TERMS OF REFERENCE – Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)

Contracting Authority: European Commission

1. CONTEXT

1.1 Background

Plant protection products (PPPs) and their residues are regulated in the EU by Regulation (EC) No 1107/2009[1] and Regulation (EC) No 396/2005[2]. The regulations are included in the REFIT program of the European Commission and should be evaluated in order to assess if they meet the needs of citizens, businesses and public institutions in an efficient manner.

PPPs, also called *pesticides*, are used to protect plants against pests or diseases. The Commission approves active substances, i.e., the agent used to achieve the protective effect, for the use in PPPs. In order to protect consumers, the Commission also sets maximum residue levels (MRLs) for pesticides, i.e., the highest levels of pesticide residues that are legally tolerated in or on food or feed, including imported products.

Regulation (EC) No 1107/2009 is in force since June 2011 and lays down the rules and procedures for approval of active substances and authorisation of all PPPs on the EU market. Prior to the entry into force of this Regulation, PPPs on the market were regulated by Directive 91/414/EEC[3]. However, after years of experience gained from the implementation of the Directive, it appeared necessary to improve certain aspects related to the approval and authorisation procedure and also adapt it to new scientific and technical developments.

Regulation (EC) No 396/2005 sets MRLs for pesticides in or on food and feed to protect all consumer groups. This regulation is applicable since September 2008 with the entry into force of Regulation (EC) No 2008/149[4]. Previously, apart from some exceptions regulated at EU level[5], most MRLs were set or regulated at national level[6] resulting in a fragmentation of the internal market for food products and difficulties for importers having to deal with differing national rules on MRLs. The 'national approach' also generated concerns about the safety of pesticide residues to consumers as foods exceeding the MRLs in one Member State would be acceptable in others.

The objective of the evaluation is to perform an evidence-based assessment of the implementation of the PPP and MRL regulations and address synergies, gaps, inefficiencies and burdens in line with the objectives of the REFIT programme. The external study will be an input in the evaluation which will inform the Commission in its decision-making and could be useful to improve the implementation on the EU rules on pesticides.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
[2] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/
[3] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.
[4] Commission Regulation (EC) No 149/2008 of 29 January 2008 amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto, available at
[5] See e.g., Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals; Council Directive 90/642/EEC of 27 November 1990 on the fixing of maximum levels for pesticide residues in and on certain products of plant origin, including fruit and vegetables.
[6] See the analysis on the legal framework prior to the adoption of Regulation (EC) No 396/2005 reported in the Explanatory Memorandum of the Proposal COM/2003/117 final.

1.2 Objectives of the pesticide legislation

The objectives of the pesticide legislation are broken down into general, specific, and operational objectives. The initial proposals - COM(2006)3887[7] and COM(2003)1178[8] - leading respectively to Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 explain in more detail which were the objectives of the initiatives leading to their adoption.

1.2.1 General objectives of the pesticides policy area

- to ensure a high level of protection of human and animal health and the environment with regard to PPPs used in the European Union;
- to ensure a high level of protection of human health with regard to pesticide residues on food and feed of plant and animal origin;
- to improve the functioning of the internal market for plant protection products and for food and feed of plant and animal origin;
- to safeguard the competiveness of the European agriculture and improve agricultural production.

1.2.2 Specific objectives of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005

- to ensure coherence of the rules and procedures between the placing on the market of PPPs and MRL setting;
- to facilitate the substitution of hazardous substances with other substances or by alternative methods;
- to ensure safety for users, consumers, bystanders, animals and the environment, including vulnerable groups of consumers;
- to allow an efficient use of resources for risk assessment and risk management in the policy area of pesticides;
- to shorten the time for new products to come on the market;
- to make relevant information available for applicants, importers, users, public authorities and consumers.

1.2.3 Operational objectives of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005

- to ensure that only authorised PPPs, that fully comply with their conditions of authorisation, are placed on the market and that these products are used in line with their conditions of authorisation;
- to define clear criteria for risk assessment, risk management, MRL setting and establish data requirements for active substances and PPPs as well as rules on labelling;
- to establish geographical zones for mutual recognition according to climatic, agronomic and other relevant conditions and facilitate the mutual recognition of PPPs;

[7] European Commission, Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market, COM(2006)388 final, Brussels, 12.7.2006.

[8] European Commission, Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products of plant and animal origin, COM(2003)117 final, Brussels, 14.3.2003.

- to set a centralised procedure for active substance approvals and MRL setting and coherence of rules / procedures between placing on the market of PPPs and MRL setting;
- to facilitate the sharing of tests and studies involving vertebrate studies and allow to take into account the newest scientific evidence;
- to set harmonised rules for controls / monitoring;
- to define clear responsibilities for the EFSA, Member States, Commission (risk assessment, risk management, control) in active substance approvals, product authorisations and MRL setting;
- to link approval, authorisation and MRL setting procedures, simplify procedures and shorten approval times for active substances and PPPs;
- to implement simplified data protection and data sharing provisions.

1.3 Description of the intervention and intervention logic

1.3.1 Activities

The objectives of the regulatory framework for pesticides are to be achieved by certain activities, specified in the PPP and MRL regulations. For example, a high level of protection of human and animal health and the environment is ensured by time-limited approvals and rigorous assessments of the risks of substances for human health, animal health and the environment; a high level of protection of consumers with regard to pesticide residues in food and feed is ensured by setting MRLs at EU level.

In Regulation (EC) No 1107/2009, active substances are approved for 10 years and thereafter re-evaluated in the light of the most recent science[9]. Low-risk substances are approved for 15 years and basic substances have indefinite approval periods. All PPPs undergo a double authorisation procedure before they can be placed on the market. First, a comprehensive assessment of the active substance is carried out by experts of Member States, followed by a peer review performed by the European Food Safety Authority (EFSA). A decision on approval is then taken by the Commission at EU level under the examination procedure. Only when approved, Member States can authorise PPPs containing an active substance in accordance with harmonised EU standards - referred to as the uniform principles[10]. The authorisation defines the origin, the precise formulation, its hazard classification and conditions of use, etc. In order to evaluate active substances and PPPs in the light of most recent science, there are legal acts specifying the EU data requirements for active substances[11] and PPPs[12].

A novelty in Regulation (EC) No 1107/2009 compared with Directive 91/414/EEC is the categorisation of active substances on EU level with certain properties:

[9] See Commission Implementing Regulation (EU) No 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

[10] Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles of evaluation

[11] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

[12] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

- Basic substances with unlimited time approvals,
- Low-risk substances that enjoy longer approval periods and longer data protection,
- "Candidates for Substitution" (CfS): Member States shall assess PPPs containing such substances with the aim of substituting them, whenever possible, with non-chemical control or prevention methods, or by products containing substances that require less risk-mitigation measures.
- Substances that meet the "cut-off" criteria: this concept provides for specific criteria which, in principle, lead to the non-approval of active substances without performing a complete risk assessment. These criteria concern substances with certain properties, such as mutagenic, carcinogenic, toxic for reproduction or with endocrine disrupting properties, or with a combination of persistent, bioaccumulative and toxic properties.

On the basis of Regulation (EC) No 396/2005, MRLs are established following a first assessment by a Member State and a subsequent scientific opinion of EFSA, taking into account international *Codex Alimentarius* levels. Due to climatic conditions and pest pressure in third countries, or for pesticides not approved or crops not grown in the EU, MRLs are set in order to allow for imports of agricultural products - provided that consumer safety is not compromised. The process is analogous to the MRL setting.

Implementing Regulation (EC) No 547/2011 sets out the labelling requirements for plant protection products[13]. The aim is to inform users and consumers of special risks to human or animal health or to the environment, also including potential safety/precaution measures.

The objective of improving the functioning of the internal market is to be reached through harmonisation of the standards underpinning the authorisation and placing on the market of PPPs and the setting of MRLs at EU level. For this purpose, Regulation (EC) No 1107/2009 introduced the zonal evaluation of PPP applications. It entails that the assessment of any PPP application is performed by only one Member State on behalf of the others for each of one of the three geographical zones: *north / central / south*. The system provides for mutual recognition of the zonal evaluation by the other Member States belonging to the same zone.

1.3.2 Intervention logic

The intervention logic for Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 is enclosed as Annex to the Terms of Reference. The diagram maps out the needs that the legislation was aiming to satisfy, the objectives that were defined, the inputs needed, the activities supposed to be carried out, the expected outputs, results and finally the long term impacts of the legislations. The arrows provide guidance how the different elements relate, e.g., which of the actions that were supposed to lead to an expected output and result, etc.

