

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
1	EQ	Evaluation Question (ToR)	JC	<i>Explanatory Notes / Judgement criteria</i>	I	<i>Explanatory Notes / Indicators</i>
2		Relevance (EQ1)				
3	1	To what extent do the original objectives of the “General Food Law Regulation” correspond to the current needs of the society within the EU, reflect policy trends of today, taking into account developments at Union and international level, and fit the Union's institutional, legal, economic and political landscape?		Overarching question with links to a number of EQs		<i>Correspond</i> = relevance of GFL objectives in addressing current societal needs and policy trends. This issue is addressed by examining the extent to which the GFL has met its core original objectives (protection of human life/health; protection of consumer interests; free movement of food in the internal market; free movement of feed in the internal market) and the extent to which it is adequate to address other objectives/needs as well as specific trends of today. <i>Links:</i> With EQ3, 4 and 5: the extent to which each of the original core objectives of the GFL have been met With EQ19: addresses the adequacy and relevance of the scope and general definitions of the GFL. With EQ7: contribution of the GFL to meeting other interests/needs which are the Union's objectives
4			1	• Contribution of the GFL and its implementation in achieving its original core	1a	• Extent to which original objectives of the GFL have been met (<i>see also indicators of EQ3, EQ4 and EQ5</i>) (surveys; interviews; Expert panel)
5					1b	• Extent to which the original core objectives of the GFL are still relevant (interviews; Expert panel)
6			2	• Adequacy of the GFL to address other objectives/needs and current	2a	• Extent to which the current GFL framework is adequate to address other objectives/needs: innovation potential; consuming healthier food/nutritional needs of general population; competitiveness of the food supply chain; other (surveys; interviews; Expert panel)
7					2b	• Extent to which the current GFL framework is adequate to address specific current trends: sustainability/food waste; food quality; food availability; distance selling including e-commerce; globalisation of trade; other (surveys; interviews; Expert panel)
8		EU added value (EQ2)				
9	2	What is the European <i>added value</i> of the EU food safety regulatory framework established by the “General Food Law Regulation” (compared to what could be achieved by MS at national and/or regional levels as well as international (Codex, OIE) level)?		Overarching question with links to a number of EQs → <i>The indicators selected here are designed to provide an overview; findings from EQs/case studies will be used to complete the analysis</i>		<i>Added value</i> = includes a range of components in terms of the positive contributions of the GFL as a framework, i.e. benefits over the counterfactual of not having the GFL (i.e. compared to what could be achieved by MS at national and/or regional levels, or at international level (Codex, OIE)). We have defined components of added value and developed indicators for each component. This includes: contribution to the internal market objective (EQ5); potential reduction in regulatory costs and burden (link to EQ 29); improving internal coherence (EQ32).
10			1	• Benefits of EU-level operation: key advantages of the GFL compared to what could be achieved by Member States at national and/or regional	1a	• Extent to which the GFL offers added value, compared to counterfactual (no GFL): in terms of: providing a single, uniform framework to develop EU rules on food/feed safety; improving coherence of food safety rules (across MS; between sectors); raising the overall level of food safety standards applying across the EU; facilitating trade with third countries; facilitating enforcement across the EU; allowing simplification, thus leading to reduction in regulatory costs and burden), according to stakeholders (surveys; SME panel; interviews; Expert Panel)
11					1b	• Extent to which dealing with food safety at the national level would lead to lower or higher cost-benefit ratio (compared to having the GFL and national implementation) (interviews; case studies)
12			2	• Public health, consumer protection and economic impacts of non-EU approach to food safety	2a	• Problems from a sub-EU-level approach (e.g. compared to areas where there is no harmonisation) (interviews; Expert Panel)
13					2b	• Gaps in dealing with food safety at international level (e.g. compared to: areas where there is no harmonisation; previous national, rather than EU, membership of international organisations (Codex, OIE, IPPC)) (interviews; Expert Panel)
14		Effectiveness (EQ3 to EQ24)				

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	H	I	J	K	L	M	N	O	P	Q	R
	Combined q/naire	MS CA survey	Stakeholder survey	SME Panel	EQ	MS CA workshop	FBO/NGO workshop	Interviews main phase	Case Studies	Literature review	Expert Panel
1											
2											
3					1			x	x	x	x
4	1	3	5								
5											
6	2a	4a	6a								
7	2b	4b	6b								
8											
9					2	x	x	x	x	x	x
10	50	40	37								
11											
12											
13											
14											

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	A	B	D	E	F	G
15	3	To what extent has Regulation (EC) No 178/2002 and its implementation contributed to achieving the objective of protection of consumers' health and interests including <i>fair practices in food trade</i> ? (Article 5.1)		Overarching question with links to a number of EQs → <i>The indicators selected here are designed to provide an overview; findings from other EQs/case studies will be used to complete the analysis</i>		<i>Fair practices in food trade (Article 5.1) = not misleading consumers (i.e. it is defined in the context of the protection of consumers' interests); link to EQ6.</i> <u>Links:</u> <i>With EQ1: correspondence of these original objectives to current needs/trends.</i> <i>With several EQs (e.g. EQ 6, 8, 15, 16) : EQ3 is examining the extent to which each of the core provisions of the GFL (i.e. on protection of consumers interests (Art. 8), placing safe feed/food on the market (Art. 14/15), allocation of responsibilities (Art. 17), traceability (Art. 18), imports (Art. 11), withdrawals and recalls (Art. 19/20)) have contributed to achieving this objective.</i>
16			1	• Contribution of the GFL and its implementation in achieving these objectives	1a	• Extent to which, overall, the GFL and its implementation contributed to achieving the specific core objectives (protection of human life/health; consumer interests) (surveys; SME panel)
17					1b	• Extent to which current provisions of the GFL and MS implementation are considered satisfactory by consumers (interviews: BEUC; other NGOs) (<i>see also indicators of EQ6</i>)
18					1c	• Trend in consumer trust in public authorities/food safety (e.g. Eurobarometer)
19					1d	• Extent to which MS have taken measures to implement Article 8, including those aimed at preventing fraud and misleading practices (Art. 8) (survey MS CAs) (<i>see indicators of EQ6</i>)
20					1e	• Extent to which the requirements for FBOs to place safe food/feed on the market and to verify compliance with food law have ensured a high level of protection of consumer health (<i>to feed into EQ8</i>) (surveys; interviews: BEUC; other NGOs)
21					1f	• Aspects considered relevant/not relevant for establishing whether a food/feed is safe (<i>see also indicators of EQ 8</i>) (surveys; interviews: BEUC; other NGOs)
22					1g	• Extent to which the GFL provision (Art. 14.7; Art. 15.4) that food/feed is deemed safe when it complies with EU food/feed law (i.e. the GFL and secondary legislation) have proved effective in protecting consumer health (<i>to feed into EQ10</i>) (surveys; interviews: BEUC; other NGOs)
23					1h	• Extent to which the GFL provisions on the allocation of responsibilities along the supply chain have contributed to a high level of protection of consumer health and interests (<i>to feed into EQ8</i>) (surveys; interviews: BEUC; other NGOs)
24					1i	• Extent to which the current provisions on traceability have: assisted in containing a food/feed safety problem; contributed to maintain consumer trust and confidence to the safety of food (<i>see also indicators of EQ 15</i>) (surveys; SME panel; interviews: BEUC and FBOs)
25					1j	• Extent to which the current provisions on withdrawals and recalls have: ensured a high level of protection of consumer health; restored consumer confidence/trust in food (<i>to feed into EQ8</i>) (surveys; interviews: BEUC; other NGOs)
26					1k	• Extent to which current provisions on imports of feed/food from third countries have ensured consumer confidence/trust in imported feed/food (<i>see also indicators of EQ 16</i>) (survey FBOs; interviews: BEUC; other NGOs)
27					1l	• Extent to which the requirements for FBOs to notify public authorities in case food/feed is considered at risk, and to collaborate with public authorities on actions taken to reduce risk have ensured a high level of protection of consumer health (<i>see also indicators of EQ 8</i>) (surveys; interviews: BEUC; other NGOs)
28					1m	• Extent to which MS CAs have implemented restrictions on imports of unsafe feed/food; trend in restrictions imposed (<i>see also indicators of EQ 16</i>) (MS CA survey)
29			2	• Evidence of failures/gaps/problems, post GFL (trend to date)	2a	• Cases of failures and reasons for failure (interviews; Expert panel)
30						• Trend in the number of food safety incidents (RASFF notifications on food safety incidents e.g. cases of food poisoning 2008-2013; ECDC/EFSA annual report on zoonoses and food-borne outbreaks (Salmonella, Lysteria, Campylobacter)) (see note)
31	4	To what extent have the <i>provisions in food law</i> taken into account the protection of animal health and welfare, plant health and the environment and been efficient and effective in		Overarching question with links to a number of EQs		<i>Provisions in EU food law: screening secondary legislation/interviews. Where are these objectives included? Are there any places they could be in but are not?</i> <u>Desired results</u> = <i>effective and efficient protection of animal health and welfare, plant health and the environment; maintaining public trust</i>

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	H	I	J	K	L	M	N	O	P	Q	R
15					3	x	x	x	x	x	x
16	1	3	5								
17											
18											
19	21 22	19a 20									
20	4a	6a	8a								
21	5a	7a	9a								
22	6a	8	10a								
23	8	10	11								
24	13 4b	13 6b	16 8b	12							
25	19 4c	17 6c	19 8c								
26	24		20								
27	4d 4e	6d 6e	8d 8e								
28	26	22									
29											
30											
31					4			x		x	x

