

EVALUATION AND FITNESS CHECK (FC) ROADMAP				
TITLE OF THE EVALUATION/FC	REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)			
LEAD DG – RESPONSIBLE UNIT	DG SANTE Unit E4	DATE OF THIS ROADMAP	17/11/2016	
TYPE OF EVALUATION	Evaluation  Ex-post  REFIT	PLANNED START DATE	11/2015	
		PLANNED COMPLETION DATE	11/2018	
		PLANNING CALENDAR	<a href="http://ec.europa.eu/smart-regulation/evaluation/index_en.htm">http://ec.europa.eu/smart-regulation/evaluation/index_en.htm</a>	
This indicative roadmap is provided for information purposes only and is subject to change.				

A. Purpose
(A.1) Purpose
<p>The general objective of the evaluation is to perform an evidence-based assessment of the implementation of the legislation on plant protection products and pesticides residues. The evaluation should assess in particular the accomplishment of the objectives, the efficacy of the enforcement as well as the effectiveness of the pesticides legislation. Moreover, the analysis should identify the problems of compliance and underline which factors hinder the achievement of the objectives of the legislation. The evaluation should identify both critical areas and best practices in order to provide lessons for future actions in this policy area.</p> <p>The results of the evaluation will be the basis on which the Commission will draft the report to the European Parliament and the Council on the implementation of the plant protection products and pesticides residues legislation. The evaluation could be useful to improve the implementation on the EU rules on pesticides and might trigger legislative proposals in this policy area.</p>
(A.2) Justification
<p>Regulation (EC) No 1107/2009 lays down the rules and procedures for approval of active substances and authorisation of products. Plant protection products must contain active substances approved at EU level. Before products can be placed on the market or used, they must be authorised in the Member States concerned in accordance with harmonised EU standards, referred to as uniform principles.</p> <p>Regulation (EC) No 396/2005 lays down the rules and procedures on the setting of EU maximum residue levels (MRL), i.e. the highest levels of pesticide residues that are legally tolerated in or on food or feed when pesticides are applied correctly according to the Good Agricultural Practice.</p> <p>Both legislative acts oblige the Commission to report to the European Parliament and the Council on the functioning and implementation of these pieces of legislation. The report should consider in particular the functioning of the system of mutual recognition of products authorisations, the functioning of the zonal system of authorisation consisting in the division of the EU into three zones, the implementation of the comparative assessment of plant protection products (PPP) containing candidates for substitution, the application of the criteria for the approval of substances used in PPP (active substances, safeners and synergists) and its harmonised control, the effects of the provisions concerning data protection of tests and studies involving vertebrate animals. Moreover, the report should consider the implementation of the EU harmonized system of MRLs setting.</p> <p>Stakeholders and Member States raised on numerous occasions several issues related to difficulties in the implementation of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005.</p> <p>The Commission Communication COM(2015) 215 on "Better regulation for better results - An EU agenda"</p>

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*".<sup>1</sup> In the Commission Work Programme for 2016, the evaluation of the pesticides legislation is included in the REFIT programme<sup>2</sup>.

## B. Content and subject of the evaluation

### (B.1) Subject area

PPP, 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 PPP (i.e. the end product) in a very strict regulatory framework. It also sets maximum levels for their residues (MRLs) in foodstuffs, in order to protect consumers, and regulates the use of PPP to further reduce possible risks and impacts. PPP are indispensable in agriculture but their use may involve risks to human and animal health and to the environment. Food and feed containing pesticides residues above the allowed MRLs must not be placed on the EU market (including imported products).

