e. the second layer of action has not been used during serious food/feed safety incidents experienced during the last decade. Regarding the first layer of action, there are diverging assessments among respondents whether or not it has been sufficient to ensure the management of previous food/feed safety incidents: Just over a third considered that the first layer of action had been sufficient for the management of past serious food/feed safety incidents, a nearly similar number of respondents indicated that it had not been sufficient, while another third of respondents did not know.

The case study regarding the E.coli outbreak in 2011 confirms that the first layer of action has been partly insufficient for the management of this incident. During the outbreak, a clearer crisis management structure within the European Commission would have been beneficial, according to key stakeholders involved, either a crisis unit or a similar structure that could be activated without formally declaring a crisis. There is also a broad consensus that additional measures are needed for crisis management at EU level. The measures considered most necessary are regular crisis simulation exercises, a greater role of the EC in the coordination of Member States' efforts and specifically the coordination of the communication to the public/relevant competent authorities, as well as a step-wise approach for escalating measures of crisis management. In the light of the experience gained over the years and especially in the aftermath of the *E.coli* in sprouts crisis in 2011, the Commission intends to revisit the 2004 general plan on crisis management to ensure a stronger focus on prevention and preparedness.

2.2.12 Administrative burden

2.2.12.1 Specific concerns on costs and burden

All of the key GFL requirements have entailed a fair and proportionate burden on business operators, according to a large majority of stakeholders and MS CAs. More specifically:

According to the vast majority of consulted stakeholders (FBOs, consumer organisations, NGOs and MSs), the food/feed safety requirement and the primary responsibility obligation (including own controls) have largely entailed a fair and proportionate burden on business operators. Despite on average a positive feedback, FBOs noted that the burden associated with the primary responsibility obligation and the food/feed safety requirements is distorted by the impact of additional requirements posed by other EU secondary legislation and differential implementation by MS CAs; private standards also distort the calculation of regulatory costs and burden, and the distinction between regulatory and non-regulatory is not straightforward, since these are often intertwined with regulatory requirements.

The majority of the consulted stakeholders (FBOs, consumer organisations, NGOs and MSs) also consider that all the other main GFL requirements have largely entailed a fair and proportionate burden on operators: the requirement to establish one step back - one step forward traceability, the requirements on withdrawals/recalls of food/feed at risk (although FBOs have highlighted the non-uniform implementation by MSs), the requirement to notify public authorities in case food/feed considered at risk; and, the requirement to collaborate with public authorities on actions taken to avoid or reduce risk.

The most burdensome Information Obligations (IOs)[32] stemming from the provisions of EU food law are those associated with: certification of products or processes; cooperation with audits and inspection by public authorities in the context of withdrawals/recalls (; information labelling for third parties; cooperation with audits and inspection by public authorities in the context of secondary legislation, e.g. official controls; and, application for individual authorisation or exemption. Between 42% and 51% of consulted FBOs ranked these IOs as being amongst the three most burdensome obligations of EU food law (out of the 11 IOs considered).

According to the consulted FBOs, the administrative costs and burden related to the implementation of EU food law, as a proportion of total operational costs and staff numbers, generally tend to decline as the business size increases. In particular, annual administrative costs including training, as a share of total operational costs, represent on average 8.5% for micro-enterprises, declining to 7.8% for small enterprises, 6.7% for medium enterprises and 5.1% for large enterprises. Similarly, the total number of FTEs involved, as a share of total staff numbers, represent on average 7.4% for micro-enterprises, 6.9 % for small enterprises, declining to 6.1% for medium and large enterprises.

The case studies on traceability and operators' primary responsibilities have found that, according to FBOs, the benefits conferred by these provisions of the GFL outweigh the costs of setting up and operating the required systems. These provisions have ensured an efficient (fair and clear) distribution of responsibilities amongst FBOs along the food supply chain, as well as between FBOs and MS CAs.

SME respondents ranked the costs of complying with traceability, labelling, authorisation, registration and certification as the most costly of all food-related requirements. This is followed by the costs of meeting the requirement for own controls, with the costs of meeting contractual

[32] Information obligations (IOs) defined on the basis of the Standard Cost Model (SCM).

obligations/private standards coming in third place. Respondents indicated that the three most demanding administrative tasks carried out under EU food law obligations are traceability record keeping, certifying products or processes, and Information labelling for customers and consumers. The share of administrative costs spent on EU feed/food law administration is quite different amongst SMEs. For over a quarter of SME respondents, costs for EU food law in general (not limited to the GFL Regulation) account for 0-5% of total administrative costs, for nearly one fifth around 5-10%, for one tenth between 10-15% and for another tenth they account for 20% or more. It is nonetheless noted that nearly 30% of the SME respondents indicated that they do not know. When comparing the benefits and costs of EU food law, 18% of SME respondents indicated that benefits outweigh costs, 24% that benefits break even with costs, while for 32% of SME respondents benefits do not outweigh costs. Nonetheless, nearly a quarter of SME respondents indicated that they do not know.

To alleviate the burden on FBOs (and in particular SMEs) relating to the identification and familiarisation of food labelling requirements, the Commission is currently setting up a Food Labelling Information system, as announced in the Commission Communication on 'Better Regulation for Better Results – An EU Agenda'.[33] The latter system will provide a comprehensive and reliable overview of all applicable EU and MS requirements for food labelling per food product.

2.2.12.2 Potential for simplification – potential for cost and burden reduction

Overall, there is consensus amongst all consulted parties that the GFL provisions encourage proportionality in administrative burden. Some FBOs have, nevertheless noted some potential for simplification and reduction of administrative costs and burden - mainly through soft interventions - in relation to the following:

- The obligation of verification: This includes notably the possibility for control authorities to take into account the results of operators own checks, provided that a system is in place to ensure that they are reliable. This is already the case as laid down in the Official Controls Regulation.[34]
- Withdrawals of unsafe food/feed: A common problem with these provisions, as highlighted by the food industry, is the broad and differential interpretation by authorities in practice of the food safety criteria resulting to larger quantities of food products than necessary being removed from the market, even in cases when internal traceability may be in place. The Commission has developed EU guidelines[35] to assist, amongst others, MS CAs in their determination as to whether foods fulfil the applicable food safety criteria.

[33] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Better Regulation for Better results – an EU agenda', COM(2015)215, dated 19.5.2015.

[34] Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The latter Regulation will be repealed and replaced as of December 2019 by **Regulation (EU) 2017/625 on official controls and other official activities.**

[35] Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal Health, dated 26

As regards the interaction of the GFL with other EU secondary food legislation, FBOs have noted that further harmonisation has the potential of reducing administrative burden (e.g. food contact materials, contaminants). Another area where there is potential for simplification relates to the specific authorisation procedures in other EU secondary food legislation (e.g. health claims, enriched food) as well as to the requirement of multiple parallel or successive authorisation procedures for the same substances. In addition to the cost of preparing complex dossiers and providing demanding data requirements, the length, unpredictability and uncertainty of the outcome of the authorisation procedures is identified by operators as a major concern/burden for undertaking the investment required. For actions taken by the Commission to address these concerns, see above under Section 2.2.4.2.

2.2.13 Summary of micro- and small-enterprises responses

To ensure that the views of micro- and small-enterprises are taken into account, a more detailed analysis of their responses in the context of the SME survey was undertaken. The main findings are as follows:

Compliance with legal requirements

Many respondents reported difficulties in responding to constantly changing legal requirements as operators often do not have enough time and resources to follow and adopt them. A large number of respondents find it hard to understand and interpret requirements set by the EU legislation. For many respondents, it is not clear where to find the relevant information on legal requirements and which authorities should be addressed in order to obtain it. Furthermore, a large number of respondents complained that local and national authorities are often unwilling to cooperate with operators and fail to provide them with updated information and clarifications regarding the implementation of legal requirements.

Hiring of an external consultant

A large number of respondents reported that they hired an external consultant for traceability and HACCP system implementation, and implementation of labelling requirements. Consultants were also hired to help with the application of legal requirements in general and training of the personnel.

Obligations and conditions imposed by suppliers/customers

Many respondents find it hard to obtain required information from their suppliers *e.g.* information on the country of origin of the product. As there are no official controls imposed on suppliers, sometimes they do not fulfil food safety requirements; provide incomplete documentation and no certificates to guarantee the quality of raw materials supplied. Respondents indicated that many customers require the adoption of additional food quality and safety standards that are not obligatory by the EU law. According to respondents, proliferation of such private standards increases

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January 2010, at p. 10, to be found at:
https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf.

the production costs. Respondents reported that customers also ask for certificates and additional proves that private standards are implemented in the company. Sometimes, customers also demand to provide analysis reports. In many cases, customers require at least participation in regular audits or ask to execute external audits.

Traceability systems (not limited to food safety)

According to respondents, there is a huge quantity of traceability information to be managed, *e.g.* surveillance of allergens entering into the production process, which is required by other EU secondary food legislation. Respondents made some positive comments on the implementation of traceability system, stressing that it helps to attract new customers and expand to new markets. Furthermore, it gives consumer an accurate information on the product and maintains consumer' trust.

General comments

Overall, a large number of respondents representing small- and micro- enterprises emphasized that the EU legal requirements regarding food safety are established for large companies as for smaller companies the costs of their implementation are too high and might be detrimental for businesses. There were also suggestions to establish separate legislation that small businesses should comply with.

Respondents stressed that the variety of products in the food retail sector makes it difficult for small companies to comply with labelling obligations. Bakeries and other artisanal producers are especially concerned as often they change ingredients used and expand their range of products. Hence, for them to adapt to changing and complex labelling requirements is particularly burdensome. Respondents noticed that complying with labelling requirements increase the cost of a product and that might make it less competitive in the EU external markets. There is also a lack of understanding among the producers and suppliers abroad about costly labelling requirements in the EU.

There are different labelling requirements in export destinations that operators have to comply with, *e.g.* products with labelling accepted in France can be refused on Swiss or the US market. However, this is an inherent part of international trade.

Respondents replied that they need help in dealing with a wide range of issues related to the EU food safety legislation, such as the implementation of HACCP principles, traceability, food safety specifications, labelling rules under the Food information Regulation, internal audits, setting up of quality dossiers and implementation of food quality systems, understanding novel food regulation. Operators also need advice and trainings regarding the interpretation of the food safety, hygiene and labelling rules.

Commission's reply to the points raised

To assist stakeholders, EU guidelines have been developed in close cooperation with MS CAs to facilitate a cost-effective implementation of the GFL Regulation[36] and other relevant EU secondary food legislation (such as the HACCP systems[37] and the Food Information Regulation[38]). The Better Training for Safe Food Programme ('BTSF') of the Commission has also been acknowledged by MS CAs as greatly contributing to the understanding and enforcement of EU food law, ensuring a more coherent implementation of the GFL Regulation framework across the Union. As stated earlier, to address the costs for FBOs, and in particular SMEs, with respect to the identification and familiarisation with horizontal and vertical food labelling rules at both EU and national level, the Commission is currently setting up a Food Labelling Information system. The objective of this system is to provide a user friendly IT solution which will help the users to identify the food they wish as well as the MS in which they want to market that food and automatically retrieve all relevant mandatory EU and national labelling indications. Finally, the Commission and EFSA are currently setting up electronic systems to manage the authorisation process in the area of regulated products (*e.g.* food improvement agents and novel foods) to support innovation for FBOs and in particular SMEs during the authorisation process. The objective is to simplify the process and alleviate burdens for the applicants, but also to ensure a more efficient use of the Commission and MS resources, while enhancing the transparency of the authorisation procedures.

[36] Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal Health, dated 26 January 2010, at p. 10, to be found at:
https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf.

[37] Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles (OJ C 278, 30.7.2016, p.1).

[38] For more information, *see* at https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en.

11 Appendix 4a – Mapping of stakeholders (General GFL study and RASFF study)

A. General GFL study

Figure 3: List of relevant stakeholders in the food supply chain, including consumer groups and relevant NGOs targeted by the consultations in the context of the General GFL study (except MS CAs, non-EU and international organisations)

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
		All EU-level associations		
	AAF	European Starch Industry Association	PFP	n
	AESGP	Association of the European Self-Medication Industry		y
	AIJN	European Fruit Juice Association	FDE	n
	AIPCE-CEP	Association des industries du poisson de l'Union européenne		n
NGO	ANIMALS ANGELS	Animal Welfare Association		n
	AVEC	Association of Poultry Processors and Poultry Trade in the EU		y
NGO	BEUC	Bureau européen des unions de consommateurs		y
	CAOBISCO	Chocolate, biscuits & confectionery of Europe	FDE	n
	CEEREAL	European Breakfast Cereal Association	FDE	n
	CEEV	Comité Européen des Entreprises Vins		n

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	CEFIC	Conseil Européen des fédérations de l'industrie chimique		y
	CEFS	Comité Européen des Fabricants de Sucre	PFP; FDE	n
	CELCAA	Comité Européen de Liaison des Commerces AgroAlimentaires		y
NGO	CES/ETUC	Confédération Européenne des Syndicats/European Trade Union		n
	CIBE	International Confederation of European Beet Growers		n
	CLITRAVI	Liaison Centre for the Meat Processing Industry in the EU	FDE	n
	COCERAL	Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'Union Européenne		y
	COFALEC	Confederation of EU Yeast Producers	FDE	n
	COPA-COGECA	Committee of Agricultural Organisations in the EU		y
	CULINARIA EUROPE	Federation of Associations and Enterprises of Industrial Culinary Product Producers in Europe	FDE	n
	ECA	European Cocoa Association	PFP	n
	ECCA	European Crop Care Association		n
	ECF	European Coffee Federation	FDE	n
	ECFF	European Chilled Food Association		n

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	ECPA	European Crop Protection Association		y
	ECSLA	European Cold Storage and Logistics Association		n
	ECVC	European Coordination Via Campesina		n
	EDA	European Dairy Association	FDE	y
	EFBW	European Federation of Bottled Waters	FDE	n
	EFFAT	European Federation of Food, Agriculture and Tourism Trade Unions		n
	EFPRA	European Fat Processors and Renderers Association		n
	EFM	European Flour Millers	PFP	n
	EHIA & ETC	European Herbal Infusions Association and European Tea Committee	FDE	n
	EHPM	European Federation of Associations of Health Product Manufacturers		y
	ELC	Federation of European Specialty Food Ingredients Industries		n+
	EMRA	European Modern Restaurant Association		y
	ENSA	European Natural Soyfood Association		n
NGO	EPHA	EU Public Health Alliance		n
Forum	ERRT	European Retail Round Table		n
	ESA snacks	European Snacks Association	FDE	n
	ESA spices	European Spice Association	FDE	n
	ESA seeds	European Seed Association		n

