Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation" - GFL)

Draft Final Report

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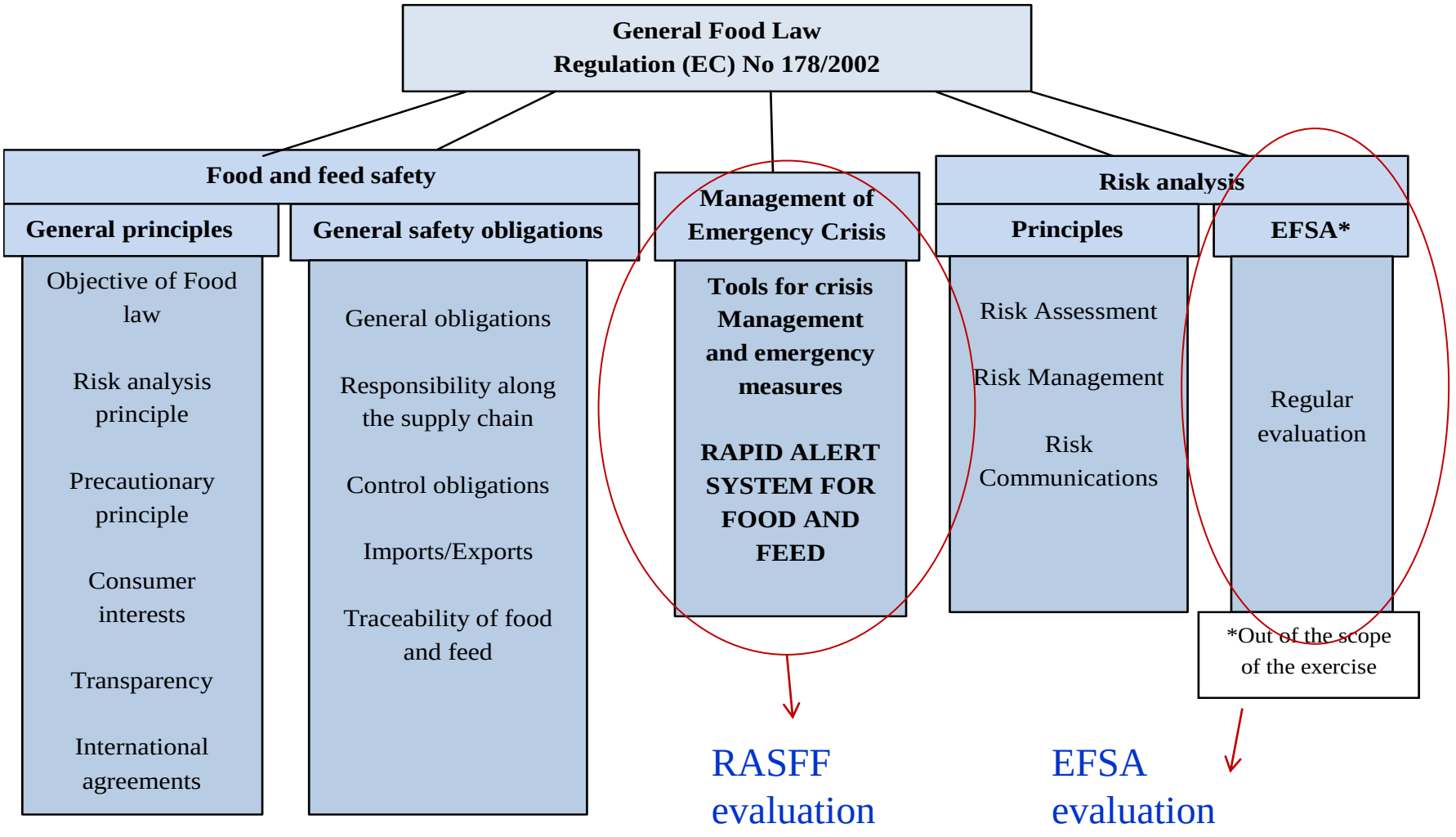
Presentation structure

