TECHNICAL SPECIFICATIONS

SANTE/2017/E5/076

Study supporting the Evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition

DG Unit: SANTE E5 (assisted by A1, A3)

1. CONTEXT/INTRODUCTION

This annex provides the terms of reference (ToR) for a study to be carried out by a contractor intended to support the evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition[1].

The purpose of this ToR is to describe the aim and scope of the study and give instructions and guidance for submitting a tender.

1.1 Background of the existing intervention

Feed additives are products used in animal nutrition to improve the quality of feed and the quality of food of animal origin, or to improve the animals' performance and health. Feed additives may not be put on the market unless authorisation has been given following a scientific evaluation demonstrating that the additive has no harmful effects on human and animal health and on the environment and unless it is established that they have specific effects determined by the legislator.

The feed additives Regulation is part of a wider legal framework governing food and feed safety such as the Regulation (EC) No 178/2002 "General Food Law"[2], Regulation (EC) No 183/2005 on feed hygiene[3], Regulation (EC) No 767/2009 on the marketing of feed[4], Directive 2002/32/EC on residues in feed[5], Regulation (EC) No 1829/2003 on genetically modified food and feed[6] and Directive 90/167/EEC on medicated feed[7], which is currently being revised.

The feed additives Regulation was adopted in 2003 as part of the actions contained in the White Paper on Food Safety, which aimed to ensure the highest standards of food safety in the EU. With a view to bringing coherence to the EU legislation in a "farm to table" approach, the White Paper announced new rules on additives in feedingstuffs, aimed at clarifying and simplifying pre-

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

[2] Regulation (EC) 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.02.2002, p.1

[3] Regulation 183/2005 which lays down requirements for feed hygiene, OJ L 35, 8.02.2005, p.1

[4] Regulation (EC) 767/2009 on the placing on the market and use of feed, OJ L 229, 1.09.2009, p.1

[5] Directive 2002/32/EC on undesirable substances in animal feed, OJ L 140, 30.5.2002, p. 10

[6] Regulation (EC) No 1829/2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p.1

[7] Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, OJ L 92, 7.4.1990, p. 42

existing legislation laid down in Directive 70/524/EEC concerning additives in feeding-stuffs[8] whose provisions were complex and subject to uneven implementation.

An overview of the legal situation of feed additives before the adoption of the Regulation is presented in a separate Annex to the ToR.

1.2 Objectives of the existing intervention

The general objectives of the Regulation, which reflect the principles of the General Food Law, are:

1. High level of protection of human health
2. High level of protection of animal health and welfare
3. High level of protection of the environment
4. Ensure the effective functioning of the internal market

The details on how the objectives were to be attained are described in this section:

1. To ensure a high level of protection of human health:

   A. Protection of citizens' health by:

   - banning the use of antibiotics as feed additives, thus contributing to fight against antimicrobial resistance;
   - linking certain types of feed additives to an authorisation holder to increase control and traceability;
   - by ensuring adequate supervision and monitoring of feed additives and traceability through a system of authorisation holders;
   - by ensuring enforcement and control at Member State level.

   B. Protection of consumers' health and interests in relation to feed additives:

   - by setting safety and efficacy criteria for feed additives to ensure the consumers are not mislead with regard to the quality of the food.

   C. Protection of workers and users health:

   - by ensuring adequate labelling of feed additives and safe handling of feed containing feed additives through the establishment of a safety assessment for each feed additive authorised.

2. To ensure a high level of animal health and welfare:
   - by ensuring that only safe and efficacious feed additives are placed on the market;
   - by meeting the nutritional and physiological needs of the animals;
   - by ensuring that feed is safe and attractive to animals;
   - by improving digestibility of feed;
   - by introducing a safeguard threshold re-authorising feed additives every 10 years.

[8] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs, OJ L 270, 14.12.1970, p. 1

3. Protection of the environment:
    - by assessing potential harmful effects of feed additives on the environment;
    - applicants have to prove the lack of toxicity of the feed additives on the environment;
    - by authorising feed additives which lower the impact of animal production on the environment.

4. Ensuring the effective functioning of the internal market:

    A. Increase of productivity:

    - by using the appropriate categories of feed additives which increase animal production, stimulate or improve digestion, etc;
    - by meeting the physiological needs of the animals;
    - by reducing the costs of production;
    - by setting common rules for pets and thus developing a growing market;
    - by establishing the public and free EU Register of Feed Additives;
    - by establishing EU guidelines to help applicants build the scientific dossier.

    B. Ensure good functioning of the internal market for feed additives producers:

    - by harmonising the authorisation procedure;
    - by ensuring predictability of authorisations and of categories and functional groups to which the feed additive belong;
    - by ensuring timely authorisations;
    - by setting labelling rules which apply throughout the EU.

Regulation 1831/2003 aimed at simplifying significantly the rules on feed additives, in particular as regards the authorisation process. Authorisations are for specific animal species and with maximum dosage allowed and, for new feed additives, are limited to a ten-year period. Applicants have to demonstrate the absence of any risk for human health, animal health and the environment (safety criteria) and the additive's positive effect for the animal (efficacy criteria). The European Food Safety Authority (EFSA) is assessing the application with respect to set criteria and issues its opinion. Within three months of receipt of a favourable EFSA opinion, the Commission proposes a draft Commission Regulation authorising the additive for a ten year period. All authorisations are renewable for ten year periods upon application at least one year before the expiry date. Authorisations in certain categories are linked to an authorisation holder who is responsible for the placing on the market and the implementation of the post monitoring plan.

The Regulation also phased out in 2006 antibiotics authorised as feed additives and used as growth promoters. The feed additives Regulation was adopted at a time when the focus was oriented towards increase of animal production and performance of production. The current needs of the society have evolved and the focus changed towards sustainable production. In addition problems such as antimicrobial resistance become more prominent to which novel solutions need to be found which may not necessarily fit within the current quite prescriptive system of feed additive authorisation.