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	EUCOFEL	Trade of fruit and vegetables		n
	EUPPA	European Potato Processors	FDE	n
	EUROCHAMBRES	Association of European Chambers of Commerce and Industry		n
	EUROCOMMERCE	European Representation of Retail, Wholesale and International Trade		y
	EUROCOOP	European Community of Consumer Cooperatives		y
	EUROGLACES	European Ice Cream Association	FDE	n
NGO	EUROGROUP FOR ANIMALS	Eurogroup for animal welfare		y
	EUROPABIO	European Association of Bioindustries		y
	EUSALT	European Salt Producers' Association		n
	EUVEPRO	European Vegetable Protein Federation	PFP	n
	EUWEP	European Union of Wholesale with Eggs, Egg Products and Poultry and Game		n
	FDE	FoodDrink Europe		y
	FEDIMA	Federation of EU manufacturers and suppliers of ingredients to Bakery, Confectionary and Patisserie industries	FDE	n
	FEDIOL	European Vegetable Oil and Proteinmeal	PFP	n
	FEDIAF	European Pet Food Industry Federation	FDE	n
	FEEDM	European Federation of Honey Packers & Distributors	FDE	n

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	FEFAC	European Feed Manufacturers' Federation		y
	FEFANA	EU Association of Specialty Feed Ingredients and their Mixtures		y
	FERM	Federation of European Rice Millers		n
NGO	FESASS	Fédération européenne pour la santé animale et la sécurité sanitaire		y
NGO	FoEE	Friends of the Earth Europe		y
	FOODSUPPLEMENTS EUROPE			n+
	FOODSERVICE EUROPE	European Federation of Contract Catering Organizations		y
	FRESHFEL	European Fresh Produce Association		y
	FRUCOM	European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs		n+
NGO	FVE	Federation of Veterinarians of Europe		n
	HOTREC	European Trade Association of Hotels, Restaurants and Cafés in Europe		n
NGO	IFAH-EUROPE	International Federation for Animal Health Europe		y
NGO	IFOAM-EU GROUP	International Federation of Organic Agriculture Movements — European Union Regional Group		y
	IMACE	International Margarine Association of the countries of Europe	FDE	n

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	INDEPENDENT RETAIL EUROPE	EU representation of groups of independent retailers to EU and international institutions		y
NGO	Labelling Matters	Labelling Matters		n
	OEIT	European Organisation of Tomato Industries		n
Forum	PAN EUROPE	Pesticides Action Network		y
	PFP	Primary Food processors		y
	PROFEL	European Association of Fruit and Vegetable Processors	FDE	n
	SpiritsEUROPE	European Spirits sector	FDE	n
	SEMOULIERS	Union des Associations des Semouliers de l'UE		n
	SLOW FOOD	Slow Food Associazione Internazionale		y
	SNE	Specialised Nutrition Europe	FDE	n
	The Brewers of Europe	The Brewers of Europe	FDE	n
	UEAPME	European Association of Craft, Small and Medium-sized Enterprises.		n
	UECBV	Union européenne du commerce du bétail et de la viande		y
	UNAFPA	Union of Organisations of Manufacturers of Pasta Products of the European Union	FDE	n
	UNESDA	Union of European Beverages Associations	FDE	n

Notes:

1) n+ indicates stakeholders that are not members of the Advisory Group on the Food Chain but who have requested to attend the Advisory Group for issues relating to the GFL.

2) This figure lists organisations active at EU level only. National member organisations of these stakeholders were targeted via their EU counterparts.

B. RASFF study

Contributing stakeholders (MS CAs, agencies, consumer associations, industry associations) to the RASFF survey

1. ACCOE

2. Administration for food safety, veterinary sector and plant protection (Slovenia)

3. AGES (Austria)

4. Amt für Lebensmittelkontrolle und Veterinärwesen, FL-9494 Schaan (Liechtenstein)

5. APC EUROPE S. A.

6. BEMEFA vzw www.bemefa.be

7. Bundesamt für Verbraucherschutz - Federal Office of Consumer Protection and Food Safety (BVL) (Germany)

8. CENTRAL CONTROLLING AND TESTING INSTITUTE IN AGRICULTURE (CCTIA)

9. Central institute for supervising and testing in agriculture (Slovakia)

10.Central Institute for Supervising and Testing in Agriculture (Slovakia)

11.COCERAL

12.Coop de France Nutrition Animal

13.Czech Agriculture and Food Inspection Authority (CAFIA)

14.Czech Agriculture and Food Inspection Authority (CAFIA)

15.DGAV-DSECI-DIM (Portugal)

16.ECDC

17. Estonian Veterinary and Food Board

18. EuroCommerce

19. European Association of Chemical Distributors (Fecc)

20. European Crop Protection Association

21. European Spice Association

22. Federal Agency for the Safety of the Food Chain (Belgium)

23. Federal Office for Food Safety and Veterinary Affairs (Switzerland)

24. FEDERATION OF HELLENIC FOOD INDUSTRIES

25. FEDIAF

26. FEDIOL

27. FEFAC

28. FEFANA Asbl

29. Finnish Food Safety Authority Evira

30. FNICGV

31. FNLI (Federation of the Dutch Food and Grocery Industry)

32. Food and Drink Federation

33. Food and Veterinary Service (Latvia)

34. Food Safety Authority of Ireland

35. Food Safety Commission MALTA

36. Food Standards Agency, United Kingdom

37.FOOD SUPPLEMENTS EUROPE

38. FoodDrinkEurope

39. FoodServiceEurope

40.FRENCH MINISTRY IN CHARGE OF AGRICULTURE AND FOOD

41.Główny Inspektorat Sanitarny (Chief Sanitary Inspectorate) (Poland)

42. Hellenic Food Authority (EFET)

43.Huevos Guillen S.L.

44. IACA

45. International Meat Trade Association

46. Irish Shellfish Association

47. MIAVIT NUTRICION ANIMAL S.L

48. MINISTERO DELLA SALUTE (Italy)

49. Ministry of Agriculture (Croatia)

50. Ministry of Agriculture and Food (Bulgaria)

51.Ministry of Agriculture and Rural Development of the Slovak Republic

52. Ministry of Agriculture of the Czech Republic

53. Ministry of Agriculture, Food and Environment (Spanish Feed Contact Point for RASFF)

54. Ministry of Agriculture, Livestock and Food Supply (Brazil)

55. Ministry of Food, Agriculture and Fisheries. Danish Veterinary and Food Administration

56. National Food Agency (Sweden)

57. National Food Chain Safety Office (Hungary)

58. National Food Chain Safety Office Food and Feed Safety Directorate (Hungary)

59. National Sanitary Veterinary and Food Safety Authority (Romania)

60. Nestlé S.A.

61.Norwegian Food Safety Authority

62. Public Health Services, Medical and Public Health Services, Ministry of Health (Cyprus)

63.PURATOS NV

64. Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) (SENASA: National Service of Agrifood Health and Quality - Ministry of Agriculture, Livestock and Fisheries of Argentina)

65. Spanish Agency for Consumer Affairs,Food Safety and Nutrition

66. State Food and Veterinary Service of the Republic of Lithuania

67. State Food and Veterinary Service of the Republic of Lithuania

68. Swedish Board of Agriculture

69. The Netherlands Food and Consumer Product Safety Authority (NVWA)

70. The State Veterinary and Food Administration of the Slovak Republic

71. U.S. Food and Drug Administration

72.UECBV

73. VBT

74. Verband der Fleischwirtschaft e. V. (VDF)

75. Veterinary and Food Board (Estonia)

Contributing stakeholders (MS CAs, agencies, consumer associations, industry associations) to the crisis management survey

1. Administration for Food Safety, Veterinary Sector and Plant protection (Slovenia)

2. Bemefa

3. BFMA

4. Brazilian Ministry of Agriculture, Livestock and Food Supply

5. Chief Sanitary Inspectorate (Poland)

6. Danish Veterinary and Food Administration

7. Direction Générale de la Concurrence, de la Consommation et de la Répression des fraudes (DGCCRF) - General Directorate in charge of competition, consumption and frauds (France)

8. ELC - Federation of European Specialty Food Ingredients Industries

9. Estonian Veterinary and Food Board

10. EuroCommerce

11. European Centre for Disease Prevention and Control

12. Federal Agency for the Safety of the Food Chain (aka FASFC or Belgian Food agency)

13. Federal Ministry of Food and Agriculture (Germany)

14. Federal Office of Consumer Protection and Food Safety (Germany)

15. FEDERATION OF HELLENIC FOOD INDUSTRY

16. FEDIOL

17. FEFAC

18. FEFAC

19. Finnish Food Safety Authority Evira

20. FNICGV

21. FNLI (Federation of the Dutch Food and Grocery Industry)

22. Food and Veterinary Service (Latvia)

23. Food Safety Authority of Ireland

24. Food Standards Agency (U.K.)

25.FOOD SUPPLEMENTS EUROPE

26. FoodDrinkEurope

27. General Directorate for Food and Veterinary Affairs (Portugal)

28.HELLENIC FOOD AUTHORITY (EFET)

29. IACA

30. Ministry in charge of agriculture and food (France)

31.Ministry of Agriculture (Czech Repulic)

32. Ministry of Agriculture and Food (Bulgaria)

33. Ministry of Economic Affairs (EZ) and the Ministry of Health, Welfare and Sport

(VWS) / Netherlands Food and Consumer Product Safety Authority (NVWA)

34. Ministry of Health (Austria)

35. National Food Chain Safety Office (Hungary)

36. National Sanitary Veterinary and Food Safety Authority - Romania

37. Nestlé S.A.

38. Nordic Sugar

39. OCU organización de Consumidores y usuarios (Spain)

40. Public Health Services, Medical and Public Health Services, Ministry of Health (Cyprus)

41.PURATOS NV

42.SPANISH AGENCY FOR CONSUMER AFFAIRS, FOOD SAFETY AND NUTRITION (AECOSAN)

43. STATE GENERAL LABORATORY (Cyprus)

44. Swedish Board of agriculture

45. The Norwegian Food Safety Authority

46. U.S. Food and Drug Administration

47.UECBV

12 Appendix 5 – The General GFL study

To be found at:

https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

13 Appendix 6 – The RASFF study

To be found at:

https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

14 Appendix 7 – EFSA intermediary evaluation report in the context of the Fitness Check of the GFL Regulation

1 Baseline for the EFSA evaluation

Based on the White Paper on Food Safety[39], the baseline for the present EFSA intermediary evaluation report is as follows:

Before Regulation 178/2002 (further referred to as the GFL), the scientific opinions were provided by eight sectorial Scientific Committees, of which five covered, directly or indirectly, the feed and food areas. In addition, a Scientific Steering Committee provided advice on multidisciplinary matters, BSE, harmonised risk assessment procedures, and co-ordination of questions which cut across the mandates of more than one of the sectorial Committees (e.g. anti-microbial resistance). The Committee Secretariats were provided by the Commission services. A Directorate of around 40 staff was in charge of supporting the work of the nine Scientific Committees. Between their creation (10 June 1997) and the publication of the White paper (12/01/2000), the Scientific Committees[40] (5 food and 3 non-food) had provided approximately 256 opinions.

The system was characterised by a lack of capacity to cope with the increase in the demands placed upon it in terms of protection of public health, in terms of development of innovation (authorisations) and in terms of rapid and flexible response in case of crisis. Other gaps identified included the following:

- The absence of effective information gathering systems, also covering the new Members States, to ensure the availability of accurate, up-to-date, scientific data supporting the risk assessment, in particular in the areas of epidemiological information, prevalence figures and exposure data.
- The lack of scientific networks with Member States aimed at pooling knowledge and reducing the time-consuming preparatory work required from scientific experts producing the scientific opinions.

2 Methodology

EFSA's operation is subject to a mandatory external evaluation every 6 years, under the GFL Regulation. The last external evaluation of EFSA dates back to 2012, which covered the period January 2006 to December 2010 ('EFSA 2012 evaluation'[41]). As time had elapsed since 2010 and since the next external evaluation was scheduled for 2017/2018, the Commission proceeded to an internal intermediate report of EFSA covering the period 2013-2014; where significant, more recent data

[39] See fn. 7 of Appendix 2.
[40] Food, Animal Nutrition, Veterinary-Public Health, Plants, Animal Health and Animal Welfare, Cosmetic products & non-food products, Medicinal products and medical devices, Toxicity, Ecotoxicity and Environment
[41] To be found at http://www.efsa.europa.eu/en/keydocs/docs/efsafinalreport.pdf.

were taken into account. The present intermediate report updates the EFSA 2012 evaluation on the basis of input received from EFSA and MS[42] and addresses the evaluation questions set out in the mandate of the Fitness Check. It also takes into account the results of the Impact Assessment on the establishment of fees for EFSA[43].

The views of stakeholders and MS, contained in the present intermediary report, mainly stem from the surveys conducted in the context of the EFSA 2012 evaluation; where more recent views were expressed, these have been taken into account.

3 Relevance

3.1 Relevance of the objectives related to EFSA

EFSA's increased scientific capacity was needed to support the reform of the food law given the high number of questions posed to the risk assessors. Between 2007 and 2016, EFSA has delivered on average around 529 scientific outputs per year (see also Table 2). These figures have to be contrasted with the baseline as set out in the White Paper on Food Safety, pursuant to which the former Scientific Committees[44] (food and non- food) had provided some 256 opinions in the period June 1997-January 2000 (thus around 100 per year for all the Committees but less when only the food Committees are considered).

A stronger EU centralised expertise capacity was also required to address the more complex questions of the last years (e.g. new methodologies to perform cumulative risk assessment).

EFSA's wide scope covering the whole food chain from animal health, plant health to food safety and nutrition allowed for a global scientific view of the food chain, which is important in an increasingly globalized food market.

The agency model chosen for EFSA coincided with trends in MS and at EU level to establish risk assessment bodies as scientifically autonomous or specialised bodies/agencies[45]. It facilitated the scientific cooperation with national agencies which was foreseen in the GFL. It allowed cooperation with the other EU scientific agencies, which despite not being explicitly foreseen in legislation was encouraged by several EU initiatives.[46]

[42] Meetings of the Expert Group of General Food Law on 29 June 2015 and on 16-17 September 2015 with MS; Meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on 21-22 September 2015 with stakeholders (industry, consumer organisations and NGOs).
[43] See ft. 9 of Appendix 2.
[44] Food, Animal Nutrition, Veterinary-Public Health, Plants, Animal Health and Animal Welfare, Cosmetic products & non-food products, Medicinal products and medical devices, Toxicity, Ecotoxicity and Environment
[45] ECHA, EMA, ECDC at EU level and ANSES/France, FSA/UK, FSAI/Irl, Bfr/DE, BFSA (RAC)/Bulgaria, HAH/Croatia, DTU/DK, AESAN/Spain, EVIRA/Finland, EFET/Greece, ISS/Italy, NVWA/NL, OSQCA/LT, MCCAA/Malta, ASAE/Poland, SLV/SW at national level.
[46] IIWG on agencies, network of EU agencies.

3.2 Consideration of other objectives

EFSA's wide scope explicitly covering nutrition and plant health proved to be in line with the evolution of food law in the area of nutrition given the adoption of two new Regulations on nutrition and health claims[47] and on the addition of vitamins and minerals and other substances[48] in 2006 and of a Regulation on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control[49] in 2013) and the occurrence of new international scientific divergences appearing in the area of plant health (e.g. citrus black spot).

3.3 Relevance of the legislative framework of the GFL in relation to current trends and needs

The current trend in the EU of encouraging private/public partnership in scientific research could reduce the pool of high level scientific experts able to contribute to EFSA's work because of EFSA's strict rules on independence.