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	A	B	D	E	F	G
32			1	• Contribution of the GFL to meeting these objectives	1a	• Extent to which these aspects (protection of animal health; animal welfare; plant health; the environment - AH/AW/PH/ENV) were sufficiently taken into account, where appropriate, in the general framework of the GFL (surveys; interviews; Expert panel)
33					1b	• Gaps/failures identified in secondary legislation (food law) with specific provisions on AH/AW/PH/ENV, which are due to the general framework introduced by the GFL (surveys; interviews; Expert panel)
34	5	To what extent has Regulation (EC) No 178/2002 and its implementation contributed to achieving the objective of the internal market (Article 5.2)		Overarching question with links to a number of EQs → <i>The indicators selected here are designed to provide an overview; findings from other EQs/case studies will be used to complete the analysis</i>		<u>Links:</u> <i>With EQ1: correspondence of these original objectives to current needs/trends.</i> <i>With several EQs (e.g. EQ 12, 8, 15) : EQ5 is examining the extent to which each of the core provisions of the GFL (i.e. on traceability (Art. 18.), withdrawals and recalls (Art. 19/20)) have contributed to achieving this objective.</i> <i>The impact on SMEs is particularly important here (case study; SME Panel).</i> <i>RASFF notifications by MS may also demonstrate different approaches of Member States in the application of certain GFL requirements e.g. the risk analysis principle (RASFF study).</i>
35			1	• Contribution of the GFL implementation on this	1a	• Extent to which the GFL and its implementation contributed to achieving these core objectives (free movement of food and feed in the internal market) (surveys; interviews; Expert panel)
36					1b	• Extent to which aspects considered relevant in establishing whether a food/feed is safe, as well as those not considered relevant (<i>see indicators of EQ 3</i>), have contributed to the effective functioning of the internal market (surveys)
37					1c	• Extent to which the GFL provisions on the allocation of responsibilities along the supply chain have: facilitated the placing on the market of feed/food products; contributed to the effective functioning of the EU internal market; created a level-playing field for all feed/food operators in the EU (<i>see also indicators of EQ 12</i>) (surveys)
38					1d	• Extent to which the current provisions on traceability have contributed to: ensure fair trading amongst FBOs; avoid/limit unnecessary disruption of trade (<i>see also indicators of EQ 14</i>) (surveys; SME panel)
39					1e	• Extent to which the current provisions on withdrawals and recalls have contributed to avoid/limit unnecessary disruption of trade (<i>see also indicators of EQ 15</i>) (surveys)
40					1f	• Extent to which, and areas in which, there have been differences in implementation/application of the GFL amongst MS (<i>see also indicators of EQ 24</i>) (surveys)
41			2	• Evidence of failures/gaps/problems, post GFL (trend to date)	2a	• Cases of failures and reasons for failure (interviews; Expert panel)
42					2b	• Changes to barriers to trade within the internal market following implementation of the GFL, compared also to pre-implementation of the GFL (elimination of previous barriers; creation of new barriers) (interviews; Expert panel)
43	6	To what extent were the provisions of Article 8 of Regulation (EC) No 178/2002 and their implementation instrumental and successful in achieving a higher level of protection of consumers' interests, in particular through the prevention of fraud and of misleading		<i>Link to: EQ13; the food fraud study</i>		<u>Links:</u> <i>With EQ13: the success of Article 8 depends also on implementation of provisions (under Art 17.2) for MS to lay down rules on measures and penalties applicable to infringements in food/feed law (EQ13).</i> <i>With EQ24: Article 8 is covered by EQ24, therefore to feed into EQ24.</i> <i>Link to separate study on food fraud (to use findings from that study where relevant).</i>
44			1	• Implementation by MS: development of national legislation based on Art. 8	1a	• Extent to which MS have adopted measures to implement the provisions of Article 8 of the GFL, in order to address: a) fraudulent/deceptive practices; b) food adulteration; c) any other misleading practices (survey of MS CAs)
45			2	• Extent to which measures taken at MS level are sufficiently dissuasive	2a	• Extent to which MS have in place sanctions/penalties to address infringements of food/feed law (Art. 17.2); nature of MS sanctions/penalties (criminal/ administrative); extent to which these have been an effective deterrent and reasons why they have been effective/not effective (survey of MS CAs) (<i>see indicators of EQ13</i>)

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	H	I	J	K	L	M	N	O	P	Q	R
32	54	44	41								
33	54	44	41								
34					5	x	x	x	x	x	x
35	1	3	5								
36	5c	7c	9c								
37	8	10	11								
38	13	13	16	12							
39	19	17	19								
40	53	43	40								
41											
42											
43					6	x		x		x	x
44	22	20									
45	see EQ13										

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46			3	<ul style="list-style-type: none"> Evidence of failures/gaps/problems, in MS implementation (trend to 	3a	<ul style="list-style-type: none"> Extent to which fraud occurs as a result of failures in the GFL provisions and MS implementation (<i>Use relevant indicators/evidence from the food fraud study</i>)
47				For all 3 JC:	b	<ul style="list-style-type: none"> Extent to which current provisions of the GFL and MS implementation in this area are considered satisfactory by consumers (interviews: BEUC; other NGOs)
48	7	To what extent have the provisions of Regulation (EC) No 178/2002 and their implementation contributed to or hindered the achievement of other interests or needs in particular competitiveness of the food supply chain, innovation, sustainability/food waste, e-commerce, global trade?		<p>Overarching question with links to a number of other EQs →</p> <p><i>The indicators selected here are designed to provide an overview; findings from other EQs/case studies will be used</i></p>		<p><u>Links:</u></p> <p><i>With EQ1: this EQ is an overarching 'external coherence' question. It covers other legitimate interests/needs which are Union objectives.</i></p> <p><i>With EQ16: with aspects covering trade.</i></p>
49			1	<ul style="list-style-type: none"> Contribution of the GFL implementation in meeting other legitimate interests/needs which are not currently amongst its core or subsidiary objectives, but which are Union 	1a	<ul style="list-style-type: none"> Extent to which the current GFL framework is adequate to address these interests/needs and current trends (innovation; competitiveness of the food supply chain; sustainability/food waste; distance selling including e-commerce, globalisation of trade) (surveys) (<i>see EQ1 indicator 2a</i>)
50					1b	<ul style="list-style-type: none"> Extent to which there is interaction/inter-services consultation in policy development/implementation amongst policy departments pursuing these objectives within the COM and MS (interviews with: COM services (SANTE, AGRI, GROW, TRADE, ENV; MS CAs)
51					1c	<ul style="list-style-type: none"> Cases where other Union objectives (competitiveness, innovation, food waste, e-commerce, global trade) have specifically been facilitated by the GFL provisions (interviews: supply chain; NGOs)
52			2	<ul style="list-style-type: none"> Evidence of failures/gaps/problems, post GFL (trend to date) 	2a	<ul style="list-style-type: none"> Cases where other Union objectives (competitiveness, innovation, food waste, e-commerce, global trade) have specifically been hindered by the GFL provisions (interviews: supply chain; NGOs)
53	8	<p>To what extent have the obligations on food/feed business operators and public authorities to:</p> <ul style="list-style-type: none"> - place only safe food/feed on the market (compliant with food/feed safety legislation) (Articles 14, 15) - verify that food/feed is compliant with relevant legislation (Article 17.1) - withdraw/recall food/feed at risk (Article 19.1, 19.2, 20.1 and 20.2) and - notify public authorities in case food/feed considered at risk (Articles 19.3 and 20.3) <p>a) ensured a high level of protection of</p>		<p>Overarching question with links to a number of other EQs →</p> <p><i>To improve consistency, EQ8 and EQ9 will be eventually merged in a 'withdrawals and recalls' chapter.</i></p> <p><i>In addressing EQ8/9, it is important to consider what was there before the GFL, and what was the difference</i></p>		<p><u>Point b) 'fit for purpose': effective and efficient withdrawals/recalls</u></p> <p><u>Links:</u></p> <p><i>Protection of consumers' health: link to indicators of EQ3.</i></p> <p><i>Cooperation with MS CAs: link to indicators of EQ9 (EQ8 and EQ9 to be eventually merged when reporting)</i></p> <p><i>With EQ14: role of traceability requirements</i></p> <p>Relevant case studies: traceability;FBO responsibilities</p> <p><i>(Implementation of Article 17.1: case study on FBO responsibilities including self-controls).</i></p> <p><i>Notification requirements (Articles 19.3 and 20.3): link to RASFF study indicators.</i></p> <p><i>(Note: caveats of analysis of RASFF data highlighted in Inception Report.)</i></p>
54			1	<ul style="list-style-type: none"> Contribution of MS implementation of these core GFL provisions to ensuring a high level of protection of consumer's health 	1a	Use indicators of EQ3: 1a to 1j

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	H	I	J	K	L	M	N	O	P	Q	R
46											
47											
48					7			x		x	x
49	2a 2b	4a 4b	6a 6b								
50											
51											
52											
53					8	x	x	x	x	x	
54											