- **Study objectives, scope and tasks (ToR)**
- **Main findings (EQs)**
- **Overall assessment (evaluation criteria)**
- **Conclusions and recommendations**

GFL evaluation context

- The FCEC study will feed into the Commission's "***Fitness Check"*** of the GFL.
- The Commission's Communication on ***Smart Regulation*** introduced ***Fitness Checks*** as comprehensive policy evaluations assessing whether the regulatory framework for an entire policy sector is **fit for purpose**.
- Objective of a ***Fitness Check*** is to identify excessive regulatory burdens, overlaps, gaps, inconsistencies and/or obsolete measures, and the cumulative impact of legislation.
- The GFL "Fitness Check" ultimately forms part of *REFIT*, which is the European Commission's ***Regulatory Fitness and Performance programme*.**

GFL evaluation: scope



GFL evaluation: criteria

Theme 1: Relevance and EU added value

Theme 2: Effectiveness

- *Protection of consumers' health and interests*
- *Safety requirements*
- *Distribution of responsibilities*
- *Traceability*
- *Imports/exports*
- *Integrated food law*
- *Implementation and enforcement*

Theme 3: Efficiency

Theme 4: Internal coherence (EU food law)

Theme 5: External coherence (MS interventions)

Theme 6: Complementarity (EU policies e.g. CAP)

Fine tuning of methodology

Challenges and limitations of the study:

a) Cross-cutting linkages between EQs and themes;
b) Comparing against absence of the GFL;
c) GFL implementation through secondary legislation;
d) Limitations of using quantitative indicators/data availability;
e) Time constraints;

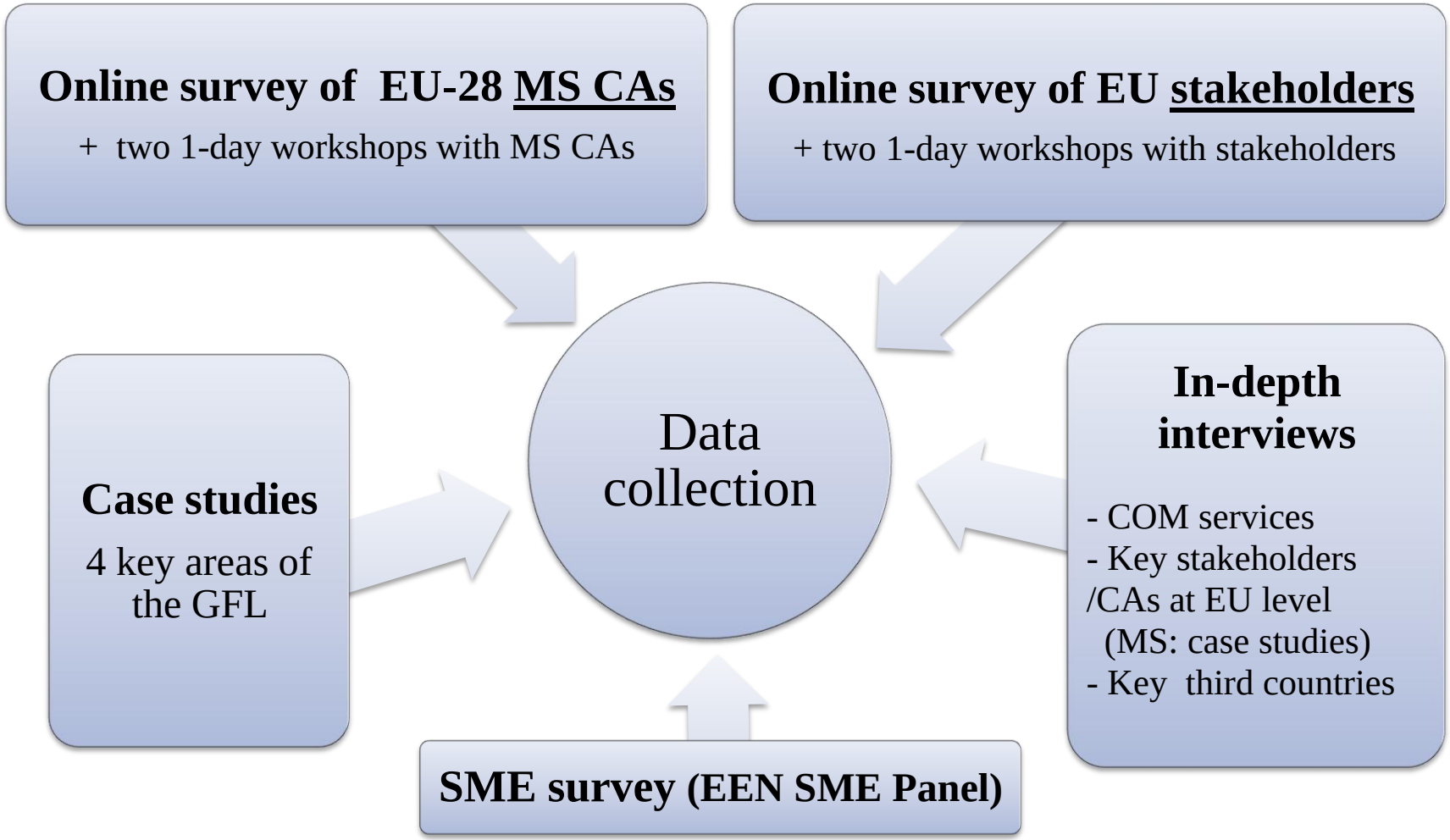
Challenges and caveats of using certain quantitative indicators:

f) Analysis of indicators in relation to consumer protection ;
g) Analysis of effectiveness and efficiency;
h) Analysis of regulatory burden ;

Mitigating measures involve:

- **Wide ranging consultation**
- **Comprehensive matrix of EQs, judgement criteria, indicators**

Overview of data collection tools



Data collection scope

Tool	Aim	
Online surveys (x2)	Collection of data and experience from the 28 MS CAs and food chain	*survey of MS CAs and survey of food chain stakeholders (FBOs/consumers/NGOs)*
Workshops (x2)	Discussion of issues with MS and food chain	*Advisory Group: 19 December 2014; 6 May 2015* *MS Expert WG: 16 January 2015; 27 April 2015*
SME panel	Data collection from SMEs (15 question limit)	*Managed by Europe Enterprise Network (EEN)*
Case studies	Examination of specific topics in depth	*Working Documents with case study questions widely disseminated including via workshops*
In depth interviews	In depth data collection through structured interviews	*Interviews build/deepen data collection on the basis of feedback received to the Working Documents*

Case studies

	Areas covered	Scope of GFL
1	**Traceability**	Art. 18
2	**Distribution of responsibilities**	Art. 17.1 *Art. 14 and 15; Art. 19 to 21*
3	Risk analysis	Art. 6 and 7 as implemented by Ch. III/national authorities
4	Transparency	Art. 9 and 10 (Section 2)

10 MS covered: AT, EE, FI, FR, DE, HU, IT, NL, SK, UK

Main findings (EQs)

- Overall, the GFL as such has achieved its core objectives (protection of human health; internal market);
- Considerable improvements, compared to the baseline pre-GFL, have been observed in all areas, including traceability, FBO responsibilities, risk analysis, transparency;
- This has brought about enhanced harmonisation (secondary legislation; intra EU), which enabled better targeting of food safety risks and the effective functioning of the internal market;
- Some problems, and therefore need for improvement, have been indicated mostly at the level of:
  - Implementation in some secondary legislation
  - Member State enforcement (differences)

Main findings (EQs)

- The consensus is the general horizontal framework introduced by the GFL and its implementation/application at EU/national level contributed to achieving the **core objectives** of the GFL.
- According to both stakeholders and MS CAs, **all of the core requirements of the GFL have had positive impacts** in terms of ensuring food/feed safety in the EU.