All PPP on the EU market are evaluated according to the criteria laid down in Regulation (EC) No 1107/2009. Prior to the entry into force of this Regulation, the placing of plant protection products on the market was regulated by Directive 91/414/EEC.<sup>3</sup> However, after numerous 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. This led to the adoption of Regulation (EC) No 1107/2009<sup>4</sup>. Like under the previous legislative framework, active substances are approved for 10 years and thereafter re-evaluated in the light of most recent science. All PPP undergo a double authorisation procedure before they can be placed on the market. The approval of an active substance is done by the Commission at EU level, following a comprehensive assessment by experts of Member States and of the European Food Safety Authority (EFSA). Only when approved, Member States can then authorise PPPs containing these substances. The authorisation defines the source of active substance to be used in the PPP, the precise formulation of the PPP, its classification and conditions of use. As a new element the mutual recognition of the authorisations by Member States belonging to a specific geographical zone (in total three zones with similar conditions as concerns e.g. climate, soils, or agricultural production) was introduced. Also new was the listing at EU level of substances with certain properties as candidates for substitution, so that 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 which require less risk mitigation measures. New elements were also the introduction of cut-off criteria for the evaluation, i.e. substances with certain characteristics (such as carcinogens or highly persistent or with endocrine disrupting properties) cannot be admitted into the (re-)evaluation process.

Regulation (EC) No 396/2005 sets MRLs for pesticides to protect all consumer groups. This Regulation is applicable since September 2008 with the entry into force of Regulation (EC) No 2008/149. Previously, apart from some exceptions regulated at EU level<sup>5</sup>, most MRLs were not harmonized and regulated under national rules<sup>6</sup>. This lack of harmonization created fragmentation of the EU internal market for food products as well as difficulties for importers who had to deal with national rules on MRLs. The national approach generated also concerns about the safety of pesticide residues to consumer as there were cases where food exceeding the MRLs in one Member State would be acceptable in other Member States. At present, on the basis of Regulation (EC) No 396/2005, MRLs are established following a scientific opinion of EFSA and taking into account international Codex

<sup>1</sup> [http://ec.europa.eu/smart-regulation/docs/com2014\\_368\\_en.pdf](http://ec.europa.eu/smart-regulation/docs/com2014_368_en.pdf), p. 12.

<sup>2</sup> [http://ec.europa.eu/atwork/pdf/cwp\\_2016\\_annex\\_ii\\_en.pdf](http://ec.europa.eu/atwork/pdf/cwp_2016_annex_ii_en.pdf).

<sup>3</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, available at <http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31991L0414>.

<sup>4</sup> See the Commission Staff Working Document, "Report on the Impact Assessment for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products", available at [http://ec.europa.eu/food/plant/pesticides/legislation/docs/report\\_impact\\_assessment\\_2006\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/legislation/docs/report_impact_assessment_2006_en.pdf).

<sup>5</sup> See eg, Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1445877585048&uri=CELEX:31986L0362>; 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, available at [http://ec.europa.eu/food/plant/pesticides/max\\_residue\\_levels/eu\\_rules/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/max_residue_levels/eu_rules/index_en.htm).

<sup>6</sup> 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, at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52003PC0117>.

Alimentarius levels, where acceptable. Currently a comprehensive review exercise of all existing MRLs is ongoing. For pesticides not approved or crops not grown in the EU, "import tolerances" can be 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.

#### (B.2) Original objectives of the intervention

The main general objectives of the policy area are:

- to ensure a high level of protection of human and animal health and the environment with regards to plant protection products 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 functioning of the internal market for plant protection products and for food and feed of plant and animal origin;
- to safeguard of the competitiveness of the European agriculture and improve agricultural production.

The general objectives of the pieces of legislation are:

- to shorten the time for new products to come on the market;
- to ensure that PPPs are re-authorised following re-approval of their component active substances;
- to allow an efficient use of resources for risk assessment and risk management in the policy area of pesticides;
- to ensure coherence of the rules and procedures between the placing on the market of PPP and MRLs setting;
- to facilitate the substitution of hazardous substances;
- to ensure safety for users, consumers and the environment, including vulnerable groups of consumers;
- to make relevant information available for applicants, importers, users, public authorities and consumers.