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	A	B	D	E	F	G
55			2	• Contribution of MS implementation of these core GFL provisions to performing fit for purpose	2a	• Extent to which the requirements for FBOs to place safe food/feed on the market (Art. 14/15) and to verify compliance with food law (Art 17.1) have contributed to fit for purpose withdrawals and recalls? (<i>relevant also for EQ9</i>) (surveys; case studies)
56					2b	• Extent to which the traceability requirement (Art. 18) has contributed to fit for purpose withdrawals and recalls? (<i>relevant also for EQ9</i>) (surveys; SME Panel; case studies)
57					2c	• Extent to which the requirement to withdraw/recall food/feed at risk (Art 19.1, 19.2; Art. 20.1, 20.2) has contributed to fit for purpose withdrawals and recalls? (<i>relevant also for EQ9</i>) (surveys; case studies)
58					2d	• Extent to which the requirements for FBOs (Art. 19.3 and 20.3) to: notify public authorities in case food/feed is considered at risk, and to collaborate with public authorities on actions taken to reduce risk, have contributed to fit for purpose withdrawals and recalls (<i>relevant also for EQ9</i>) (surveys; case studies)
59					2e	• Extent to which the combined application of traceability and withdrawals/recalls have: ensured targeted withdrawals/recalls; resulted in withdrawals/recalls of safe feed/food (surveys; SME panel)
60					2f	• Extent to which FBOs comply with the actions required in the context of withdrawals and recalls (Art. 19; Art. 20) (<i>relevant also for EQ9</i>) (MS CA survey; SME panel; case studies)
61					2g	• Cases where MS CAs have restricted marketing or required withdrawal/recall of compliant feed/food because there were reasons to suspect that the feed/food was unsafe (<i>relevant also for EQ11</i>) (MS CA survey; case studies)
62			3	• Evidence of failures/gaps/problems, post GFL (trend to date)	3a	• Trend in incidents of withdrawals/recalls, split by injurious to health; unfit for human consumption (analysis of RASFF and MS data, to the extent available/possible) (<i>see Note: RASFF data not systematic to provide trend and caveats in interpretation - see Inception Report</i>)
63					3b	• Overview of specific reasons of RASFF notifications and of food recalls (RASFF study; interviews)
64					3c	• Cases of failures of withdrawal/recall system, and reasons for failure (interviews; literature review e.g. relevant FVO reports)
65	9	To what extent have the provisions of the “General Food Law Regulation” and their implementation contributed to improving cooperation between authorities and operators and thereby made actions taken to avoid or reduce risks posed by food/feed placed on the market more efficient and effective? (Articles 19.2, 19.3, 19.4 and 20.2,		To improve consistency, EQ8 and EQ9 will be eventually merged in a 'withdrawals and recalls' chapter.		<p><u>Links:</u> Focus of EQ9 is on cooperation between MS CAs and FBOs in the context of withdrawals and recalls (responsibilities of FBOs/CAs). With EQ8: eventually to be merged under one chapter on withdrawals/recalls. With EQ3: (Art. 14/15).</p> <p>Relevant case studies: traceability;FBO responsibilities (Implementation of Article 17.1: case study on FBO responsibilities including self-controls).</p>
66			1	• Extent to which there is cooperation in withdrawals/recalls	1a	• Extent to which FBOs have complied with detailed responsibilities on cooperation with MS CAs, as laid down in Articles 19 and 20 (covers specific FBO actions) (MS CA survey)
67					1b	• Extent to which FBOs have contacted authorities to require assistance in the case of withdrawals and recalls (FBO survey)
68					1c	• Extent to which MS CAs have provided assistance in the case of withdrawals and recalls (surveys; SME panel) (<i>SME panel = assistance provided more generally</i>)
69			2	• Impact of cooperation to effectiveness of actions taken (outcome)	2a	• Comparison with procedures/speed/targeting of withdrawals/recalls pre-GFL (interviews; case studies)
70			3	• Impact of cooperation to efficiency of actions taken (outcome)	3a	• Comparison with cost of recalls pre-GFL of withdrawals/recalls pre-GFL (interviews; case studies)

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	H	I	J	K	L	M	N	O	P	Q	R
55	4a	6a	8a								
56	4b 13	6b 13	8b 16	12							
57	4c	6c	8c								
58	4d 4e	6d 6e	8d 8e								
59	19	17	19	12							
60	16	15		15							
61	7	9									
62											
63											
64											
65					9	x	x	x	x	x	
66	16	15									
67	18		18								
68	17 18	16	18	16							
69											
70											

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71	10	To what extent has the provision that food/feed is deemed safe when it complies with specific EU provisions, or in their absence to specific national provisions, governing food/feed safety proved sufficient in order to achieve the objective of protection of health of consumers? (Article 14.7 and 9 and 15.4 and 6)		<p><i>Sufficiency of these Articles in meeting objective of protecting consumer health to be demonstrated by extent to which there are failures (see Note).</i></p> <p><i>To improve consistency, EQ10 and EQ11 will be eventually merged in a single chapter</i></p>		<p><i>Note: Overall these provisions work well, but there are some cases where gaps or problems can be identified. Therefore focus is on exploring further these cases.</i></p> <p><i>Art 14.9 and 15.6: key areas identified where MS specific provisions can be introduced are: on a horizontal basis, the organisation of withdrawals/recalls and official controls in MS; and, on a sectoral basis, GM, food contact materials and, to some extent, additives (e.g. DK nitrates).</i></p> <p><i>Links: This EQ is also of relevance for answering EQ33; the issues raised by EQ28 may also be relevant (differences in MS markets and cultures) Results to feed also into EQ3.</i></p>
72			1	<ul style="list-style-type: none"> Evidence of failures/gaps/problems, post GFL (trend to date) 	1a	<ul style="list-style-type: none"> Extent to which the GFL provision (Art. 14.7; Art. 15.4) that food/feed is deemed safe when it complies with EU food/feed law (i.e. the GFL and secondary legislation) have proved effective in protecting consumer health (see also indicators of EQ3) (surveys; interviews: BEUC; other NGOs; Expert Panel)
73					1b	<ul style="list-style-type: none"> Cases where this provision has not proved effective in protecting consumers' health, and reasons (surveys; interviews: BEUC; other NGOs; Expert Panel)
74					1c	<ul style="list-style-type: none"> Extent to which there may be 'borderline' cases of unsafe food or feed that are currently not sufficiently addressed by definition of unsafe food or feed (Art. 14.2, cases a and b, to Art. 14.6) or feed (Art. 15.2 to 15.3) (interviews; Expert panel)
75					1d	<ul style="list-style-type: none"> Cases where the lack of harmonised EU provisions, therefore recourse to MS provisions (Art. 14.9; Art. 15.6) has not proved sufficient in protecting consumers' health, and reasons. E.g. vitamins/minerals, food supplements, food contact materials (interviews: BEUC; other NGOs; Expert Panel)
76	11	To what extent and how efficiently and effectively have the public authorities taken further actions when food/feed was discovered unsafe despite its conformity with the legislation? (Articles 14.8 and 15.5) How significant has this been in terms of achieving the objectives?		<p><i>Contribution of the MS implementation of these Articles towards meeting objective of protecting consumer health to be demonstrated by extent to which there are failures (see note)</i></p> <p><i>To improve consistency, EQ10 and EQ11 will be eventually merged in a single chapter</i></p>		<p><i>Note: Art 14.8 and 15.5 are rarely applied in practice.</i></p>
77			1	<ul style="list-style-type: none"> Evidence of failures/gaps/problems, post GFL (trend to date) 	1a	<ul style="list-style-type: none"> Cases where action was taken under Articles 14.8 and 15.5, i.e. restrictions to place food on the market or requirement to withdraw/recall from the market of compliant food/feed because there were reasons to suspect that the food/feed was unsafe (MS CA survey)
78					1b	<ul style="list-style-type: none"> Actions taken in respect of these incidents, and impacts in terms of achieving the objectives (interviews)
79	12	How have the rules concerning the allocation of responsibilities in the food chain been applied? To what extent have they contributed to a consistent allocation of responsibilities in the field of food law across the EU? (Article 17) To what extent has this proved to be significant for achieving the objectives? Has the allocation of responsibilities produced efficient and effective results?		<p><i>This EQ feeds into many EQs</i></p> <p>→</p> <p><i>Contribution of Art.17 provisions to efficiency/effectiveness: see EQ25 (fair and proportionate burden) and EQ29 (concerns and burdens)</i></p> <p><i>Contribution of provision to achieving the (core) GFL</i></p>		<p><i>Analysis of this issue more generally has two dimensions:</i></p> <ul style="list-style-type: none"> - sharing of responsibilities between MS CAs (official controls) and FBOs (self-controls; other elements in contractual obligations or standard business practices) - sharing of responsibilities amongst FBOs along the supply chain <p><i>The allocation of responsibilities amongst FBOs is the backbone of the GFL; hence this issue is the subject of a dedicated case study: FBO responsibilities under Art. 17.1 including self-controls .</i></p> <p><i>Links:</i></p> <p><i>With EQ3, EQ5, and EQ8: the significance of Art. 17 in terms of meeting the objectives of the GFL feeds also into the issues explored under EQ3, EQ5 and EQ8.</i></p> <p><i>With EQ25 and EQ29: the effectiveness and efficiency of the results of Art. 17 also feeds into the issues explored under EQ25 and EQ29.</i></p>

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
71					10			x	x	x	x
72	6a	8	10a								
73	6a	8	10a								
74											
75											
76					11	x		x		x	
77	7	9									
78											
79					12	x	x	x	x	x	

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
80			1	• Application of Article 17 (evolution since the GFL)	1a	• Extent to which FBOs perform verification controls internally to their own systems (self-controls) to ensure compliance with the core requirements of EU/national food law (case study; SME panel)
81					1b	• Extent to which FBOs perform verification controls to their suppliers to ensure compliance with the core requirements of EU/national food law (case study; SME panel)
82					1c	• Extent to which FBOs had such procedures/instruments in place, to ensure compliance with the core requirements of EU/national food law, prior to the introduction of the GFL (case study)
83					1d	• Adjustments made by FBOs to apply Art. 17.1 in practice, including constraints and difficulties encountered (case study)
84					1e	• Extent to which FBOs at the various stages of production, processing and distribution apply self-controls to verify compliance with the core requirements of EU/national food law which are relevant to their activities (surveys)
85					1f	• Extent to which additional requirements (i.e. the provision of additional information to demonstrate compliance with the core requirements of EU/national food law) are imposed on FBOs by their customers (case study; SME panel)
86					1g	• Extent to which COM guidelines have been useful; extent to which further national guidelines have been issued/been useful (COM guidelines: surveys) (all guidelines: case study)
87					1h	• Extent to which there are differences in MS interpretation of the requirements of Article 17.1, including its implementation through secondary legislation (surveys; case study)
88			2	• Extent to which Art.17 has delivered effective results	2a	• Extent to which Art. 17 has ensured an effective allocation of responsibilities along the supply chain, in terms of contributing to the following outcomes: a high level of protection consumer health and interests; facilitating the placing on the market of feed/food products; effective functioning of the internal market; strengthening trust along the 'farm to table' supply chain; ensuring a consistent implementation of the 'farm to table' policy (surveys)
89					2b	• Impact of the Art. 17.1 (self-control) requirement in ensuring food/feed safety in the EU (surveys; case study)
90			3	• Extent to which Art. 17 has delivered efficient results	3a	• Extent to which Art. 17 has ensured an efficient allocation of responsibilities along the supply chain, in terms of contributing to the following outcomes: a fair and clear distribution of responsibilities amongst FBOs along the 'farm to table' supply chain; a fair and clear distribution of responsibilities between FBOs and MS CAs; reducing administrative burden (e.g. by avoiding unnecessary repetition of controls); freed up resources at MS CA level to focus on enforcement issues; created a level playing field for all FBOs in the EU (surveys; case study)
91					3b	• Extent to which Art. 17.1 provided the lowest cost solution for ensuring food safety and consumer protection (case study)
92					3c	• Extent to which FBOs apply certain elements in contractual obligations or standard business practices, to ensure a fair allocation of responsibilities vis-a-vis suppliers and customers (case study)
93					3d	• Extent to which MS CAs consistently take into account FBO own controls in the risk profiling and control plans (case study)
94					3e	• Costs of Art. 17.1 for FBOs (e.g. as % of total production costs) (case study)
95					3f	• Benefits: extent to which implementation of Art. 17 has provided benefits in terms of the following outputs: better targeted controls; better targeted withdrawals; better targeted prevention/early response (<i>to be used in combination with the outcomes identified under indicator 2a and 3a</i>) (case study)
96					3g	• Extent to which the benefits of Art. 17 exceed the costs of setting up and operating primary responsibility provisions (FBO survey; SME panel) (case study)
97					3h	• Estimated cost:benefit ratio (FBO survey; SME panel) (case study) (<i>SME panel = cost-benefit ratio in broad qualitative terms</i>)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
80				15							
81				9							
82											
83											
84	9	11	12								
85				9 10							
86	52	42	39								
87	53	43	40								
88	8	10	11								
89	51	41	38								
90	8	10	11								
91											
92											
93											
94											
95											
96	10		13	20							
97	15		17	20							

