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COMMISSION STAFF WORKING DOCUMENT

Synopsis report

Accompanying the document

Report from the Commission to the European Parliament and to the Council

Mid-term evaluation of Regulation (EU) No 652/2014 of the European Parliament and of the Council laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC

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SYNOPSIS REPORT

1. INTRODUCTION

The present report presents the outcome of the stakeholders' consultation conducted for the mid-term evaluation of Regulation (EU) No 652/2014 on the management of the food and feed expenditure (hereinafter: the Regulation). The consultation covered aspects relating to the evaluation criteria used in this context, namely relevance, added value, efficiency, effectiveness, and coherence. It addressed both the direct beneficiaries of the grants awarded under the Regulation, notably the central veterinary and phytosanitary Competent Authorities (CAs) of EU Member States (MSs), as well as the European and the National Reference Laboratories (EURLs and NRLs) representatives, and stakeholders which are indirectly involved in the funded activities, especially farmers, consumers, food-industry and retailers representatives.

Stakeholders had the opportunity to provide their feedback on a Commission evaluation roadmap on the mid-term evaluation on Regulation (EU) No 652/2014¹, during a 4-week period starting on 9 June 2016. In addition, an open public consultation (OPC)² of all interested parties has been conducted using the European Commission 'Public consultations' website and the DG SANTE 'Consultations and feedback' web page. The open public consultation was carried out between 16 December 2016 and 17 March 2017.

A targeted on-line stakeholder consultation was conducted, and complemented by targeted interviews of different stakeholders' representatives.

1.1 OPEN PUBLIC CONSULTATION

No feedback was submitted on the evaluation roadmap.

The OPC received replies from 5 participants only: 2 citizens and 3 stakeholders responding of behalf of an organization or association. The low participation in these consultations is not unexpected, considering the highly technical nature of the Regulation. Both respondents who submitted their reply as individuals (a communication expert from Spain and a freelance consultant from France) consented to the publication of their contributions but in an anonymous form. The three stakeholders participating in the OPC were the International Federation for Animal Health - Europe AISBL, the ANGEV-PRO.CIV. (Italy), and the Estonian Veterinary and Food Board (Estonia). The low number of respondents did not allow separate analysis of the replies, but have been used for confirmation of the other information collected.

Four out of the five replies to the OPC focus on animal health issues, while one is focused on plants. The general pattern of the answers was very much in line with the findings obtained from the stakeholder consultation (questionnaires). There is an indication that the respondents had some difficulty in seeing the contribution of the Regulation to the functioning of the market and its impact on trade.

¹ http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_142_evaluation_cff_en.pdf

² http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20161213_food-and-feed-exp_en.htm

1.2 TARGETED STAKEHOLDER CONSULTATION

Targeted questionnaire surveys have been used to acquire specific information from particular stakeholders' groups. The stakeholders were identified by the stakeholder mapping exercise³.

Targeted questionnaires have been developed for stakeholders representing:

1. CAs, industry (including farmers organisations, food-industry representatives, retailer representatives, veterinary organisations), EU and national associations, international organisations, and NGOs (including consumers organisations);
2. EURLs;
3. Better Training for Safer Food (BTSF).

The targeted on-line questionnaire surveys were carried out between 21 December 2016 and 31 January 2017 (upon request a few respondents were allowed to submit after this date).

1.3 TARGETED ON-LINE QUESTIONNAIRES

Based on the stakeholder prioritisation, four questionnaires were developed for organisations with a high stake and high power at EU (Commission representatives) and national (MSs CAs representatives) levels, and for the organisations with a low stake and high power at EU level (EU branch organisations representatives). These groups were invited directly to complete the questionnaires.

Overall, a high response rate of 78% was reached for the invited stakeholders.

2. RESULTS OF EACH CONSULTATION ACTIVITY

2.1 OPEN PUBLIC CONSULTATION

The respondents in the OPC generally evaluated the Regulation to be relevant. No one identified any unmet need from the programme. They considered the Regulation to have a satisfactory EU added value. The respondents also considered the Regulation to be satisfactory in terms of effectiveness. Nevertheless, the plant health-respondent made a comment on the large scale killing of trees due to fight the "Xylella" pest in a southern EU region and the impact this has on the landscape; a specific question was raised on the criteria that are used to determine the zone in which trees had to be culled. The respondents in the OPC considered the Regulation to be very efficient. The OPC did not contain replies on Coherence.