4 Effectiveness

4.1 Progress towards achieving the objectives of the GFL

The following objectives were pursued with the establishment of EFSA:

- Delivery of high level and independent scientific advice and quick support in case of crisis;
- EFSA collecting and managing data supporting the risk assessment;
- EFSA functioning in networks with MS in order to pool expertise, promote common scientific views and support EFSA's scientific tasks;
- Independent, transparent functioning and an independent risk communication role.

4.1.1 Delivery of scientific outputs

EFSA's scientific outputs include: scientific opinions (generic opinions on public health issues and opinions on authorisation dossiers submitted to EFSA for safety assessment), statements and guidance, scientific reports and in the pesticides sector reasoned opinions and conclusions on pesticides peer review. EFSA's provision of scientific outputs and technical support comes from both external requests – mandates and questions from the Commission, the European Parliament (EP) and the MS – and EFSA's self-tasking function, and relate to either ordinary or emergency situations.

[47] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9. Corrected version in OJ L 12, 18.1.2007, p. 3.

[48] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods, OJ L 404, 30.12.2006, p. 26.

[49] 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 (OJ L 181, 29.6.2013, p. 35).

4.1.1.1 EFSA's workload and delivery of its scientific outputs

EFSA's workload sharply increased from 2008 to 2011 with a high peak of questions in 2008 and several peaks from 2009 to 2013. The number of questions is now decreasing. The Commission is the main requester.

Table 1: Number of questions received by EFSA in the period 2006-2016

Questions for scientific output received by EFSA										
Year	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Total(Commission/MS)	**568**	**5522**	**1036**	**1194**	**951**	**680**	**774**	**616**	**457**	**382**

(Source: EFSA RAW Updated figure 4 of the **EY** 2012 external evaluation)

The 2008 peak was linked to the adoption of the new Regulation on health and nutrition claims providing, amongst others, for an assessment of more than 4000 claims already used on the market. The Impact Assessment on fees for EFSA showed that most of the questions received concerned applications regarding regulated products and that out of a total of 9456 applications received from 2003 to 2010, 7982 (84.4%) were concerning reviews.[50] Figures from *EFSA apdesk* also indicate that in 2013, 458 authorisation dossiers were received and in 2014, 478.

Progress on the delivery of scientific outputs[51]

*Table 2: Number of EFSA scientific outputs 2006-2016**

YEAR	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total outputs delivered*	174	283	489	636	565	658	678	607	651	602	481
Linked to authorisation dossiers	130	180	292	492	399	472	434	380	340	306	321

**A scientific output can reply to one or several questions.*

Since its creation, EFSA has delivered approximately 4500 scientific opinions.

4.1.1.2 Reliability of the scientific outputs

The scientific quality of EFSA outputs, in particular of its scientific opinions is a key element, since it supports the adoption of EU risk management measures. A sound scientific basis is also essential in

[50] Table 5 and Graph 3 of Annex V to the Impact Assessment (see ft. 9).
[51] EFSA's scientific outputs include scientific opinions, reasoned opinions and conclusions on plant protection products, on pesticides, statements of the Panels, Panel Guidance, Guidance/Statement/Scientific report of EFSA.

an international context[52] requiring a link between a scientific risk assessment and the acceptable level of acceptable risk decided upon by the EU public authorities. A number of guarantees for a reliable scientific quality are enshrined in the EFSA system as established by the GFL Regulation and other EU secondary food legislation (*e.g.* on authorisation procedures):

- EFSA has to perform a full risk assessment in line with international definitions (Article 6 of Regulation 178/2002 and Article 3 on definitions);
- The legislation on authorisations and the correlated EFSA guidance[53] require that specific studies are submitted by applicants and that these studies, in order to provide validated scientific evidence, respect international protocols and good laboratory practices.
- Several scientific Panels provide the multidisciplinary expertise needed to cover the wide scientific scope of EFSA. Each Panel includes 19 experts of the different scientific disciplines needed for the specific area covered by the Panel.
- A Scientific Committee provides guidance for harmonised methodologies.

The EFSA 2012 evaluation[54] positively assessed the reliability of the scientific outputs because of the internal quality system of EFSA, the external review of scientific opinions, the general harmonisation guidance produced by the Scientific Committee. In addition, the scientific outputs are considered as reliable by the majority of stakeholders (89% of the respondents) and by international organisations.

Some criticisms have however been expressed: internal quality system was considered too complex, opinions could be clearer by describing more transparently the link between data and conclusions, as well as lack of internal consistency despite the Scientific Committee harmonisation guidance. NGOs have further criticised the use of industry data for assessing authorisation dossiers and have suggested a stronger cooperation with research institutions in order to better deal with the most controversial risk assessment and for EFSA to commission independent testing. [55]

The budget and staff allocated to the production of scientific opinions has been constantly increasing to face the high number of questions received (the 2007 EFSA annual report[56] indicates that the executed budget of the Units linked to the delivery of scientific opinions (including pesticides) is around 7.5 million with around 100 "FTE" while in 2015[57] EFSA has an executed budget of 32 million for Activity 1 (general scientific opinions) and Activity 2 (assessment of regulated products) and 201 "FTE".

The internal quality system, now based on ISO 9001, has been completely redesigned following the EFSA 2012 evaluation.

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[52] *E.g.* WTO Agreement on the Application of Sanitary and Phytosanitary Measures ('SPS agreement').
[53] See at: https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance .
[54] See Section 3.1.2 thereof.
[55] Conflicts on the menu, CEO, 2012, to be found at: https://corporateeurope.org/sites/default/files/publications/conflicts_on_the_menu_final_0.pdf.
[56] See at: http://www.efsa.europa.eu/en/corporate/pub/ar07.
[57] EFSA 2015 annual report, to be found at: https://www.efsa.europa.eu/en/corporate/pub/ar15.

The "Quality External review" conducted by an independent and external group of experts (ERWG) checks a sample of EFSA opinions and the results have progressively improved. Negative comments in external experts' reviews have been progressively reduced (1.4% in 2011 according to the EFSA 2012 evaluation and none in 2014).

EFSA's programming includes the production of an increased number of general guidance harmonisation documents by the EFSA Scientific Committee to address the criticisms expressed in the EFSA 2012 evaluation on the lack of internal harmonisation.

EFSA has also created additional Panels to reinforce its expertise[58] and has now 70% of its staff devoted to scientific activities, resulting in increased support for the work of the EFSA Panels (*e.g.* specific EFSA units focusing on risk assessment methodologies, data collection and analysis).

The increasing trend of EFSA's outputs citations in scientific journals mentioned in the EFSA 2012 evaluation is confirmed:

Table 3: number of citations of EFSA's publications

	2006	2007	2008	2009	2010	2011	2012	2013	2014
N. of citations of EFSA publications in scientific papers	13	19	35	132	293	487	1559	1948	2126

Table 12 in the 2012 evaluation as updated by EFSA

EFSA's opinions are also referenced by the main food safety agencies in non- EU countries and international bodies[59].

4.1.1.3 Fitness for purpose of the scientific outputs

Scientific opinions are delivered to clients that use them for specific purposes. The main client is the Commission and to a lesser degree the Member States. The largest number of questions/mandates sent by the Commission and the Member States relate to authorisation dossiers which are sent to EFSA according to the applicable EU secondary food legislation based on applications made to the Commission (or to the Member States) by industry.

The questions on general public health issues are less numerous but often address issues which are fundamental to the management of risks in the areas of plant health, animal health and welfare, microbiological risk, contaminants and nutrition.

[58] *I.e.* Panel on Plant Health and the splitting of Panel on food additives, flavourings, processing aids and food contact materials in two new ones.
[59] See for example at:
http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm449901.htm
http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=1376

For the risk managers, it is important that the opinion provided by EFSA is clear and allows for the adoption of risk management measures.

Globally EFSA opinions are suitable as a basis for EU risk management measures. The results of the quality feedback from the Commission to EFSA show that all randomly selected EFSA opinions were usable as a scientific basis for EU risk management measures[60], even if requests for improvements on clarity, coherence and consistency were in some cases expressed by Commission's services.

However, the EFSA 2012 evaluation[61] found that despite high scientific quality, the EFSA guidance documents were too theoretical and create problems for adequate implementation. This had a particular impact on the industry when the guidance concerns the preparation and the presentation of application dossiers. Clear guidance is necessary to help applicants submitting dossiers that meet EFSA's requirements.

A letter sent to EFSA on behalf of 11 industry federations, dated 17 February 2014, called for clearer and stable guidance and an increased dialogue with EFSA on the interpretation of the guidance. [62]

Following the EFSA 2012 evaluation and the said 2014 letter , EFSA put in place a series of corrective actions (*e.g. a* new catalogue of services to applicants) and pilot actions on guidance (*e.g.* involvement of risk managers and stakeholders at an early stage of the drafting of the guidance). This is more developed under Section 5 on efficiency.

It is also essential for fitness for purpose that EFSA meets the deadlines included in the mandate sent by risk managers since respect for these deadlines is important in order to act in accordance with the EU work programme, to respect legislation providing for specific deadlines on authorisations and to act quickly in situation of emergencies/crises. For applicants/industry, it is also important that the assessment of the authorisation dossier by EFSA is timely. For new substances or new claims[63], it is crucial that innovation is on the EU market as soon as possible. The interest is to start having a return on investment. It might also be in some cases linked to the fact that the product is protected by intellectual property rights for a limited period (the time of the assessment taking place during this period).

Table 4: Percentage of EFSA's outputs issued within deadline requested

[60] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/qmr14.pdf
[61] See Section 3.1.2 of the EFSA 2012 evaluation.
[62] To be found at: http://www.efsa.europa.eu/sites/default/files/assets/141002-letter.pdf. *See also* http://www.efsa.europa.eu/en/events/event/141002.
[63] According to the 2013 IA on fees, not all authorisation dossiers managed by EFSA concern new substances or products since a significant number concern old substances already on the market and requiring a review.

	2006	2007	2008	2009	2010	
% of total scientific outputs and supporting publications	59%	65%	87%	80%	79%	

(Source: EY elaboration on EFSA's data and EFSA update based on annual reports)

Timeliness*	2011 Target	2011 Achieved	2012 Target	2012 Achieved	2013 Target	2013 Achieved	2014 Target	2014 Achieved	2015 Target	2015 Achieved
A1 General scientific opinions	85%	85%	90%	81%	95%	75%	90%	98%	100%	92%
A2 Regulated products **	85%	85%	90%	81%	95%	87%	90%	77%	90%	84%
A3 Data collection	85%	85%	90%	81%	95%	75%	90%	85%	90%	90%

**till 2013 the indicator was provided jointly for 3 Activities*

*** excluding reasoned opinions on MRLs*

The more recent tables distinguish between Activity 1 (A1) that relates to the delivery of scientific opinions/statements linked to general public health questions (Animal health and welfare, microbiological risk, contaminants, plant health), Activity 2 that relates to authorisation dossiers submitted to EFSA assessment and Activity 3 that relates to data collection tasks.

They show that though the timeliness situation is satisfactory in the areas of general public health questions and data collection, there are problems of timeliness in the area of authorisations, in particular on maximum residue levels (MRLs) of plant protection products.

In addition, even when the legal deadlines are respected in the area of authorisation, long 'stop-the-clock' procedures[64] on authorisation dossiers hamper quick access to the market for industry since they *de facto* extend the legal deadlines for the assessment of authorisations. This is the case in particular, in the period 2012-2014 for some categories of feed additives, where the average number of days for assessment was estimated at 542 days (stop-the-clock delays included) *vs.* 191 days (without stop-the-clock delays), for food contact materials where the average was estimated at 583 days (delays included) *vs.* 399 days (without delays) and for nutrients sources (NUTRI) where the average was estimated at 502 days *vs.* 389 days (without delays). However, in other areas such as in food additives where an increase in the number of 'stop-the-clock' procedures has been observed, the delays attributed to 'stop-the-clock' procedures are more limited: 673 days (stop the clock delays included) *vs.* 644 days (without delays).

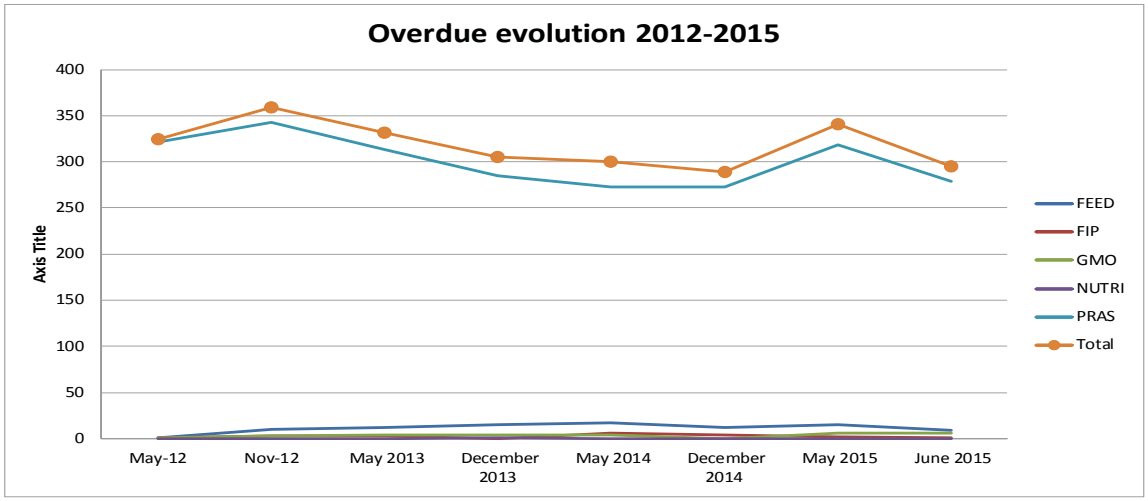
There are also "overdue" or backlogs in the system as also identified in Chart 34 of the EFSA 2012 evaluation which identified 1131 authorisation dossiers applications as "work in progress".

[64] During the scientific assessment, if EFSA cannot conclude on the basis of the information available, it may request the applicant to provide additional information within a given timeline. As a consequence the scientific assessment is stopped until the information is supplied (thus extending or suspending the deadline for the delivery of the opinion).