In 2003 the feed additives Regulation introduced rules for feed business operators for placing feed additives on the market. The Commission should establish implementing rules for the preparation and presentation of applications for authorisation of feed additives, through comitology and after consultation with EFSA. These implementing rules established in Regulation (EC) No 429/2008 cover general provisions including definitions, general principles; a general description of the studies to be provided with an application for authorisation of feed additives, and specific requirements for specific situations and categories of feed additives. These rules are currently being amended.

State of Play and Preliminary assessment

Since the entry into force of the Regulation in 2004 and until now the Commission has received more than 2000 requests to authorise feed additives. Some 1500 feed additives have been authorised under the new legislation and 6 additives were denied authorisation. Feed additives which were authorised following the Directive 70/524 continued to stay on the market under certain conditions. The Commission withdrew from the market some 2600 feed additives which had been authorised based on the previous Directive.

According to the Regulation, feed additives are granted 10 year authorisations. In order to continue to stay on the market after this period they have to undergo a new scientific assessment by EFSA and be re-authorised by the Commission. Some 1000 feed additives have already undergone this process of re-authorisation.

Based on the experience gained with the authorisation process the following problems have been identified:

- Effects of feed additives (Art 5(3)): EU legislation predetermines the effects that feed additives must have in order to enter the market. However, the evolution of the needs of a modern husbandry or the requests of its sustainability in the context of the fight against antimicrobial resistance cannot be implemented under present provisions. This is seen by the feed additives sector as an obstacle to the development of new products.
- Modification of existing authorisations (Art 13(3)): The Regulation requires the Commission to adopt a Regulation each time there is an administrative change in the authorisation holder (sale of marketing rights, change of legal form of the company, change of EU representative, etc.). These small administrative changes which have to be implemented through Regulation result into several amendments per year.

  Moreover, legal provisions for the modifications of existing authorisations are foreseen only for additives linked to an authorisation holder, but not for the majority of existing generic authorisations of feed additives. For a change of the generic authorisation an applicant has to go through a full authorisation procedure, which is disproportionate.
- Labelling rules for feed additives (Art 16): The labelling requirements on feed additives are not as flexible as the more recent ones established for the placing on the market of feed in the Regulation 767/2009 on feed marketing. For example, the notion of "labelling"- a document accompanying the label, very useful to present additional information on the product - does not exist in the feed additives legislation. Industry is requiring the possibility to use these new tools for labelling.
- Rules on confidentiality (Art 18): the Regulation requires the Commission to take a Decision on each request of confidentiality sent by the applicant and linked to the

authorisation of a feed additive. Commission adopts almost 50 confidentiality decisions every year. This involves a long administrative procedure which includes extensive consultation with the applicant before taking a decision.

- Rules on data protection and data sharing (Art 20): the rules on data protection are set in order to protect know-how and this protection is limited to 10 years. However, before the end of the 10 year period, companies are encouraged to share data in order to avoid repetition on animal tests. The rules set in the regulation are not clear enough to allow the Commission to take a balanced decision on sharing data. Until now, no Commission decision has been taken on requests for data sharing.
- Role of European Union Reference Laboratory (EURL's) (Art 21)- is not enough specified. The Regulation foresees the role of the EURL with regard to a first application for an authorisation but not in case of renewal of authorisations. For example, the methods of analysis presented by the applicant in its first authorisation cannot be re-evaluated by the EURL in the context of a renewal of authorisation due to lack of clear legal basis.

1.3 Rationale and purpose of the evaluation

The purpose of this exercise is to evaluate how the feed additives legislation has performed in delivering its objectives and to what extent it is still relevant.

The evaluation should help the Commission to have a better understanding of where, and why, the current EU legislation has worked well or not so well, identifying factors which have helped or hampered achievement of the objectives. It should allow the Commission to understand whether the legislation is still adapted to the needs of society and in line with other Commission priorities such as fostering jobs and growth.

The evaluation should:

- assess the progress made in attaining the objectives of the existing legislation;
- establish whether the legislation has delivered the expected benefits;
- establish whether the objectives remain relevant; and
- where appropriate, identify potential areas for improvement.

The Feed Additives Regulation has not undergone an evaluation since its entry into force in October 2003. In the light of the 13 years since its entry into force and the finalisation of several hundred authorisations of feed additives and considering the context of the Commission's Better Regulation Policy, an evaluation of the Regulation appears timely and appropriate. Amongst others, the evaluation will look at difficulties which have been identified during its implementation, from experience gained from discussions with the Member States, meetings with the applicants, consultants and from EFSA output. Some such difficulties concern – for example - the operation of certain elements of the authorisation process and exceedingly complex procedures, which impact competent authorities of the Member States, businesses and the Commission.

1.4 Scope of the evaluation

The evaluation will examine the performance and impacts of Regulation 1831/2003 as a whole from the date of adoption in October 2003 until now.

It will cover all Member States and third countries as far as relevant for assessing the competitive position of the EU feed additives industry.

It will focus in particular on the following aspects:

- definitions of the Regulation;
- relevance and legal clarity of provisions and procedures;
- criteria and procedure to authorise feed additives;
- adaptation to technical and scientific progress;
- criteria and procedure for the modification of existing authorisations;
- procedure for confidentiality and data protection;
- quantification of costs and benefits including assessment of administrative burden;
- consistency with the relevant feed legislation;
- labelling of feed additives;
- potential gaps and areas not sufficiently covered by existing provisions that lead to concrete problems on the ground.

The evaluation will look at the interactions with other relevant pieces of EU legislation in food and feed area. It will cover the relevance of the legislation in the context of fight against antimicrobial resistance and against objectives such as animal welfare, sustainable livestock production and protection of the environment. The costs linked to the implementation of the Regulation will be analysed and compared with the benefits achieved. The impact of the legislation on growth and jobs will be assessed as well as the enforcement of the legislation by the Member States.

Evaluation questions

Effectiveness:

1. To what extent did the Regulation meet its objectives (e.g. ensure that feed additives placed on the market are efficacious, safe and ensure the protection of animal health and welfare, human health and the environment)?
    - To which extent did the efficacy assessment of feed additives ensure that feed additives are effective? How do the achievements compare to Directive 70/524?