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
98	13	To what extent have the public authorities applied penalties or other measures for infringements of EU food law? (Article 17.2) What impact did those have on effectiveness of the implementation of the Regulation?		<i>In addressing EQ13, it is important to consider what was there before the GFL in terms of penalties or other measures for infringements, and what was the difference made by the GFL Art. 17.2. This needs to take into account the fact that responsibility allocation under Art 17 aims to ensure an integrated approach to the management of food safety issues along the food chain</i>		<i>Effectiveness of implementation of the GFL: Do measures introduced on the basis of Art. 17.2 provide a 'sufficient deterrent'?</i> <u>Links:</u> <i>Link to EQ6: the effectiveness of Article 8 (EQ6) depends also on the effectiveness of implementation of provisions (under Art 17.2) for MS to lay down rules on measures and penalties applicable to infringements in food/feed law. Does Art. 17.2 provide 'sufficient deterrents'? The case studies of traceability and self-controls will also be used to collect data on this issue. Allocation of responsibilities along the chain: this is also linked to the penalty system. Are current regulatory provisions sufficient to address cross-border supply chain issues? There is also a link to the food fraud study, which can provide relevant data/findings.</i>
99			1	• Incidence of application of penalties or other measures	1a	• Extent to which rules have been introduced in MSs' national legislation on the basis of Article 17.2, regarding penalties and other measures applicable to infringements in food and feed law, whether administrative, criminal, or a combination (MS CA survey)
100					1b	• <i>To the extent data are available:</i> Trend of penalties/other measures applied, during 2003-13; explanation of any observed trends (literature review; food fraud study; interviews with MS CAs)
101			2	• Effectiveness of penalties/other measures	2a	• Extent to which rules introduced in MSs' national legislation, on the basis of Article 17.2, have been an effective deterrent from committing further infringements (MS CA survey) (interviews with MS CAs; food fraud study; Expert panel)
102			3	• Reasons for observed	3a	• Reasons why rules are not effective (MS CA survey) (interviews with MS CAs; food fraud study; Expert panel)
103	14	What is the role played by the traceability requirements? (Article 18). Has Article 18 been a sufficient tool for food and feed tracing?		<i>To improve consistency, EQ14 and EQ15 will be eventually merged in a 'traceability' chapter. In addressing EQ14/15, it is important to consider what was there before the GFL, and what was the difference made by the GFL Art. 18.</i>		<i>Traceability is a key direct requirement of the GFL; hence this is the subject of a dedicated case study. Traceability rules were further explained in the COM guidance document (January 2010). Traceability was already applied by FBOs prior to the GFL, although not necessarily in the form required by Art. 18 (one step forward, one step back), but this requirement is expected to have been generalised after the GFL. The analysis will provide a description of how traceability systems and procedures in place to allow for traceability information to be made available to MS CAs (Article 18.3) have evolved, following the introduction of this requirement by the GFL. The impact on SMEs is particularly important here (case study; SME Panel). The Commission guidance document (January 2010) is a key source of information on Art. 18.</i> <u>Links:</u> <i>Link to EQ8: the provision of this information is important in the case of withdrawals and recalls.</i>
104			1	• Evolution of traceability since the GFL	1a	• Extent to which FBOs applied one step back one step forward traceability prior to the introduction of the GFL (FBO survey; SME panel) (case study)
105					1b	• Improvement in rate of application (case study)
106					1c	• Adjustments made by FBOs to apply traceability in practice, including constraints and difficulties encountered (SME panel; case study)
107					1d	• Extent to which COM guidelines have been useful; extent to which further national guidelines have been issued/been useful (COM guidelines: surveys) (all guidelines: case study)
108					1e	• Extent to which the Art. 18 requirement to have in place one step back one step forward traceability improved tracing of food/feed in the EU, compared to the situation prior to the GFL (surveys; SME panel)
109			2	• Provision of traceability information to MS CAs	2a	• Extent to which the necessary traceability information is made available to MS CAs by FBOs when requested (MS CA survey)
110					2b	• Cases of failure of information to be provided (MS CA survey)
111			3	• Sufficiency of Art. 18 traceability for food/feed tracing along the chain	3a	• Extent to which the GFL requirement to have in place one step back one step forward traceability is sufficient to trace food/feed across the full supply chain (i.e. can be linked to provide full chain traceability, including in cross-border transactions) (surveys; SME panel) (case study)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
98					13	x		x		x	x
99	20 21a	18 19a									
100											
101	21b	19b									
102	21c	19c									
103					14		x	x	x	x	
104	11		14	11							
105											
106				11							
107	52	42	39								
108	12	12	15	12							
109	14	14									
110	14	14									
111	13	13	16	13/14							

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
112					3b	• Extent to which there are differences in MS interpretation of the requirements of Article 18, including on internal traceability (surveys) (case study)
113					3c	• Cases of failures and costs involved (case study)
114					3d	• Extent to which a more extended traceability requirement is necessary: in specific product sectors; horizontally across all sectors of the feed/food supply chain (SME panel; case study)
115	15	What is the current added value of the traceability requirement in terms of improved safety of food/feed?		See also notes of EQ14 (EQ14 and EQ15 to be merged).		<u>Added value:</u> identify the key advantages of the EU approach compared to what could be achieved by Member States at national and/or regional level <u>Links:</u> Results to feed also into EQ2 (added value of the GFL).
116			1	• Benefits of the traceability requirement, in terms of achieved outcomes	1a	• Extent to which the implementation of one step back one step forward traceability has provided benefits in terms of achieving certain outcomes (such as improving food/feed safety; avoiding unnecessary disruption of trade; enabling consumers to be provided with accurate information) (surveys; SME panel) (case study)
117					1b	• Impact of the traceability requirement in ensuring food/feed safety in the EU (surveys) (case study)
118					1c	• Cases of successes/failures, in terms of achieved outcomes (surveys) (case study)
119			2	• Benefits of EU-level operation of traceability, compared to non-EU level	2a	• Extent to which the EU-level operation of traceability has provided benefits in terms of achieving better outcomes than a non-EU level approach (case study)
120					2b	• Cases of successes/falures of EU-level operation (case study)
121					2c	• Likely problems/gaps from a sub-EU-level approach (case study)
122			3	• Costs vs benefits	3a	• Costs of traceability (e.g. as % of total production costs) (FBO survey) (case study)
123					3b	• Extent to which the benefits of traceability exceed the costs of setting up and operating traceability systems (FBO survey; SME panel) (case study) (SME panel = refers to benefits vs costs of FBO obligations more generally)
124					3c	• Estimated cost:benefit ratio (surveys) (case study)
125	16	To what extent has the "General Food Law Regulation" influenced quality and quantity of trade?		<i>Trade: Internal market trade is covered by EQ5. EQ16 focuses on trade with third countries (imports/exports). In addressing EQ16, it is important to bear in mind that the drivers of trade are more global and extend beyond food law as such. Therefore, emphasis will be on the qualitative rather than quantitative impact of</i>		<u>Impact: covers both positive and negative impacts</u> <u>Quality = safety</u> <u>Links:</u> With EQ2: many of the components of added value identified under EQ2 relate to international trade; hence findings of EQ16 should feed into EQ2 to provide evidence on whether the GFL has provided added value in terms of a (positive) impact on international trade. With EQ7: international competitiveness - how have costs and product safety recognition worldwide been affected by the GFL? With EQ15: impact of traceability (Art. 18) in terms of acceptance/use of EU standards in international trade and avoiding/limiting trade disruption (traceability case study) With EQ17: restrictions to EU exports imposed at MS level (findings of EQ17 to feed into EQ16) With EQ18: alignment to international standards is expected a priori to improve coherence With EQ21: implementation of precautionary principle
126			1	• Positive/negative impacts of the GFL on EU feed/food imports	1a	• Extent to which the GFL has facilitated/adversely affected EU feed/food imports from third countries, as determined by several outcomes (quantities imported; quality/safety; consumer trust and confidence in imported feed/food; business trust and confidence in imported feed/food; acceptance/use of EU food/feed safety standards in international trade; avoiding/limiting the impact of a feed/food crisis in the EU) (FBO survey) (third country interviews)
127					1b	• Cases where the above positive/negative impacts have been identified and resulting benefits/losses (e.g. In import value/volume; geographical presence etc.) (FBO survey) (third country interviews)
128			2	• Positive/negative impacts of the GFL on EU feed/food exports	2a	• Extent to which the GFL has facilitated/adversely affected EU feed/food exports to third countries, as determined by several outcomes (quantities exported; quality/safety; consumer trust and confidence in EU exported feed/food; business trust and confidence in exported feed/food; acceptance/use of EU food/feed safety standards in international trade; avoiding/limiting the impact of a feed/food crisis on international trade) (FBO survey) (third country interviews)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
112	53	43	40								
113											
114				9/10							
115					15		x	x	x	x	x
116	12 13	12 13	15 16	12							
117											
118	12 13	12 13	15 16								
119											
120											
121											
122	15		17								
123	15		17	20							
124	15		17								
125					16			x		x	x
126	24		20								
127	24		20								
128	25		21								