The main operational/specific objectives of these pieces of legislation are:

- to define clear criteria for risk assessment, risk management, MRLs setting and data requirements as well as facilitate the substitution of hazardous substances;
- to facilitate the mutual recognition of PPPs;
- to set a centralised procedure for active substance approvals and MRLs setting and coherence of rules / procedures between placing on the market of PPP and MRLs setting;
- to facilitate the sharing of tests and studies involving vertebrate studies and allow to take into account the newest scientific evidence;
- to set harmonized rules for controls / monitoring;
- 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 responsibilities for EFSA, Member States, Commission (risk assessment, risk management, control) in active substance approvals, products authorisations and MRLs settings;
- to link approval, authorisations and MRL settings procedures, simplify procedures and shorten approval times for a.s. and PPPs;
- to establishment of geographical zones according to the climatic conditions for mutual recognition;
- to establish data requirements for active substances and PPPs as well as rules on labelling;
- to implement simplified data protection and data sharing provisions.

The initial proposals COM(2006)388<sup>7</sup> and COM(2003)117<sup>8</sup> leading respectively to Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 explain in more details what where the objectives of the initiative leading to the adoption of these pieces of legislation.

#### (B.3) How the objectives were to be achieved

The objective to ensure a high level of protection of human and animal health and the environment was intended

<sup>7</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52006PC0388&rid=1>.

<sup>8</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52003PC0117>.

to be achieved by the assessment of the risks of the substance for human health, animal health and the environment prior to approval of active substances at EU level and the plant protection products at national and zonal level. In this respect, Regulation (EC) No 1107/2009 sets strict criteria for the approval of substances (including hazard-based "cut-off" criteria which lead in principle to the non-approval of the active substance without performing risk assessment) and for the authorisation of plant protection products. In order to evaluate substances and products in the light of most recent science, legal acts specifying the EU data requirements for substances<sup>9</sup> and PPPs<sup>10</sup> as well as uniform rules for the assessment and evaluation of plant protection product by national authorities<sup>11</sup>. Moreover, for all substances covered, the European Food and Safety Authority (EFSA) performs a peer review.

The objective to ensure a high level of protection of human health with regard to pesticide residues on food and feed of plant and animal origin was intended to be achieved by setting of MRLs at EU level.

The improvement of the functioning of the internal market was intended to be reached by the harmonisation of the standards relevant for the authorisation and placing on the market of plant protection products and the setting of maximum residue limits at EU level. Regulation (EC) No 1107/2009 also provides for procedures for the approval of active substances and the legislation implementing the Regulation set out the procedure for the renewal of active substances<sup>12</sup>. Moreover, a Regulation sets out the labelling requirements for plant protection products<sup>13</sup>.

Numerous guidance documents and Commission Staff Working Documents were published to achieve the objectives of the legislation on authorisation of active substances and authorisation of plant protection products<sup>14</sup>.

MRLs are set following the first assessment by a Member State, followed by a scientific opinion by EFSA in which MRL values are recommended.

The intervention logic for Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 can be found in the Annex I to this Roadmap.

## C. Scope of the evaluation/FC

### (C.1) Topics covered

The evaluation will assess the implementation and the functioning of the EU legislation on plant protection products and pesticides residues in all 28 Member States<sup>15</sup>. For plant protection products, the evaluation will encompass the timeframe starting from the entry into force of Regulation (EC) No 1107/2009 in June 2011 until 30 June 2016. 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 shall encompass the timeframe starting from September 2008, when Regulation (EC) 396/2005 started to be fully applicable due to

<sup>9</sup> Commission Regulation (EU) No 283/2013 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, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0283&qid=1443002520253&from=EN>.

<sup>10</sup> Commission Regulation (EU) No 284/2013 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, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32013R0284&rid=1>.

<sup>11</sup> 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, publicly available at <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0546&rid=1>.

<sup>12</sup> 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, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32012R0844&rid=1>.

<sup>13</sup> 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, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32011R0547&rid=1>.

<sup>14</sup> For instance, 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.

<sup>15</sup> The assessment of the implementation in Croatia will start as of the date of its accession to the European Union on 1 July 2013.

the entry into force of Regulation 2008/149, until 30 June 2016. Directive 2009/128/EC on the sustainable use of pesticides<sup>16</sup> will not be considered for the purpose of this evaluation as will be object of a separate evaluation in the future.

For plant protection products, the topics concerned by the evaluation are the issues for which, according to the legislation, the Commission shall report to the European Parliament and the Council, i.e.