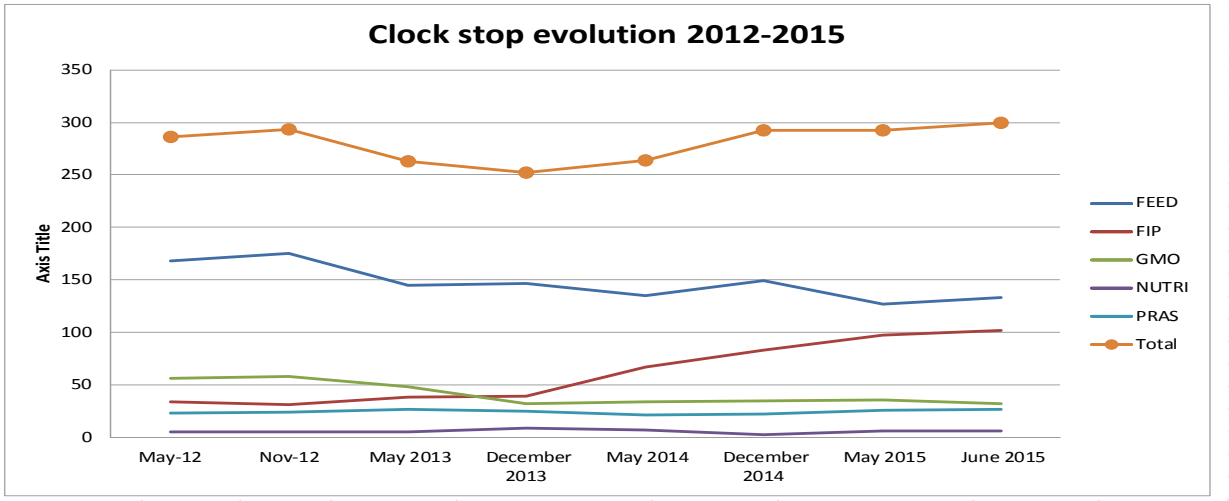
EFSA has overtime reduced its number of backlogs and 'stop-the-clock' procedures in most sectors. Nevertheless, from May 2012 to June 2015, the number of overdue scientific opinions was still high in the area of plant protection products (PRAS) sector, while the number of 'stop-the-clock' procedures remained high in the feed additives sector (FEED) and significant in the area of GMOs and it has even increased for food improvement agents (FIP) (Table 5).

Table 5: Evolution of overdue requests and 'stop-the-clock' procedures

	May-12	Nov-12	May 2013	December 2013	May 2014	December 2014	May 2015	June 2015
FEED	1	10	12	15	17	12	15	9
FIP	1	3	3	0	6	4	2	1
GMO	1	3	4	4	4	0	6	6
NUTRI	0	0	0	1	0	0	0	0
PRAS	322	343	313	285	273	273	318	279
Total	**325**	**359**	**332**	**305**	**300**	**289**	**341**	**295**



	May-12	Nov-12	May 2013	December 2013	May 2014	December 2014	May 2015	June 2015
FEED	168	175	145	147	135	149	127	133
FIP	34	31	38	39	67	83	97	102
GMO	56	58	48	32	34	35	36	32
NUTRI	5	5	5	9	7	3	6	6
PRAS	23	24	27	25	21	22	26	27
Total	**286**	**293**	**263**	**252**	**264**	**292**	**292**	**300**



As table 6 below shows, EFSA has a **good track record** in responding **swiftly to demands in crisis or emergency situations**. In the period 2006-2013, there were 13 Commission requests for urgent scientific support. On average, EFSA provided its scientific assessment in 2-3 days in simple cases, 8-14 days in more complex cases while in three cases, it responded in 27-30 days with one specific case which took 46 days. The timing has also to be understood on the basis that EFSA is asked for scientific advice in the case of crisis only when the risk is unknown or not well known thus requiring it to collect and analyse data.

Table 6: List of requests for urgent advice, per year and requestor, and number of days to respond

REQUEST	YEAR	REQUESTOR	NUMBER OF DAYS TO DELIVER
Melamine in food and feed	2007	EC	30
Mineral oil in sunflower oil	2008	EC	29
Melamine in infant milk	2008	EC	3
Dioxins in Irish pork meat	2008	EC	2
Inks for food packaging in breakfast cereals	2009	EC	13
Nicotine in wild mushrooms	2009	EC	14
Chlormequat in table grapes	2010	EC	2
Volcanic ash	2010	EC	6
STEC 0104	2011	EC	8
STEC 0104	2011	EC	27
Schmallenberg virus	2012	EC	10
Review of Seralini publication	2012	EC	8
Phenylbutazone in horse meat	2013	EC	46

(Source: EY elaboration on EFSA's data, 2012 and EFSA updates 2012 and 2013)

In summary, EFSA has delivered its scientific advice and support in line with the initial objectives in terms of quality and timeliness in the area of general public health (animal health and welfare, plant health, contaminants and general nutrition). However, in a context of a sharp increase of the number of authorisation dossiers received from 2008 to 2011, there are still problems of timeliness with delays in certain areas of authorisations (e.g. MRLs of pesticides, feed additives, food improvement agents and GMOs) and backlogs in particular in the pesticides MRLs sector.

EFSA has also fulfilled the initial objectives with regard to the delivery of swift scientific support in case of emergencies/crisis.

4.1.2 Independence

The independence of EFSA and of its experts together with the excellence of its scientific expertise underpin the quality and credibility of the scientific advice delivered by EFSA. In contrast with other EU agencies, such as the European Medicines Agency ('EMA') and the European Chemicals Agency ('ECHA'), MS do not appoint members of its Scientific Panels. This also contrasts with the situation prior to the creation of EFSA when Member States directly provided scientific expertise through their representation in the relevant scientific committees reporting to the Commission. As an element of its independence from risk managers, EFSA's Management Board is composed of 14 individuals appointed, after an open call, on the basis of their independence and competence, plus a representative of the Commission.

EFSA's Scientific Committee and Panels are composed of independent high level scientific experts, who are responsible for adopting EFSA's scientific opinions (i.e. an extra layer of independence). The scientific experts are appointed by EFSA's Management Board following a strict selection procedure based on criteria of scientific excellence and independence after an open call.

The scientific experts, the members of EFSA Management Board and Advisory forum and the EFSA Executive Director have to make an annual declaration of interests (DoI) and a declaration of commitment to act independently. They also have to declare at each meeting any interest which might be considered as prejudicial to their independence in relation to the items on the agenda (specific DoI). All the declarations are public on the EFSA's website.

The EFSA 2012 evaluation concluded that EFSA is generally independent and has one of the most advanced and robust systems in place for ensuring independence. It has fulfilled its obligations to operate in an independent manner and despite criticism, no major changes in EFSA's structures and procedures on independence are required. Nonetheless, it also acknowledges that independence is a key issue in terms of trust and that stakeholders are divided. The EFSA 2012 evaluation thus recommended an increased level of transparency of procedures and better communication to address the perceived links of EFSA with industry.

A European Court of Auditors report was also published in 2012 on conflicts of interest in agencies[65] and has made a certain number of recommendations to the audited agencies, one of which was EFSA.

In the aftermath of the EFSA evaluation report and the Court of Auditors report, EFSA has further refined and strengthened its system:

- All staff make a DoI before taking up employment and make an annual DoI.
- No scientific expert can attend a meeting if its annual Doi and its specific DoI have not yet been screened to identify any potential conflicts of interests. A central point (EFSA legal Unit) (as requested by the European Parliament), is now in charge of all the prior screenings.

[65] European Court of Auditors, Management of conflict of interest in selected EU Agencies, Special report No 15 [2012].

- EFSA is the first agency to put in place a breach of trust policy (i.e. action taken if an individual fails to report an interest or omits key information).

- The selection process of the members of the Scientific Committee/Panels includes an external Board of three high level scientists (plus two observers, one from the European Parliament and one from the Commission) supervising the integrity of the process. The EFSA Management Board makes the final appointment by checking (on the basis of a detailed report which is publicly available[66]) that the criteria for the selection of the proposed members (including independence) have been met.

- EFSA rules are applicable to members of EFSA's Scientific Committee, Scientific Panels, Working Groups, members of its Networks, other external experts, hearing experts, staff of other EU bodies, bodies and agencies participating in EFSA's meetings (except as observers), contractors, grant beneficiaries. Management Board members have to sign the code of conduct, which provide for ethical coverage and independence.

EFSA has also clarified and reviewed its implementing rules regarding the Policy on Independence in line with the recommendations of the EFSA 2012 evaluation:

- The revised procedure for the screening of annual, special and oral declarations of interests of the members of the Authority's Scientific Committee, Scientific Panels and Working Groups has introduced the criteria upon which the screening is based.

- The scope of conflicts of interests has been clarified with new definitions regarding, inter alia, the obligation to declare even the smallest economic interest.

- A two-year cooling-off period is applied, following employment by the Authority, "on a risk-based approach" for experts being employed by the food industry.

EFSA also ensures strict implementation of its independence rules and monitors it, as Table 7 indicates in terms of Declaration of Interests (DoI):

Table 7: Screening of DoIs – Results 2014

DoIs Screened	Meeting agenda items scrutinised	Potential conflicts prevented	Breach of trust procedures	Staff members leaving EFSA
4439 sDoIs 2523 aDoIs	34456	sDoIs: 92 agenda items 53 aDoIs rejected	0	Total: 20 Private sector: 2 Restrictions: 2

Results 2014 (Source EFSA) ADOI= annual declaration of interests; SDOI: specific declaration of interests related to the items on the agenda; oral DOI: oral declaration of interests before the beginning of a meeting)

In addition, a specific progress indicator with a target of 100% DoI checked beforehand is published in the EFSA annual report. It monitors the rule according to which no experts can attend a meeting in

[66] See at http://www.efsa.europa.eu/en/mb120315/docs/mb120315-ax7.pdf.

EFSA without having her/his DoI checked beforehand. EFSA achieved in 2014 99.8% of this target and in 2015 99.7%.

Despite these additional rules, criticisms of EFSA's independence still persist on the part of certain NGOs. In the period 2012-2013, NGOs brought three complaints against EFSA to the European Ombudsman.[67] In 2015, one of these cases led to a recommendation to EFSA in as regards the presumption of independence of universities (universities being partly financed by private bodies).[68]

The European Parliament scrutinises each year in the framework of the discharge procedure the independence of EFSA[69]. In the framework of the 2016 exercise in Parliament for the granting of the 2014 discharge to EFSA, the European Court of Auditors produced a follow-up[70] of the recommendations made in its N°15/2012 special report on the "Management of conflict of interest in selected EU agencies". This follow-up concludes that the selected agencies (amongst which was EFSA) and the Commission had implemented the 11 recommendations (8 fully implemented and 3 implemented for the most part as they required legal actions not in the competence of EU agencies. The Parliament in its decision of 28 April 2016[71] granted the discharge to EFSA. This decision acknowledges the progress made by EFSA on independence, encourages EFSA efforts to provide access to its data (i.e. open data policy) but recommends two further steps: (a) to establish a cooling-off period "on all material interests related to the companies it regulates, and (b) to work with academia on specific measures ensuring that experts (1/3 of EFSA experts) working for these institutions declare all relevant information to EFSA.

EFSA regularly reviews its independence policy to refine it and take account of experience. In June 2017, EFSA adopted a revised independence policy to further strengthen its impartiality and protection against improper influence.[72]

EFSA is also active in its self-tasking function. In the period 2007-2014, it delivered 60 self-tasking opinions. This activity is also another facet of its independence, as it shows that EFSA is capable of working on new scientific challenges, and/or emerging issues, on its own motion.

Globally EFSA has strict rules in place preventing conflicts of interests, implements them in a rigorous way and regularly revises and improves them. However, this remains a sensitive issue in terms of public perception and the stakeholders still have different points of views: in particular NGOs (supported by some members of the European Parliament and some MS) still call for more stringent rules as they advocate that any link with industry must be considered as a conflict of interest. They advocate that EFSA experts should be excluded from any link with food industry funding, including

[67] Case 0622/2012/ NGO v EFSA (Testbiotech); Case 2522/2011/ NGO v EFSA (PanEurope)
[68] Case 346/2013/SID, NGO v EFSA (Gene Watch). To be found at: htpp://www.ombudsman.europa.eu/en/cases/decision.faces/en/58868/html.bookmark
[69] All EU agencies are screened with regard to financial aspects and independence aspects.
[70] Follow-up of Special Report No 15/2012 - Management of conflict of interest in selected EU Agencies (clearing letter 12 January 2016 sent to EFSA, COM, EP). Not published.
[71] See at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P8-TA-2016-0172+0+DOC+XML+V0//EN.
[72] EFSA's policy on independence, adopted by EFSA's Management Board on 21 June 2017, to be found at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf.

private-public partnerships or food industry funding in areas different from the ones the experts contribute to. Nevertheless, other stakeholders (including some MS as expressed in the meeting of the Expert Group of the General Food Law, dated 29 June 2015) consider that the system is already too strict and that there is little room to go further without depriving EFSA of valuable expertise, in particular because of the trend for private/public partnership in science. EFSA has recently adopted a new independence policy providing for a two-year cooling off period on managerial, employment, consultancy activities, memberships in scientific advisory bodies undertaken by its experts with legal entities pursuing private or commercial interests, which partly addresses some of these concerns. A similar cooling off period is also applicable with respect to research funding from legal entities pursuing private or commercial interests.[73]

4.1.3 Data collection

EFSA work on data collection aims at providing up to date and comparable data on biological and chemical contamination impacting the safety of the food chain and on food consumption. Both are prerequisites for an informed risk assessment and risk management. The effectiveness of EFSA's data collection relies heavily on the commitment of the MS to provide and share data according to the requirements defined by EFSA.

The EFSA 2012 evaluation found that data was globally accessible and available in the four thematic areas identified by GFL (*i.e.* food consumption and the exposure of individuals to risk related to the consumption of food, incidence and prevalence of biological risk, contaminants in food and feed, and residues) but called for further improvements on accessibility of the data. It underlined that EFSA had allocated significant resources to data collection[74]. It identified as a main constraint the lack of resources in MS to provide quality data and considered that accessibility of data could be further improved.

EFSA's budget dedicated to data collection, scientific cooperation and networking has evolved from €23.6 to €24.6 million in the period 2011-2015.

EFSA's Unit responsible for collecting and analysing data (DATA) has reinforced its activities regarding harmonisation, transfer and validation to improve the quality of data collected from MS[75]: For example, the standard sample description which was initially developed in 2010 has been further updated and other guidances have been drafted (IT protocol for exchange, guidance on the EU menu methodology). Some MS have signalled certain difficulties, as in their opinion, EFSA new IT systems was introduced too rapidly, despite EFSA training. [76]

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[73] EFSA's policy on independence, adopted by EFSA's Management Board on 21 June 2017, to be found at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf.

[74] According to the EFSA 2012 evaluation, 7.23% of its budget in 2011 was dedicated to data collection activities. Moreover, the percentage of data collection activities entrusted to MS and co-financed by EFSA through grants increased from 18.83% in 2007 to 45.82% in 2011. See at pp. 62-63.

[75] See Table 15 of EFSA 2012 evaluation.

[76] Meeting of the Expert Group on General Food Law, dated 29 June 2015.

Two data EFSA collection groups composed of MS experts on pesticides residues and zoonoses were operating prior to 2012. Since then, three new additional groups have been established on molecular typing data collection, veterinary drug residues, and a stakeholder platform on food chemical occurrence.

EFSA has also constructed a Scientific Data Warehouse containing a large body of data collected, e.g. on zoonotic diseases, antimicrobial resistance, foodborne outbreaks, pesticide residues, chemical contaminants, food consumption and chemical hazards. The system includes specific web reporting tools and is accessible at different levels pursuant to the Scientific Data Warehouse's access rules – which have been agreed with the data providers. [77] The EFSA Comprehensive Food Consumption Database includes individual dietary records from nearly 100,000 people in 23 MS with partly accessible data.