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
129					2b	• Cases where the above positive/negative impacts have been identified and resulting benefits/losses (e.g. in export value/volume; geographical presence etc.) (FBO survey) (third country interviews)
130			3	• Trend in restrictions on third country imports (<i>for restrictions on exports, see</i>	3a	• Extent to which MS CAs implement restrictions on the import of food/feed on the basis that it is not compliant with EU food/feed law and therefore deemed unsafe (MS CA survey) (third country interviews)
131					3b	• Trend on restrictions implemented on imports, if data are systematically recorded (MS CA survey) (third country interviews)
132					3c	• Reasons why restrictions were imposed (MS CA survey) (third country interviews)
133			4	• Trend in rejections at EU border of third country imports	4a	• Trend in border rejections of imports (RASFF data); implications (literature review; RASFF study; interviews with COM; third country interviews)
134			5	• Coherence between the GFL and third country food	5a	• Extent to which the GFL is coherent with third country food law systems; key issues identified where there is lack of coherence (<i>see also link to EQ 18</i>) (Expert Panel; third country interviews)
135			6	• Impact of level of coherence on EU imports/exports to third	6a	• Cases where coherence has positively affected trade vs cases where lack of coherence has negatively affected trade; benefits and costs, as determined by these cases (interviews with COM; interviews with FBOs) (third country interviews)
136	17	To what extent have the public authorities implemented restrictions of the export of unsafe food/feed? (Article 12) With what impact on achieving the objectives?		<i>Article 12 = MS can ban exports to third countries of EU feed/food potentially injurious to health when there is no relevant legislation in the country of destination</i>		<u>Links:</u> With EQ16: to feed into EQ16. With EQ21: implementation of precautionary principle
137			1	• Trend in restrictions on EU exports of unsafe food/feed	1a	• Extent to which MS CAs have taken measures to ban the export to third countries of feed/food injurious to health or unsafe feed/food under Article 12 (MS CA survey)
138					1b	• Trend on restrictions implemented on exports, if data are systematically recorded (MS CA survey)
139					1c	• Reasons why restrictions were imposed (MS CA survey) (MS CAs interviews)
140			2	• Impact of these restrictions on the objectives of the GFL	2a	• Impact of identified restrictions on achieving the objectives of the GFL, in terms of avoiding the export to third countries of feed/food potentially injurious to health (MS CAs interviews)
141	18	To what extent have international standards been used in the development or adaptation of EU Food Law and national legislative acts?		<i>Most of the provisions and general requirements of the GFL are based on international standards. Hence, in addressing EQ18, the focus is on identifying best practices and any gaps/deviations from international standards.</i>		<u>Links:</u> With EQ16 (and EQ17): alignment to international standards is expected a priori to improve coherence. With issues covered under EQ2: to feed into EQ2(added value of the GFL)
142			1	• Incidence of use of international standards in EU food law and national legislation (identify best practices; gaps)	1a	• Cases of best practices (cases where standards are used; with what impacts) (Interviews with COM; Codex Alimentarius; third countries) (Expert panel)
143					1b	• Cases where standards not used; reasons why; with what impacts (Interviews with COM; Codex Alimentarius; third countries) (Expert panel)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
129	25		21								
130	26	22									
131	26	22									
132	26	22									
133											
134											
135											
136					17			x		x	
137	27	23									
138	27	23									
139	27	23									
140											
141					18			x		x	x
142											
143											

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
144	19	To what extent have the provisions of the “General Food Law Regulation” ensured a comprehensive, integrated and effective approach to food chain management? Did the definitions laid down in Articles 2 and 3 contribute to an integrated approach to food law? Was the scope correctly defined? (Article 4.1)		<i>Focus in EQ19 is on the provisions of the GFL covering definitions and scope (i.e. Art. 2, 3 and 4.1). The White Paper has aimed to ensure a comprehensive and integrated approach.</i>		<i>Food chain management = food safety management along the food chain. Links: There are links to many other EQs where the objective has been to ensure an integrated and comprehensive approach, e.g. on traceability (EQ14/15) and FBO responsibilities more generally. Literature review: to be assisted by internal SANTE cross-checking of GFL definitions vis-a-vis secondary legislation (desk study of co-decision acts) (to feed also into EQ32).</i>
145			1	• Adequacy of definitions (Article 2, 3) and scope (Article 4.1) in terms of allowing/ensuring an integrated approach to food	1a	• Extent to which definitions of food (Art. 2), of feed (Art. 3.4), of food BO (Art. 3.3), of feed BO (Art. 3.6), retail (Art. 3.7), placing on the market (Art. 3.8), risk (Art. 3.9) and scope (Art. 4.1) are sufficiently broad to provide an integrated approach to feed/food safety management (surveys) (Expert Panel)
146					1b	• Extent to which definitions of food (Art. 2), of feed (Art. 3.4), of food BO (Art. 3.3), of feed BO (Art. 3.6), retail (Art. 3.7), placing on the market (Art. 3.8), risk (Art. 3.9) and scope (Art. 4.1) are relevant to address the objectives of food law? (surveys) (Expert Panel)
147			2	• Identification of areas/aspects	2a	• Cases of areas/aspects of the food/feed chain considered to be missing from the scope of Article 4.1 (surveys) (interviews COM/FBOs/MS CAs) (Expert Panel)
148					2b	• Cases of areas/aspects of the food/feed chain considered to be missing from the definitions of Articles 2 and 3 (surveys) (interviews COM/FBOs/MS CAs) (Expert Panel)
149	20	To what extent has the principle of risk analysis been applied efficiently, coherently and consistently in drawing up food law measures and in their application? (Article 6). Have the three components of risk analysis (risk assessment, risk management and risk communication) been clearly defined and consistently, efficiently and effectively applied? How did the separation of and the interface between risk assessment and risk management function in practice? To what extent have other legitimate factors been taken into account in the risk management process? What were mostly those legitimate factors? How has this influenced achieving the objectives?		<i>The GFL requires that national and EU measures on feed/food should be based on risk analysis, except where this is not appropriate to the circumstances or the nature of the measure. The set of criteria/indicators selected below aim to identify the extent to which the three components of risk analysis have been applied, and with what impacts. In addressing EQ20, it is important to consider what was there before the GFL, and what was the difference</i>		<i>Efficiency/effectiveness: risk analysis should determine effective, proportionate and targeted measures (GFL whereas (16) to (19)) Coherently = in the same way (including coherence between sectors, e.g. between feed and food) Consistently = systematically Links: Focus of indicators listed under EQ20 is on Art 6(3) i.e. definite RM measures; in drawing conclusions on the issues raised by EQ20, the findings of EQ21 and EQ23 will also be use. With EQ21: The analysis of the precautionary principle and other legitimate factors pertains both to EQ20 and EQ21 (with regards, respectively, to Art 6(3) on definite RM measures, and Art 7 on provisional RM measures). With EQ23: There is no definition of risk communication in Article 6; Art 10 deals with public information in case of serious risk (EQ23). A dedicated case study on risk analysis will cover all these issues.</i>
150			1	• Application of risk analysis at MS/EU level	1a	• Extent to which EU measures on feed and food have been adopted on the basis of a risk analysis (surveys) (case study)
151					1b	• Cases of EU measures not adopted on the basis of a risk analysis (surveys) (case study)
152					1c	• Extent to which MS applied risk analysis prior to the introduction of the GFL (case study)
153					1d	• Adjustments made by MS CAs to apply risk analysis as laid down in Article 6 in practice, including constraints and difficulties encountered (case study)
154					1e	• Extent to which national MS measures on feed and food have been adopted on the basis of a risk analysis, following Article 6 of the GFL (surveys) (case study)
155					1f	• Cases of national MS measures not adopted on the basis of a risk analysis (surveys) (case study)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
144					19	x	x	x		x	x
145	3a	5a	7a								
146	3b	5b	7b								
147	3	5	7								
148	3	5	7								
149					20	x	x	x	x	x	x
150	28	24	22								
151	28	24	22								
152											
153											
154	29	25	23								
155	29	25	23								