2.2 TARGETED QUESTIONNAIRES

RELEVANCE

On relevance for **Animal Health measures**, results from the study questionnaires indicated that respondents are of the opinion that the Regulation meets the required needs for veterinary programmes and emergency measures. A majority of the respondents of the CAs and the EU Commission considered that the objectives of the Regulation are valid and in accordance with

³ Mid-term evaluation of Regulation (EU) No. 652/2014 (IBF International Consulting, 2017), Appendix C

the current food chain needs in the MSs. EU branch organisations on a whole gave somewhat lower scores.

The percentage of respondents that either strongly agree or agree with this opinion varies between 85% and 92%. Few respondents disagreed. Five respondents disagreed with the statement that the needs regarding “implementing enhanced biosecurity measures during outbreaks” were well addressed. A need for increased possibilities to co-fund preventive measures was also expressed by some respondents.

The answers to the open questions of the stakeholder questionnaires on the relevance of animal health emergency funding needs can be summarised as follows:

- there were some requests to add more categories of costs eligible for co-financing;
- co-financing should be dependent on a MS' success in the execution of veterinary programmes;
- there was general agreement among stakeholders that co-funding opportunities for animal health provided by the Regulation are an essential tool to ensure disease prevention and the timely and efficient control of animal diseases.

On relevance for **Plant Health measures**, the majority (around 75%) of respondents from all survey groups consider the Regulation in line with food chain needs of the MSs. More than 80% of the respondents agree or strongly agree with the statement that the co-funded surveys concerning plant pests address the need to detect pests timely and support MSs in actions on plant health control, prevention and eradication. All stakeholders have the same opinion. The only organisation that disagrees is the European Professional Beekeepers Association.

Regarding specific needs, the majority is slightly lower (around 65%) in considering that the Regulation is valid and in accordance with the need to protect free external and intra-EU trade in plants and plant products, which can be considered as an indirect objective of plant health policy. Chief Plant Health Officers (COPHs) do not differ in their opinion from other stakeholders. Although the number of respondents is low (5), representatives of EU branch organisations are rather neutral in their opinion that the Regulation is in line with food chain needs of the MSs.

On relevance questions for **EURLs**, 36 responses were received out of the 45 EURLs. When asked to give a score on match between their activities and the current needs for official controls in EU, EURLs' Directors consider all activities to match well with the needs.

The majority of respondents considered that no relevant activities are currently missed by the EURLs. Still, 38% of the EURLs mentioned that the following topics should be addressed in order to have better official controls:

- more research in new techniques in order to decide if there are real alternatives for the official diagnostic tools;
- support to official national laboratories from third Countries that export food to the EU;
- ability to respond to emerging problems at short notice, i.e. with additional funding rapidly available.

It was also discussed whether training of NRLs could be done in the home laboratories of the NRL instead at the EURLs facilities, but due to other work obligations the EURLs have limited resources to meet this request, so only one or two NRLs could be trained in their laboratories each year. This approach is therefore not efficient, although training at the home facilities would have the advantage of targeting specific problems of each NRL.

On relevance for **BTSF** activities, replies to the targeted questionnaires to National Contact Points (NCPs) in EU and third countries, showed that the relevance for the BTSF training subjects was evident. The vast majority considered that both basic and advanced training should be offered in the context of this EU initiative, while a minority of 7% considered basic training not necessary, likely to be covered by trainings offered by the MSs authorities themselves.

When asked to identify the ten most important trainings for meeting the needs for official controls in their country, there was a large agreement between EU and non-EU NCPs, exception made for some topics where there were substantial divergences, such as contingency planning (41 % for EU NCPs versus 12 % for non-EU NCPs); Food hygiene flexibility (44% versus 4%); EU law enforcement in Sanitary and Phytosanitary fields (19% EU versus 0% Non-EU).