  - Detailed findings presented by EQ.
  - General findings of case studies are positive.

Main findings: traceability (Art. 18)

Key findings:

- The impact of the GFL has generally been positive: although traceability already in place pre-GFL, Art. 18 has brought about greater harmonisation in implementation across EU feed/food businesses.
- Costs for implementing Art. 18 could not be established, but benefits - according to both MS CAs and FBOs - outweigh costs.
- Benefits of traceability assessed by industry to have been '*significant*':
  - possible to trace within a short time frame all products affected by one ingredient/one supplier;
  - alignment of procedures/communication across MS;
  - better targeted withdrawals/recalls;
  - for consumers: affected products more rapidly/effectively differentiated from non-affected products.

Distribution of responsibilities (FBOs) (1)

Key findings:

- Impact of GFL has generally been positive: although systems already in place pre-GFL, Art. 17.1 has brought about greater harmonisation in implementation (GMPs, HACCP, verifications; private certification).
- Nonetheless, secondary legislation lays down the specific requirements against which FBOs have compliance responsibility and legal liability (furthermore, liability rules/sanctions: MS law).
- Both benefits and costs determined by provisions in specific secondary legislation (e.g. hygiene: HACCP).

Distribution of responsibilities (FBOs) (2)

Key findings:

- Costs for implementing Art. 17.1 could not be established, but benefits - according to both MS CAs and FBOs - outweigh costs.
- Benefits of traceability assessed by industry to have been largely achieved, particularly in terms of ensuring consumer protection and trust amongst FBOs along the supply chain.
- However, fuller benefits e.g. in terms of better targeted withdrawals/recalls to some extent hampered by lack of harmonised implementation by MS CAs.

Risk analysis/PP (Art. 6 and 7)

Key findings:

- Impact of GFL has generally been positive.
  - Separation of risk assessment and risk management (EU, MS);
  - Coherence/complementarity with MS interventions: creation of independent scientific bodies for risk analysis;
  - Efficiency gains: cost savings from the central approach followed at EFSA; pooling of EU/MS scientific resources;
  - Effectiveness: improved scientific basis/transparency of measures adopted both at national and EU level; *risk analysis process, including consideration of other legitimate factors had a substantial positive impact on consumer health and protection*.
- Some concerns over coherence/consistency in implementation in secondary legislation (harmonised and non-harmonised areas), including application of legitimate factors, deadlines foreseen etc.

Transparency (Art. 9 and 10)

Key findings:

- Impact of GFL has generally been positive, particularly in the case of public information (Art. 10):
  - **Public consultation** (Art. 9): more systematic application; involvement of wider spectrum of stakeholders/interest groups; increase in general public consultation (facilitated by online tools).
  - **Public information** (Art. 10): continues to improve, taking into account lessons learnt from previous crises (e.g. dioxin, E. coli, etc.).
- Some concerns over coherence/consistency in implementation on a systematic basis (application of Art.10 remains ad hoc i.e. case by case – difficult to establish fixed rules), as well as amongst MS - this can be counter-productive in terms of ensuring consumer trust/confidence.
- Process of developing public information mechanisms remains dynamic.

Overall assessment: relevance (1)

- Although the context of the GFL has evolved considerably since 2002 (baseline), **original objectives**, i.e. the protection of human health and the effective functioning of the internal market, continue to be considered by all consulted parties as the **core relevant objectives that EU food law needs to address**. Furthermore, both original objectives have largely been met.
- Adequacy of current GFL framework to address **other objectives/ needs and current trends** - **mixed feedback**:
  - **positive aspects**: GFL lays down principles and general requirements that allow it to best adapt to actual needs;
  - **negative aspects**: in practice, mainly, due to shortcomings identified with secondary legislation ; however, these are not linked to systemic problems with the GFL provisions or the relevance of the GFL objectives.

