EXPERT GROUP ON GENERAL FOOD LAW –

FITNESS CHECK OF REGULATION (EC) NO 178/2002 (THE 'GENERAL FOOD LAW') –

CHAPTER ON EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

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Brussels

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DG SANTE introduced the discussion by explaining the general framework of the fitness check on Regulation 178/2002.

The purpose of the fitness check is to assess the fitness for purpose of Regulation 178/2002. Such an evaluation implies to address the effectiveness, efficiency, coherence, the EU added value and the relevance of EFSA.

The fitness check addresses both the adequateness of the EFSA system with the provisions and objectives of Regulation 178/2002 and the concrete implementation of these provisions (EFSA's processes in particular) since it is important to identify which problems/concerns result from the legal provisions and which problems/concerns come from modalities of implementation.

With regard to EFSA, it was decided to base the evaluation on the last EFSA external evaluation report (2012). Given that the results of this external evaluation cover the period January 2006 to December 2010, some of the results need to be updated, completed and cross-checked.

The aim of this working group is to update the findings on the cooperation between EFSA and Member States (MS). This was done on the basis of a document:

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The update was made in collaboration with EFSA and two representatives of EFSA attended the meeting.

The summary below includes the comments made during the meeting and the written comments submitted afterwards.

I. General comments

Some MS specified in their written comments how they have integrated cooperation with EFSA in their national systems and participation in the diverse EFSA networks, Panels and working groups.

Globally the updates provided in the working document were approved.

There were some comments on the update related to the increase of the average age of the national experts contributing to EFSA's work:

- It was highlighted that the pool of experts available for participation in EFSA's activities was shrinking while the demand for professional expertise was increasing.
- Some MS explained that the advanced age of Panel members was linked to the need for experienced risk assessment scientists.
- It was pointed out that the pool of available experts was further limited by the current trend on public/private RTD projects which was not compatible with EFSA's strict rules on independence.

Some clarifications were provided on the update on mandates:

- Even if MS sent some mandates to EFSA, it was consistent that most mandates came from the Commission since the food safety aspects were harmonised at the EU level. It was also pointed out that EFSA often replied late to the mandates sent by MS, as in the case of acrylamide and of botanicals.

II. Main positive and negative aspects of the cooperation with EFSA

<u>Positive points</u>

Member States stated to benefit in particular from EFSA's risk assessment and the EU harmonisation thereof. EFSA's scientific opinions are important for the EU system and need to be of high quality and independent.

It was considered that the separation of risk assessment and risk management has been a crucial accomplishment of the GFL. The fact that the responsibility for providing the scientific basis for EU regulations and for the risk assessment of substances submitted to pre-market approval lies with one separate and independent body is essential for the trust in the EU food safety system.

Most MS also identified as positive cooperation: the exchange of information, the sharing of expertise, best practices and methodologies, the centralisation of data, the coordination

with national risk assessment bodies in case of emergencies/crises and the liaison role on risk communication.

MS welcomed the EFSA training activities and the increase of its budget on grants (including the financing of focal points) and procurements.

Several MS highlighted the smooth cooperation with EFSA and approved the evolution of the role of the Advisory Forum (AF) towards the identification of common interests and the development of shared projects.

Several MS acknowledged that countries with limited national capacity to undertake work in areas covered by EFSA's remit drew particular benefit from the agency's activities.

Negative points

As regards the mobilisation of experts, several MS confirmed that there were a number of disincentives for experts to participate in EFSA's activities. Were in particular identified as having a negative impact: the strict rules on independence, the insufficient recognition of the experts' contribution to EFSA for the scientists' career, the amount of time required, the fact that in some cases experts were doing too much routine work, the high workload, and at a lesser degree the location of EFSA in Parma and the low financial compensation for experts.