EU ADDED VALUE

On EU added value for **Animal Health measures**, more than 80% of the respondents indicated they fully or to a large extent agree EU co-funded veterinary and emergency measures contribute to: improve actions to cope with exceptional circumstances; improve the MSs action on animal health control, prevention or eradication; support MSs to conduct emergency vaccination campaigns; improve the actions in destruction and transport of carcasses during eradication programmes.

However, a proportion (35-40%) of the respondents – mainly representatives of the competent authorities in the MSs – indicates that they only to some extent or not at all agree with the fact that the EU co-funded veterinary measures contribute to: improve and harmonise contingency plans that prevents an emergency to become a crisis; improve cooperation and coordination in the rapid response network by appropriate and timely communication; enhance bio-security measures in case of disease outbreaks; improve the control of transmissible diseases in animal and zoonoses.

The respondents from the EU Commission were more positive on the EU added value than the other respondents. Still, they had some reservations regarding the EU added value enhancing biosecurity measures in case of disease outbreaks.

The comments made by the respondents to open questions in the questionnaires indicated that the cooperation between MSs under the Regulation promoted the knowledge and sharing of the experience on the measures implemented. They also highlighted that, since animal diseases and plant pests are cross-border problems, MSs benefit from measures taken in other MSs. Economies of scale resulting from common measures, instead of multiple MSs doing the same thing, also provide EU added value. The respondents put emphasis on the fact that, without the availability of EU funding, the full implementation of programmes will be hampered or MSs will have to charge additional costs to food chain partners, threatening the functioning and harmonization of the internal market. The Regulation provides support to the national budgets, ensuring a national financing of measures to prevent and control animal diseases. Based on the stakeholders' opinion, should the funding under the regulation be withdrawn, fewer measures will be implemented and result in reduced export possibilities and lower productivity.

On EU added value for **Plant health measures**, most respondents agree with the statement that co-financing of emergency measures by the EU speeds up the eradication of a pest in the case of an outbreak (70% answered fully or to a large extent), contributes to take harmonised

actions on plant health control, prevention or eradication (75% answered fully or to a large extent) and improves the capacity to cope with exceptional circumstances (75% answered fully or to a large extent). 21% of CAs and a minority of other stakeholders considered that measures co-funded under the Regulation enhance the sustainable use of pesticides.

As regards **EURLs**, most participants in the survey (89%) indicated that NRLs cannot perform high quality tests that are in uniformity of analytical results with other NRLs across Europe, via other means than by EURLs guidance and coordination. One participant mentioned that the OIE Diagnostic Manual provides guidance on the selection and validation of appropriate tests for diagnosis. This answer would indicate that if the EURLs stopped existing, there is still a medium (OIE) to guide NRLs to appropriate tests, but there will be no control on the NRLs performances. In addition, adaptations of the OIE Diagnostic Manual have to pass a lengthy process of discussion and negotiation, and must be accepted by voting in the general assembly. The EURL concept is better adapted to adopt new technologies more quickly.

If the EU co-financing for EURLs is withdrawn, 86% of participants thinks the EURLs activities would cease completely. Some consequences for this will be that: priority tasks such as proficiency testing and training activities would not be possible; some staff would have to be financed on ad-hoc basis; national interest would exceed EU interests; additional activities at national level could not be added, considering that resources are limited in terms of permanent staff; it is unlikely that EU MS would finance EURL fully, as it is not a task nor duty of any EU MS to assist other EU laboratories; the Commission will lose technical support. All in all, the survey shows that the EU financial support to the EURLs is necessary and provides EU added value.

As for EU added value of the **BTSF** initiative, it is important to assess if the programme has met needs which are not met by national trainings in the areas covered by the Regulation. 91% of the participants in the online survey indicated that trainings are also organized at national level. When the participants were asked to evaluate the BTSF training contribution to better controls in relation to national/other training programmes, 81% answered that BTSF provide better networking within EU MSs; 62% indicated that BTSF provides better harmonization between EU countries, and 57% answered that BTSFs provides a higher level of trainings than by national training programmes only. No participant indicated that BTSFs do not contribute to better official controls.