Several important new initiatives have been initiated: e.g. projects on molecular typing of food-borne pathogens (jointly with ECDC's corresponding database on human data) to support epidemiological investigations of food-borne outbreaks; on pests and diseases of apple fruit present in the EU to support plant risk assessments; on food additive usage and occurrence to support the review of old food additives; on food composition to support reference dietary values and a "TSE" data base.

EFSA is also active in international data sharing: i.e. transmission of chemical occurrence data from EFSA chemical database to the electronic data submission system of the World Health Organisation (WHO). The transmission of European contaminant occurrence data from EFSA to WHO for use in international risk assessments strengthens data sharing at international level. Summary statistics from the EFSA comprehensive food consumption database are also incorporated in an international food consumption database developed by the Food and Agricultural Organisation (FAO), contributing to international data sharing.

EFSA has met the requirement of data collection in the four areas listed in the GFL (i.e. zoonoses, chemical contaminants, pesticides residues and food consumption). It has made further progress, in particular in terms of access to data, new networks with MS, new web reporting tools and new projects supporting the identification and management of risks linked to food. Compared to the pre-2002 situation where, in particular, food consumption data was almost non-existent, or was only available at national level and not harmonised at EU level, EFSA has made considerable progress.

4.1.4 Cooperation with MS

4.1.4.1 General scientific cooperation with MS

The GFL provides for cooperation with the national risk assessment bodies. The objective is to pool scientific knowledge, to share data and methodologies and to promote synergies and cooperation on common issues. Another important objective of the cooperation is to avoid divergences of scientific opinions.

[77] See also https://www.efsa.europa.eu/en/supporting/pub/en-768.

EFSA's Advisory Forum, composed of representatives of MS bodies which undertake similar tasks to EFSA, aims at facilitating this cooperation. EFSA can also allocate grants to specific national scientific organisations designated by MS and the EFSA Management Board (Article 36 organisations) when they support EFSA's scientific work. EFSA also funds by procurement the externalisation of some of its scientific work to national organisations.

As stated earlier, unlike other EU agencies (*e.g.* EMA, ECHA), the GFL establishing EFSA does not require each Member State to appoint an expert as a member of its Scientific Committee and Panels but provides instead for an open procedure (*i.e.* call for expression of interests to which experts reply in an individual and voluntary basis).

The experts selected to be members of EFSA's Scientific Committees and Panels and their WGs or contributing to EFSA networks, are employed[78] by national scientific bodies, *i.e.* national risk assessment agencies, academia, and public research bodies. This implies that these national organisations agree that experts employed by them spend part of their work time in EFSA.

The EFSA 2012 evaluation found that the cooperation system established between EFSA and National Risk Assessors has promoted the exchange of information, best practice and methodology. Moreover, progress was made with the creation in 2008 of national focal points, financially supported in part by EFSA grants, to support the exchange of data and expertise between EFSA and MS. It also indicated that a significant part of EFSA budget was being increasingly allocated to scientific cooperation activities between EFSA and National Risk Assessors (from 6% in 2009 to 11% in 2011). It, nevertheless, signalled some weaknesses: less than 25% of the "Article 36" organisations involved at least once in Article 36 grants, grants not attractive enough, and while all MS having in place a counterpart of EFSA a significant number of these counterparts not having a capacity of scientific expertise to enable/permit them to significantly contribute to EFSA's work. Finally, it has signalled a series of challenges for the mobilisation of experts in the short to medium term: geographical location and time to travel, experts having to deal with conflicting priorities (i.e. their own job and their involvement in EFSA), criticisms regarding the independence of experts, small financial compensation even if the attractiveness of EFSA is still positive (such as the high quality of EFSA outputs, contacts with other experts, EU work recognised internationally, public interest work, good on CV).

Since 2012, EFSA has fundamentally developed a more partnership type approach. The Advisory Forum "AF" agenda has been adapted to facilitate MS taking a more leading role in advising on priorities and in identifying common priorities with the aim of promoting more work sharing[79].

EFSA now uses its cooperation tools and budget to support cooperation projects in a more targeted way. In the period 2011-2015, 40 grant agreements amounting to about €8.7 million and, annually, 30 Focal Point agreements amounting to about €4.36 million were successfully awarded to MS, Norway and Iceland. During the same period, EFSA also signed over 500 scientific procurement

[78] Except retired persons.
[79] Annual Report on Scientific Cooperation 2015, to be found at: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/scientificcooperation15ar.pdf.

contracts amounting to about €35.84 million. Globally, EFSA allocates a little more than 10 million per year to the scientific cooperation, corresponding to around 13% of its annual budget.

Pursuant to an external review commissioned by EFSA on the impact of scientific grant and procurement projects on its tasks in 2014 ('2014 external review'),[80] the most common reason why Article 36 organisations did not apply for grants was that the published science grant and procurement calls were not relevant to their organisation's area of work. The list of Article 36 organisations is now entirely renewed (i.e. 33 new, 29 deleted) and includes 345 organisations from MS, Iceland and Norway). Also in line with the findings of the 2014 external review, thematic grants on priority themes are now launched with a ceiling of €500,000 thereby encouraging large strategic project proposals on issues of common interest (with the co-financing by EFSA being limited to 50% instead of 90%). This approach was signalled as positive in a recent report of the European Court of Auditors[81].

EFSA also currently uses more long term procurement contracts than it did in the past. This facilitates the national bodies in better planning their budgets and allocation of resources over the years.

The 2014 external review further indicated that for the period 2009-2012, 37 out of the 45 grant projects (82%) and 101 of the 225 procurement projects (45%) had published deliverables on the EFSA website.[82]

Training on risk assessment has also been developed by EFSA to build capacity on regulatory risk assessment in MS and "candidate" countries: for example 12 training courses took place in 2015 targeting a total of 300 experts from MS and candidate countries.[83]

At the meeting of the Expert Group on General Food Law, which took place on 29 June 2015, MS confirmed their general approval of the evolution of the role of the Advisory Forum but stressed the need to have larger grants for studies contributing to EFSA's work in order to adequately meet the costs incurred. Most MS called for less administrative systems for cooperation and, in particular, for simpler ways to revise the Article 36 list. The current EFSA administrative modalities for revising the list might be part of the administrative burden but it could also partly result from Commission Regulation (EC) No 2230/2004 implementing the modalities of Article 36 network[84].

All MS have highly valued the cooperation. MS with a high level of scientific capacity consider that the increasing complexity of the risk assessment issues and a more globalised world make EU

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[80] External review of the impact of scientific grant and procurement projects on delivering EFSA's tasks – Review report, [2014] to be found at: http://www.efsa.europa.eu/en/supporting/pub/en-695.
[81] European Court of Auditors, Agencies' use of grants, Special Report No 12 [2016].
[82] Indicatively, grants and 39 procurements contributed to scientific opinions when 18 grants and 10 procurements contributed to guidance documents. See Table 3 of the 2014 external review.
[83] See also:
https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/scientificcooperation15ar.pdf.
[84] Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64).

cooperation essential. MS with less scientific capacity recognise the support they receive through the cooperation mechanisms in relation to sharing of data, methodologies and the training on risk assessment. MS have further highlighted declining resources at the national level with both positive and negative impacts: restriction of resources can work as an incentive for increased cooperation with EFSA but it can also hinder the participation of national experts in EFSA's activities.

In conclusion, set against the initial objective of the White Paper to remedy through cooperation with MS "*the lack of scientific networks with Member states aimed at pooling knowledge and reducing the time-consuming preparatory work required of scientific experts producing the scientific opinions*", the scientific cooperation between EFSA and the MS has enabled the pooling of knowledge, the sharing of information and a better common understanding of the risks linked to the food chain. The progress achieved has also to be considered against the baseline. Prior to 2002, the Commission had partly funded 23 scientific projects managed by the MS to support the Scientific Committee on food for an average annual cost of around €300,000.[85] Currently the annual budget for the cooperation activities with MS is much larger (i.e. € 10 million), though this amount is still considered as insufficient by the MS as not always covering the cost of their contribution to EFSA.

1.1.1.1 Effectiveness of the mobilisation of experts

Around 1500 external scientific experts[86] contribute to EFSA's work, some **on a regular basis as** members of EFSA Scientific Committee/Panels and some on a more ad hoc basis as to Panels, WGs or EFSA networks. Experts from all countries and scientific organisations can contribute to EFSA's work, provided that the set criteria on excellence and independence are met.

The total number of Panel / Scientific Committee members is 213.[87] Since its creation, EFSA has undergone eight different renewal processes of its Scientific Committee and Panels.

Based on the latest Panel renewal for the period 2015-2018 that took place in 2014, the figures on expert mobilisation are as follows: 935 applicants expressed an interest in Panel/Scientific Committee membership and 807 were judged valid and eligible. Of those, 414 candidates were classified as “above the threshold” and 380 shortlisted candidates remained after the screening of the Annual DoIs. In March 2015, EFSA's Management Board appointed 171 shortlisted candidates[88]. 34 candidates classified "above the threshold" were disqualified because of EFSA's independence rules.

The nationality of the appointed candidates (for 8 Scientific Panels and the Scientific Committee) is provided in Table 8 below.

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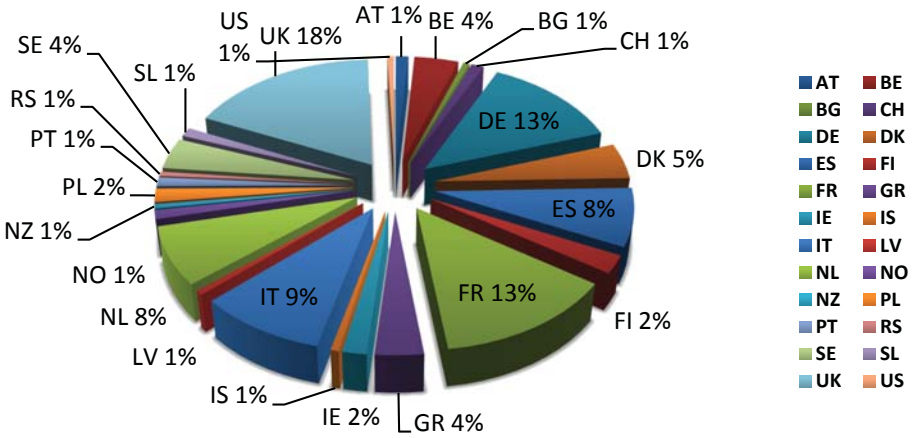
[85] Council Directive 93/5/EEC of 25 February 1993 on assistance to the Commission and cooperation by the Member States in the scientific examination of questions relating to food. In the former system, the main burden on costs was on Member States, the Commission only funding costs of coordination.
[86] 150 Working Groups take place each year in EFSA with an average of 10 external experts
[87] Based on data available on 1 July 2015.
[88] See 64th meeting of EFSA's Management Board – Minutes of the Public Session, dated 19 March 2014, to be found at: http://www.efsa.europa.eu/sites/default/files/assets/150319-m.pdf.

Table 8: Nationality of Scientific Committee and Panels' members (selection 2014)



The distribution of experts per MS in Scientific Committee/Panels show that 69% of experts originate from 6 MS, while 86% originate from 10 MS. A similar tendency had also been stated in the EFSA 2012 evaluation: 59% of experts originating from 6 MS and 71% from 10 MS. However, this finding needs to be seen in perspective since the distribution of experts by MS is analogous to the level of research expenditure in these MS in a context where they are selected on the basis of their scientific excellence and not their nationality.

Furthermore, the average age of experts has increased by two years, *i.e.* from 53.6 years in 2012 to 55.3 years in 2015,[89] while some Panels in the area of authorisations have encountered problems in attracting new members. In the context of the Expert Group on General Food Law meeting of 29 June 2015, the MS acknowledged a number of disincentives for experts to participate in EFSA's activities: the strict rules on independence in a context of increasing trend of public-private partnership in scientific research, the insufficient recognition for the scientists' career, the amount of time required[90], the modest financial compensation for the experts and their employers, the fact that in some cases experts were doing too much routine work, the high workload, and the location of EFSA in Parma. However, some MS consider that the time spent in EFSA by national experts and the EFSA independence rules are not yet significant disincentives for the experts and their employers.

The compensation system for experts has been adapted in 2013 [91] with the view to facilitate participation by video/web conferences and more adequately compensate the time spent by the experts (indemnity of the Chair: €385 regardless of the duration of the meeting; rapporteur indemnity: €770 per rapporteur; €100 per hour with ceiling of €385 for participation in video/web

[89] *Id.*

[90] In the last EFSA Expert survey, the experts indicated an average estimate of 4 days per month spent in EFSA with Chairs and vice-Chairs of the Scientific Committee and Panels providing higher estimate (around 6.5 days per month).

[91] Experts' Compensation Guide - Decision of the Executive Director laying down the rules on the reimbursement of expenses incurred by third parties from outside EFSA invited to attend meetings in an expert capacity", European Food Safety Agency, 2013, EFSA/FIN/POL/I/2013, to be found at: http://www.efsa.europa.eu/sites/default/files/Experts_compensation_guide.pdf.

conference for experts and €150 per hour with a ceiling of €770 for chairing a video/web conference).

EFSA scientific staff (*e.g.* the new EFSA Units on assessment and methodological support and on evidence management and the Panel Secretariat) increasingly support the work of the Panels by conducting preparatory work, such as literature research, modelling, and data collection including draft opinions.

EFSA is planning to integrate its scientific work in an international scientific journal to increase the recognition of the work of its experts.

1.1.1.2 Cooperation to address divergences

Table 9 below depicts the few cases of scientific divergences between EFSA and national risk assessment bodies (11 from a total of more than 4500 scientific opinions). Article 30 of GFL provides for a specific cooperation procedure in case of such divergences through the Advisory Forum. The latter procedure has worked well since it has resolved most of the cases, *i.e.* only 4 divergences out of 11 cases were eventually confirmed at the end of the procedure as effective scientific divergences, two of which concerned the same substance. Nevertheless, as those two concerned a politically sensitive matter (Bisphenol A), they have attracted considerable public attention. Divergences, even when only apparent, or with a scientific explanation create a negative perception of the robustness of science underpinning EFSA's opinions.

Table 9: List of scientific divergences subject to Article 30 procedure (2006-2014)

YEAR	TOPIC OF THE CONTROVERSIAL ISSUE	UNIT RESPONSIBLE	RESULT OF DIVERGENCE
2006	QRA tallow	BIOHAZ	Solved
2008	MON 810	GMO	Solved
	Threshold of Toxicological Concern	Sc. Committee	Solved
2009	Risk assessment of lycopene	ANS	Confirmed
2011	Sweeteners	ANS	Solved
	Coumarin	NDA	Solved
	Bisphenol A	CEF	confirmed
2012-2014	Bisphenol A	FIP	Confirmed
	Caffeine	Nutrition	Solved
	Perchlorate	BIOCONTAM	Solved

Mycotoxins T2/HT2	BIOCONTAM	Confirmed

Although MS in general have a policy aimed at avoiding duplication of work with EFSA, as evidenced also by the small number of scientific divergences, some MS consider that in some cases duplication and divergence can be useful and promote progress in science. [92]

MS also value the effectiveness of the Article 30 procedure in solving scientific divergences and the role of the EFSA Advisory Forum in facilitating its implementation.