- To which extent did the safety assessment of feed additives ensure safeguarding human and animal health and the environment? How do the achievements compare to Directive 70/524?
- What elements of the authorisation procedure of feed additives are key drivers for its effectiveness and what elements hinder its effectiveness? Why?
- What role does the risk assessment play in meeting the objectives of the Regulation?
- To which extent did the risk assessment allow sound decision making?

2. How did the Regulation impact the competitiveness of the EU feed additive industry?
   - How does the authorisation procedure for feed additives affect the competitiveness between EU and non EU feed business operators?
   - What factors support or hinder the competitiveness?
   - Which Non–EU countries recognise the EU authorisation procedure to allow companies to directly enter their market and why?

Efficiency:

3. To what extent are the costs of the implementation of the Regulation justified given the benefits achieved?
   - What are the compliance costs and administrative costs linked to the requirements of the Regulation (labelling, monitoring, etc.…)?
   - To what extent are the risk assessment and the risk management process sufficiently cost-effective, efficient and flexible (e. g.: in terms of procedural timeliness)?

Coherence:

4. To what extent are the provisions of the Regulation coherent with the feed legislation (legislation on feed hygiene, marketing of feed, residues in feed, legislation on genetically modified food and feed and medicated feed) allowing for a clear and consistent rules for use of additives in feed. What are the consequences of incoherencies, if any?

5. To what extent are the provisions consistent with other related legislation on food and chemicals allowing for consistent assessment and management of risk (General Food Law, Regulation on classification, labelling and packaging of substances and mixtures (CLP)[9] and Regulation on Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH)[10]? What are the consequences of incoherencies, if any?

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008

[10] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p.1

- Are there loopholes or greyzones to be addressed? How does this impact competitivity?
- Are there overlaps or inconsistencies which hinder effective and efficient application of the regulation?
- What elements support the use of coccidiostats and histomonostats as feed additives?

6. To what extent are the provisions within the feed additives legislation coherent?

Relevance:

7. To what extent has the Regulation been pertinent to addressing the problems identified at the time resulting from previous Directive? (e.g. uncertainty for industry due to lengthy and provisional authorisations and uneven implementation; contribution to antimicrobial resistance due to authorised use of antibiotics; ….)
8. To what extent is the Regulation suitable for addressing the current needs of fight against antimicrobial resistance, sustainable livestock production, animal welfare, protection of the environment?
9. To what extent has the Regulation provided for the possibility and/or flexibility for adaptation to technical and scientific progress?
    - In particular, are the definitions, procedures and criteria in the feed additive Regulation still clear and relevant in the light of scientific and technical developments, in the light of present needs of livestock production and pets?
    - What conclusions may be drawn from the experience so far concerning the re-authorisation process?
    - Is the provision for a '10-year authorisation period' considered to be still adequate?
    - Have there been new issues/developments since the adoption of the Regulation that are not properly addressed by the Regulation (e.g. role of EURL, export of non-authorised feed additives, etc)?
    - Are there any provisions which create unnecessary administrative burden?

EU added value:

10. To what extent has the Regulation achieved results which could not have been achieved by MS action alone and to what extent is EU level intervention still warranted?

2. RATIONALE AND AIMS OF THE STUDY

2.1 Scope of the study

The study to be produced by the contractor shall cover all the issues and respond to all the questions identified in section 1.4. It shall furthermore provide the Commission with an economic analysis of the sector which will be used to assess the state of play and competitiveness of the feed additive sector and to answer the evaluation questions (see below section 2.3).

2.2 Main stakeholders

In preparing the study, input will have to be sought from a broad range of key stakeholders concerned with the application of the feed additives legislation, namely:

a) Public authorities: Member State Competent Authorities (MS CA);

b) Commission representatives (DG SANTE);

c) Representative of relevant EU Reference Laboratories;

d) The European Food Safety Authority (EFSA);

e) Feed additives industry;

f) Farmers;

g) Other stakeholders: citizens, NGO's, research community and other actors which have an interest in the area of feed additives.

As part of the bid, tenderers may provide any further suggestions on appropriate stakeholders (or sub-groups of the stakeholders listed above) and explain why they should be included. The bid should also include indications of how the different stakeholders will be contacted and how the responses will be used in the study.

2.3 Content of the study

(1) Economic overview of the feed additives sector:

The study shall include an economic analysis of the sector which will be used to assess the state of play and competitiveness of the feed additive sector and answer the evaluation questions.

(2) Evaluation questions

The study shall assess the effectiveness, efficiency, coherence, relevance and EU added value of Regulation (EC) No1831/2003. The evaluation questions to which the study shall answer (structured on the basis of the five evaluation criteria) are listed in section 1.4.

3. DESCRIPTION OF TASKS

All tasks performed under this contract shall comply with the Better Regulation Guidelines and the associated Toolbox[11].

Each tenderer is asked to set out in its bid the specific methodology that it proposes to deliver the work, together with a detailed timeline.

3.1 Tasks under the assignment

The contractor should carry out the study in four main phases, including at least the steps illustrated in Sections 3.1.1 to 3.1.4. *Tenderers might suggest in their bid additional relevant evaluation tools.*

All tasks described in these specifications are the responsibility of the contractor but must be carried out in close co-operation with DG SANTE.

The bid should explain how the evidence base for the study will be collected and the approach to the triangulation of data to secure the robustness and validity of the results. The bid shall include the proposed methodology, with an explanation of how the analysis will provide a logical progression from: data collection; analysis of role of EU intervention over time, i.e. analysis of changes over time and consideration of why something has happened and any links to the EU action); identification and validation of findings; to drawing of conclusions.

The bid shall also include:

- *a draft of the evaluation matrix, covering at least: the evaluation questions in section 1.4, judgement criteria, indicators, data sources, methods, limitations, if any;*
- *a draft of the intervention logic developed on the basis of the input in Chapter 1.2.*

3.1.1 Inception phase

Task 1: Structure the study

Under this task, the contractor shall finalise the structure of the process and approach based provided in the accepted bid, taking into account the Commission comments, offered notably during the kick-off and inception meetings. The contractor shall take into account the remarks made by the Commission on the proposal in order to refine and improve where necessary the proposed methodology.