Overall, the respondents indicate that **BTSF** meets needs which are not met by national training, including the expertise and technical knowledge provided by the EU programme.

EFFECTIVENESS

On effectiveness for **Animal Health measures**, there was general consensus amongst the stakeholders that EU co-funded veterinary measures contribute to prevent outbreaks to become a crisis, and effectively to control the presence of transmissible diseases in animals and zoonoses.

A large share of the respondents agreed to a large extent that the EU co-funded measures for the prevention of transmissible diseases in animals and of zoonoses contribute to: reduce the number of cases of diseases in humans linked to zoonoses; reduce and effectively control the transmissible diseases in animals; increase the number of MSs or regions free from animal diseases; overall reduce the incidence, prevalence and number of outbreaks. However, respondents were less positive (70%) that the EU co-funded measures contributed to

preventing the occurrence of outbreaks of animal diseases and zoonoses which pose a risk to human and animal health.

As main factors contributing to the success of control and eradication programmes, the following were mentioned: the availability of co-funding from the EU; the availability of adequate procedures in place and the well-trained staff⁴ to execute the programmes; good coordination and communication between different stakeholders; the flexible and transparent design of the Regulation which contributes to achieve good results, and the merger of all former legislation into a single regulation is in line with this; flexible and quick reaction of the EU co-funding in case of any new disease, including the availability of EU vaccine banks; coordination from the Commission on the measures to be implemented and co-financed.

Main obstacles experienced in achieving the results were: the administrative burden, which was considered high, both at the level of EU and in MSs; reporting requires a huge administrative effort, which in some cases is not considered to be balanced compared to the measures adopted and amount of financial contribution received; lack of sufficiently trained personnel available in some MSs; procurement procedures for buying equipment or vaccine which are time consuming.

Several problems have been identified for rabies programmes that contain activities (part of the programme) in third bordering countries. The main problems are linked with completely different legislation in these countries compared to the EU.

On effectiveness for **Plan Health measures**, 75% of the respondents considered the co-funded measures fully or largely effective with respect to the objectives of timely detection of plant pests and immediate eradication. With respect to enabling free trade, this figure is around 60%.

A majority of respondents is of the opinion that the EU co-funding allows MSs to take adequate measures in case of an outbreak. However, a small majority (53%) considers the financing is not timely. MSs applying for a grant to compensate costs of emergency measures have to take measures immediately, and to submit the request afterwards. The data provided by the Commission show that payments to the MS before the implementation of the Regulation could take place three or more years after the costs have been incurred.

Respondents to the questionnaire have been asked for factors playing an important role in achieving results and listing the main obstacles. Most important factors are: the financial contribution by the EU; the timely and high quality decision making; the commitment of skilled employees. The major observed obstacles are: the administrative burden; a complex decision making in the case of multiple pests and diseases; lack of human resources.

The majority of respondents to the targeted questionnaire agree that the co-funded survey programme contribute to achieve the specific objectives of the Regulation. At least 65% of the respondents answered that they fully or to a large extent agree with respect to the achievement of the objectives of enhanced bio-security control, prevention or eradication relating to plant health. With respect to sustainable pesticide use, only a minority have chosen those answers.

The outcome of the target interviews indicates that the overall effectiveness of the **EURL** programme is high. Most EURLs (76%) believe the eligible cost categories listed in the

⁴ Availability of well trained staff differs between countries. EU MS recognise that well trained staff contributes to success of the programmes, and, conversely, if not available, may deteriorate the performance of the programmes

Regulation are sufficient. The remaining minority of EURLs give examples of cost categories they believe are missing, such as: subcontracting; import of biological material from EU countries or third countries; website; publication fees; costs for quality management; training for EURL staff. The support from NRLs to contribute to the fulfilment of the tasks of the EURL is considered to be very strong. 52% of the respondents consider that they do not have sufficient mandate (in the meaning of influence, deciding power, and authority) in their relation with the NRLs to contribute to a high quality of analytical results at the NRLs. They suggest that EURLs might be more systematically consulted as regards the revision of regulations of concern for them.