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
156			2	• Impact of measures taken on the basis of risk analysis	2a	• Extent to which, where national and EU measures on feed/food have been adopted on the basis of a risk analysis, certain outcomes were achieved (unjustified barriers to the free movement of feed/food have been avoided; EU/national measures have been: effective, proportionate, targeted to protect health) (surveys) (case study)
157					2b	• Extent of and cases of positive/negative (intended/unintended) impacts of national/EU measures adopted on the basis of a risk analysis, including in terms of protection of human health/life and impact on innovation (surveys) (case study)
158			3	• Consideration of legitimate factors in MS/EU RM process	3a	• Extent to which 'other' legitimate factors (economic feasibility; societal factors, traditions, environmental impacts, ethical impacts, feasibility of controls) are taken into account in MS/EU risk management process (MS CA survey) (Expert panel) (case study)
159					3b	• Cases where 'other' legitimate factors were taken into account (MS CA survey) (case study)
160					3c	• Impact of the use of "other legitimate factors" on the objectives of the GFL (case study) (Expert panel)
161			4	• Separation of RM and RA process in practice, at EU level	4a	• Extent to which the separation between risk assessment and risk management at EU level is functioning in practice, following the GFL: is risk assessment independent, objective and transparent?; is the balance between science and other legitimate factors in risk management decisions transparent? is it consistent amongst sectors of EU food law? is the foreseen process of interactive exchange of information and opinions among all interested parties consistently applied at EU level? (case study) (Expert panel)
162					4b	• Cases where boundaries are unclear and difficulties encountered with following the definitions of risk assessment, risk management and risk communication (case study) (Expert panel)
163			5	• Separation of RM and RA process in practice, at MS level	5a	• Extent to which the separation between risk assessment and risk management at MS level is functioning in practice, following the GFL: is risk assessment independent, objective and transparent?; is the balance between science and other legitimate factors in risk management decisions transparent? is it consistent amongst Member States / sectors of national food law? is the foreseen process of interactive exchange of information and opinions among all interested parties consistently applied at national MS level? (case study) (Expert panel)
164					5b	• Extent to which there are differences between Member States in applying risk analysis as laid down in Article 6 and reasons why (case study) (Expert panel)
165					5c	• Cases where boundaries are unclear and difficulties encountered with following the definitions of risk assessment, risk management and risk communication (case study) (Expert panel)
166	21	To what extent have the public authorities implemented the precautionary principle? (Article 7). How has the precautionary principle been used and interpreted? What was its impact on innovation and consumer protection?		<i>The set of criteria/indicators selected below aim to assess the way in which the precautionary principle has been used and interpreted by MS, identifying potential differences in use and interpretation and potential impacts of differential approaches. As such, EQ21 also feeds into the issues raised by EQ20. In addressing EQ21, it is important to consider what was there before the GFL, and what was the difference</i>		<u>Links:</u> <i>With EQ20: The analysis of the precautionary principles and other legitimate factors pertains both to EQ20 and EQ21 (with regards, respectively, to Art 6(3) on definite RM measures, and Art 7 on provisional RM measures).</i> <i>Focus of indicators listed under EQ21 is on provisional RM measures; in drawing conclusions on the issues raised by EQ21, the findings of EQ20 and EQ23 will also be used, where relevant.</i> Case study on risk analysis will also cover the implementation of the precautionary principle. <i>(Note: Identification of impacts to be carried out in case study context, to the extent that differences in application and interpretation of precautionary principle and their impacts on levels of innovation and consumer protection can be identified in the context of case study. These points are to be covered by the case study on RA including the PP, to the extent allowed by scope vs depth of analysis).</i>
167			1	• Incidence and approach of use of the precautionary	1a	• Extent to which MS applied the precautionary principle prior to the introduction of the GFL (case study)
168					1b	• Extent to which MS CAs have taken provisional risk management measures on the basis of the precautionary principle (Article 7) (MS CA survey) (case study) (Expert panel)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
156	30	26	24								
157	30	26	24								
158	31	27									
159	31	27									
160											
161											
162											
163											
164											
165											
166					21	x	x	x	x	x	x
167											
168	32	28									

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
169					1c	• Cases of: measures taken; legitimate factors provided (possibility of harmful effect; scientific uncertainty; other); duration of measures (MS CA survey) (case study) (Expert panel)
170					1d	• Extent to which the precautionary principle (Article 7) has been applied correctly (surveys) (case study: more detailed criteria, including the extent to which the justification for the risk management decisions at EU/national level is transparently communicated) (Expert panel)
171					1e	• Cases where the precautionary principle has not been applied correctly (surveys) (case study: more detailed criteria, including transparency in communication) (Expert panel)
172					1f	• Extent to which there are differences between Member States in applying the precautionary principle as laid down in Article 7 and reasons why (case study) (Expert panel)
173			2	• Impact of measures taken on the basis of the precautionary principle	2a	• Impact (positive/negative, or intended/unintended) of the measures taken on this basis, including on consumer protection and innovation (case study) (Expert panel) (<i>see Note</i>)
174					2b	• Cases of continuing failures/gaps in the application of the precautionary principle (surveys) (case study) (Expert panel)
175	22	To what extent has the gradual adoption of the General Food Law harmonised framework in the Member States ensured transparency through public consultation of stakeholders during the preparation, evaluation and revision of food law? (Article 9). With what impact?		<i>In addressing EQ22, it is important to consider what was there before the GFL, and what was the difference made by the GFL Art. 9. EQ22 covers both the GFL and secondary legislation based on the GFL.</i>		<i>Article 9: public consultation and Article 10: public information, to be covered by dedicated case study on transparency .</i> <i>Identification of impacts to be carried out in case study context.</i> <i>(Note: To the extent that differences in application and interpretation of transparency principle and their impacts can be identified in the context of the case study).</i>
176			1	• Incidence and approach of public consultation	1a	• Extent to which MS applied public consultation prior to the introduction of the GFL (case study)
177					1b	• Adjustments made by MS CAs to apply public consultation as laid down in Article 9 in practice, including constraints and difficulties encountered (case study)
178					1c	• Frequency of public consultation during the preparation, evaluation and revision of EU food/feed law (surveys)
179					1d	• Frequency of public consultation during the preparation, evaluation and revision of national food/feed law (surveys)
180					1e	• Frequency and comprehensiveness of consultation of FBO stakeholders along the chain (farmers, food processors, distribution/retail, traders, other industry, consumers, other NGOs) during the preparation, evaluation and revision of food/feed law at national level (MS CA survey)
181					1f	• Extent to which MS CAs involve key elements of the consultation process (consultation groups: ad hoc or permanent; internet consultations, workshops, invitation for comments/positions, cost/benefit analysis, feasibility/impact/evaluation studies) (MS CA survey) (case study)
182					1g	• Extent to which FBOs are sufficiently consulted by MS CAs, during the preparation, evaluation and revision of food law at national level <i>Sufficiently = input has been sought in a structured manner and has been taken into account by the CAs in a balanced way.</i> (FBO survey) (case study)
183					1h	• Extent to which there are differences between Member States in applying public consultation as laid down in Article 9 and reasons why (case study) (Expert panel)
184			2	• Impact of public consultation	2a	• Impact (positive/negative, or intended/unintended) of applying public consultation, including on consumer confidence/trust and stakeholder confidence/trust (case study) (Expert panel) (<i>see Note</i>)
185					2b	• Cases of continuing failures/gaps in public consultation (surveys) (case study) (Expert panel)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
169	33	29									
170	34	30	25								
171	34	30	25								
172											
173											
174											
175					22	x		x	x	x	x
176											
177											
178	35	31	26								
179	36	32	27								
180	37	33									
181	38	34									
182	39		28								
183											
184											
185											

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
186	23	To what extent have the provisions of the “General Food Law Regulation” and its implementation ensured adequate /appropriate information to the public in case of a significant risk (information on measures by public authorities to prevent, reduce or eliminate risks)? (Article 10) With what impacts?		<i>The set of criteria/indicators selected below aim to assess the way in which the risk communication under Article 10 was applied in practice and potential impacts of differential approaches. In addressing EQ23, it is important to consider what was there before the GFL, and what was the difference made by the GFL Art. 10.</i> ☐		Article 9: public consultation and Article 10: public information, will be covered by dedicated case study on transparency . <i>(Note: Identification of impacts to be carried out in case study context, to the extent that differences in application and interpretation of transparency principle and their impacts can be identified).</i> <u>Links:</u> With EQ20: risk communication. The analysis of risk communication under Article 10 pertains both to EQ20 and EQ21 (with regards, respectively, to Art 6(3) on definite RM measures, and Art 7 on provisional RM measures). Link with RASFF provisions , including Article 52 (confidentiality rules for RASFF) and other transparency elements arising from the conclusions of the RASFF study.
187			1	• Incidence and approach of public information provision	1a	• Extent to which MS provided public information prior to the introduction of the GFL (case study)
188					1b	• Adjustments made by MS CAs to apply public information as laid down in Article 10 in practice, including constraints and difficulties encountered (case study)
189					1c	• Analysis of trigger points/modalities for MS CAs communicating to the general public a potential food/feed safety risk (in the event of withdrawals/recalls; in response to press reports; as soon as there are reasonable grounds to suspect risk, only after completion of inter-services consultation with all CAs involved, only once notified to the COM/RASFF network, only once measures are taken; other) (MS CA survey) (case study)
190					1d	• Type of information provided: product details; producer; lot numbers; other (MS CA survey) (case study)
191					1e	• Extent to which the process of risk communication improved over time, in particular taking into account lessons learnt from previous crises (e.g. dioxin, e-coli etc.) (surveys) (case study) (Expert panel)
192					1f	• Extent to which there are differences between Member States in providing information to the public as laid down in Article 10 and reasons why (case study) (Expert panel)
193			2	• Impact of public information	2a	• Extent to which risk communication of potential food/feed safety risks to the general public has been appropriate and clear (i.e. adequate), in particular in terms of providing information on: nature of risk, extent/seriousness of risk, type of food or feed at risk, measures taken by authorities to prevent, reduce, eliminate the risk (case study)
194					2b	• Impact (positive/negative, or intended/unintended) of public information on: consumer confidence/trust; preventing/managing crises; limiting unnecessary disruption of trade; limiting financial damage (surveys) (case study) (Expert panel) (see Note)
195					2c	• Cases of continuing failures/gaps in risk communication (surveys) (case study) (Expert panel)
196	24	With reference to questions on Articles 6, 7, 8, 9, 10, 11, 12, 14, 15, 17, 18, 19, 20 to what extent have the provisions of the “General Food Law Regulation” been interpreted and enforced in a consistent and harmonised way? To what extent does this influence achieving of the objectives? To what extent do insufficiencies in interpretation and enforcement cause distortions in public health protection and the market?		This EQ covers almost all GFL areas in the scope of this study. Overarching EQ: link to several EQs and all 4 case studies → <i>The selected judgement criteria/indicators are designed to provide an</i>		<u>Links:</u> <i>This EQ is fed/feeds into several EQs (link to EQ 20, 21, 22, 23, 6, 17, 8, 9, 10, 11, 12, 13, 14, 15, 25, 3, 4, 5).</i> Link to all 4 case studies: risk analysis, traceability, FBO responsibilities, transparency <u>Other indicators:</u> <i>The overarching indicator of compliance levels is relevant here (based on FVO reports), but there are caveats in comparability/interpretation of this indicator across Member States and through time (see Inception report).</i>
197			1	• Interpretation and enforcement of GFL in a	1a	• Extent to which there have been differences in the implementation/application of the relevant Articles of the GFL by MS (surveys) (case studies) (Expert Panel)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
186					23	x		x	x	x	x
187											
188											
189	40	35									
190	43	38									
191	41	36	29								
192											
193											
194	42	37	30								
195	42	37	30								
196					24	x	x	x	x	x	x
197	53	43	40								