This will all be reflected in a **stand-alone inception report**, which will include:

[11] https://ec.europa.eu/info/better-regulation-guidelines-and-toolbox_en

1) the evaluation matrix which, as a minimum, show the links between the evaluation questions and sub-questions, success criteria, targets / qualitative and quantitative indicators, data sources, analytical methods proposed, stakeholders involved ;
2) the state of play summarising the current situation of the feed additives in the EU and explaining how the intervention has been implemented and what problems have been identified;
3) the intervention logic;
4) a list of all data sources to be used and of data to be collected , the data collection approach;
5) the consultation strategy, including the categories of stakeholders whose input will be collected and details of the type and number of interviews to be conducted;
6) the methodology of the analysis (quantitative and qualitative) that will be undertaken, including the case studies to be performed, and the
7) the timetable for completion of each deliverable
8) develop a baseline scenario based on the input in the Annex "Legal situation before the adoption of the Regulation" and set up points of comparison to be used within the study.

Any subsequent suggested deviation from the process and approach as explained in the accepted inception report must be notified to DG SANTE in a timely manner, providing due justification for the suggested changes and an explanation of any impacts the changes might have on the work to be delivered any associated risks and mitigating measures.

In this phase, and prior to the delivery of the inception report, the contractor shall carry out the preliminary desk and field research to ensure that the approach adopted is robust and sufficient to meet the requirements of the study set out in these terms of reference. As part of this preliminary work, the contractor will make at least four exploratory interviews outside the general interview programme. The contractor's proposals about the latter shall be discussed at the kick-off meeting but the broad aim of the interviews should be to hear stakeholders' views on the Regulation and the approach to the evaluation, as well as to identify sources of relevant evidence. A list of contacts for the preliminary interviews will be set in an Annex to the ToR.

3.1.2 Data collection phase

As part of their bid, the tenderers must explain what will be done to collect data necessary for the purposes of the study. Data collection shall include desk research, gathering of factual evidence (e.g. reports, statistics, case studies), field research and consultation. Tenderers shall identify in their bid the data sources that will be used. The study shall be based on data which is representative of the 28 Member States. Extrapolations from representative samplings may be carried out only if they can be adequately justified. Particular attention shall be paid to the sampling procedure when extrapolation and statistical inference of the data is needed. Extrapolations should be strongly evidence-based and the methodology and assumptions used should be clearly described. Data should be aggregated and presented in a consistent format, to allow for comparisons and for dissemination purposes. All data collected for this study, including primary data collected expressly for the study, shall be provided to DG SANTE at the end of the contract. Primary data are considered the intellectual property of the Commission Services and cannot be re-used in other work without permission. When collecting and analysing primary data, the contractor shall comply with applicable data protection rules.

Task 2: Desk research

The contractor shall take stock and analyse all relevant statistics, complaints, case law and infringements, studies, reports, research and materials issued or endorsed by the EU institutions, European or national stakeholders associations, individual stakeholders, as well as Member States' authorities. An initial list of data sources is presented in section 7.1.

Tenderers should indicate in their bid how data will be validated and used. As new data sources may constantly be added, the list in section 7.1 shall be updated as part of the inception, the intermediate and the final reports. The aim of this iterative task is to ensure that all existing quantitative and qualitative evidence that is pertinent to the study and the wider evaluation is collated, and its relevance to one or more of the evaluation questions presented in section 1.6 ascertained and explained.

A detailed description of the legal situation of feed additives before the adoption of the Regulation is provided as an Annex to the ToR.

Task 3: Implementation of the consultation strategy for the study

All consultations activities run by the contractor and all related documents (e.g. questionnaires, interview guides, lists of people to be interviewed) must be agreed by the Commission. The selection of interviewees shall be based on their knowledge of the subject and agreed with the Commission. In its allocation of time, the contractor needs to foresee sufficient time for these approvals. It should be clear at the stage of finalisation of the questionnaires and interview guides, how the evidence collected is expected to contribute to the various evaluation questions.

The contractor shall collect additional data from all the relevant stakeholders' groups (as described in Section 2.2) and ensure cross-referencing of information, including with the desk research, to identify and address any information gaps arising. To this end the preliminary desk and field research should have been completed (see Task 2).

The contractor shall choose appropriate tools and methods to ensure the coverage of all relevant stakeholders in all Member States. *The approach proposed should be outlined in the bid based on the consultation strategy provided as an Annex* (it will then be confirmed in the inception report). The contractor should make it clear the resources required for each consultation activity outlined and present the expected minimum response rate or number of interviews that will be conducted.

Tenderers shall explain in their bid if there are any specific details or limits to the approach on offer e.g. the number of questions to be asked, the analysis offered in terms of the type of question (open vs closed questions), languages regimes.

The results of the consultation activities shall be summarised in a report covering all the stakeholder consultation activities conducted, reflecting overall positions, highlighting any key differences between the various groups and / or emerging from the different activities. The individual responses to the consultations should be provided no later than 2 weeks after the end of the consultation.

As a minimum requirement the field research should take the form of:

(a) survey – questionnaire(s) adapted to each category of stakeholders and addressed to each of the following stakeholders groups: Member State authorities, EFSA, industry stakeholders, other stakeholder groups.

(b) targeted interviews (minimum 10 face to face interviews and minimum 15 videoconference/audioconference interviews) – addressed to the stakeholders representing Member States authorities, EFSA and industry stakeholders;

(c) a public consultation.

TARGETED CONSULTATION

The contractor should use targeted consultations to collect the views of the different categories of stakeholders. The contractor shall ensure that public consultation and targeted consultations are complementary. Targeted consultation should include the following tools and may be complemented as necessary.