1.4 Implementation – State of Play

Implementing complex legislation, such as the PPP and MRL regulations, is a process that can take several years after entering into force. Although to date, most of the measures and activities are provided under both regulations have been implemented, stakeholders and Member States have on numerous occasions informed about implementation difficulties, e.g., in the areas of

[13] Commission Regulation (EU) No 547/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products.

mutual recognition and authorisation. The situation regarding the implementation of the regulations is as follows.

The initial approval of an active substance is valid for 10 years, after which it must be renewed on the basis of an updated assessment made in light of the most recent scientific evidence. Work programmes[14] have been established to manage the renewal process for all actors involved, specifying the procedure and distributing the work among Member States. The most recent renewal programme (AIR IV) began in 2016[15].

The current list containing active substances identified as CfS was published in January 2015.[16] The comparative assessment to be performed by Member States for applications of PPPs containing CfS is therefore still relatively recent.

Cut-off criteria are applicable since June 2011 for new active substance applications. For the risk assessment, this means that in some cases applicants have included studies in order to demonstrate a negligible exposure. The work to establish criteria to identify active substances with endocrine disrupting properties is ongoing. Before the final criteria are agreed upon, interim criteria should be applied (see point 3.6.5 in Annex II of Regulation (EC) No 1107/2009).

The EU Pesticides database provides a free-of-charge, complete and up-to-date set of data on the status of all active substances (whether approved or not) and on MRLs. It is complemented with the Plant Protection Products Application Management System (PPPAMS), a database on authorisations. The PPPAMS increases transparency of authorisations in Member States as well as facilitating the implementation of mutual recognition and parallel trade permits within zones. Since July 2016, the submission of authorisations under Article 53 of Reg (EC) 1107/2009 (so called emergency authorisations) is mandatory within the system. The Commission is currently working with Member States to collect data on all existing authorisations held in national databases in order to populate the system.

Work is ongoing to identify the co-formulants which are not accepted for inclusion in PPPs. The implementing rules of Article 27 of Regulation (EC) No 1107/2009 are not yet established. A work programme to review safeners and synergists should be established according to Article 26 of Regulation (EC) No 1107/2009, however, this work has not started. The same can be said about the detailed rules for the authorisation of adjuvants, see Article 58 of Regulation (EC) No 1107/2009, which is still to be implemented.

The updating of MRLs is an ongoing exercise as appropriate MRLs are a pre-condition for the authorisation of PPPs. Currently, a comprehensive review exercise of all existing MRLs is ongoing.

Other parts of Regulation (EC) No 396/2005 are not yet fully implemented, e.g., the development and application of a methodology to take into account cumulative and synergistic effects of pesticides is still ongoing. Also, work to establish a list of harmonised concentration or dilution

[14] These work programmes were called "Annex I Renewal" (AIR) projects under Directive 91/414/EEC and "Active Ingredient Renewal" (AIR) projects under Regulation (EC) No 1107/2009. See the page renewal of approval on the DG SANTE website.

[15] Commission Implementing Regulation (EU) 2016/183 of 11 February 2016 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest.

[16] List of candidates for substitution, available at https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_cfs_draft-list.pdf

factors for certain processing and/or mixing operations has not yet started, neither has the establishment of specific MRLs for feed and for fish.

Numerous pieces of secondary law, guidance documents and Commission Staff Working Documents have been published to achieve the objectives of the legislation.[17] EU case-law has provided for further clarification of certain aspects of the pesticides legislation[18].

1.5 Evaluation and Monitoring Provisions

1.5.1 Monitoring Provisions

According to Article 68 (monitoring and controls) of Regulation (EC) No 1107/2009, Member States must carry out official controls in order to enforce compliance with this Regulation and prepare yearly reports to the Commission on the scope and the results of these controls. These reports[19] can provide information on how this Regulation is implemented. Member States shall also submit the information listed in Article 31(1) of Regulation (EC) No 396/2005 to the Commission, the European Food Safety Authority and the other Member States every year. These reports will be made available to the Contractor by the Commission.

According to Article 30 of Regulation (EC) No 396/2005 Member States are to report annually on their national pesticides residues monitoring programmes. On this basis, EFSA prepares an Annual Report including also EU-wide coordinated monitoring programmes. This report gives a good overview on the residue situation in foods on the market. The most recent report is with 2014 monitoring data.[20]

Article 68 of Regulation (EC) No 1107/2009 indicates that the Commission experts shall carry out general and specific audits in the Member States for purposes of verifying the official controls carried out by the Member States. On the basis of this provision, the "Health and Food Audits and Analysis" Directorate of the Directorate General for Health and Food Safety (DG SANTE) carries out audits in Member States. The audit reports cover authorisations, controls on marketing and use, and pesticides.[21]

Under Article 29 of Regulation (EC) No 396/2005 the Commission shall prepare a coordinated Multiannual Community Control Programme. The programme should identify specific samples to be included in the national control programmes, taking into account problems that have been identified regarding compliance with the MRLs set out in this Regulation, with a view to assessing consumer exposure and the application of current legislation.

[17] For instance, Commission Regulation (EU) No 283/2013; Commission Regulation EU) No 284/2013; See Commission Implementing Regulation (EU) No 844/2012; Draft Guidance document on Comparative Assessment and Substitution of Plant Protection Products in accordance with Regulation (EC) No 1107/2009; Working document on emergency situations according to Article 53 of Regulation (EC) No 1107/2009; Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009; Guidance document on data protection; Guidance document on renewal of authorisations under Regulation (EC) No 1107/2009; Questions and Answers document in relation with the implementation of Regulation (EC) No 1107/2009.

[18] See e.g. General Court, judgment of 3 June 2015 in case T-578/13, *Luxembourg Pamol (Cyprus) and Luxembourg Industries* v *Commission*, on confidentiality; see also, European Court of justice, judgments of 23 November 2016 in case C-442/14, *Bayer CropScience SA-NV, Stichting De Bijenstichting* v *College voor de toelating van gewasbeschermingsmiddelen en biociden* and in case C-673/13 P, *Commission v Stichting Greenpeace Nederland and PAN Europe*.

[19] See for instance the Swedish *Annual Report on control measures according to Article 68 of Regulation (EC) No 1107/2009*, Sweden, 2015.

[20] EFSA (European Food Safety Authority), 2016. The 2014 European Union report on pesticide residues in food. EFSA Journal 2016;14(10):4611, 139 pp. doi:10.2903/j.efsa.2016.4611

[21] The individual reports as well as overview reports are publicly available at http://ec.europa.eu/food/fvo/audit_reports/

1.5.2 Previous evaluations and other reports

The Commission's impact assessment[22] which preceded the adoption of the Regulation (EC) No 1107/2009, set out (chapter 7) indicative monitoring indicators to be taken into account when assessing whether the objectives of the Regulation have been achieved pursuant to its implementation.

The Commission report COM(2014)82[23] on *minor uses* should be taken into account. Minor uses refer to PPPs with such specialised and thus limited use that the profits earned are considered insufficient for industry to apply for authorisation. The report on the implementation of these provisions could provide useful information to evaluate the effectiveness of the legislation in safeguarding the competitiveness of European agricultural production.

A workshop on zonal evaluation, mutual recognition and re-authorisation was held in June 2015. The final report from the workshop provides a good overview of the state of play of the authorisation procedures in Member States.[24]

In Ireland and the United Kingdom there have been two evaluations on the pesticide legislation. Although compiled only at an early stage in the legislation's implementation, several insights may be gained from the following reports:

- Evaluation on the pesticide legislation and the implications for agriculture in Ireland, Jess, S., Kildea, S., Moody, A., Rennick, G., Murchiel, A., and Cooke, L. (2014) European Union (EU) policy on pesticides: Implications for agriculture in Ireland.
- A report on the simplification of the EU Pesticides Regulatory Regime, done by HSE (UK) in 2013.

For the assessment of the implementation and functioning of the pesticides legislation, the following studies commissioned by the Commission should also be taken into account:

- Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU.[25]
- Interpretation of the WSSD 2020 chemicals - Goal and assessment of EU efforts to meet the WSSD commitment.