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
198			2	• Impact of any identified differences in	2a	• Extent to which differences in implementation/enforcement (of any of the listed GFL Articles) hinder the achievement of the GFL core objectives: a) public health protection; and b) the internal market (surveys) (case studies) (Expert Panel)
199					2b	• Cases of differences in implementation, reasons why and problems caused (surveys) (case studies) (Expert Panel)
200		Efficiency (EQ25 to EQ31)				
201	25	To what extent have the obligations of safety, verification withdrawal/recall, notification (Articles 14, 17, 19, 20) and their operationalization entailed a fair and proportionate burden on food/feed business operators?		<p>Overarching EQ: link to several EQs→ <i>The indicators selected here are designed to provide an overview; findings from EQs/case studies will be used to complete the analysis.</i></p> <p><i>Eventually EQ 25 to be merged with EQ29 and EQ30 under a chapter on 'administrative costs and burden for FBOs'.</i></p>		<p><i>EQ25 covers GFL core obligations for FBOs: GFL Articles 15 (feed safety requirements) and 18 (traceability) are also relevant for EQ25, therefore included in the analysis for completeness.</i></p> <p><i>Burden: Administrative costs and burden (SCM definition). Following further discussion with the SG at the inception meeting, it was agreed that a detailed full analysis according to the SCM model is not possible in the context of this study. A simplified overview analysis was agreed, in broad terms, with focus on identifying the most burdensome obligations, the distribution of burden along the chain, and the overall balance of costs/burden versus benefits of the GFL core obligations for FBOs. Quantitative data are requested, but if not available a quali-quantitative analysis will be provided.</i></p> <p><i>The impact on SMEs is particularly relevant here (FBO survey; case studies; SME Panel).</i></p> <p><u>Links:</u> <i>This EQ is fed/feeds into several other EQs (link to EQ8, 9, 12, 14, and 15, 24, 27, and 29)</i> <i>EQ8b, 9 and 12 deal with efficiency issues for these provisions.</i> <i>EQ27: efficiency/effectiveness of combining legal provisions with other tools.</i></p> <p>Link to case studies: traceability, FBO responsibilities</p>
202			1	• Impact on costs/burden for FBOs	1a	• Most burdensome information obligations (12 IOs of the SCM model) stemming from the provisions of EU food law (i.e. the GFL and secondary legislation based on the GFL) (FBO survey; SME panel)
203					1b	• Costs for FBOs following the implementation of the GFL, by size of business: annual operational administrative costs as % of total production costs, excluding capital investment, BAU costs, and private contractual obligations (FBO survey; SME panel) (case studies: traceability, FBO responsibilities)
204					1c	• Extent to which benefits, following implementation of the GFL, outweigh costs/burden for FBOs (SME panel; case studies: traceability, FBO responsibilities)
205					1d	• Distribution of costs versus benefits for FBOs at different stages of the supply chain: is there a relationship between who benefits the most and costs? (case studies: traceability, FBO responsibilities)
206					1e	• Extent to which the key GFL requirements for FBOs entailed a fair and proportionate burden on FBOs ? (relevant also for EQ9) (surveys; case studies)
207	26	To what extent can some provisions of the "General Food Law Regulation" be identified as too prescriptive or too general taking into account operational implementation?		<p>Overarching EQ: link to several EQs (e.g. EQ24) → <i>The indicators selected here are designed to provide an overview; findings from EQs/case studies will be used to complete the analysis.</i></p>		<p><i>Note : Generally, the GFL is not considered to be too prescriptive. Emphasis is therefore expected to be on whether the GFL provisions are too general.</i></p> <p><u>Links:</u> <i>This EQ is fed/feeds into several other EQs.</i> <i>With EQ24: as this covers all the core obligations of the GFL for FBOs. To the extent that differences in implementation are found between MSs, this is partly an indicator that the GFL provisions are too general.</i> <i>With EQ 27: the use of guidelines is also an indicator that the GFL provisions are too general.</i></p> <p>Link to all 4 case studies: risk analysis, traceability, FBO responsibilities, transparency</p>
208			1	• Extent to which the GFL (as implemented) is identified to	1a	• Cases where specific GFL provisions are considered to be too prescriptive, reasons why, and problems identified with the current approach (case studies) (Expert Panel)
209					1b	• Cases where specific GFL provisions are considered to be too general, reasons why, and problems identified with the current approach (case studies) (Expert Panel)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
198	1 (implicit)	3	5								
199	53	43	40								
200											
201					25		x	x	x	x	x
202	44		31	18							
203	45		32	17/19							
204				20							
205											
206	4	6	8								
207					26			x	x	x	x
208											
209											

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
210	27	To what extent have other tools such as self-regulation, guidelines, code of good practices been combined with the provisions of “the General food Law Regulation” and their implementation and has that been an efficient and effective combination of measures?				<p><i>Combined</i> = taken into account, where appropriate</p> <p><u>Links:</u> With EQ25: if such a combined approach has been effective/efficient, this has implications in terms of whether the burden on FBOs has been fair and proportionate. With EQ29/30: the application of a combined approach has implications in terms of the potential for simplification and reduction in administrative costs/burden.</p> <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p> <p>Relevant case studies: traceability; FBO responsibilities; risk analysis. Other relevant example: food labelling (FIC Regulation).</p>
211			1	• Use of non regulatory tools in combination with GFL provisions/secondary legislation	1a	<ul style="list-style-type: none"> • Extent to which other tools (private standards, guidelines, codes of good practice) have been combined with the provisions of the GFL and their implementation in secondary legislation (SME panel; case studies: traceability, FBO responsibilities) <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p>
212					1b	<ul style="list-style-type: none"> • Extent to which such a combined approach is applicable in each area of EU food law (i.e. secondary legislation) (surveys) <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p>
213			2	• Impact on efficiency	2a	<ul style="list-style-type: none"> • Extent to which certain tools (guidelines; private standards/codes of good practice) help FBOs to save money/work more efficiently in meeting legal obligations (case studies: traceability, FBO responsibilities) <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p>
214					2b	<ul style="list-style-type: none"> • Cases of best practices e.g. private standards that complement EU food law provisions in the GFL and/or secondary legislation to maximise efficiency (case studies: traceability, FBO responsibilities) <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p>
215			3	• Impact on effectiveness	3a	<ul style="list-style-type: none"> • Extent to which certain tools (guidelines; private standards/codes of good practice) help FBOs to meet legal obligations more effectively (FBO survey) (case studies: traceability, FBO responsibilities) <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p>
216					3b	<ul style="list-style-type: none"> • Cases of best practices e.g. private standards that complement EU food law provisions in the GFL and/or secondary legislation to maximise effectiveness (case studies: traceability, FBO responsibilities) <p>The Commission guidance document (January 2010) to be taken into account as a key source of information.</p>
217	28	To what extent were differences between Member State markets and cultures taken into account in the “General Food Law Regulation” and did that improve the efficiency and effectiveness of the law?		<i>In view of the open scope of this EQ, focus is on identifying specific examples demonstrating cases where this has occurred and impacts</i>		<p><u>Note</u> : important to bear in mind that at the time of drafting of the GFL, the EU had 15 MS.</p> <p><u>Links:</u> With EQ1, in terms of how the GFL reflects current enlarged EU composition and evolved food safety structures in the 28 MS, as well as needs of society in the 28 MS. With EQ10, in terms of persisting substantial differences in MS national provisions, indicating fundamental differences in cultures/markets.</p>
218			1	• Incidence of incorporation of national differences in GFL development	1a	<ul style="list-style-type: none"> • Extent to which (cases) differences between MS markets and cultures were taken into account in the GFL (interviews; MS CA workshop; literature review; Expert panel)
219					1b	<ul style="list-style-type: none"> • Extent to which (cases) the GFL has brought about a major change in national approaches to feed/food law, as applied prior and after the introduction of the GFL (interviews; MS CA workshop; literature review; Expert panel)
220			2	• Impact on efficiency	2a	<ul style="list-style-type: none"> • Extent to which the GFL has improved the efficiency of feed/food law in Member States: best practice cases, where this is demonstrated to have improved the efficiency of food law (interviews; MS CA workshop; literature review; Expert panel)
221			3	• Impact on effectiveness	3a	<ul style="list-style-type: none"> • Extent to which the GFL has improved the effectiveness of feed/food law in Member States: best practice cases, where this is demonstrated to have improved the effectiveness of food law (interviews; MS CA workshop; literature review; Expert panel)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
210					27		x	x	x	x	
211				9							
212	49	39	36								
213	47		34								
214	47		34								
215	48		35								
216	48		35								
217					28						
218											
219											
220											
221											