On the effectiveness of the **BTSF** initiative, a very large majority of stakeholders considered the workshop as well as sustained training missions (STMs) to be extremely or very effective, while the e-learning modules were considered to be moderately effective in terms of improving the official controls. The positive points are: better communication and networking between countries; e-learning tools are a good way to teach basic skills and can reach many people; STMs allow more intensive mentoring and experts can monitor the progress; e-learning is available in different languages. Some points for improvement are: technical difficulties with the e-learning programme; workshops and STMs are limited in the number of participants.

All of the participants agree that BTSF has improved official controls of food safety, especially with regards to the improvement of inspection protocols (56% of participants); some participants gave other reasons, such as the improvement of competencies of staff involved, of laboratory testing skills and of harmonization with EU rules.

80% of the participants indicates that they can send sufficient staff to the programmes. Of the remaining 20%, 56% considers that the programme offers insufficient places due to limits for participation, while 22% answered that CAs staff has no additional time due to workload. Most NCPs believe enough staff can participate in the programme, but the limited number of participants for the workshops and STMs is by some considered as restrictive since these are the most effective programmes. Another shortcoming is the language barrier, as not all the staff speaks English.

EFFICIENCY

On efficiency for **Animal Health measures**, veterinary measures were considered very efficient by all but one respondent.

There were a number of comments on the timing of the payments for emergency measures: it was suggested to receive part of the eligible amount in advance at the beginning of an outbreak to support MSs in allocated adequate resources since an early stage. One respondent indicated that, in case that there is uncertainty about getting EU co-funding, the difference in opinions about the interventions to be put in place may prevent that measures are implemented. 35% of the respondents consider the overall budget for emergency measures as appropriate, whereas 40% indicated that the budget should be increased.

For veterinary programmes, more than 90% of respondents considered resources were efficiently or very efficiently employed in animal health prevention, notably by: preventing transmissible diseases in animal and zoonoses; preventing the occurrence of outbreaks of animal diseases and zoonoses which pose a risk to human and animal health; reducing the number of outbreaks, and; controlling the presence of transmissible diseases. A number of respondents indicated that the timeframe between the implementation of the measure and the

financing provided is too long. This is considered to have a negative impact on the effective execution of the measures.

On efficiency for **Plant Health measures**, most respondents are satisfied with the extent to which the immediate eradication of outbreaks of quarantine pests has been achieved. Around 75% considers this efficient or very efficient. The vast majority of respondents is satisfied with the extent to which the timely detection of pests has been achieved by Plant Health measures. Around 80% considers this as efficient or very efficient. Respondents of public bodies (MSs CAs and the European Commission) are more positive than respondents from private organizations.

No respondents consider the available budget is too high. More than half of the respondents argue for higher budgets and also half of respondents argue for an adjusted allocation of the budget over different measures.

Overall, the **EURLs** activities were considered to be efficient. 70% of the EURLs think that modern techniques (e-learning, webinars) could be used to increase efficiency, but these are very costly to develop and introduce, and cannot fully replace face to face meetings that is needed for in-depth technical discussions, and an essential part of the laboratory networking. A small majority of EURLs (58%) consider that EURLs with multiple mandates can work more efficiently than EURLs with a single mandate. However, economy of scale might only be reached for administrative and organizational aspects of EURL activities (workshops, sending out samples for PTs), but not for technically highly advanced laboratory work that is very compound-specific. A mandate as EURL for a limited period of time instead of an undefined period of time is considered not efficient by almost all respondents. 55% of respondents indicated that the EURL would not gain efficiency when its mandate would be extended.

95% of participants of the survey answered that there is sufficient communication between them (the NCPs) and the CA in their country on the **BTSF** programme. There were no suggestions on how to improve the communication. 88% of NCPs answered that there is sufficient communication between them and DG SANTE on the BTSF programme. The communication to the CA is thought to be efficient by the NCPs. The communication with the Commission is overall considered efficient, but could be improved by more meetings and minutes of these meetings. Also, a quick response to questions would make BTSF more efficient, since a slow response gives a delay in actions.