REACH - the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals entered into force in 2007. The classification of substances is done under REACH and therefore important to PPPs. REACH requires the Commission to report regularly on the progress and the achievement of the Regulation's objectives. The last report was published in 2013[26] and the next evaluation report is expected to be published in June 2017. The evidence for the REACH Review is gathered from a large number of studies and reports, see overview of thematic studies.[27]

The Commission (DGs ENV and GROW) is currently conducting a 'fitness check' on chemicals legislation (excluding REACH) as part of the REFIT programme. There are several studies (both

[22] See the Commission Staff Working Document, "Report on the Impact Assessment for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products".
[23] European Commission, Report from the Commission to the European Parliament and the Council on the establishment of a European fund for minor uses in the field of plant protection products, COM(2014)82 final, Brussels, 18.2.2014.
[24] EU Workshop on Zonal Evaluation, Mutual Recognition and Re-authorisation. Final report. 2-4 June 2015. Dublin Castle, Ireland
[25] See Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU, 02.03.2015.
[26] See the conclusions of the REACH Review and the final Report and the Commission Staff Working Document on the REACH review
[27] See Overview of thematic studies providing evidence for the 2017 REACH REFIT evaluation (REACH Review 2017)

finalised and ongoing) supporting the chemical fitness check that are relevant for the evaluation of the pesticide legislation. The finalised studies should be taken into consideration and close interaction with the ongoing studies are expected.

- Cumulative Cost Assessment for the EU Chemical Industry[28], finalised April 2016.
- Study in support of the Fitness Check on chemical legislation (excluding REACH), finalised in January 2017.
- Second study supporting the Fitness Check on the most relevant chemicals legislation, expected in July 2017.
- Study on the Cumulative Health and Environmental Benefits of Chemicals Legislation, expected in April 2017.
- Study on the international comparison of cumulative regulatory costs for the chemical industry, expected in Q3 2017.

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

There is an ongoing cumulative risk assessment project funded by EFSA[29] and DG SANTE[30]. External scientific reports and EFSA reports are published throughout the course of the project.

2. SPECIFICATIONS OF THE ASSIGNMENT

2.1 Objectives of the evaluation

In the Communication on "Better regulation for better results - An EU agenda", the Commission announced an evaluation of the pesticides regime[31]. The Commission Work Programme for 2016 included this evaluation in the REFIT programme[32]. The general objective is to perform an evidence-based assessment of the implementation of both the legislation on plant protection products and pesticides residues. The evaluation will inform the Commission in its decision-making and could be useful to improve the implementation on the EU rules on pesticides. The external study will be used by the Commission to draft the report to the European Parliament and the Council on the functioning and implementation of Regulations (EC) No 1107/2009 and (EC) No 396/2005.

As this evaluation is part of the REFIT programme of the European Commission , meaning that there will be an increased focus on efficiency with an in depth quantitative examination of regulatory (including administrative) costs and benefits and aspects for simplification. Where

[28] See final report of Cumulative Cost Assessment for the EU Chemical Industry, 2016. ISBN:978-92-79-53493-5
[29] See recent press release from EFSA *"Pesticides: breakthrough on cumulative risk assessment"*
[30] See dedicated DG SANTE website on Cumulative Risk Assessment
[31] COM(2014)368, Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook, p. COM(2015) 215, p. 12, in which the Commission underlined that "*reviews and comprehensive evaluations are underway and will prepare the ground for possible future action across a wide range of policies and legislation – for instance on … pesticides*".
[32] COM(2015)610 Annex 2. Communication from the commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions. Commission Work Programme 2016. *No time for business as usual.*

appropriate, it is expected that evaluation findings pinpoint areas where there is potential to reduce inefficiencies, in particular regulatory burden, and simplify the measure.

2.2 Scope of the evaluation

The study shall collect data and examine a series of questions that will allow the Commission to evaluate progress made in attaining the objectives of the pesticide legislations, as well as establish whether it has delivered the expected benefits, and whether this has been achieved at proportionate cost. The study shall also establish whether the objectives remain relevant given recent developments in the sector.

The study should assess in particular the efficiency, the effectiveness, the relevance, the coherence as well as the EU added value of the pesticides legislation. The analysis should identify potential problems of compliance and underline which factors hinder the achievement of the objectives of the legislation. The study should assess the implementation and the functioning of Regulations (EC) No 1107/2009 and (EC) No 396/2005 in all 28 Member States[33] and identify both critical areas and best practices in order to provide lessons for future actions in this policy area. For this purpose, the establishment of a comprehensive baseline (situation in 2008 before enter-into-force of the current legislative regime) is a necessary precondition which the study should establish

For PPPs, the evaluation will encompass the timeframe starting from the entry into force of Regulation (EC) No 1107/2009 in June 2011 until present. Information available at the time of the preparation of the Commission proposal for the Regulation on placing on the market of PPP will also be assessed. For pesticides residues, the evaluation will encompass the timeframe starting from September 2008, when Regulation (EC) 396/2005 started to be fully applicable due to the entry into force of Commission Regulation (EC) No 149/2008, until present.

Whilst the main scope of the study is the support of the ex-post evaluation, a couple of issues which could help with the forward looking reflection are included in chapter 2.4 - *Other tasks under the assignment*. Directive 2009/128/EC on the sustainable use of pesticides will not be considered for the purpose of this evaluation as it will be the object of a separate assessment in the future. However, the pre-existing situation and legal framework should be taken into account by the study in order to describe the baseline and assess progress made.

The evaluation will cover the implementation and functioning of Regulation (EC) No 1107/2009. Included in the evaluation are both areas for which the Commission is obliged to report to the European Parliament and the Council[34], as well as areas where difficulties have been identified.

Detailed evaluation questions are listed in the next chapter, however, the overarching issues covered by the ex-post evaluation are:

- application and impact of the approval criteria;
- scope and definition of the Regulations;
- authorisations of PPPs in Member States;
- level of harmonisation in implementation;
- assessment of administrative burden;

[33] The assessment of the implementation in Croatia will start as of the date of its accession to the European Union on 1 July 2013.
[34] See Article 82 of Regulation (EC) No 1107/2009.

- level of clarity of the rules;
- availability of PPPs;
- functioning of the enforcement rules;
- adaptation to technical and scientific progress;
- transparency, confidentiality and data protection.

The evaluation will consider both Regulation (EC) No 1107/2009 as well as the implementing rules setting out data requirements for substances and products, uniform principles for authorisation of PPPs, labelling requirements for PPPs and outlining the procedures for the renewal of substances. Procedural guidelines will also be considered in the assessment.[35]

The scope of the evaluation does not include the link with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixture. This issue is included in a separate "fitness check" of the Commission.[36] Nor does the scope of the evaluation address the criteria for endocrine disrupting properties, as the criteria are not yet established by the Commission.

The evaluation for MRLs will cover the implementation and functioning of Regulation (EC) No 396/2005. Detailed evaluation questions are listed in the following chapter, and relate to one or several of the following areas:

- scope and definitions of the Regulation;
- consistency, relevance, and legal clarity of procedures;
- provisions on MRLs;
- adaptation to new concepts, technical and scientific progress;
- consistency with other relevant food legislation;
- comitology procedures;
- potential gaps and areas not sufficiently covered by existing provisions.

As a major element, the evaluation will assess the links, synergies, gaps and potential contradictions between Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 as the procedures related to the approval of substances and the granting of product authorisations are intimately linked with the setting of MRLs, e.g. PPPs can only be authorised if MRLs in relevant foodstuffs are established. Since Regulation (EC) No 396/2005 came into force before Regulation (EC) No 1107/2009, the procedures for MRL setting are currently not aligned with the procedures for approval of substances and product authorisations.

2.3 Evaluation questions

The study should assess the effectiveness, efficiency, coherence, relevance and EU added value of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005. The evaluation questions are structured on the basis of the five evaluation criteria. The Contractor is encouraged to be particularly vigilant to unintended effects (positive and negative) caused by the legislation and include any such findings in the answers to the evaluation questions.

[35] See Guidelines on Active Substances and Plant Protection Products on the DG SANTE website.
[36] See the Roadmap of the fitness check on the most relevant chemicals legislation (excluding REACH).

2.3.1 Effectiveness

1. To what extent has Regulation (EC) No 1107/2009 contributed to the reduction of animal testing and what have been the effects of the provisions concerning data sharing of studies involving vertebrate animals?

2. To what extent has the implementation of Regulation (EC) No 1107/2009 established a well-functioning zonal system and granting of authorisations and renewal of authorisations at Member State level? Particular attention should be given to: (a) the functioning and implementation of emergency authorisations; (b) the timelines for granting authorisations and renew authorisations; (c) the authorisation of products containing new active substances, in particular innovative products; (d) mutual recognition of product authorisations; and (e) the labelling of plant protection products. What factors supported or hindered effectiveness?