Overall assessment: relevance (2)

- The **GFL cannot aim to address a range of diverse objectives**, although it should ensure coherence with other EU and MS policy trends (largely achieved). The GFL delivers well because it is focussed on its core objectives.
- **Potential synergies**, but also **conflicts**, between food safety and other objectives/needs and current trends were highlighted. This is also indicative of the divergence of viewpoints and interest groups that are affected by the broader GFL policy framework.

Overall assessment: effectiveness (1)

- Effectiveness: covers both **outputs and outcomes**. The combined (overarching) effect of GFL provisions aims to deliver improved feed/food safety, a measure of outcome assessed in all cases.
- **Scope and general definitions** (Articles 2, 3 and 4.1): sufficiently broad to ensure an integrated approach to food safety management, a key factor contributing to effective implementation.
- **Traceability** (Article 18): ability to cover the full supply chain has enabled the effective tracing of affected products throughout the chain, in the event of food safety (e.g. dioxin, e-coli) and non-safety related incidents (e.g. horse meat fraud).
- **Allocation of responsibility** (Article 17): a novelty of EU food law, endorsed by FBOs, has contributed to the effective functioning of the internal market. Nonetheless, in practice, system tested by ability to ensure compliance along the full chain across the EU. Complexity of the supply chain and attribution of liability/sanctions (MS law) are key constraints.

Overall assessment: effectiveness (2)

- **Withdrawals/recalls** (Articles 19 and 20): combined effect of GFL provisions contributed to fit for purpose implementation (effective and efficient). Effectiveness: speed of reaction has greatly improved. Improved traceability (in particular when further enhanced by internal traceability, voluntarily put in place by operators), and cooperation between operators and MS CAs are key contributing factors. Nonetheless, shortcomings remain, in particular variable level of implementation of withdrawals/recalls between MS due *inter alia* to difficulties in practice with interpretation Articles 14 and 15.
- **Risk analysis** (Article 6): separation of risk assessment from risk management effectively implemented (MS level; EU level). Where national and EU measures on feed/food have been adopted on the basis of a risk analysis, positive outcomes were achieved and measures were largely effective and proportionate.

Overall assessment: efficiency (1)

- *Note: achievement of effective outcomes correlated with efficiency gains.*
- All of the core GFL requirements for FBOs (as laid down in Articles 14, 15, 17, 18, 19 and 20) have entailed a **fair and proportionate burden**.
- The low level of prescriptiveness, combination of legal requirements with self-regulation, and adaptability to national markets and cultures have acted as **important mitigating factors** that allowed an efficient, fit for purpose implementation.
- **Recalls/withdrawals**: although costs are not comparable before and after the GFL, according to the industry, there has been a reduction in the costs of risk/crisis management which *inter alia* can be attributed to the enhanced and harmonised traceability system in place.
- **Risk analysis**: important efficiency gains; a) cost savings from the central approach followed at EFSA reducing the need for national risk assessments and, b) the pooling of scientific resources involved in EU/national assessment bodies.

Overall assessment: efficiency (2)

- **Regulatory costs and burden** related to the implementation of EU food law, as a proportion of total operational costs and staff numbers, generally **tend to decline as business size increases**.
- Specific concerns, for **micro/small companies**, include difficulties in understanding/interpreting requirements of EU food law, particularly in secondary legislation which entail the actual costs/burden (rather than the GFL), coupled with differential interpretations of legal requirements in the MS and lack of support in some cases from MS CAs. Furthermore, need to consider the **cumulative regulatory burden** of all EU legislation (increased over time).
- **Exemptions/simplified rules for micro-enterprises**: best practice example the exemption provided in the hygiene package (to apply GMPs); otherwise, in practice, not many such exemptions.