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
222					3b	<ul style="list-style-type: none"> • Extent to which the GFL has achieved a greater harmonisation of national approaches to feed/food law across the EU, and whether this has led to an improved level of feed/food safety in the period since the GFL was introduced (interviews; MS CA workshop; literature review; Expert panel)
223	29	Which specific concerns and burdens for business (particularly SMEs) and public authorities have been identified in the implementation of the “General Food Law Regulation” (including in the application of its fundamental definitions, principles and requirements in related specific pieces of food law)?		<p>Overarching EQ: link to most other EQs, with regards to:</p> <ul style="list-style-type: none"> • Identification of specific concerns/burdens for FBOs stemming from the GFL • Differences to the general case for SMEs • Identification of specific concerns/burdens for public authorities • Assessment of actions taken in the context of the Action Programme for Reducing Administrative Burdens in the EU 		<p><i>Links: This EQ is fed/feeds into most other EQs, where evidence of failures, problems, and burden are identified. Hence, a synthesis of relevant results from the other EQs will be used to feed EQ29.</i></p> <p><i>In addition, to evidence from linking EQs (to address the judgement criteria identified here), the overarching indicator of the GFL regulatory costs and burden is relevant for addressing EQ29. This has been merged under EQ30 to improve the flow of the analysis.</i></p> <p><i>Concerns and burdens refer to regulatory costs/burdens which are the target of simplification under the SMART Regulation (link to EQ30 and 31: see below).</i></p> <p><i>Baseline (admin costs of IOs) provided in the food safety area by 2009 Report for DG ENT, focuses on three Directives and four Regulations (relating to AH, PH, GM, and the old labelling Directive), rather than the GFL framework or EU food law more generally.</i></p> <p><i>In addressing this question, it is noted that a counterfactual would be the regulatory costs and burdens likely to have been incurred in the absence of the GFL (EQ2: added value); a priori, the GFL is expected to have contributed in reducing regulatory burden by streamlining legislation and setting a common framework, in comparison to what would have been the situation otherwise.</i></p> <p>SME panel: specific questions on EQ29/30 for SMEs, on the basis of the experience gained:</p> <ul style="list-style-type: none"> • Problems for SMEs to comply with the general GFL legal obligations (Q 5/6); as well as, general awareness of their obligations (Q 4) • Extent to which external consultant needs hiring (Q 7/8); • Extent to which national authorities have provided assistance (Q 16); • Costs of complying with food/feed law requirements (Q 17); • Areas in which SMEs are experiencing most burdensome administrative requirements: three most burdensome obligations (Q18); • Share (%) of administrative costs stemming from EU food law over all administrative costs stemming from legal obligations (Q19)
224	30	To what extent is there a potential for (legislative, non-legislative) simplification and reduction of regulatory costs and burdens in the area of General Food Law?		<p>Overarching EQ: link to several EQs →</p> <p><i>Some of the indicators selected here are designed to provide an overview; findings from EQs/case studies will be used to complete the analysis.</i></p> <p><i>Eventually EQ 25, EQ29 and EQ30 to be merged under a chapter on 'administrative costs and burden for FBOs'.</i></p>		<p>Notes :</p> <p><i>The GFL principles and general requirements are considered to have brought EU food and feed law a step closer to smarter legislation. Assigning primary responsibility to FBOs and the adaptation of requirements according to size of business and sector are key provisions that in principle should encourage proportionality in regulatory burden. Furthermore, this is a dynamic situation with a number of revisions to secondary legislation recently concluded/currently ongoing; impact analysis carried out in this context provides useful insight into ongoing simplification and regulatory burden reduction. E.g. Novel Foods proposal aims to provide a reduction in admin burden.</i></p> <p><i>As agreed with the SG, the analysis excludes (ie simply makes reference w/o further analysis) areas where simplification is currently under way; e.g. one area where significant costs/burden have been identified is authorisation procedure for novel foods; this is being addressed by 2013 novel foods proposal streamlining this inter alia with a centralised procedure (applications to COM) and a simplified procedure based on 'substantial equivalence'; another area is the 2013 Official Controls review.</i></p> <p>Links:</p> <p><i>With EQ2: the contribution of the GFL in terms of allowing simplification, thus leading to a reduction in regulatory costs and burden has been identified as one of the potential elements of the GFL added value (EQ2), and is thus incorporated in that part of the study (survey question: 49).</i></p> <p>Relevant case studies: traceability; FBO responsibilities; risk analysis.</p>
225			1	<ul style="list-style-type: none"> • Areas where simplification would be possible (including legislative and in terms of implementation) 	1a	<ul style="list-style-type: none"> • Extent to which there is potential for (legislative, non-legislative) simplification in the key obligations for FBOs stemming from the GFL (FBO survey; case studies)
226					1b	<ul style="list-style-type: none"> • Cases (analysis of specific areas) where simplification potential exists, including actions taken in the context of ongoing/recent revisions to secondary legislation (case studies). In particular, by type of simplification: <ul style="list-style-type: none"> - areas where legislation can be replaced by GMPs or guidelines - areas where simplification is possible (but legislation remains essential)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
222											
223	44		31	x	29	x	x	x	x	x	x
224					30	x	x	x	x	x	x
225	45 46		32 33								
226											

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
227	31	Which reduction of costs in quantitative terms can be achieved? What are the specific costs, benefits (quantitative and qualitative) and risks		On the basis of EQ30/1b (specific cases where reductions in costs could		<i>For reduction in costs: link to EQ30 indicator. Indicators on costs reduction merged under EQ30. EQ30 1b and 2c: Cases (analysis of specific areas) where simplification potential exists and potential reduction in costs that can be achieved.</i>
228			1	• Potential regulatory costs and burdens reduction	1a	• Cost reductions involved in the cases identified under EQ30/1b: expected annual cost saving in regulatory costs and burden resulting from simplification, in % terms compared to the current baseline (for baseline see: EQ25/1b) (case studies)
229			2	• Impacts (positive and	2a	• Benefits of simplification (other than reduction in costs) in the identified cases (case studies)
230					2b	• Potential risks of simplification, in the identified cases (case studies)
231		Coherence (EQ32 to EQ33)				
232	32	To what extent has the “General Food Law Regulation” contributed to internal coherence of the EU food law?		Overarching EQ: link to most other EQs → <i>The indicators selected here are designed to provide an overview; findings from EQs/case studies will be used to complete the analysis.</i>		<u>Links:</u> <i>With EQ2: internal coherence was identified to be a component of added value (EQ2)</i> <u>Internal coherence:</u> <i>refers to coherence between the GFL and secondary legislation/within secondary legislation; this issue is also addressed by EQ19 and EQ24 (including coherence in implementation across the EU).</i> <i>The period covered could be limiting in establishing this: not all secondary legislation has been updated; for several pieces of secondary legislation revisions are ongoing.</i> <i>Literature review: to be assisted by internal SANTE cross-checking of GFL definitions vis-a-vis secondary legislation (desk study of co-decision acts) (see also EQ19).</i>
233			1	• Contribution of GFL to internal coherence of EU	1a	• Extent to which the GFL has contributed to internal coherence of food safety rules across Member States (surveys) (case studies) (Expert panel)
234					1b	• Extent to which the GFL has contributed to internal coherence of food safety rules between the key areas of secondary legislation (surveys) (case studies) (Expert panel)
235	33	To what extent has the EU food safety regulatory framework established by the “General Food Law Regulation” worked together with other Member States interventions which have similar objectives?				<u>Links :</u> <i>With EQ20: this EQ covers issues of implementation raised by EQ20: risk analysis and precautionary principle.</i> <i>With EQ28: There is also an implicit link with issues raised by EQ28: differences in MS markets and cultures, to the extent these influence MS national interventions.</i> • This is particularly pursued in teh context of: - RA/RM/RC by food safety agencies/structures in MS vs COM/EFSA approach; - Application of the mutual recognition principle (DG GROW); <u>Note: this EQ does not cover issues raised by EQ10.</u> The GFL provisions covered by EQ10 (Art 14.9 and 15.6) are key areas identified where MS specific provisions can be introduced as follows: on a horizontal basis, the organisation of withdrawals/recalls and official controls in MS; and, on a sectoral basis, GM, food contact materials and, to some extent, additives (e.g. DK nitrates).
236			1	• Identification of national interventions with relevance to the GFL objectives (e.g. creation of independent scientific bodies for risk analysis)	1a	• Extent to which interventions have been put in place at national level which have similar objectives to the EU food safety regulatory framework established by the GFL (MS CA workshop)
237					1b	• Cases (examples) of such national interventions (MS CA workshop)

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
227	45		32		31	x	x	x	x	x	x
228											
229											
230											
231											
232					32			x	x	x	x
233	50	40	37								
234	50	40	37								
235					33	x		x	x	x	x
236											
237											

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	A	B	D	E	F	G
238			2	• Coherence between the objectives of relevant national interventions and of the GFL (e.g. creation of independent scientific bodies for risk analysis)	2a	• Extent to which national interventions have worked in synergy (i.e. complementary or conflicting) with the EU food safety regulatory framework established by the GFL (MS CA workshop)
239					2b	• Cases (examples) of national interventions that have complementary objectives (MS CA workshop) (Expert panel)
240					2c	• Cases (examples) of national interventions that have conflicting objectives (MS CA workshop) (Expert panel)
241		Complementarity (EQ34)				
242	34	To what extent has the EU food safety policy framework established by the “General Food Law Regulation” proved complementary to other Union interventions/ initiatives in the field of Food policy such as the Common Agriculture Policy (CAP)?		<i>Note: in terms of scope, this EQ can only provide a broad overview of the extent of complementarity and key areas where problems might be identified</i>		<u>Key fields of EU policies of relevance to the GFL:</u> CAP, environment (link to EQ4), trade (link to EQ16-18), enterprise and internal market (growth and competitiveness; smart regulation: link to EQ29-31). Focus is on the CAP (the other areas are discussed in context of other EQs). Interviews with other COM services (DG AGRI, DG TRADE, DG ENT, DG ENV). Interviews with stakeholders. Expert panel.
243			1	• Identification of the relationship/complementarity between the GFL and other aspects of food policy	1a	• Extent to which the GFL is complementary to other interventions/ initiatives in the field of food policy
244					1b	• Extent of inter-services consultation, at EU and at MS level
245			2	• Evidence of potential failures/gaps/problems	2a	• Cases (examples) of areas of overlap
246					2b	• Cases (examples) of gaps in coverage
247					2c	• Cases (examples) of contradictions

Appendix 5_Annex 2b: EQs judgement criteria and indicators

	H	I	J	K	L	M	N	O	P	Q	R
238											
239											
240											
241											
242					34			x		x	x
243											
244											
245											
246											
247											