3. What are the economic, social and environmental impacts (both qualitative and quantitative) of the application of the criteria for approval of active substances, including criteria listed in points 3.6.2 to 3.6.4 and 3.7 of Annex II to Regulation (EC) No 1107/2009? Particular attention should be given to: (a) the availability of PPPs on the EU market; (b) the positive and negative impacts, e.g. in terms of health and environmental protection; and (c) any unintended effects, e.g. the use of emergency authorisations, or other effects that were not foreseen by the legislator.

4. Evaluate the implementation of the comparative assessment of PPPs containing candidates for substitution, in particular: (a) to what extent have MS substituted products containing CfS? (b) what alternatives (both methods and substances) are used to substitute CfS? (c) whether the actual use of active substances listed as CfS decreased in Member States? and (d) quantify the benefits and costs, and assess the impact on administrative burden for Member States.

5. To what extent has Regulation (EC) No 1107/2009 and its implementation contributed to the general objective of competiveness of European agriculture and improvement of agricultural production? What factors supported or hindered attaining this objective?

6. To what extent have the procedures for the approval, renewal and review of active substances at EU level been effective for ensuring the availability of PPPs on the market? What factors supported or hindered effectiveness? Specific, but not exclusive, attention should be given to: (a) the approval and marketing of basic substances; (b) the approval and authorisation of low risk substances; (c) the approval of new active substances - in particular innovative substances; (d) the availability of plant protection products for minor uses; and (e) the availability of alternative methods.

7. To what extent have the provisions on MRLs applicable to products of plant and animal origin been effective in achieving the objectives to ensure a high level of protection of human health while improving the functioning of the internal market? What factors supported or hindered effectiveness? In particular, assess the current concept to; (a) establish MRLs for each substance-commodity combination, including the concept of

using default values where no specific MRL is set; (b) deal with dual and multiple use substances as well as substances that can naturally occur; (c) deal with raw, processed and composite foods; (d) deal with feedingstuffs; (e) set import tolerances; and (f) deal with temporary MRLs in general and the procedures for MRL setting in case of emergency uses in particular.

8. To what extent have the existing procedures for MRL setting, both the procedures for setting/amending/deleting MRLs following an application, and the review of existing MRLs, been effective? Identify if: (a) the existing procedures are sufficiently clear and flexible to achieve the objective of a high level of protection of human health and smooth running of the internal market; (b) the existing procedures give enough flexibility to react to unforeseen situations; and (c) the procedures could be improved to take into account the needs of trading partners.

9. To what extent and in which ways, if any, have the existing provisions on MRLs resulted in impacts on trade?

10. To what extent have the provisions of Regulation (EC) No 1107/2009 been enforceable by Member States Competent Authorities? What factors supported or hindered enforceability? Particular emphasis should be given to: (a) the controls at import; (b) manufacture; (c) re-packing; (d) distribution and use; (e) controls under Article 28(2)(c) and (d) of Regulation (EC) No 1107/2009 on PPPs intended for use in other Member States and third countries; and (f) formulation analysis.

11. To what extent have the provisions of Regulation (EC) No 396/2005 been enforceable by Member States Competent Authorities? What factors supported or hindered enforceability? Particular emphasis should be given to: (a) dual and multiple use substances and substances naturally occurring; (b) MRL setting in case of emergency uses and other unforeseen situations; and c) processed products and feedingstuffs.

12. What has been the impact of the implementation of Regulation (EC) No 1107/2009 on the: (a) free circulation of treated seeds; (b) labelling of treated seeds; and (c) traceability and control of treated seeds and trade with third countries?

13. To what extent has the non-implementation of certain aspects that were foreseen under Regulation (EC) No 396/2005 (MRLs for feedingstuffs, fish, and processed products) impacted the protection of human health and the functioning of the internal market?

2.3.2 Efficiency

14. To what extent are *all* existing timelines in both Regulation (EC) 1107/2009 and Regulation (EC) 396/2005 (and all their implementing regulations such as Regulation (EC) 844/2012) contributing to a well-functioning regulatory system? In this context: (a) which are the most critical deadlines to ensure predictability, timeliness and legal certainty, and which knock-on effects can be anticipated if deadlines are not met? (b) quantify the cost-effectiveness of the legal timelines and assess if administrative burden can be reduced while safeguarding benefits in terms of health and safety; and (c) to what

extent the time-limited approvals, leading to the need for a renewal procedure, are proportionate tools to reach the objective of protecting human and animal health and the environment in view of the costs for applicants, Member States and EU institutions?

15. To what extent have the existing procedures for MRL setting and the review of existing MRLs been efficient? Quantify the benefits and costs and assess if: (a) the existing procedures lead to unnecessary regulatory burden without additional benefits; and (b) the procedures could be improved to increase efficiency.

16. To what extent have the risk assessment and risk management processes designed in the Regulations been sufficiently cost-effective, as well as efficient and flexible (in terms of procedural timeliness) to ensure sound decision making? The respective roles of the applicants, the Member States, of the European Food Safety Authority and the Commission should be considered and costs and benefits quantified.

17. To what extent, and in which ways, have the relevant economic sectors (research, production, distribution, and trade) been impacted by the Regulations? The assessment should quantify the benefits and costs, and cover all types of enterprises with particular attention to SMEs and micro-enterprises.

2.3.3 Relevance

18. To what extent have the specific objectives of the Regulations been pertinent to: (a) the protection of human health (taking into account the evolving needs of e.g. operators, consumers, etc.), animal health and the environment; and (b) the evolving needs of EU farmers, food/feed/energy producers, growers of minor crops and the wider agri-food industry?

19. To what extent has the balancing between transparency and confidentiality rules drawn up by the EU legislator in the area of PPPs been appropriate? Evaluate: (a) in the light of the increasing desire of certain parts of civil society to participate in the decision-making process; and (b) by taking into consideration the role of scientific peer-reviewed open literature and other information submitted by third parties in the assessment of approval or authorisation of active substances.

20. To what extent have the Regulations provided for the possibility and/or flexibility for adaptation to technical and scientific progress: (a) for defining more detailed implementing provisions? (b) to integrate new concepts that are currently under development, e.g. future consideration of cumulative exposure in risk management? and (c) as regards to the scope of the legislation? In particular, are the definitions in the pesticides legislations still clear and relevant in the light of the latest scientific and technical developments (e.g., in situ production of PPPs, biostimulants, products in bulk, dual and multiple use substances)? Particular attention should be given to the scope and definition of 'active substances', 'pesticides residues', 'import tolerance' 'intermediate products', 'plant protection products', 'placing on the market', and 'naturally occurring substances'.

2.3.4 Coherence

21. To what extent Regulations (EC) No 396/2005 and (EC) No 1107/2009 have established a coherent policy in the area of pesticides? Identify areas: (a) where coherence is achieved and what factors were key to achieve coherence; (b) where coherency is not (sufficiently) achieved and why; and (c) that are not sufficiently covered by existing provisions. Attention should be given to issues raised or which have resulted in legal complaints and requests for clarification, for instance requests for clarification on the data protection rules applying to Regulation (EC) No 396/2005.

22. To what extent have the specific objectives of the Regulations translated unambiguously into legal provisions to avoid legal uncertainty and hence an unwanted negative impact on the functioning of the internal market? Identify where more clarity is needed.

23. To what extent has the legal framework been coherent with international rules and agreements related to trade, food, environment and chemicals? This includes compliance with WTO rules, compliance with other international standards setting organisations such as the OECD, FAO or Codex Alimentarius, special and differential treatment, and technical assistance provided to developing and least developed countries. Identify the main differences, overlaps and inconsistencies.

24. To what extent are provisions of Regulations (EC) No 396/2005 and (EC) No 1107/2009 incoherent with other EU legislation on agriculture, food and feed, biocides, chemicals, fertilisers, energy/bio-energy, environment, climate change, public health, consumer protection and food security, and what are the implications of these incoherencies?