4.1.5 Cooperation with EU scientific agencies and international risk assessment bodies

4.1.5.1 With other EU scientific bodies (EU agencies and the Commission Scientific Committees)

The different EU scientific agencies (ECDC, ECHA, EFSA and EMA) as well as the Commission Scientific Committees have different scope and competences that do not result in duplication. In addition, other EU secondary food legislation may provide in some cases (*e.g.* biocides, health threats) for the complementary intervention of several agencies, when different competences are needed. Similarly, a number of cross-sectorial issues, such as antimicrobial resistance, require the intervention of a multiple competence approach. In such cases, the mandates from the Commission to EFSA request the latter to collaborate with the other concerned agencies to develop a common position. Examples of cooperation between EFSA and the other EU scientific bodies include:

- With ECHA: collaboration in the harmonization/integration of risk assessment methodology for pesticides, biocides and industrial chemicals under REACH; on the risk assessment of chemicals such as BPA , the alignment of procedures for the assessment of plant protection products, the safety assessment of nanomaterials and in the area of guidance for environmental risk assessment;
- With EMA, ECDC: collaboration on antimicrobial resistance, horsemeat joint opinion;
- With ECDC: EFSA and ECDC cooperation in producing the yearly "European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks" and the yearly "European Union Summary Report" on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food; cooperation on the delivery of Rapid Outbreak Assessments (ROA) linked to food-borne outbreaks and in establishing a common database based on molecular typing to better prevent and manage food crises; EFSA/ECDC common database on vector-borne disease.
- Commission Scientific Committees (non food): collaboration on methodologies (e.g. threshold of toxicological concern, benchmark dose), endocrine active substances, environmental risk assessment, genotoxic carcinogens, nanotechnology, identifying and evaluating emerging risks.

[92] Meeting of the Expert Group on General Food Law, dated 29 June 2015.

1.1.1.1 With international bodies

As a major global trader of food and feed, the EU contributes to the development of international standards. According to the GFL, EFSA should contribute, through the provision of support on scientific matters, to the cooperation between the EU, applicant countries, international organisations and non-EU countries. More specifically, the GFL also provides that EFSA shall work in close cooperation with all organizations operating in the field of data collection, including those from candidate countries, third countries or international bodies.

In EFSA developed an international strategy[93]. The objectives of this strategy were to support the EU in its international commitments, to ensure access to international scientific data and information, to participate in risk assessment at international level, to promote coherence in risk communication and build awareness of EFSA' activities at international level. According to the EFSA 2012 evaluation, EFSA has been active on international cooperation but had a smaller number of cooperation agreements signed with international organisations and non- EU countries than EMA or ECHA. The consultation of the stakeholders in the context of that evaluation revealed that 29% of them had a poor visibility on EFSA's participation in international activities. According to international organisations, Commission and food industry representatives EFSA's international role was already acknowledged by peer agencies (EFSA scientific opinions referenced by third countries food risk management agencies[94]). The national risk assessors considered that the sharing of data with other international organisations is a priority and could be more developed. [95]

Since the EFSA 2012 evaluation, further progress has been made.

A detailed description of EFSA's international activities is set out in the Multiannual Programme on International Scientific Cooperation 2014-2016[96].

EFSA provides scientific and technical support to the EU in international standard setting bodies. This occurs in the context of Codex Alimentarius, International Plant Protection Convention's meetings, World Health Organisation's or World Organisation for Animal Health's committees. The EFSA support includes for example:

- Submission of data to calls for data issued by the FAO, WHO or CODEX Secretariat for meetings of the Joint FAO/WHO Expert Committees , as well as meetings of CODEX Committees ;
- Participation in CODEX meetings;
- Provision of scientific reports to be discussed at EC/SANTE's meetings with MS on matters to be discussed at CODEX meetings.

[93] International activities – a strategic approach, EFSA, 2009-2013
https://www.efsa.europa.eu/en/press/news/mb081219
[94] See reference in footnote 58.
[95] See Section 3.5 of EFSA 2012 evaluation.
[96] See at: https://www.efsa.europa.eu/en/corporate/pub/iscmap1416.

EFSA has signed cooperation agreements with the following organisations (International organisations: WHO, Geneva; non EU country organisations: FSA New Zealand, Australia ; Health Canada; CFSA, China; FSC, Japan; MPI, New Zealand; USDA/APHIS; USDA/ARS; USDA/FSIS ; USFDA).

EFSA has also increased its international collaboration in the sharing of data and methodologies with non- EU countries and international bodies (FAO/WHO, Codex in particular) as illustrated by the examples below:

- EFSA is member of an International Food Chemical Safety Liaison Group, which addresses risk assessment and risk management issues relating to chemical substances in food;
- EFSA participates in an International Microbiological Safety Liaison Group, which addresses risk assessment and risk management issues relating to microorganisms in food;
- EFSA organises on an *ad-hoc* basis joint events with FAO and WHO aiming at the harmonisation of methods and approaches in the area of contaminants and residues of pesticides and veterinary drugs (*e.g.* Threshold of Toxicological Concern (TTC) in 2014, International Estimate of Short-Term Intake (IESTI) in 2015). EFSA also works with FAO on Risk Assessment methodologies and tools, emergency prevention systems and emerging risks, animal health and welfare, data collection and evaluation, risk communication, capacity development, new and emerging technologies);
- EFSA also cooperates with WHO on sharing of data (occurrence of contaminants and residues of pesticides and veterinary drugs, food composition and consumption data);
- EFSA is also a member of WHO's Chemical Risk Assessment Network.[97]

The EFSA international activities support the promotion of EU standards in international standardisation bodies, and the sharing of information and methodologies with international risk assessors and major non EU countries agencies. It contributes to avoiding a scenario whereby EFSA misses significant scientific information/data relevant for its risk assessment work. It promotes a better understanding of the EU scientific basis of food safety in the world and more generally facilitates convergent scientific views since the different parties worldwide have the same level of information.

4.1.6 Transparency, openness, relations with stakeholders and risk communication

4.1.6.1 Transparency and openness

According to the EFSA 2012 evaluation, EFSA has fulfilled its obligation to operate in an open and transparent manner, as evidenced in particular by the following:

- All documents that should be made available according to Article 38 of the GFL are on EFSA's website (e.g. scientific opinions, agenda, minutes of all organs including WG of Panels/SC, annual DoIs, most scientific studies, mandates to EFSA);
- The meetings of EFSA's Management Board are public.

[97] See at http://www.who.int/ipcs/network/en/.

In the context of that evaluation, EFSA was considered as a transparent organisation by a majority of stakeholders: 78.6% of the respondents to the survey expressed a rate equal or higher than 3 out of 4, while the same rate was also achieved in interviews (i.e. with National Risk Managers, national risk assessors, EP, Consumers, Scientific Organisations, International Organisations). However, NGOs have criticised the fact that EFSA bases its risk assessment of authorisation dossiers on industry studies, which, in addition, are partly confidential. In their view, the existing EU legal rules on confidentiality excessively restrict the access to industry studies. The general provision on confidentiality with respect to information received by EFSA laid down in the GFL Regulation (Article 38) combined with the strict confidentiality rules set out in other EU secondary food legislation providing for the modalities of authorisation procedures on one hand and the general EU rules on access to documents (*i.e.* Regulation (EC) No 1049/2001) create a rather complex system for the public release of documents.

In 2012, EFSA took additional steps to open its processes to its stakeholders. Now, following a pilot project, the plenaries of its Scientific Committee and Panels are open to the public, public consultations are conducted on major draft scientific opinions and hearings of experts can be used by Panels to further inform them.

During 2013-2014, under the Transparency initiative, EFSA consulted its stakeholders on several occasions (*e.g.* NGOs, consumers, industry, national risk assessors, risk managers, academia) to collect inputs and engage with them in designing its future approach to transparency[98]. Examples of such consultations include the 2013 Stakeholder Conference on Transparency and the Open EFSA public consultation.

The EFSA 2020 strategy[99] takes on board the results of the above mentioned consultations. Recognising that society questions the role and credibility of science and that there is a growing demand for more transparency and participation, the 2020 Strategy provides for further initiatives to inform and engage stakeholders in EFSA risk assessment work.

In particular, EFSA has initiated a policy of open data and transparency steps in its risk assessment with the aim that this disclosure will make "reproducibility" of the EFSA's work possible (i.e. other scientific bodies would have at their disposal the same data as EFSA and would thus be able to reproduce its risk assessment).

EFSA also intends to enter into a dialogue with industry and MS to explore what industry could improve on a voluntary basis in terms of accessibility to the studies submitted in the context authorisation procedures and how MS could further improve access to data collected by EFSA and owned by MS.

EFSA has a well-functioning Stakeholder Platform consisting of a wide variety of interests, *i.e.* consumers, farmers, industry, Environmental NGOs and academia). An innovative initiative has been launched to involve stakeholders in the development of EFSA guidance documents impacting on

[98] See at: http://www.efsa.europa.eu/en/topics/topic/open-efsa.
[99] To be found at: https://www.efsa.europa.eu/en/corporate/pub/strategy2020.

them (i.e. the pilot group on guidance on allergenicity where designated scientific experts participate together with industry and NGOs experts).

In summary, EFSA functions transparently and has developed important new initiatives on transparency. EFSA is globally perceived as a transparent organisation but some NGOs consider that the existing legal rules on confidentiality excessively restrict the access to industry studies since a complete access to these studies is necessary in their view to be able to scrutinise the independence of EFSA's risk assessment work.

1.1.1.1 Risk communication

One of EFSA's key responsibilities according to the GFL[100] is to communicate food and feed safety scientific results to its principal partners, stakeholders and the public at large, to help bridge the gap between science and consumers.

The EFSA 2012 evaluation indicated that EFSA communication was effective and of good quality (i.e. relevant, timely, and published on the website). The outreach was also considered as good (i.e. indicatively, 3.5 million visits to EFSA website in 2011) and EFSA developed its use of social media (i.e. Twitter in 2011).

In the context of that evaluation, the stakeholders although positive (i.e. 79%) on the quality of EFSA's communication, were critical on some issues: clarity was considered satisfactory mostly for the informed public, contradictory views on the appropriate targets of EFSA's communication (i.e. the general public as against maintaining existing strategy to target National Risk Assessors and National Risk Managers that can adapt the communication content provided by EFSA to their national needs), media considering EFSA's communication as too complex, and English mostly used.

By 2015, the communication activities were supported by a budget of €7 million and 36 FTE[101]. An Advisory Forum Working Group on communication has been established and focusses on a collaborative approach with national scientific agencies' communicators.

Since 2012, EFSA's approach has evolved, reflecting some of the comments made during the external evaluation. In particular, more emphasis has been placed on explaining the impact of EFSA's work and on simplifying, wherever possible, the messages conveyed. In practice, this has resulted in a number of new measures and communications products. The most obvious is the revamp of EFSA's website in 2014 to ensure a more user-friendly, customer-oriented platform.

EFSA has also introduced specific communications products designed for lay audiences. For example, the Understanding Science series contains short videos about EFSA's scientific work explained in

[100] *I.e.:* Ensuring that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission (Article 23); Communicating in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions (Article 40); Acting in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk communication process (Article 40); Providing, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programme (Article 22).
[101] EFSA 2015 Annual Report, to be found at: https://www.efsa.europa.eu/en/corporate/pub/ar15 .

simple terms and has proven very popular with over 100,000 views for all videos. [102] In 2013, EFSA also introduced its 'Lay Summary' series to explain scientific outputs on issues of high public interest (e.g. aspartame and Bisphenol A).

EFSA has also developed its presence on social media, recognising the power of this medium to reach a broad range of interested parties (indicatively 12,000 followers on EFSA Twitter feed by mid-2015, which is high among the EU agencies using Twitter). EFSA's use of social media is complemented by the recent introduction of multimedia product, such as static and interactive infographics fitted for communicating complex information in visual form and popular with media and non-specialist audiences alike.

Indicators have also been put in place to monitor the communication activity and the message penetration. The 2014 results show that the traffic to EFSA web content was 2.4 million viewers and the total number of subscribers to online newsletters and alerts had increased to 35,000.

EFSA is the only EU body having a permanent working group: the Advisory Forum Communication Working Group (AFCWG) focussing on collaboration with counterpart national risk communicators. The Group holds regular meetings and produces specific guidelines to increase the use of best practice and share knowledge and expertise. Indicatively, it has produced Risk Communications Guidelines[103].

However, there have been some negative reports on EFSA in the media, in particular in relation to its opinions on sensitive issues, e.g. GMOs, BPA, glyphosate. Those opinions have either been at the centre of scientific divergences with some MS and/or have attracted criticisms from NGOs.

The criticisms on complexity have been addressed by EFSA since 2012. Several new tools have been put in place to simplify the messages. However EFSA's communication is limited to explaining science and cannot address the societal, or political, choices important in sensitive areas (e.g. environment versus productive agriculture).

4.2 Which main factors have contributed to or stood in the way of achieving these objectives?

4.2.1 For the delivery of scientific outputs

According to the EFSA 2012 evaluation, the adoption of several new authorisation procedures including specific processes of "reviews", after the establishment of EFSA, had the following impact:

- A sharp and rapid increase in EFSA's workload (74.5% increase between 2006 and 2011) in the authorisation sector;
- This increase was in a number of cases aggravated by a more complex workload (increase of applications of which 32% related to new products);

[102] See at: http://www.efsa.europa.eu/en/topics/videos.
[103] See at: http://www.efsa.europa.eu/en/corporate/pub/riskcommguidelines150210.htm.

- This increase included peaks of applications not foreseen because of several reviews provided for in new legislation (4187 applications for health claims in 2008).

The EFSA 2012 evaluation considers that this had impacted EFSA's capability to deliver fully in terms of scientific outputs.

The Impact Assessment on fees for EFSA also showed that out of 9466 applications received from 2003 to 2010, 7983 concerned "reviews"[104]. Some reviews concern substances/products/claims which have already been legally marketed in the EU market but are submitted to a new EU authorisation procedure (e.g. health claims or enzymes). Other reviews concern substances/products which were authorised under EU legislation for an unlimited period of time. After a rather long period of time, there is a need for reasons of public health to check that the scientific assessment underpinning the authorisation is still supported by the evolution of scientific knowledge and the public authorities may decide to assess again their safety. Reviews are therefore performed in the public interest and are not a systematic and foreseeable process.

In 2015, the state of play of the reviews subject to EFSA's safety assessment was the following: food additives (still on-going until 2020 concerning 309 food additives), feed additives (still on-going and concerning 679 feed additives), MRLs of pesticides (still on going until 2019/2020 and concerning 450 substances), flavourings (2500 initially, should have been finalised but around 300 remaining) and enzymes (starting for around 300 substances and foreseen to be finalised in 2020/2021). From approximately 4,600 consolidated claims submitted to EFSA for efficacy assessment, 267 health claims have been authorised, while 2,051 have not been authorised. In addition, 2,145 health claims are under consideration, including some 2078 claims which are subject to the ongoing REFIT evaluation on health claims made on botanicals and the general regulatory framework of the use of botanicals in foods (March 2017 data).[105]

In all the sectors impacted by a high number of stop the clocks and backlogs, except one (GMOs), there are still a high number of substances submitted for review.