Stakeholder surveys

The contractor shall draft questionnaires in English based on preliminary desk research and explorative interviews (see task 1). Questionnaires may need to be customised to different stakeholder categories such as companies, enforcement authorities, etc. - taking into account their different level of engagement and experience.

In case the answers to the questionnaires are inconclusive (e.g. low response rate, lack of and/or conflicting data), the contractor shall take necessary additional steps to clarify uncertainties and acquire a sufficiently representative sample of the opinions of relevant stakeholders. In particular, this may take form of a series of follow-up interviews with relevant stakeholders (complementary to the general interview program).

Interviews

The contractor shall prepare interview guides, carry out several structured/semi-structured interviews by phone or face-to-face if needed and analyse the results. Interview reports should be drafted to summarise the key points made during each interview, identify how they are pertinent to the study and use the evidence collected therefrom in the conclusions of the study.

Tenderers are expected to explain in their bid how they intend to select the interviewees, along with an indicative number of potential stakeholders to be consulted. The precise number of interviews, issues partners and tools will be presented to the Commission in the inception report for approval. The selection of interviewees should be based on their knowledge of the subject and agreed with the Commission. An interview guide agreed by the Commission should be sent to interviewees in advance. Interview questions shall be tailored to the target group. Interview reports should be drafted to summarise the key points made during each interview.

PUBLIC CONSULTATION

A public consultation of 12 weeks will be undertaken via the Commission central website for consultations[12] at the latest 3 months after the signature of the contract. The Commission will be responsible for preparing the questionnaire in English, French and German and uploading in an appropriate tool (e.g. EU survey). The contractor will be responsible for processing and analysing the results. The public consultation will pose questions in a non-technical language and thus provide the opportunity for the general public to respond.

The contractor shall examine all responses to the consultation and provide a draft summary to the Commission, inter alia, providing information on which stakeholder groups participated and giving an overview of the key points emerging from the consultation.

3.1.3 Data analysis phase.

Task 4: Analysis of the data collected

Tenderers shall identify, as part of their bid, the analysis they intend to conduct, explaining any data requirements and conditions which need to be met in order for said analysis to be performed. It should be clear in the bid, why a particular method is proposed and its pros/cons/risks – particularly if there may be certain issues (e.g. lack of sufficient comparable data) which could prevent the method actually being used.

In the draft evaluation matrix in the bid, the proposed method should be identified for each evaluation question.

See also Chapter 4 below. Considerable emphasis should be placed on the analysis of data available and collected during the study. In addressing the evaluation questions, quantitative indicators should be sought and used as far as possible. In particular, the contractor should map regulatory and administrative costs and benefits stemming from the Regulation. The Contractor must support findings and conclusions by explaining the degree to which these are based on opinion, analysis and objectively verifiable evidence. Where opinion is the main source, the degree of consensus and the steps taken to test the opinion should be given. Implicit assumptions and possible limitations should be clearly explained.

Task 5: Case studies

As part of the bid the tenderer shall propose at least 2 case studies. The bid shall explain the criteria on the basis of which the case studies are proposed. They should reflect the issues at stake and ensure relevant input for the overall exercise.

The contractor shall design and conduct case studies that on the basis of the real application of the legislation inform on causality for and the reasoning behind results and impact observed. It should thus inform the effectiveness and efficiency analysis.

The bid shall include at least 2 case studies covering 10 or more Member States (which will be subsequently agreed with the Commission), and the following themes:

[12] https://ec.europa.eu/info/consultations_en

- *From application to market*. Follow the authorisation process of feed additives from application to market. Such case studies could provide in-depth information on the risk assessment and risk management processes and the impacts on the market, timelines and the respective responsibilities by all stakeholders. At least five feed additives should be selected based on objective criteria and take into account the differences between the feed additives, e.g., the category of feed additive, the market share and use of the feed additive.

-*Labelling of feed additives.* Follow the labelling process for three different feed additives and three different premixtures until the placing on the market.

Task 6: Economic overview of the feed additives sector

An economic analysis of the sector of feed additives in the EU and worldwide will have to be provided. This will include an overview of the structure of the market (size and turnover of producers, analysis of the added value chain, etc.…) and the data acquired should be used to answer the evaluation questions.

It will include:

1. feed additives for pets: Overview with a quantitative and a qualitative analysis of the sector (EU and worldwide) including the following information (not exhaustive): domestic production, imports and exports (in value and in volumes over the last 10 years), employment, number and size of enterprises, geographical location, turnover and added value.

2. feed additives for livestock: overview with a quantitative and a qualitative analysis of the sector (EU and worldwide) including the following information (not exhaustive) Domestic production, imports and exports (in value and in volumes over the last 10 years), employment, number and size of enterprises, geographical location, turnover, and added value.

3.1.4 Synthesis phase

Task 7: Conclusions and recommendations

Based on the results of tasks 1-6 the contractor shall provide its conclusions for each evaluation question and summarised for each evaluation criterion. There should be a clear and logical progression between the results presented, the answers to the evaluation questions provided and the conclusions being drawn.

4. METHODOLOGY TO BE FOLLOWED

As a general principle, the methodology should respect the principles of objectivity, reliability and evidence based assessment, and should comply with the requirements of the Better Regulation Guidelines. Where relevant, tools proposed in the Better Regulation toolbox should be taken into account and made use of. Administrative burdens, if significant, should be quantified using the Standard Cost Model. Regulatory costs and benefits shall be defined according to Chapter 8 of the Better Regulation toolbox. Any further tools proposed should be sufficiently explained in the bid to allow DG SANTE to judge their merits and suitability.

In their bids, the tenderers have to outline the proposed methodological approaches for each of the tasks mentioned in Chapter 3.

More specifically the tenderers must take account of the following:

The study must be based on recognised techniques and methodologies and be conducted in such a way that the results are supported by evidence and rigorous analysis. Soundness and robustness of findings must be ensured and justified. For this purpose, triangulation of methods is required.

The tenderer should also explain advantages, limitations, and risks involved in using the proposed tools.

5. REPORTING AND DELIVERABLES

5.1 General reporting requirements

The present assignment includes the submission of a series of deliverables such as reports and presentations, in accordance with the Quality Checklist provided as an Annex.