2.3.5 EU added value

25. To what extent have Regulations (EC) No 396/2005 and (EC) No 1107/2009 resulted in added value with regards to the objectives pursued that could not be achieved at national level or in other international fora? Was the setting of the legislations on plant protection products and pesticides residues at EU level instrumental to reaching the objectives of the Regulation? What are the reasons, if any, for a lower or a higher level of harmonisation at EU level? In this context assess: (a) the EU added value of the current risk assessment process for approval of active substances and MRL setting involving several actors at national and EU level; (b) if Member States have national provisions complementing the Regulations; and (c) if substances approved at EU level are authorised in the majority or a limited number of Member States.

26. What is the added value of the identification of unacceptable co-formulants and of the assessment of safeners, synergists and adjuvants at EU level?

27. What is the added value of establishing a list of harmonised processing factors in the EU, as well as establishing EU MRLs for feedingstuffs and fish?

28. What has been the added value of having the possibility to carry out an administrative review in accordance with Article 13 of Regulation (EC) No 396/2005?

2.4 Other tasks under the assignment

1. A comprehensive baseline of the situation before adoption of the regulations has to be presented for discussion and approval.

2. In the context of evaluation question 15 it should be assessed what are the advantages and disadvantages of a system where the respective Rapporteur Member State established under Regulation (EC) No 1107/2009 would also be given the responsibility to act as Evaluating Member States for MRL assessments, compared to the current system of free choice of Member State by the applicant.

3. In the context of evaluation question 20 on the scope and definitions: the study should address the advantages and disadvantages of narrowing or further clarifying the scope of Regulation (EC) No 396/2005 as regards dual and multiple use substances. Special attention should be given to an assessment of the advantages or disadvantages to include biocides MRLs in the scope of Regulation (EC) No 396/2005.

3. METHODOLOGY

The methodology of this study should be drawn up by the Contractor taking into account the requirements that are set out in this chapter and the relevant provisions and tools in the Commission Better Regulation guidelines and toolbox[37]. The Contractor must take into account that the study must be based on recognised evaluation techniques and triangulation methods are required. In the context of the REFIT programme, the Contractor has to pay specific attention to the quantification of costs and benefits, the identification and quantification of regulatory burdens and the potential for their reduction and simplification.

The Contractor should provide, as part of the tender submitted, the choice and a detailed description of the methodology to be used to successfully address this assignment and in particular a list of the data to be collected, and the tools and methods that are intended to be used to answer each evaluation question.

The tender should also explain advantages, limitations, and risks involved in using the proposed tools. The analysis to be conducted should be identified, and a clear link between the evaluation questions addressed and the corresponding methodology proposed.

A first draft of an evaluation matrix is expected in the tender comprising the evaluation questions in judgement criteria, indicators, data sources, methods, limitations, etc.

3.1 Consultation Strategy

The consultation strategy is annexed to the Terms of Reference and describes in detail who is consulted, on what, how and when. The tender needs to propose an implementation of the consultation strategy and should be reflected in the evaluation matrix. The Contractor can

[37] see The Better Regulation Guidelines and The Better Regulation Toolbox.

propose changes to the consultation strategy, however, any suggested changes need to be justified.

The consultations should target stakeholders inside the EU (both at national and European level) and in third countries. In particular, the Contractor must foresee consultations with Competent Authorities of Member States and third countries.

Stakeholders of importance for the study are the Members of the Advisory Group on the Food Chain and Animal and Plant Health. Members comprise organisations representing the food and chemical industry, including SMEs, (manufacturing/retail/distribution), farmers and other users of plant protection products, importers, consumers and non-Governmental Organisations, in particular those dealing with public health and environmental protection, and the scientific community, e.g. those involved in FP7 and H2020 projects.

3.2 Data available and to be collected

Several sources of secondary data are already available for the evaluation. The Contractor is expected to conduct a thorough literature review/desk research to identify additional relevant data. A list of already available documents and reports can be found in sections *1.5.2 Previous evaluations and other reports* and *6.1 Basic documents*. Furthermore, the Commission, Member States, and the EFSA may possess documents that are useful in order to carry out the study. The following sources of secondary data have already been identified as useful.

Secondary data sources

- Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides.
- Emergency authorisations are granted in Member States and the Commission holds an overview table, as well as Summary Reports from PAFF meetings. Since July 2016, all information is stored in the PPPAMS.
- National authorisations of products are publicly available in national databases. A data collection on existing authorisations is currently ongoing and will be loaded into the PPPAMS during 2017.
- The EU pesticides database on active substances holds information on all approved and non-approved active substances.
- The EU pesticide database also holds information on MRLs with all MRL/crop combinations.
- Data on timelines for active substances during the risk assessment and management procedure available with the Commission. Legal acts extending approval periods are published in EurLex.
- Data on review of existing MRLs under Art. 12 of Reg. (EC) No 396/2005 are publicly available with EFSA and the Commission.
- EU Annual Reports on pesticides residues in food are publicly available on the EFSA's website.

Primary data collection

In defining primary data needs, the Contractor should in the tender clearly set out from which sources and by what means the data is to be collected. The Contractor should seek to collect and

use quantitative data. If quantitative data is not available the Contractor should clearly explain the reasons and propose mitigation measures. Expected limitations and risks regarding the data collection should be explained and the means of collection justified. This information should be included in the evaluation matrix.

While it is possible that detailed data cannot be obtained for all EU Member States, the study should be based on data from as many Member States as possible but as a minimum ensuring representativeness of the EU28 across the zones laid down for mutual recognition of authorisations and for MRL setting. Extrapolations should be carried out only if they can be adequately justified and it is expected that particular attention is 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 presentational purposes. Raw data shall be provided to the Commission.

A mix of different tools for the data collection should be applied. Primary data collection shall include as a minimum workshops, surveys with Member States and stakeholders, an open public consultation, an SME survey, in-depth interviews, case studies and focus groups. The Contractor is encouraged to identify relevant collection methods that are fit for purpose for the study to complement the required methods. When collecting and analysing primary data, the Contractor shall respect the European Commission standards for data protection.

Workshops

The Contractor **shall organise** two one day workshops with maximum 40 participants in total. These workshops should bring together the Contractors team of experts, the Commission, and a relevant number of EU experts/stakeholders – participant list to be agreed by the Commission. The Commission will provide the premises, but it is for the Contractor to prepare the background documents, assemble the list of speakers and invite participants, present the study, collect and analyse the contributions and prepare the workshop reports. The Contractor should cover all costs related to the workshops, including travel and daily allowance for participants (if necessary).

- the first workshop should be held at the beginning of the evaluation (inception stage) in order to validate the method and approach proposed by the Contractor and to invite stakeholders to give their input during the consultation stage.
- the second workshop to be held towards the end of the evaluation (draft final report) in order to discuss the results of the Contractors' analysis.

Open public consultation

An open public consultation of 12 weeks will be held via the website "Your voice in Europe". The ontractor will be responsible for preparing the questionnaire in English, which after the approval of the Commission will be translated by the Commission into all other EU official languages. The Contractor is responsible for uploading the survey in an appropriate tool and for analysing the results in all EU official languages. The open public consultation should pose questions in a non-technical language and thus provide the opportunity for the general public to respond.

Surveys with stakeholders

The Contractor should use targeted consultations to collect the specialist view of the different categories of stakeholders. The Contractor will be responsible for preparing the questionnaires (to be approved by the Commission), uploading in an appropriate tool (e.g. EU survey) and analysing the results. These consultations should take place early in the evaluation process and must cover, at least, the five mandatory evaluation criteria. There is no minimum mandatory period for targeted consultations, but sufficient time should be given in order to reach as many replies as possible.

Questionnaires shall be customised to different stakeholder categories such as companies, consumers, enforcement authorities, etc. - taking into account their different level of engagement and experience. The Contractor shall propose mitigation strategies in case of low number of replies. Operational works related to the surveys themselves will be the responsibility of the Contractor.

SME survey

The Commission has a network of SMEs and a consultation specifically targeting SMEs should be undertaken preferably using the SME panel of the EEN (e-based EUsurvey). The Contractor will be responsible for preparing the questionnaires (to be approved by the Commission) and analysing the results.

Interviews

The Contractor shall prepare interview guides, carry out a number of structured/semi-structured interviews and analyse the results. Whereas most interviews could be done via the phone or video conferencing, face to face interviews may be needed at an early stage to get a good understanding of the sector. Most interviews will be needed when analysing the information received via the targeted and public consultations.

In conducting the interviews, the Contractor shall ensure capabilities in the 24 EU languages and respect data protection and privacy standards of the Commission.