4.2.2 Trust in the reliability of EFSA scientific outputs

Despite the quality control systems in place, the reliability of EFSA's scientific opinions is criticised by NGOs in particular in relation to sensitive files (e.g. Bisphenol A) for relying on industry studies for the assessment of authorisation dossiers and for not taking into account some animal and epidemiological studies. These criticisms need to be put into perspective since the EU legislation on authorisations, as it is the case in other sectors such as pharmaceutical or chemicals, requires that the studies justifying the safety of a substance submitted for authorisation are performed and submitted by the applicant for authorisation, because of the legal principle according to which the burden of proof is on the applicant. Several guarantees also ensure that the industry studies provide sound scientific information. EFSA's scientific guidance in relation to authorisation procedures specify

[104] From 2003 to 2010, the most significant reviews concerned flavourings and claims.
[105] REFIT evaluation of (a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of (b) the general regulatory framework for their use in foods.

the types of studies to be provided as well as the international protocols and good laboratory practices that should underpin these studies. It is important for the reliability of the scientific opinions that EFSA bases its risk assessment on validated data, thus not taking into account studies which are not "validated science" (i.e. studies which are not peer-reviewed or do not respect methodologies internationally recognised such as good laboratory practices). Finally, it has to be acknowledged that EFSA not only considers the different studies submitted by the applicant to assess the risk linked to a substance submitted for authorisation, but also takes into account all validated scientific studies which are relevant to assess the risks linked to this substance.

There is a strict policy on the independence in EFSA but some groups still ask for more stringent rules. The room for strengthening the rules is however limited. There is a risk of losing valuable expertise needed to ensure the scientific quality of EFSA opinions given the increasing trend of public/private partnership in scientific research, the scarcity of good scientific experts in areas such as toxicology and the already heavy burden on experts created by the already existing rules in a context of voluntary contribution of the experts to EFSA's work.

EFSA has a strong policy on transparency and openness but one important limit to the access to EFSA documents is the respect for confidentiality as required by EU legislation (i.e. documents considered confidential because public disclosure would prejudice the competitive position of the applicant, by revealing business secrets). Some groups have requested that the whole content of industry studies submitted in the context of authorisations should be made public. EFSA cannot accede to these demands since this is not permitted by the applicable legislative framework; nevertheless it is perceived as not transparent and therefore it impacts negatively EFSA.

4.2.3 For the risk communication

The communication on risk is subject to several constraints:

- Complex scientific findings need to be translated into simple language which, nevertheless, have to be scientifically correct.
- The perception of risk is often emotional, cultural and disconnected from rational thinking (e.g. consumers expect food to be 100% safe).
- Social media intensify the diffusion of scares and often undervalue science, or scientifically validated information.

There is increasing confusion in the public on some key concepts and this creates negative perceptions of EFSA:

- Confusion between hazard and risk (the identification of a hazard does not mean that a risk for health exists and that action has to be taken).
- One negative study on a substance does not demonstrate that there is a risk for health, in particular when the study is not validated or not peer-reviewed. A scientifically valid risk assessment is based on a consistent, sound set of validated scientific studies and not on one study and takes into account the exposure to the risk.

- Divergences between different scientific bodies do not imply that one is doing "good quality work" and the other one "bad quality work". Some divergences are apparent and can be explained by different frameworks (e.g. hazard vs risk; not exactly the same substance assessed).

4.3 Beyond these objectives, has the legislative framework introduced by the GFL led to any other significant changes both positive and negative?

No significant changes either negative or positive have been identified for EFSA.

5 Efficiency

The efficiency of the GFL is analysed with respect to costs and benefits related to its implementation, with the aim of analysing the space for reduction of burden.

5.1 Costs and benefits associated with EFSA

EFSA has operated on the basis of a stabilised budget since 2010 (around €79 million including pre-accession funds and contribution from Norway and Iceland).

The average cost of a scientific output of EFSA can be assessed as: the sum of the costs (€32.94 million of Activity 1 General scientific opinions (€13.49 million) and Activity 2 opinions on regulated products (€19.45 million) divided by the number of scientific outputs (651): €50,559.

If the cost of activity 3 (26.44M) which is partly supporting the EFSA risk assessment work is added the cost of an EFSA scientific output is €91,213.

Even if the average cost of the EFSA evaluation of an authorisation dossier submitted by industry was assessed between €6872 for MRL (simple dossier) and €137,346 for GMO (complex dossier) with a rather large number of dossiers assessed for an average cost between€ 40,000 and €60,000 in the framework of the Impact assessment on fees for EFSA, the conclusion of the impact assessment was to not establish fees for industry to pay for the scientific evaluation by EFSA of authorisation dossiers.

There are still some costs for industry. In particular, the delays due to a high number of 'stop the clock' procedures can create costs for industry because of the slower emergence of innovation on the market. Delays impact mainly on new substances, claims and products submitted for authorisation. In the case of reviews, the delays do not usually create costs for industry since the product/substance remains on the market until there is a negative opinion.

The EFSA 2012 evaluation pointed out that improvements were necessary to boost EFSA's efficiency in order to face the workload of applications and to address the lack of timeliness. It was in particular recommended to improve the usability of guidance documents, to improve the dialogue with partners and to promote the harmonisation of the outputs of Panels, in particular in relation to compliance with guidance documents.

Even if the use of the stop the clock procedure is not by of itself an indication of inefficiency, its extent (Table 5) indicates that all or some of the tools making the use of this procedure more

efficient (in particular clear guidance on the content of dossiers, completeness checks, appropriate communication with applicants) might not be used in an optimal way.

The letter sent to EFSA on behalf of 11 industry federations, dated 17 February 2014[106] referred to the recommendations of the EFSA 2012 evaluation and confirmed a lack of adequate communication between EFSA and the individual applicants as a major obstacle to the businesses represented by the authors of the letter. They proposed a series of improvements: clearer and stable guidance followed in an harmonised way by the Panels, more rigorous completeness check (i.e. validity/suitability check of initial dossiers), communication and assistance from EFSA to applicants regarding requests to interpret guidance, better involvement of risk managers and stakeholders to ensure that guidance documents reflect more accurately the acceptable level of risk laid down in legislation and are clearer and usable.

Since 2013, steps have been taken to address the issues raised by industry as described below, even if there are still areas in progress.

In particular, pre-submission meetings were identified by applicants as a service which would be of added value. EFSA has established this service but not in the form of individual pre-submission meetings.

EFSA outsources part of its work to national scientific bodies some 10 million worth and thus confers some financial benefits on these national bodies. The networking organized by EFSA between national agencies benefits EFSA (i.e. increase of its capacity of expertise) but also the national scientific bodies because of the exchange of knowledge, good practice and methodology between them and EFSA. The EFSA networking also facilitates cooperation between national agencies and since EFSA's establishment, cooperation agreements have been concluded between the national agencies themselves[107].

EFSA's system is particularly cost-effective for the MS that have limited risk assessment and scientific capacity and thus benefit from EFSA's scientific advice, the sharing of data and expertise, training and EFSA's support in terms of risk communication (e.g. model press-releases, lines to take). It is potentially less cost-beneficial for MS with a significant scientific capacity of expertise since the experts they have trained and employ spend time in EFSA for rather small financial compensation. However, the MS organisations with a high level of expertise might potentially benefit more from the EFSA grants and procurements.

The EFSA 2012 evaluation stressed some different views with regard to the efficient distribution of work between the EFSA's Panel, EFSA staff and external bodies. According to several stakeholders in the context of the latter evaluation (NRM, NRA, FIR, EP), the reliance on external experts was one of EFSA's main strengths since it guarantees a wide range of qualified and updated scientists. . However, some of the FIR/A and the Scient. Org considered that there should be a reduced dependence on

[106] To be found at: https://www.efsa.europa.eu/sites/default/files/assets/141002-letter.pdf.
[107] See at: http://ww+w.bfr.bund.de/en/press_information/2010/19/bfr__dtu_and_anses_enter_into_cooperation_agreement-53404.html.

external scientists and an increased use of in-house expertise with the Panels/external experts intervening at the end of the process as peer-reviewers in order to better manage the workload and to ensure a better appreciation of EFSA's scientific role. One NRA also considered that it would reduce the level of criticism of EFSA.

5.2 Good practice relating to cost-effective implementation

EFSA has in place an activity based budget, progress indicators, internal audit and internal quality control as part of its overall drive for better efficiency. EFSA is in the process of being certified ISO 9001[108] (target for certification is 2017).

Concerning the allocation of resources, the EFSA 2012 evaluation showed that the gap between commitment and executed appropriations has progressively reduced over time. It has increased from 89% in 2006 to 98% in 2011[109]. The commitments executed are now estimated at 99.8%[110].

EFSA's own capacity of expertise is globally sufficient. The findings of the EFSA 2012 evaluation, as updated with figures to 2014, demonstrate EFSA's capacity to adapt to significant changes of workload (i.e. high increase of questions in particular in relation to authorisation dossiers) by:

- allocating more resources to its Activity 2 (applications). The budget allocated to Units responsible for applications constantly increased from 2006 to 2011. For the period 2012-2014, the budget for this activity is around €20 million and the staff allocation is around 135;
- increasing the ratio of scientific staff (current EFSA target is 75% of staff to operational activities[111]);
- creating new Panels to adapt to the changing workload[112];
- increasing the outsourcing of its tasks (from 6% of budget in 2009 to 11% in 2011). In 2009-2014, around €10 million are allocated to outsourcing, i.e. around 12.6% of EFSA's budget).

As stated in Section **4.1.4,** the tools for cooperation with MS (i.e. outsourcing of tasks) have been updated to increase the efficiency of the system in particular revision of the Article 36 list, new thematic grants, and new long-term contracts.

Since 2011, in order to plan and allocate resources more efficiently, EFSA and the Commission have developed mid-term planning enabling EFSA to be better aware of new mandates envisaged by the Commission.

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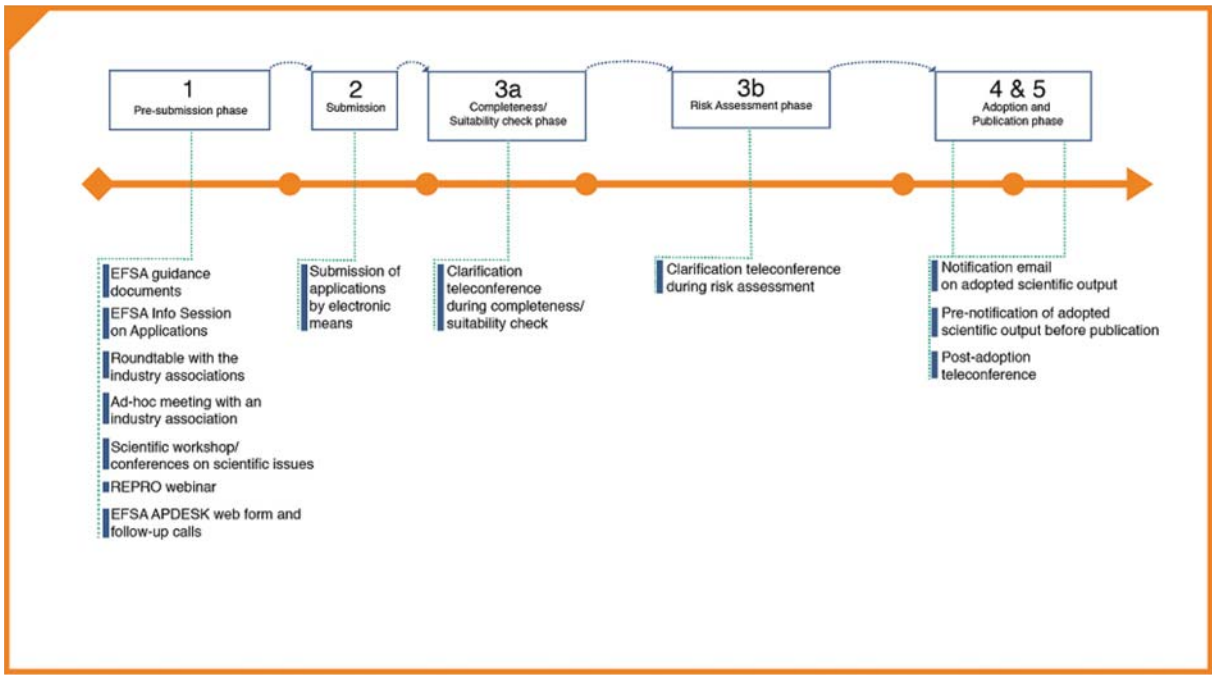
[108] EFSA programming document 2016-2019, to be found at: http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1619.pdf.
[109] See Section 3.6.1 of the EFSA 2012 evaluation (chart 21).
[110] EFSA programming document 2016-2019, to be found at: http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1619.pdf.
[111] *Id.*
[112] Commission Regulation (EC) No 575/2006 of 7 April 2006 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (OJ L 100, 8.4.2006, p. 3); Commission Regulation (EC) No 202/2008 of 4 March 2008 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the number and names of the Scientific Panels of the European Food Safety Authority (OJ L 60, 5.3.2008, p. 17).

Since 2013/2014, following the results of the 2012 external evaluation, EFSA has been more attentive to the needs of applicants submitting authorisation dossiers for clearer and more predictable guidance as well as for better dialogue.

In 2013-14, EFSA conducted a survey on stakeholders' needs regarding the application process, which was published. In general, stakeholders found the application process very complex due to the variety of workflows for each vertical scientific area, the lack of information on the status of the applications, the lack of communication with EFSA staff involved, the lack of predictability of workflows and timeline, the lack of clarity regarding the questions raised during the risk assessment and the conclusions reached in the final scientific output. Applicants would like to have the possibility to attend a pre-submission meeting with EFSA.

EFSA has increased the information specific to regulated products on its website with the publication of workflows for each specific regulated products areas (with steps and timeline), overviews and updates on regulations and guidelines for all regulated product areas, publication of all Plenary meetings dates, organisation of Information Sessions on Applications. A public Catalogue of support initiatives during the life-cycle of applications for regulated products was published in March 2015[113]. It is summarised below:

Table 10 Catalogue of support initiatives



EFSA also put in place a pilot group[114] to better involve stakeholders at an early stage in the development of guidance impacting on them with the aim of extending this procedure.

[113] See at: https://www.efsa.europa.eu/en/supporting/pub/1025e.
[114] Pilot group on allergens.

EFSA Panels are also increasing the use of the hearing procedure (hearing of external experts including industry experts) to better inform their decision process.

EFSA and SANTE also recently agreed to generally apply already existing good practice in certain sectors and regarding the early dialogue between the risk assessor (EFSA) and the risk manager (SANTE) before sending formal mandates to EFSA. This is in line with the request of industry for clearer mandates.

It can also be noted that EFSA fulfilled the commitment to lower the average cost of an MB meeting to €35,000 (partial data for 2015), following findings that EFSA average cost of MB meeting was significantly higher than those of comparable EU agencies. It has been reduced from €86,000 per meeting in 2010 to €37,000 per meeting in 2014[115].