Overall assessment: efficiency (3)

- Identified efficiency shortcomings not linked to systemic gaps or failures in the GFL principles and general requirements *per se*. while ongoing revisions to secondary legislation aiming to reduce regulatory burden.
- Hence, **limited further potential for legislative simplification and reduction of regulatory costs and burden** in relation to the key obligations stemming from the GFL.
- The identified potential was mainly in terms of **soft non-legislative interventions**, including the provision of training and guidelines.
- Beyond the GFL: further harmonisation in secondary legislation has the potential to allow a reduction of regulatory costs and burden, in view of the problems encountered in areas where harmonisation is incomplete (e.g., food contact materials other than plastics; contaminants; salmonella in feed; lack of technical solution for GM food).

Overall assessment: coherence (1)

- Compared to the baseline, there is improved **internal coherence** of food safety rules across MS, as well as between key areas of secondary legislation.
- **External coherence** of the GFL with other MS interventions that have similar objectives demonstrated in the case of the implementation of Article 6, by the creation of independent scientific bodies at MS level for risk analysis, motivated by need to respond to the safety crises of late 90s.
- Food safety objectives and provisions considered **complementary to the evolving CAP** implementation context of the shift from market support to market orientation.

Overall assessment: EU added value (1)

- *Note: in comparison to absence of a common framework by MS at national and/or regional levels or at international level (Codex, OIE).*
- The analysis of the core GFL provisions (case studies) demonstrates that EU measures and actions are particularly relevant to ensure both a **harmonised and a more global approach across the EU and in relation to third countries**. Also, fostering an improved level of food safety standards, not just at EU level but also in the international context.
- **Consumers**: improved harmonisation of food safety standards and protection of consumer health and interests (e.g. FIC Regulation).
- **MS CAs**: pioneered global safety approach for food chain, compared to previous piecemeal legal provisions and administrative structures.
- **Supply chain**: improved harmonisation of requirements contributed to ensuring the effective functioning of the internal market (level-playing field). Particularly beneficial for companies located in multiple MS.
- Examples of EU added value: traceability; risk analysis.

Conclusions

- The GFL made a positive contribution to the EU legislative *acquis* of relevance to the food and feed chain: positive impacts are widely acknowledged by all consulted parties; consensus that the GFL objectives set a new era in EU food policy design/implementation.
- The GFL is generally fit for purpose, in line with the vision and expectations outlined in the White Paper (baseline). This is an important achievement given the difficulties of having a one fits all framework legislation in this policy area, given the diverse interests of the range of issues, and affected sectors/stakeholders.
- Gaps/shortcomings arise mainly from interpretation, implementation and enforcement of the GFL/secondary legislation; no link to systemic gaps or failures in the GFL principles and general requirements. Distinction between the variable implementation of harmonised rules (e.g. GFL: withdrawals/recalls) and incomplete/lack of harmonisation (e.g. secondary legislation: contaminants, FCM, microbiological safety criteria).

Recommendations (1)

*Note: In view of findings, recommendations include mainly **soft, non-legislative interventions**.*

GFL:

- Definitions (Articles 2 and 3):consolidated list; glossary.
- Risk analysis and precautionary principle (PP) (Articles 6 and 7): guidelines; review application of the PP; establish principles of risk communication.
- Feed/feed safety requirements (Articles 14/15), allocation of responsibilities (Article 17) and withdrawals/recalls (Articles 19/20): training; review of the existing guidelines.
- Transparency: guidelines.

Recommendations (2)

Secondary legislation:

- Generalising the application of exemptions/simplified rules for micro-enterprises from certain detailed legal requirements.
- Further harmonisation in secondary legislation to allow reduction of regulatory costs and burden, in view of problems encountered (by stakeholders and MS CAs) where harmonisation is incomplete.
- Tools to this end include: review of existing guidelines (with a view to practical improvements); development of further guidelines; training, further cooperation and exchange of best practices between MS CAs.