The Contractor shall propose a number of interviews to ensure adequate input from the ground on the selected subjects, either as face-to-face or as remote interviews. 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, as a minimum, all Member State Competent Authorities should be interviewed, as well as all relevant associations and organisations representing different views in the sector in order to assure proper coverage of all interests.

Case studies

The Contractor shall use case studies in order to provide practical examples of issues with implementation of the measure. The case studies should shed light on the complexity and reveal the practical details of the legislation. They can also serve a starting point for further data collection as they may show cost-benefit relationships, including costs of compliance versus generated value added. Case studies could also be used to present examples of costs and benefits for manufactures of specific products or for best practices in enforcement of rules.

As a minimum, the tender should include case studies on the basis of the three themes mentioned below. The criteria, on the basis of which the case studies are proposed, need to be explained in the tender, which reflect the issues at stake and ensure relevant input for the overall exercise. In addition to the three themes below, the Contractor can propose other relevant case studies for the evaluation. The final selection of case studies will be done by the Commission at the time of the inception report.

1. *From application to market.* Follow the (renewal) process of active substances from application to market. Such case studies could provide in-depth information on the risk assessment and risk management processes, including the setting of MRLs and the impacts on the market, timelines and the respective responsibilities by all stakeholders. At least five active substances should be selected based on objective criteria and take into account the differences between active substances, e.g., the category of active substance, the rapporteur Member State, the market share and properties of the active substance.
2. *Trade impacts.* Identify relevant third countries (at least three), active substance, crop and pest to assess the impact of the legislation on trade.
3. *Candidates for Substitution.* A specific crop/pest, active substance and region can be used as case study to assess the authorisation process in Member States. At least two CfS in two different Member States that have been comparatively assessed since June 2015 should be selected for the case studies.

Focus groups

To complement interviews and surveys there is merit in bringing together all actors involved in specific processes of the legislation. Focus groups will be particularly useful in the collection of primary data on:

- Risk assessment
- Risk management and decision making
- MRL setting
- PPP authorisation

3.3 Data analysis

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 Regulations. 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.

There are a range of methods that can be used to analyse the data collected, such as regression analysis and other types of econometric modelling with the aim to establish causal relationships between actions and outcomes, benchmarking for comparisons between legislations, cost-benefit

analysis, and cost-effectiveness analysis to name a few.[38] The Contractor should decide what methods will be used for the analysis. In the evaluation matrix in the bid, the proposed method should be identified for each evaluation question.

The following is a *non-exhaustive* list of issues already identified that merit in-depth analysis by specialised tools are e.g.:

- **Benchmarking** against other legislations (competitiveness Q.5, transparency Q.19, trade Q.23)
- **Econometric models**, e.g., regression analysis (the use of pesticides Q.2, Q.3, Q.4d and Q.6, animal testing Q.1)
- **Cost-benefit analysis** (socio-economic and environmental impacts Q.2, Q.9, Q15, Q17 and Q.25)
- **Cost-effectiveness analysis** (efficiency Q.4c, Q.15 and Q.16)
- **Case studies** (trade Q.9, time-lines Q.14)
- **Focus groups** (risk assessment and management Q.6, Q.14, Q.15 and Q.25, authorisation Q.2, Q.4 and Q.25)

3.4 Conclusions

Conclusions should be drawn on the basis of evidence stemming from the data collected. There should be a clear and logical progression between the results presented, the answers to the evaluation questions provided and the conclusions being drawn. Conclusions should be presented for all evaluation questions as well summarised for each of the five evaluation criteria and reflect the objectives set out in chapter 2.1.

4. REPORTING AND DELIVERABLES

4.1 General reporting requirements

The present assignment includes the submission of a series of deliverables such as reports and presentations.

The Contractor will deliver the following reports at key stages of the evaluation process: kick-off meeting report, inception report, interim report, draft final report, final report with executive summary, and monthly progress reports.

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 five hard copies.

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

[38] For a more comprehensive list of methods see The Better Regulation Toolbox as well as the EVALSED: The resource for the evaluation of Socio-Economic Development - Evaluation guide.

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.

4.2 Inception Report

At the latest 1 month after signature of contract.

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 have 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. 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.

It should set out in detail, in an evaluation matrix, how the proposed methodology will be implemented and in particular lay out clearly, in tabular form, how the method allows each evaluation question to be answered via establishment of judgement criteria and within these, indicators. In addition, the table should indicate the evaluation tools chosen.

The inception report should include enough detail allowing the Commission to gain a good understanding of the empirical approach, evaluation tools and related methodological steps proposed. It should also include a comprehensive baseline of the situation in 2008 before enter-into-force of the current legislative regime to allow for a comparative analysis.

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 will also be fully clarified at this stage. 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.

4.3 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.

4.4 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.

4.5 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:

- **Title page**
- **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 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 recommended 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 of the different consultation activities* that took place. The consultation synopsis should include, at least:
    - the documentation of each consultation activity undertaken and, if applicable, reasoning as to how and why the original consultation strategy has been altered.
    - the information on which stakeholder groups participated, which interests they represented and whether all identified stakeholder groups have been reached.
    - the description of the results of each consultation activity and a comparison of their results including interdependencies, consistencies or contradictions.

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 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 logically 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 Contractors must be of high editorial quality. In cases where the Contractor does not manage to 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.

4.6 Progress Reports

The Contractor will deliver progress reports on a monthly basis summarising on one page the progress of the evaluation work (i.e. state of execution of the tasks) made with reference to the work plan. The Contractor will report particularly on the difficulties encountered and mitigation measures taken or suggestions of changes required to the work plan to ensure that the required results of the evaluation are achieved. The Commission might call for meetings if the progress reports raise concerns about progress of the study.

4.7 Other deliverables

Primary data collected should be provided as a deliverable. Any final datasets should be provided as structured data in a machine readable format (e.g. in the form of a spreadsheet and/or an RDF file) for Commission internal usage and for publishing on the Open Data Portal, in compliance with Commission Decision 2011/833/EU[39]. The data delivered should include the appropriate metadata to facilitate reuse and publication, e.g., description of the dataset, definition of the indicators, label and sources for the variables, and notes. The data delivered should be linked to data resources external to the scope of the study, preferably data and semantic resources from the Commission's own data portal or from the Open Data Portal. The Contractor should describe in the tender the approach they will adopt to facilitate data linking. The data should be submitted together with the final report.

The two workshops to be held at the inception stage and the final stage of the study are separate deliverables. The Commission will provide the premises, but it is for the Contractor to prepare the background documents, assemble the list of speakers and participants, present the study, collect and analyse the contributions and prepare the workshop reports.

5. ORGANISATION, TIMETABLE AND BUDGET

5.1 Organisation

The contract will be managed by Unit E4 “Pesticides and biocides” of the European Commission Directorate-General for Health and Food Safety.

An ISSG will be involved in the management of the evaluation. The ISSG is consulted and will comment on all deliverables from this contract and will contribute to the quality assessment of the Contractors work.

[39] See 2011/833/EU: Commission Decision of 12 December 2011 on the reuse of Commission documents

5.2 Meetings

It is expected that the Contractor participates in up to six meetings in Brussels (including meetings listed in section 4.6), and two workshops, with the Commission. For these meetings, **minutes should be drafted by the Contractor**, to be agreed among the participants.

5.3 Timetable

The indicative starting date is **May 2017**. The contract will start after both parties have signed it. The period of execution of the contract is **11 months**.

5.3.1 Kick-off meeting

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.

5.3.2 Timetable

Deadline (from starting date)	**Task**
Kick-off [T0]	After signature of the contract, the Contractor will participate in a **kick-off meeting**.
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.
Feedback on inception report [T0 + 2 months]	The Contractor will receive **written feedback** from the Commission 2 weeks after the meeting in Brussels. The Contractor will deliver the final version 2 weeks after receiving the feedback.
Workshop #1 [T0 ±2 months]	**First workshop** held at the beginning of the study (inception stage) in order to validate the method and approach proposed and to invite stakeholders to give their input during the consultation stage.

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.
Feedback on interim report [T0 + 7 months]	The Contractor will receive **written feedback** from the Commission 2 weeks after the meeting in Brussels. The Contractor will deliver the final version 2 weeks after receiving the feedback.
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.
Feedback on draft final report [T0 + 10 months]	The Contractor will receive **written feedback** from the Commission 2 weeks after the meeting in Brussels. The Contractor will deliver the final version 2 weeks after receiving the feedback.
Workshop #2 [T0 + 9 months]	**Second workshop** towards the end of the study (draft final report) in order to discuss the results of the Contractors' analysis .
Final Report [T0 + 11 months]	Taking account of the Commission's comments and the discussion and output of the second workshop, the Contractor sends the **final report and executive summary** to the Commission.