5.3 Obstacles to cost-effective implementation

The EFSA 2012 external evaluation has indicated that the frequent adoption of other EU secondary food legislation requiring EFSA to carry out risk assessment and the limited consultation of EFSA during the EU legislative process have reduced EFSA's capacity to adequately plan its workload and, consequently, reallocate its resources. Indicatively, some stakeholders have considered that the EU legislators, while approving new EU food legislation, seem to hardly consider their impact on EFSA's work, without modifying the resources at their disposal.[116]Indeed, the adoption of subsequent EU food legislation has had an impact on EFSA's activity in two ways.

Firstly, it has influenced EFSA's flexibility, limiting sometimes rooms for action and imposing different processes and reducing standardisation, mainly in relation to the evaluation of regulated products (in particular EFSA having to operate on the basis of 34 different EU Directives and Regulations defining 39 workflows). This also had a negative impact on the harmonisation of processes between Panels and impacted on EFSA's capability to plan adequately

Secondly, the legislative framework had an impact on EFSA's capacity to adequately plan and allocate its resources because of poor exchanges with the EU institutions during the legislative process and the limited notice of official communications.[117] In particular, the large number of applications created by the reviews was not always estimated in advance, or not precisely at least and this diminished the ability of EFSA to plan adequately the allocation/division of its resources. This also led to not taking them into account in budgetary terms. No extra budget or staff was foreseen in the financial fiches accompanying the new authorisation procedures, adopted following the establishment of EFSA, since the assumption at the time was that EFSA budget and staff was still growing and fit to face the potential extra workload created by the new legislation. It is only recently that 10 extra contractual posts were allocated for EFSA in order to reduce the backlog relating to the review of the MRLs of pesticides.

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[115] The former high costs were partly due to the legal requirement (existing only for EFSA) that its Management Board meetings have to be public.
[116] EFSA 2012 external evaluation, at p. 178.
[117] *Id.*, at pp 179-180.

The tools at the disposal of EFSA to overcome peaks have revealed shortcomings:

- The EFSA 2012 evaluation[118] pointed out that the independent experts members of the Panels, voluntarily allocated part of their time to EFSA and thus their availability was limited.[119]
- The financial compensation system for the experts and their employers regarding their scientific contribution to EFSA is rather modest[120] and might not be proportionate to the amount of time required in some Panels dealing with authorisations.
- Except in the case of plant protection products, EU secondary food legislation setting out the authorisation procedures does not establish a mandatory requirement that MS have to perform specific scientific work contributing to EFSA risk assessment task. The GFL only provides for a system of incentives, *i.e.* grants to national bodies included in the Article 36 network contributing to EFSA's work and possibility for EFSA to use procurements to outsource work to national bodies.
- As indicated under effectiveness (Section 4.1.4.2), the outsourcing of work to national bodies via grants and procurements mainly contributes to EFSA's work on data collection and general scientific advice and not to EFSA's tasks related to authorisations.
- As stated in Section 4.1.4, the funding per year of grants and procurements linked to preparatory work is limited (around €10 M per year), thus potentially limiting the extent of the incentives to do preparatory work for EFSA.
- As described in Section 5.1, EFSA has developed the support from its staff to the Panels but the volume of this support is limited by the need to respect the specific decision process of the independent Panels. However, this might need to be further analysed since in the plant protection products' sector where MS perform the initial risk assessment and where EFSA staff (and not the Panels) have a significant role , there are also significant backlogs in a context of a high workload.

To address the impact of the high workload of EFSA in the area of authorisations, the Commission undertook an impact assessment on the establishment of fees for EFSA in 2013.[121] Although it acknowledged the high workload of EFSA in the area of authorisations, the latter impact assessment concluded that the imposition of fees for EFSA was not workable because of the complexity of the legal framework, embracing 19 different pieces of EU legislation. An in-depth analysis of the options considered showed that none of those proposing the introduction of fees would ensure EFSA a satisfactory income, nor would they result in significant savings for the EU budget. In addition, the perception of EFSA's independence could be damaged.

The possibility to allocate routine authorisation applications to EFSA staff or to national organisations, the Panels being not involved or only in charge of peer-review, was also addressed in

[118] See Section 3.6.2 of the 2012 external evaluation.
[119] See Section 3.6.2.3 of the 2012 external evaluation.
[120] More specifically, €385 for a full day meeting, €770 for rapporteur (see effectiveness section).
[121] Commission Staff Working Document, '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, dated 11.2.2013.

the framework of the Impact Assessment on fees for EFSA[122] in the context of the already high workload on authorisations. The Impact Assessment indicated that this option was discarded since "*the consultation of Member States on 17 January 2012 showed that they were not in favour of the possibility of reducing EFSA's Scientific Panels' involvement or exclusion in the assessment of routine authorisations. They also considered that it would be extremely difficult to draw a clear distinction between routine and complex authorisations. Finally, in order to preserve EFSA's Panels specific scientific role, they reaffirmed the need for the Panels to continue to be responsible for the adoption of the opinions related to all authorisation applications".*

Almost all current reviews are planned to be finalised by 2020, except enzymes (2021), and there is no plan to launch new reviews. This should allow EFSA to plan and allocate resources in a more stable way in the future.

There also a number of extra costs for EFSA compared to similar EU agencies:

- The costs linked to the selection of its experts. While in EMA and ECHA, the experts are selected and designated by the MS, EFSA has to perform a selection process involving during 18 months, 3.3 FTEs for the renewal of the eight Scientific Panels and the Scientific Committee and 1.7 FTE for the renewal of the ANS and CEF Panels.
- The absence of an international airport in Parma obliges EFSA to organise a shuttle system between the Milan airports and the EFSA premises (at a cost of around 0.7 M per year).
- The independence policy is costly for EFSA (i.e. 4.7 FTE and €235.000).

5.4 Specific challenges to SMEs

An EFSA survey on stakeholder needs with regard to authorisation dossiers was performed in 2013[123]. The survey concluded that there was no specific evidence of a greater desire for information among SMEs. This, according to the contractor's interpretation, was probably because small companies are typically keen to retain a consultant to support them in the preparation of their technical dossiers.

In practice, the use of consultants was, common among both SMEs and large companies, with 90% of SMEs using a consultant to submit their application. The research also found that companies have similar needs regardless of the scientific area of the regulated products they were active in.

EFSA thus focussed on the general improvement of its services to applicants since this was the most urgent improvement required to meet the needs of applicants including the SMEs.

[122] *Id.*.
[123] See at http://www.efsa.europa.eu/en/supporting/doc/482e.pdf.

6 Coherence

The coherence of the risk management, risk assessment and risk communication and the cooperation between the two actors responsible for these functions e.g. the risk assessor and the risk manager is essential to ensure that the risk analysis process defined in Article 6 of Regulation 178/2002 is properly implemented.

In particular, the risk assessor needs to fully understand the mandate for risk assessment delivered by the risk manager in order to deliver a risk assessment that is fit for purpose i.e. "scientific advice supporting risk management measures".

The EFSA 2012 report[124] concluded that the Commission (DG SANTE) and EFSA have actively collaborated (i.e. an interface unit in DG SANTE, regular bilateral meetings, roadmaps etc.). The report also points out that DG SANTE representatives attend the scientific meetings in EFSA as observers (with the possibility to reply to requests for clarification of the mandates) thus ensuring the necessary dialogue on the mandate for risk assessment sent by the risk managers.

As already set out /explained in Section 4.1.5, EFSA also works in cooperation with other EU scientific agencies and the relevant international bodies.

There were few cases of a divergence between EFSA and International organisations in the field of food safety.

In 2007 EFSA delivered an opinion on a GM potato in which it considered that the antibiotic resistance maker gene *nptII* which confers resistance to two families of antibiotics (i.e. kanamycin and neomycin) could be authorised since the families of antibiotics concerned were not important for the protection of human health. However, since after this opinion, WHO classified these families of antibiotics as important for human health, EFSA issued a second opinion revising its initial position.

The recent divergence between EFSA and IARC on glyphosate appears as an apparent divergence since IARC's opinion on glyphosate was also divergent with the view of another WHO/FAO scientific body (i.e. JMPR which is the food safety risk assessment scientific body of CODEX ALIMENTARIUS/WHO/FAO).

When JMPR recently adopted a scientific opinion confirming the EFSA opinions on glyphosate, WHO published a specific press release explaining the divergence between JMPR and IARC (see main extracts below): This is not a real divergence, as explained by the WHO/OMS itself in its Summary Report, and related press release of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), published on 16 May 2016.

An extract of the above-mentioned press release is set out below:

"Hazard" and risk: what is the difference?

[124] See Section 3.4.2.1 of the EFSA 2012 evaluation.

Scientific studies of the potential health effects of hazardous chemicals, such as pesticides, allow them to be classified as carcinogenic (can cause cancer), neurotoxic (can cause damage to the brain), or teratogenic (can cause damage to a fetus). This process of classification, called "hazard identification," is the first step of "risk assessment".

An example of hazard identification is the classification of substances according to their carcinogenicity to humans carried out by the International Agency for Research on Cancer (IARC), the specialized cancer agency of WHO.

The same chemical can have different effects at different doses, which depends on how much of the chemical a person is exposed to. It can also depend on the route by which the exposure occurs, e.g. ingestion, inhalation or injection.

Why does WHO have 2 distinct processes for "hazard identification" and "risk assessment"?

"Hazard identification"—in particular the IARC classification of substances in terms of their carcinogenicity—is the first step of the "risk assessment" process. Classification of an agent as a carcinogenic hazard is an important indication that some level of exposure, for example from occupation, environment, food, etc., could result in an increased risk of cancer.

Risk assessment for pesticide residues in food, as conducted by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), establishes a safe intake level after assessing the level of risk. Acceptable daily intakes (ADIs) are used by governments and international risk managers, such as the Codex Alimentarius Commission, to establish maximum residue limits (MRLs) for pesticides in food. MRLs are enforced by national authorities to ensure that the amount of pesticide residues consumers are exposed to through eating food over a lifetime will not have adverse health effects.

IARC's hazard identification can inform the JMPR's risk assessment, and thus the two processes can be complementary. For example, IARC may identify new evidence from scientific studies on the carcinogenicity of a chemical and, when necessary, JMPR conducts an evaluation or a re-evaluation of the safety of that chemical as it is used in agriculture and occurs in food.

7 Added value of EFSA

EFSA provides scientific opinions for the entire the EU, thus ensuring a harmonised level of protection based on high quality and independent scientific advice

The increased scientific capacity of EFSA has met the increasing requests for scientific advice from risk managers that derived from the reform of the entire food and feed safety law. In addition, EFSA's increased capacity enabled the finalisation of the review of 1000 pesticides[125] which were on the market before 1993. All reviewed pesticides underwent a detailed risk evaluation with respect to their effect on humans and on the environment and, as a result, only 26% (around 250) remained on the market.

The building of a data collection capacity filled one of the main gaps identified in the food safety system (in particular the absence of sound EU food consumption data upon which to evaluate the exposure of consumers to risks). The improvement of the data collection system is also of added value for the risk managers who are better informed on the trends in safety in the food chain and constitutes an asset at international level to scientifically base the EU's positions.

[125] See at: http://europa.eu/rapid/press-release_IP-09-402_en.htm?locale=en.

The EFSA 2012 external evaluation found that 84% of the respondents indicated that EFSA's international activities provide added value in particular signalling that:

- EFSA's capacity to recruit the best experts is recognised internationally (Some NRAs however indicated that EFSA is sometimes regarded as not providing its own opinion but rather those of its independent external experts);
- EFSA's high international rating depends on the issues treated. It is high for flavourings, biological hazard, zoonoses, animal welfare and pesticides;
- EFSA results are taken into account in the working groups of OIE and Codex Alimentarius preparing international standards;
- EFSA is considered as setting a high level of protection, thus considered by consumers as having a positive influence on food safety but this high level is considered by international organisations as not always relevant in other areas of the globe.

EFSA also provides added value by providing key scientific support to the Commission and Member States in the international standardisation bodies (Codex Alimentarius, OIE, IPPC, EPPO, FAO, WHO) since part of these discussions are based on science. EFSA international cooperation and the related sharing of data is also strengthening the scientific basis of the EU risk assessment, ensuring that the EU risk assessment methodologies are maintained at a high level, are internationally recognised and contribute to the promotion of the EU standards.

7.1 Added-value for the internal market

EFSA networking with national risk assessment bodies facilitates a common understanding of scientific issues linked to food safety thus avoiding divergences within the EU.

The Article 30 procedure on scientific divergences is not always providing solutions when the issues are partly political but it still solves at an early stage a number of potentially conflictual questions and it thus provides an additional value in the food safety system.

EFSA provides scientific advice and technical support in cases of safeguard clauses, thus facilitating science based and consistent solutions.

EFSA's activities promote unified methodologies for safety assessment in non-harmonised areas (for example EFSA worked with MS to provide a methodology for assessing the safety of botanicals)

7.2 Added value on crisis/emergency management

EFSA data collection capacity contributes to better quality and more rapid scientific support in case of emergencies/crisis (i.e. EU" food consumption data and for each MS immediately available for the calculation of exposure to a specific risk).

The technical support of EFSA is an asset in the management of crisis/emergencies. The joint work of EFSA and ECDC on two databases (i.e. an EFSA database on molecular typing of food-borne pathogens from food, feed and animal samples corresponding to an ECDC data base on human data) will contribute to epidemiological investigations of food-borne diseases and will facilitate the identification of emerging risks as well as the management of emergencies/crises.

7.3 Added value for MS

According to the ESA 2012 evaluation, 77% of MS risk assessors and risk managers consider that their national food agency/body benefits from EFSA's activities in terms of costs (i.e. EFSA inputs, sharing of expertise, risk assessments, communication support, methodologies and training).

15 Appendix 7a – List of abbreviations (EFSA intermediary report)

ADoI	Annual Declaration of Interest
AF	Advisory Forum (Risk Assessors)
AFCWG	Advisory Forum Working Group on Communication
Cons.	Consumer Organizations
DGs	Directorates General
DoI	Declaration of Interest
EC	European Commission
ECHA	European Chemicals Agency
ED	Executive Director
EFSA	European Food Safety Authority (hereinafter as well referred to as "the Authority")
EMA	European Medicines Agency
EP	European Parliament
FIR/A	Food Industry Representatives/Applicants
FP	Focal Points
FSA	Food Standard Agency
FTE	Full Time Equivalent (staff)
IEP	Information Exchange Platform
ILSI	International Life Sciences Institute
IOs	International organizations
MB	Management Board
MEP	Member of the European Parliament
MS	Member States
NGOs	Non-Governmental Organizations (other than Consumer Organizations)
NRM	National Risk Managers
NRA	National Risk Assessors
SC	Scientific Committee
SDoI	Specific Declaration of Interest
Scient. Org.	Scientific organizations
SOP	Standard Operating Procedure

16 Appendix 8 – Reviewed Literature

Note: This list excludes references to EU legislation, Commission guidance documents and European case-law.

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