The Contractor shall deliver the following reports at key stages of the evaluation process, using for the final report the appropriate template provided in the Annexes to the ToR: kick-off meeting report, monthly progress report, inception report, interim report, draft final report, final report with executive summary.

All reports must be drafted in English, professionally edited and critically assessed as they provide the basis for tracking the quality of the work done by the Contractor and submitted according to the timetable below to the Commission in electronic format. Electronic files must be provided to the Commission in MS-Word with the charts in Excel. Additionally, besides Word, the Final Report must be delivered in Adobe ® Acrobat pdf format and in three hard copies.

All reports shall be delivered in two versions, one final and one with track changes, and shall be accompanied by a summary document describing if and how all comments made on the previous deliverable have been taken into account, on a comment by comment basis.

Each report (except the final version of the Final Report) should have an introductory page providing an overview and orientation of the report. It should describe what parts of the document, on the one hand, have been carried over from previous reports or been recycled from other documents, and on the other hand, represent progress of the study with reference to the work plan. They should be accompanied, where requested, by appropriate annexes and delivered in accordance with the deadlines and requirements set out in the Terms of Reference.

Reports must be approved by the Commission which will consult an Inter Service Steering Group on all deliverables. The Commission may ask for complementary information or propose adjustments in order to redirect the work as necessary.

It is essential that all the reports are clear, concise, unambiguous and comprehensive. They should also be understandable for non-specialists. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be

published. A structured and precise elaboration of add-ons based on previous deliverables at every stage of the process is requested, for instance, this could be done via colour-coding parts of the report developed at the tender, inception, interim and draft final stage.

5.2 Inception Report

At the latest 1 month after signature of contract.

It should include the points 1 to 8 set out in "Task 1: Structure of the study"

The contractor's strategy to formulate inputs to evaluation questions shall be summarised in an evaluation matrix (example see table below) and included in the Inception Report, together with a complete intervention logic.

Evaluation questions	Judgement criteria/evaluation indicators	Data sources/lines of evidence	Data collection method	Analytical methods to process the data
Relevance				
Q1.				
Q2.				
…				

An inception report will describe the methodology proposed by the Contractor and how it is going to be implemented in detail, after e.g. having further examined the sources of secondary and primary data that will be used for the study. It shall not exceed 40 pages, annexes excluded.

The inception report will be discussed with the Commission in order to finalise the study methodology in a meeting held in Brussels 2 weeks following its delivery. The Commission will send written comments to the Contractor at the latest 2 weeks after the meeting held in Brussels, after which the Contractor has 2 weeks to submit a final version of the inception report.

The inception report will show the understanding of the task by the Contractor and completes the structuring phase of the study, the study design, fine tune the methodology (ies) combining quantitative and qualitative tools. It aims at describing the organisation of the work, adapting and substantiating the overall approach, the methodology and working assumption required for each evaluation question, and/or specific task requested, as well as the work plan outlined in the proposal.

The Contractor will submit the draft questionnaires for the surveys and indicative interview guides used for the consultations. The questionnaires will be discussed and before launching the surveys the questionnaires need the final approval by the Commission. The known sources of information, contact persons in Member States, as well as the way the Contractor will interact

with Member States representatives should be fully clarified at the kick-off meeting. The inception report should also include a draft list of case studies and the approach how they will be carried out. The final list of case studies will be agreed with the Commission.

5.3 Interim Report

At the latest 6 months after signature of contract.

The report is to be produced after the desk and field research has been completed, and should include a summary of the results so far and a first analysis.

The report must as a minimum provide:

- An overview of the status of the study;
- A description of problems encountered and solutions found;
- A summary of initial findings and results of the data gathering;
- An assessment of the data, whether it meets expectations and will provide a sound basis for responding to the evaluation questions;
- A conclusion whether any changes are required to the work plan, or any other solutions should be sought in order to ensure that the required results of the study are achieved. If any such issues are identified, they are subject to approval by the Commission;
- A proposal for the final structure of the Final Report, as well as a structure of the Executive Summary.

The report must not exceed 80 pages, annexes excluded and should allow for checking whether the study is on track and whether it has focused on the specified information needs, and also allow for a decision on any necessary remedial measures.

The interim report will be discussed with the Commission in order to clarify any outstanding issues in a meeting held in Brussels 2 weeks following its delivery. The Commission, may request changes and will send written comments to the Contractor at the latest 2 weeks after the meeting held in Brussels, after which the Contractor have 2 weeks to submit a final version of the interim report.

5.4 Draft Final Report

At the latest 9 months after signature of contract.

This document should deliver the results of all tasks covered by these Terms of Reference and must be clear enough for any potential reader to understand.

The report should take into account the comments made earlier on in the process by the Commission and be divided into a main report and annexes. The main report is limited to 130 pages and should present, in full, the answers to the evaluation questions, the results of the analyses and conclusions of the study. It must contain a description of the study, the context of the evaluation study, and the methodology used (including an analysis of its strengths and

weaknesses). The annexes should collate the technical details of the study, and must include questionnaire templates, interview guides, and any additional tables or graphics, as well as references and sources.

The draft final report will be discussed with the Commission in order to clarify any outstanding issues in a meeting held in Brussels 2 weeks following its delivery. The Commission, may request changes and will send written comments to the Contractor at the latest 2 weeks after the meeting held in Brussels, after which the Contractor have 2 weeks to submit a final version of the draft final report.

5.5 Final Report

At the latest 11 months after signature of contract.

The Final Report follows the same format as the draft final report. The document must take into account the feedback from the Commission on the draft final report, insofar as these do not interfere with the autonomy of the Contractor in respect of the conclusions they have reached.

The Commission may request changes and will provide written comments to the Contractor at the latest 4 weeks following the delivery of the final report, after which the Contractor have 2 weeks to submit a final version of the draft final report.