5.4 Budget

The estimated maximum budget for the evaluation study, covering all the results to be achieved by the Contractor as listed above, is **EUR 350.000**.

6. REFERENCES

6.1 Basic documents

The website of DG SANTE provides for useful information on the pesticides legislation.

An indicative list of relevant stakeholders is available at the Europa website.

Other existing documentation is mentioned under section *1.5 Evaluation and Monitoring Provisions* of the Terms of Reference.

6.2 Documents and information to be provided after contract signature (not exhaustive)

Contributions concerning the review of the pesticides legislation sent to the Commission by Member States and stakeholders.

7. REQUIREMENTS

7.1 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. 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 PPP market (both globally and within the EU), including authorisations, marketing and use of PPP, chemical sector production and trade, the role of innovation, and research and development. Expertise in food production and plant health, food supply chain including retail, trade and consumer behaviour is considered an advantage.

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. In particular, among the members of the team, the following requirements are a minimum and should be clearly identified:

- At least 5 years expertise in evaluation methods, including analytical techniques, tools and assessment methodologies of public policy, as well as expertise in data collection.
- At least 5 years expertise in the EU agriculture and food sector.
- At least 5 years expertise in the PPP sector in the EU, including pesticides residues.

All staff-related issues will be clarified during the kick-off meeting.

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.

7.2 Absence of conflict of interests

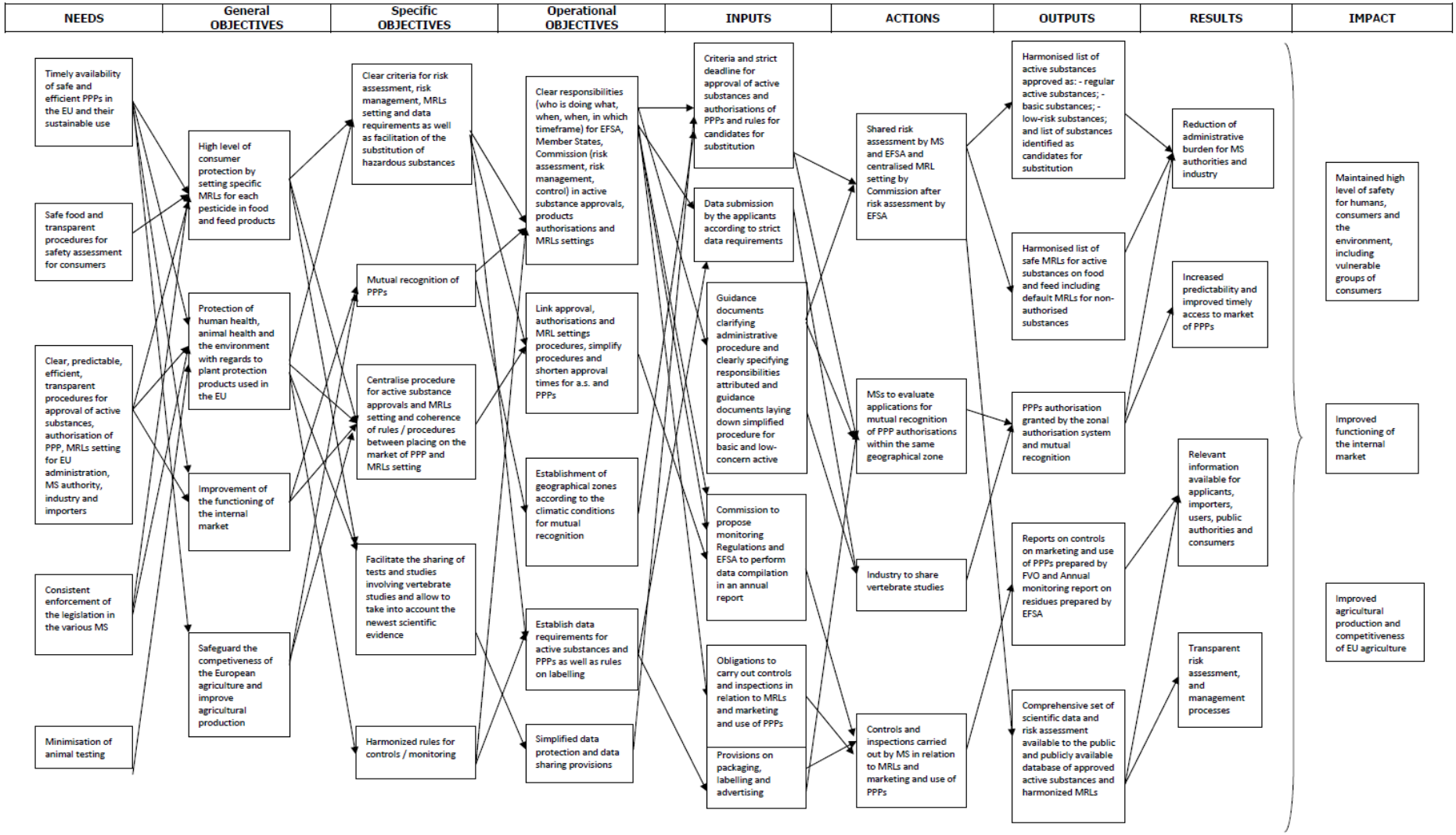
The Contractor shall ensure that both their organisation and the individual experts proposed for this study are not in a situation of conflict of interest regarding this specific assignment, and shall include a Declaration of absence of conflict of interest as part of the tender. In addition, the Staff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

8. ANNEXES

8.1 Annex 1: Intervention logic[40]

[40] See also the intevention logic included annexed to the Roadmap.

Annex 1: Intervention logic for the legislation on plant protection products and pesticides residues



8.2 Annex 2: Stakeholder Consultation Strategy

Stakeholder Consultation Strategy

REFIT Evaluation of the EU legislation on plant protection products and pesticides residues

1. Context

The present stakeholder consultation aims to provide broad and high quality information to support the REFIT evaluation of the EU legislation on pesticides. This initiative will perform an evidence-based assessment and evaluate the effectiveness, efficiency, coherence, relevance and EU added value of the plant protection product (PPP) and pesticide residue regulations. The evaluation is foreseen to be finalised in the second half of 2018.

PPPs are used to protect plants against pests or diseases. The Commission approves active substances, i.e., the agent used to achieve the protective effect, for the use in PPPs. In order to protect consumers, the Commission also sets maximum residue levels (MRLs) for pesticides, i.e., the highest levels of pesticide residues that are legally tolerated in or on food or feed. PPPs and their residues are regulated in the EU by two regulations; Regulation (EC) No 1107/2009, and Regulation (EC) No 396/2005.

An Inter Service Steering Group (ISSG) has been set up to take into account the input of relevant Directorates-General of the European Commission throughout the process. The Commission will be assisted by an external contractor both for the data collection and analysis phase.

The current strategy document will (1) set out the objectives and scope of the public consultation, (2) map key stakeholders, and (3) establish consultation methods and tools which ensure accessibility. A website will be set up to provide a centralised source of information on all stakeholder consultation activities and their outcomes. A synopsis report will document all consultation activities, summarise the responses and give feedback to the stakeholders on how their input was used (and if not, why). This synopsis report will be discussed in the ISSG and annexed to the evaluation.

2. Objectives and Scope

The consultation aims at collecting factual information, data and knowledge on the application of the Regulations. It also aims at drawing upon the experience of different stakeholders with the implementation of the relevant rights and obligations established under the Regulations, and collecting particular views and opinions on different aspects of the Regulations and their effects. Among other elements, the consultation activities will cover the five main evaluation criteria, namely:

- **Effectiveness** of the intervention,
- **Efficiency** in relation to resources used,
- **Relevance** in relation to identified needs and problems,
- **Coherence** with other interventions with common objective, and
- **EU added value** compared to what could have been achieved by Member State or international action.

The key aspects stakeholders will be consulted on are the positive and negative impacts of the Regulations, the risk assessment and risk management processes, the authorisations of PPPs in Member States, the administrative burden of the Regulations, transparency and confidentiality,

and the enforcement of the rules.

3. Relevant stakeholders

The next section will help to identify the key stakeholders, with particular attention to the groups that are often challenging to reach (e.g., farmers and SMEs). The consultations should target stakeholders inside the EU, both at national and European level, and in third countries.