Some MS stressed that the independence issue had to be reviewed because:

- There are a scarce number of high level experts in the areas covered by EFSA.
- Leading scientists might be excluded from EFSA's work thus widening the gap between science and the "real world".
- The best scientists are likely to have had some industry funding and such links should not be considered as automatically undermining their integrity and professionalism.
- Resources allocated to the management of the independence are diverted away from EFSA's core functions.
- There is still a misunderstanding between conflict of interests and declaration of interests.

It was also clarified by some MS that EFSA's rules on independence or the time spent by the experts had no significant impact on the participation of their experts in EFSA activities.

Most MS considered that declining resources at the national level had both positive and negative impacts: they worked as an incentive for increased cooperation with EFSA but were also hindering participation in EFSA activities.

As regards grants and procurements, a large number of MS stated that they lacked financial attractiveness and several MS stated that the procedures, in particular the ones linked to the Article 36 grants, were too bureaucratic.

One MS considered that too much of EFSA's resources were targeted to applications for authorisation (new system on electronic submission) when some more fundamental public health tools were neglected (the current Information Exchange Platform).

Some MS also pointed out the difficulties in data sharing due to the continuously changing environment, e. g. SSD systems.

III. Article 36 list and grants and procurements

Most MS confirmed that the review of the Article 36 list was justified, since many organisations on the list never participated in EFSA's work. It was explained by several MS that some valuable organisations did not participate because the calls were not in their area of expertise/work or not within the priorities of their own work programme. It was also difficult for MS to delete organisations once they were listed for diplomatic reasons.

Several MS pointed out that the procedures on the Article 36 grants were too bureaucratic (complex reporting system and budgetary forms) and more burdensome than the ones for tenders. The amount of the grants is low, not adequately compensating the costs incurred[1], and not attractive because of the need to co-finance (however rather attractive when the proposed topic is already part of the priorities of the applicant to the grant). Several MS also considered that the procedures to be included in the Article 36 list or to revise the list were too heavy.

Some MS indicated that the new system of thematic grants should make the grant system more attractive but one MS questioned the usefulness of the Article 36 list since grants could be granted on the basis of the general financial rules.

On the positive side some comments highlight that these cooperation tools have promoted the working together with EFSA but also between MS, thus promoting shared approaches and building understanding and relationships, which opens up the portal for future opportunities. Some MS also specify that contracts are generally well structured with clear deadlines and well-designed templates.

IV. Coherence of scientific opinions (Article 30)

Some MS pointed out that it was important to harmonise scientific opinions before issuing them and that the situation of misalignments was mostly found between EFSA and MS having significant risk assessment capacities.

[1] One MS specified in its written comments that this was in particular related to rules on the number of working days and calculation of salary costs.

MS with limited risk assessment capacities and some MS with significant risk assessment capacity have a general policy to not duplicate EFSA's risk assessment, thus avoiding risk of divergences.

Several MS however indicated that divergent opinions should be accepted as part of the scientific work since they were also a way to make progress in science.

Most MS considered the Article 30 procedure (management of divergent opinions) as a positive tool which helps clarifying whether there are "real" divergences or semantic ones. The recent adoption by the AF of practical modalities in cases where the Article 30 procedure is triggered was considered as an additional progress. The current building of an EU shared risk assessment agenda should also help in early identification of divergences.

Several MS also explained that it was useful to carry out complementary work at national level when the risk assessment required the consideration of specific conditions in the MS (e. g. different dietary patterns or climatic conditions).

V. Added value and costs for Member States

MS acknowledged that EFSA was of great added value. They explained that only cooperation throughout the EU had the capacity to address increasingly complex problems. The centralisation of data by EFSA was also considered of added value for the EU and at international level (WHO).

Main costs related to EFSA's activities were variable according to the MS (in some cases linked to organisation of events and trainings, in other cases mostly linked to national experts employed by the national agencies contributing to EFSA and spending time and efforts in EFSA).