COHERENCE

On coherence for **Animal Health measures**, all respondents evaluated the animal health policy at least complementary and/or synergistic. Regarding whether state aid related to animal health emergencies was consistent with the Regulation emergency funding, respondents from the Commission and the MSs' CAs evaluated it as neutral to complementary. EU branch organisations consider the Regulation to be complementary and or synergistic. Two respondents (out of 40) evaluated state aid to be contradictory.

On coherence for **Plant Health measures**, the vast majority considers the Regulation as coherent with EU plant health policies. 40% considers it as synergistic and 50% as complementary. Only 1 respondent observed contradictions.

On **EURLs**, most NCPs are familiar with Regulation (EC) No 882/2004, which is considered fully (44%) or to a large extent (34%) coherent with the Regulation, according to the

Directors of EURLs. Horizon 2020 and Council Directive 2000/29/EC are not known by most participants. In the few cases that director of EURLs are familiar with H2020 and Council Directive 2000/29/EC, they are of the opinion that these are in synergy with the Regulation.

When asked about the coherence of **BTSF**, 41% of NCPs indicated that Regulation (EC) No 882/2004 is fully in line with the training programme. Even if most NCPs answered "NA/Do not know" for Horizon 2020 and Council Directive 2000/29/EC, 25% of them considers the programme coherent to a large extent with Council Directive 2000/29/EC, and 18% of NCPs with Horizon 2020. For Horizon 2020 and Council Directive 200/29/EC however, the survey showed that the knowledge is not sufficient for most NCPs.

No conflicts of BTSF with other EU regulation were identified.

2.3 STAKEHOLDERS INTERVIEWS

On the basis of the literature review and the on-line survey, a questionnaire was prepared as guidance for semi-structured interviews with representatives of the European Commission (DG SANTE and DG AGRI), and with selected stakeholders (CAs, industry representatives, targeted NGOs) in a number of MSs.

The interviews were carried out by team members using an interview guide to facilitate uniformity in the way questions are addressed and are answered (avoiding interviewer-bias). The aim of the interviews was to identify achievements, good practices, problems and challenges regarding implementation of the CFF Regulation. The main purpose of the interviews was to fill information gaps that remained after the other stakeholder consultations.

A number of scoping interviews with Commission's representatives involved in the implementation of the Regulation and with its evaluation were also conducted at the start of the evaluation study.

2.4 TARGETED STAKEHOLDER INTERVIEWS FOR MAIN STUDY

Based on the assessment of the results from the questionnaires, several stakeholders were identified to be interviewed. Due to unavailability and/or unresponsiveness and the mandatory deadlines of the reporting, no main stakeholder interview could be completed for France.

The interviews with the main stakeholders in general confirmed the findings of the on-line questionnaire. There was general agreement among stakeholders that co-funding opportunities provided by the Regulation on animal health are an essential tool to ensure disease prevention and the timely and efficient control of animal diseases. Some specific points were mentioned by Copa-Cogeca (the EU union representing farmers and agricultural co-operatives), which strongly supports the animal emergency measures, but recommends preventive measures that "address the sources where outbreaks are". This confirms an overall call for specific attention for preventive measures in the Regulation.

2.5 CASE STUDY INTERVIEWS

Based on the assessment of the results from the desk study and questionnaires, several stakeholders were identified to be interviewed for the case studies. Due to unavailability and/or unresponsiveness of some stakeholders and the mandatory deadlines of the reporting,

no interviews could be completed for salmonellosis, and for bovine ovine and caprine brucellosis.

The case study interviews overall confirmed the findings from the targeted on-line questionnaire, but allowed a more in-depth evaluation of the interaction between the Commission and CAs, especially in terms of flexibility and administrative burden.

3. FEEDBACK TO STAKEHOLDERS

The participants to the open consultation and targeted consultation have been informed about the nature and set-up of the evaluation, and that the findings would be used for analysis, and that the EU would communicate about the results of the study. The interviewees received an interview transcript for review after the interview was conducted, with the invitation to amend or approve the transcript.