Stakeholders of importance for the evaluation are the Members of the Advisory Group on the Food Chain and Animal and Plant Health which comprises organisations representing the food and chemical industry, including SMEs, (manufacturing/retail/distribution), farmers and other users of plant protection products, importers, consumers and non-governmental organisations (NGOs), in particular those dealing with public health and environmental protection and the relevant scientific community, e.g., those involved in FP7 and H2020 projects. The list of members is non-exhaustive but provides a starting point of stakeholders that will be consulted.

Public authorities. Member State Competent Authorities (MS CA) are important actors as agencies in Member States are directly involved in the risk assessment processes for PPPs and MRLs. The authorisation of PPPs are done nationally with mutual recognition within geographical zones. Furthermore, MS CA is responsible for enforcement on national territory. MS CA also act as risk managers in the framework of comitology together with the European Commission. The level of interest, support and influence varies from Member State to Member State.

Commission representatives. The Commission has a risk management role, facilitates the application of the Regulations, adopts Regulations in the framework of comitology, fixes MRLs for all food and animal feed, as well as coordinates the work of Member States. The work of the Commission also includes organising working groups with experts from Member States on numerous topics, and is involved in the drafting of guidance documents on how to practically implement the Regulations.

The European Food Safety Authority (EFSA). The EFSA is key in the risk assessment processes of both PPPs and MRLs.

Pesticides industry. The interest of the pesticide industry is strong, as they are directly affected by the Regulations. There are important EU level organisations representing the sector, e.g., *ECPA*, *ECCA* and *IBMA*. The pesticide industry can be said to be composed of two main groups: large multinational agri-business and chemical companies, and smaller firms, e.g. companies producing generic compounds. The financial capacity as well as ability to research and innovate differs vastly – throughout the consultation these differences within the sector need to be duly accounted for. SMEs are strongly impacted, but it is a group with a high risk of being excluded, therefore particular emphasis will be given to ensure their views are collected and taken into consideration.

Food industry. The interest of the food industry is strong as businesses are directly affected when ensuring compliance with the Regulations. The food industry is global and affected businesses are located both within and outside the EU. There are important EU level associations representing different sectors of food businesses, e.g., *FDE, FRESHFEL, FRUCOM* and *SNE,* just to name a few. Therefore, particular emphasis will be given to ensure their views are collected and taken into consideration.

Farmers. The end-users of plant protection products are directly affected as their livelihood to a large extent depends on available inputs to protect their crops. Farmers are also a

particularly vulnerable group regarding their health and close environment as they are directly exposed to the pesticides they use. It should be noted that there are two main farming systems in Europe, 'conventional' and 'organic', and farmers using both systems need to be proportionally consulted. There are EU level organisations representing farmers, e.g., *Copa-Cogeca* and *COCERAL*.

Citizens and consumers. Citizens as consumers are also end-users as they are exposed to pesticides through food and water, as well as when they use pesticides in gardening. There is an increasing consumer interest in the area of pesticides and the evaluation, especially the public consultation, is expected to attract considerable attention from civil society. Consumer organisations such as *BEUC* will be part of targeted consultations.

NGOs (e.g. environmental, health, and animal welfare organisations). There are numerous NGOs with high interest in the area of pesticides, e.g., *Eurogroup for Animals, Friends of the Earth, Greenpeace* and *PAN*. The list of NGOs that are members of the Advisory Group on the Food Chain and Animal Health may not cover the whole range of stakeholders with an interest in the issue of pesticides; most notably, pesticides may be of secondary interest for certain associations in the context of their primary interests. Therefore they will be part of targeted consultations.

Research and innovation community (e.g. academia). These stakeholders are indirectly affected as they are involved in developing the scientific methods used in the risk assessment. This category also includes experts, either from the academia or the private sector, who are subcontracted to develop methodologies or assessments of technologies for industry or public authorities.

International organisations and third countries. Third countries have high stakes in terms of trade in pesticides and treated food and feed and are directly affected of any changes in MRLs. There are also organisations like *Codex Alimentarius* and other international standards setting organisations such as the *OECD* with high interest.

Media. Journalists have demonstrated a strong interest over the years. Even though they have low stake, their influence is high and they will therefore be part of targeted consultations.

While the stakeholder consultation does not cover inter-institutional consultations, the importance of the European Parliament should be noted as Members of the European Parliament have demonstrated an increasing interest in the topic.

4. Consultation tools

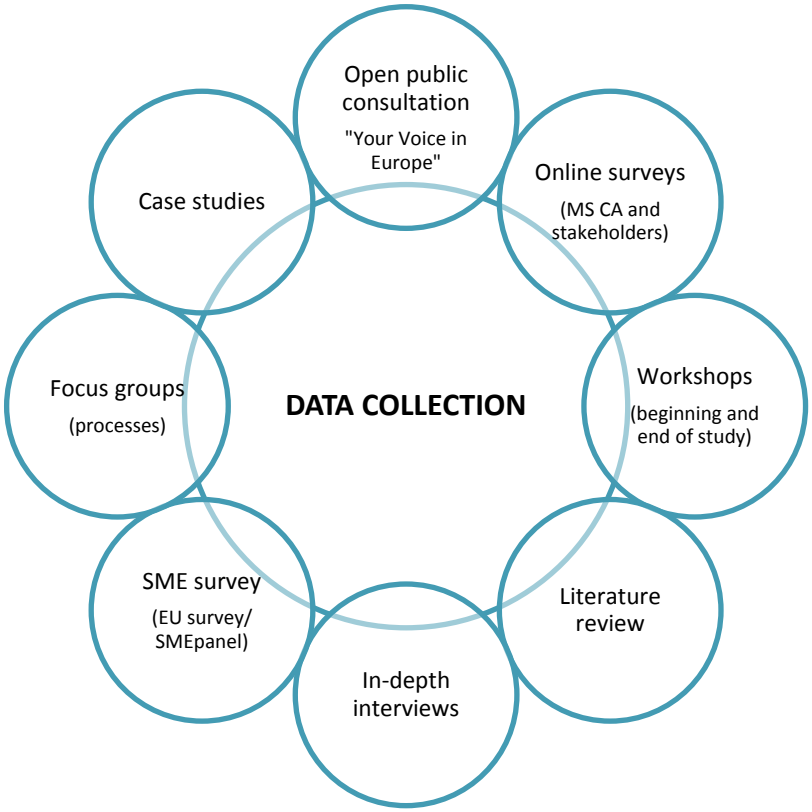
The data collection strategy envisages the use of the following consultation tools which is depicted in figure 1 below.

- Two **workshops** to bring together the experts and a relevant number of EU stakeholders. The first workshop will be held at the beginning of the evaluation while the second workshop should be held toward the end of the evaluation;
- O**nline surveys,** of Member State Competent Authorities and of stakeholder organisations, both business and non-business organisations. The surveys will be launched relatively early in the evaluation process in order to allow time to follow up with in-depth interviews;
- **SME consultation** via the e-based SME survey will be launched early in the evaluation process;
- **Open public consultation** via '*Your Voice in Europe'* with a questionnaire available in all official EU languages to target citizens as well as the maximum possible number of

stakeholders. The launch of the public consultation is foreseen early in the evaluation process;

- **Case studies** to shed light on the complexity and practical details of the legislation. The case studies will have a geographical focus (Member State /third country) and/or be active substance, crop or pest specific. There is merit to conduct some of the case studies early in the process as they can provide information where to collect relevant data. Other case studies will used in order to follow up on information collected during the open public consultations and online surveys;
- **Focus groups** to bring together all stakeholders involved in a specific process of the legislation, i.e., risk assessment, risk management and decision making, MRL setting and PPP authorisation. These focus groups should be held in a natural succession with the risk assessment process first, followed by the other focus groups in the order described above;
- In depth **interviews**. These interviews aim to further investigate, clarify and analyse elements that came up in the context of the online surveys or focus groups. They will be conducted throughout the entire evaluation process, both at Member State level (also in the context of the case studies), and at EU level. Furthermore, interviews will be carried out with selected third countries.

Figure 1. Overview of the data collection strategy for this evaluation



5. Website and dissemination

DG SANTE will set up a webpage dedicated to the evaluation which will serve as the major information tool concerning the consultation process. It will contain subpages for the different types of consulting work performed, inform about the envisaged timeframes and all relevant information on the consultation activities planned.