The MS with limited risk assessment capacities consider that the benefits of EFSA are obvious in their case: EFSA outputs and the sharing of expertise cover most of their national needs for risk assessment. In addition, they benefit in terms of reinforced expertise (quick access to data and expertise via the AF and the EFSA system of focal points and trainings on risk assessment via the BTSF programme).

Some MS clarified that even if they had costs because of the time the experts they employ spent working for EFSA, these costs were still bearable. In particular, they considered that these costs were translated into benefits since the contribution to EFSA was part of the priorities of the national organisations and that globally EFSA was providing good value for money.

VI. Expectations and suggestions for the future

<u>Panel system and participation of experts</u>

Some MS questioned the sustainability of the existing Panel system, since criticisms on independence and a high work load might act as disincentives for the mobilisation of these voluntary experts. There were suggestions from some MS that EFSA should evolve towards a more decentralised system involving peer-review/rapporteur system.

It was underlined that in a context of a finite number of experts that can be involved in EFSA's work, it was essential to ensure that their time was used as effectively as possible.

A pragmatic approach was recommended by some MS in order to ensure access to the best expertise.

There were suggestions to re-consider EFSA's independence rules without compromising EFSA's core values, to extend the period of membership of Panel members beyond 3 years, to make use of additional ad hoc Panel members from national regulatory agencies in some cases, to increase the support role of the Panels' secretariat on the preparation and edition of scientific opinions, to aim at shorter scientific opinions more digestible by risk managers, focussed on what directly contributes to answering the question and fitter for publishing (and thus helping scientists in their career).

Networks

Some MS considered that EFSA networks should work more effectively. New networks should be established only on an ad hoc basis, and upon completion of its mandate the network should be terminated.

The Advisory Forum

Several MS suggested that the AF beyond its important current role of sharing of information should focus on the identification of shared priorities and on divergences (both preventing and tackling them).

Focal points

Most MS pleaded for a greater role of the focal points in supporting the work of EFSA and as interface between EU and national levels.

Grants and procurements

Globally, even if the Article 36 grants have proved to be useful for general preparatory work and data collection, simpler and more incentive systems are called for.

Several practical suggestions for simplification were made on grants and procurements: streamlining of procedures to update the Article 36 list, simpler approach on the administrative protocols of tenders, Article 36 organisations to provide for legal identity, bank information and declaration of honour only once, more time for the preparation of

project proposals and facilitation of the formation of consortia, feed-back by EFSA on the use by the Panels of the preparatory work undertaken by MS.

Risk communication and data collection on the EU level

Some MS suggested that in the future, EFSA should put more efforts into the development of risk communication activities and should invest more in the collection of data at EU level.

Efficiency

Some MS pleaded for stricter adherence to the mandate and procedures, including the timescale, and for less bureaucracy and more flexibility.

In order to prevent problems linked to the introduction of new reporting IT systems, EFSA should take into consideration the IT expertise of MS at the outset.

EFSA's guidance documents for risk assessment can be useful at national level but they need to be accessible/easy to find.

Maintenance of Member States' risk assessment capacity/support to EFSA

Some MS underlined that the modalities on the maintenance of the risk assessment capacities of MS should be examined since they are linked to their support to EFSA e. g. through their experts.

It was stressed that there is a need to optimise the use of resources since there was a shared view that several MS do not have a high capacity of expertise in a number of areas covered by EFSA's remits.

Bilateral meetings with Member States

EFSA could make more use of bilateral meetings to encourage the creation of joint projects. Besides, regular meetings with MS about the overall functioning of EFSA could be incorporated in EFSA's plans for annual activities.

Cooperation with international bodies and EU agencies

In order to improve the process of evaluating substances, it was underlined that EFSA needs to explore synergies with the work undertaken by other international organisations and with other European agencies (EMA, ECHA, ECDC) in particular in relation to the harmonisation of methods and approaches.

The Commission invited the participants to provide additional written comments by mid-August preferably.

Written comments were received from eight MS and one EEA country and are included in the above summary.