The final report must be structured along the lines of common standards, formatted as requested by the Publication Office, respecting the Commission's visual identity and containing all identifiers and disclaimers, and should include:

- **Table of contents**
- an **Abstract** of no more than 200 words in English, French and German. The purpose of the abstract is to act as a reference tool helping the reader to quickly ascertain the evaluation study's subject;
- an **Executive Summary** of no more than 6 pages (1 page = 1500 characters). The Executive Summary summarises the evaluation study's main conclusions and the main evidence supporting them (factual data and synthesis of analysis). After being agreed with the Commission, it should be translated into French and German by a professional translator;
- an **Introduction** outlining the purpose and scope of the study;
- a **Background** with a description of the measure and its objectives (intervention logic), baseline scenario and state of play;
- a section on **Methodology**, explaining how the study has been carried out and over what time period. Provide a transparent account of what has been done, any changes from the original plan and any mitigating measures taken. List any known limitations e.g. data, timing, etc. and explain the mitigating measures taken. An overall analysis of the reliability of the available data should be included. Detailed information in the annexes;

- a **State of play** summarising the current situation of the feed additives in the EU and explaining how the intervention has been implemented and what problems have been identified;
- a section with all the **Answers to the evaluation questions** which should be analytical, using tables/graphs/pictures to illustrate the analysis. Use the information collected to analyse how far the outputs and outcomes observed match the expectations stated when the initiative was adopted. Bring together different sources of data, clearly referenced so that the reader can investigate further if they wish, and provide unbiased and critical judgements of what has or has not been achieved. If there is insufficient data or evidence to do so, this should be clearly stated. Ensure triangulation of data;
- **Conclusion** which should summarise the main conclusions of the study by the five evaluation criteria. There should be a clear and logical progression between the results presented, the answers to the evaluation questions provided and the conclusions drawn;
- **Technical annexes**, minimum annexes concerns: task specifications, compilation of all requested country-based information, procedural information concerning the process to prepare the study, stakeholder consultation, and methods and analytical models used in the study. The report must also include a **synopsis report** of the different consultation activities that took place analysing the results of all the consultations carried out during the study. This synopsis report should include, at least:
    - A key outline of the consultation strategy, referring to the consultation objectives as defined, identified stakeholders and selected consultation methods and tools;
    - Documentation of each formal consultation activity, including, if applicable, an explanation as to how and why the initial consultation strategy was modified;
    - Information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached;
    - Short description of the methodology and tools used to process the data;
    - Description of the results of each consultation activity, including qualitative and interpretative analysis; if different consultation activities have been undertaken in the context of the same consultation scope, a comparison of their results including interdependencies, consistencies or contradictions in relation to contributions and main stakeholder categories;
    - Information on identified campaigns for public consultations (where organisations call their members to participate in the consultation with suggested responses). The information should include the share of contributions and their viewpoint;
    - For ad hoc contributions received outside the formal consultation context, a separate paragraph should be added describing the origin of the contributions;
    - Where applicable, a paragraph summarising the feedback received on the roadmap;
    - Explanation on how the information gathered in the context of the consultation work as well as feedback received has been taken into account into the further work on the initiative, evaluation or fitness check. Where relevant, this should include explanation on why certain widely supported views were not or not entirely considered;
    - If national Parliaments have contributed, it is recommended to inform in a separate paragraph which national Parliament contributed (Member State and chamber) and what issues they addressed.

The Commission will publish the final report, the executive summary, the abstract, the annexes and a summary of the quality assessment of the evaluation study's final report on the Commission's website.

In principle, the Commission will publish all studies. For this purpose, the contractor must ensure that there are no restrictions based on confidentiality and/or intellectual property rights expected from a third party.

In order to ensure the necessary level of quality for the study, the Contractor should always bear in mind that:

i. The study must respond to the information needs, in particular as expressed in the evaluation questions and task specifications, and following discussions with the Commission;
ii. The methodology and design must be appropriate for obtaining the results needed to address the tasks and answer the evaluation questions;
iii. The collected data must be appropriate for their intended use and their reliability must be ascertained;
iv. Data must be analysed systematically to address the tasks and answer the evaluation questions and to cover all the information needs in a valid manner;
v. Findings must follow logical from and be justified by the data/information analysis and interpretations based on the pre-established criteria and rationale;
vi. To be valid, conclusions must be non-biased and fully based on findings and supported by data;

The study must comply with the quality criteria and the state of the art in the field, and assessments should be well argued on the basis of rigorous qualitative and quantitative analysis. The reasoning followed in the analysis, indicating among other things, the underlying hypotheses of the reasoning, and the limitations of the analysis, must be clearly described. Any judgements provided should be clear and explicit. The study should be conducted in such a way that the results can be used to improve policy decision-making and thus improve future actions.

In view of its publication, the final report by the contractor must be of high editorial quality. In cases where the contractor does not produce a final report of high editorial quality within the timeframe defined by the contract, the Commission can decide to have the final report professionally edited at the expense of the contractor (by deduction of these costs from the final payment).

The contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes. At the request of the Commission, the contractor should provide presentations to interested stakeholder groups, as it may be needed.

The copyright of the reports remains with the Commission.

5.6 Raw data

Any non-processed raw/source data (datasets, replies to surveys, replies from different sources, etc.) collected within this Study shall be provided to the Commission together with the final report.

6. ORGANISATION, TIMETABLE AND BUDGET

6.1 Organisation

The contract will be managed by Unit E5 "Animal nutrition, veterinary medicinal products" of the European Commission Directorate-General for Health and Food Safety.

A steering group will be involved in the management of the evaluation. This steering group is consulted and will comment on all deliverables from this contract and will contribute to the quality assessment of the Contractor's work.

6.2 Meetings with the Commission

It is expected that the Contractor participates in up to six meetings in Brussels with the Commission. For these meetings, minutes should be drafted by the Contractor, to be agreed among the participants. **The travel and subsistence costs incurred for these meetings are not reimbursed separately and they must be included in the staff fees.**

6.3 Proposed team

The tender must include a description of the proposed team, its composition, its expertise and the work effort planned for each member in terms of man/days for each task of the project.

The contractor is expected to put together a strong and experienced team of a minimum of 4 members to perform the specified services.
The team should include:

- a team leader (senior contractor) category II with complete university degree.
- a coordinator of category III with complete university degree.
- two experts of category IV.

Considering the scope of the study, it is required that the team will have expertise in the fields of law, economics and science in relation to the questions presented. The team must have the capacity to process and analyse complex economic data related to health, environmental and consumer-related topics. The team should furthermore demonstrate knowledge of the feed additives market (both globally and within the EU), including authorisations, marketing and use of feed additives, production and trade, the role of innovation, and research and development.

The project leader must be fluent in English and the team must have the capacity to work in all languages needed for the data collection.

6.4 Timetable

The indicative starting date is Q1 2018. The contract will start after both parties have signed it. The period of execution of the contract is 11 months.

Kick-off meeting(within two weeks of the signature of the contract)

After signature of the contract, the Contractor will participate in a kick-off meeting, which will be held in Brussels. The overall objective of a kick-off meeting is to arrive at a clear shared understanding of what is required by the Commission. In particular, the meeting should therefore accomplish the following:

- Introduction to the Commission of the Contractor's team members and verification of the composition and eligibility of the Contractor's team.
- Review of the project scope and objectives and ensure the Contractor's general understanding of the Terms of Reference.
- Review of the overall planning/timelines and milestones.
- Review of the project responsibilities and deliverables (including their structure).
- Verification of the proposed general approach to the work methodology.
- Validation of the proposed workflow.
- Identification of main challenges.
- Confirming next steps.

Following the meeting, a clear set of minutes detailing agreements and conclusions should be drawn up by the Contractor and approved by both parties.

The following outline work plan and indicative timetable are envisaged:

Deadline (from starting date)	**Task**
Inception Report [T0 + 1 month]	Contractor provides the Commission with the inception report. A meeting is organised in Brussels 2 weeks after delivery of the report. *First payment*
Interim Report [T0 + 6 months]	Desk and field research completed. Contractor provides the Commission with the interim report. A meeting is organised in Brussels 2 weeks after delivery of the report.
Draft Final Report [T0 + 9 months]	Contractor provides the Commission with the draft final report. A meeting is organised in Brussels at the latest 2 weeks after delivery of the report.
Final Report [T0 + 11 months]	Taking account of the Commission's comments the Contractor sends the final report and executive summary to the Commission. *Final payment*

6.5 Budget

The estimated maximum budget for the study of the action, covering all the results to be achieved by the Contractor as listed above, is **EUR 125000.**

6.6 Award Formula

The weighting applied to the award formula is "40/60" whereby price shall count for 40% and quality for 60%.

$$\text{score for tender X} = \frac{\text{cheapest price}}{\text{price of tender X}} * 100 * 40\,\% + \text{total quality score (out of 100) for all award criteria of tender X} * 60\,\%$$

7. REFERENCES

7.1 Basic documents

1. The website of DG SANTE provides for useful information on feed additives: https://ec.europa.eu/food/safety/animal-feed/feed-additives_en

2. The fitness check on the General Food Law Regulation is about to be finalised and the Commission Staff Working Document is expected to be published in June 2017. There have been two external studies in support of the fitness check.

   - Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation")
   - Study on RASFF/Emergencies/Crisis management

3. EU Register of feed additives: Register of feed additives authorised for use in the EU under the provisions of Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

4. Rapid Alert System for Food and Feed (RASFF): Notifications of any serious health risks deriving from feed additives (by selecting relevant hazard category) and any measures taken:

   https://ec.europa.eu/food/safety/rasff_en

5. EFSA Panel on Additives and Products or Substances used in Animal Feed:

   https://www.efsa.europa.eu/en/panels/feedap

6. Health and Food audit reports: DG SANTE audits, inspections and related non-audit activities aimed at ensuring that EU legislation on food and feed safety is properly implemented and enforced:

   http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

7. EFSA Chemical Contaminants Occurance data: Aggregated statistics on the analysis of data collected from the Member States as regards chemical contaminants found in food or feed due to food production, distribution, packaging or consumption:

   https://www.efsa.europa.eu/en/data/chemical-contaminants-data

8. Report on the use of coccidiostats and histomonostats as feed additives

9. A review of the work of the EU Reference Laboratory supporting the authorisation process of feed additives in the EU

10. Fitness check of the most relevant chemicals legislation:

http://ec.europa.eu/environment/chemicals/better_regulation/index_en.htm

11. The REACH REFIT Evaluation:

http://ec.europa.eu/environment/chemicals/reach/review_2017_en.htm

12. Summary minutes of the Standing Committee on Plants, Animals, Food and Feed, section Animal Nutrition:

https://ec.europa.eu/food/animals/committees/sc_animal-nutrition_en

8. REQUIREMENTS

8.1 Resources

The Contractor is responsible for proposing the adequate team of evaluators to be involved, describe their skills and qualifications, quantify the input of each member of the team in terms of days and explain the distribution of tasks between the different evaluators.

The Contractor shall also ensure that experts are adequately supported and equipped. In particular, sufficient administrative, secretarial and interpreting resources, as well as junior experts, must be available to enable senior experts to concentrate on their core evaluation tasks.

8.2 Absence of conflict of interests

The Contractor shall ensure that both their organisation and the individual experts proposed for this study are not in a situation of conflict of interest regarding this specific assignment, and shall include a Declaration of absence of conflict of interest as part of their offer. In addition, the Staff Regulation cooling off period needs also to be respected in case the project works with former European Commission staff.

8. OWNERSHIP OF THE RESULTS

The Commission retains all rights relating to the reports and other deliverables produced under this contract and to their reproduction and publication under the conditions as specified in Article II.10 of the General Conditions of the Framework Contract. The Commission will be responsible for deciding the possible dissemination of the findings and conclusions of the assessment and its related materials produced under this work contract.

9. ANNEXES

1. Consultation strategy
2. Legal situation of feed additives before the adoption of the Regulation
3. Roadmap
4. List of contacts for preliminary interviews