- mutual recognition of products authorisations,
- the functioning of the zonal system,
- the functioning of the comparative assessment of plant protection products containing candidates for substitution,
- the application of the criteria for approval, including "cut-off" criteria;
- the effects of the provisions concerning data protection of studies involving vertebrate animals.

In addition, the evaluation will cover the implementation and functioning of Regulation (EC) No 1107/2009 with regard to the following areas for which difficulties have been identified such as lack of harmonised implementation, high administrative burden, lack of clarity of the rules, difficulties to ensure compliance or enforcement or a need for adaptation to technical and scientific progress:

- Approval and renewal procedure (including application of the "cut-off" criteria),
- Renewal of authorisations,
- Placing on the market of treated seeds,
- Emergency authorisations,
- Approval of basic substances,
- Approval of low risk substances,
- Minor uses,
- Labelling of plant protection products,
- Definition of plant protection products,
- How the goal of competitiveness of the European agriculture and improvement of agricultural production is taken into account in this legislative framework,
- Transparency and confidentiality,
- Role of scientific peer-reviewed open literature in the assessment of active substances.

This part of the evaluation will consider both the 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.<sup>17</sup>

The scope of the evaluation does not include the link with the legislation on classification and labelling of substances and mixtures.<sup>18</sup> This issue is included in a separate "fitness check" of the Commission.<sup>19</sup> Nor does the scope of the evaluation address the criteria for endocrine disrupting properties, since this work is still ongoing, i.e. these criteria are not yet established by the Commission.

For maximum residue levels, the evaluation will address in particular

- Scope of Regulation (EC) No 396/2005 and definitions
- Procedures for setting, modifying, deleting and reviewing MRLs
- Provisions on MRLs applicable to products of plant and animal origin, including provisions on compliance with MRLs and on processed and composite products
- Possibilities for adaptation to technical and scientific progress and for defining more detailed

<sup>16</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32009L0128>.

<sup>17</sup> See references of the legal acts mentioned under section B.3 above.

<sup>18</sup> Regulation (EC) 1272/2008 on the classification, labelling and packaging of substances and mixtures.

<sup>19</sup> A "roadmap" of this fitness check will be shortly published here: [http://ec.europa.eu/smart-regulation/roadmaps/index\\_en.htm](http://ec.europa.eu/smart-regulation/roadmaps/index_en.htm).

implementing provisions

- Consistency with other relevant food legislation

The evaluation should also cover the links between Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 as the procedures related to the approval of substances and granting of products authorisations are intimately linked with the setting of MRLs, e.g. substances can only be approved if MRLs in relevant foodstuffs are established.

The pre-existing situation and legal framework will also be taken into account by the evaluation in order to assess whether, and to what extent, the aims of the pieces of legislation has been achieved.

#### (C.2) Issues to be examined

- **Effectiveness:**
  - To which extent have the objectives been achieved as a result of the implementation of Regulations (EC) No 396/2005 and 1107/2009?
  - Where expectations have not been met, what factors have hindered their achievement?
  - Which unintended effects were observed?
  - Did other factors influence the results observed?
  - The answers to these questions should address the situation at both EU and at MS level.
- **Efficiency:**
  - To which extent the costs for the Commission including EFSA, Member States, operators involved in the approval of substances and authorisation of plant protection products, in the setting of MRLs have been justified and evenly distributed given the effects achieved?
  - Are there issues which pose particular problems for SMEs and micro-enterprises?
  - Which benefits were achieved from the implementation of the legislation?
  - Is the legal framework generating unnecessary regulatory burden and which actions could reduce regulatory burden or potential alternative policy mechanisms that could improve cost-effectiveness?
- **Relevance:**
  - Are the objectives of the Regulations pertinent to the evolving needs, problems and issues in field of placing on the market of PPPs and pesticides residues today?
- **Coherence:**
  - To which extent Regulations (EC) No 396/2005 and (EC) No 1107/2009 established a coherent policy in the area of pesticides?
  - To which extent is the legal framework coherent with agricultural policies, food policies, environmental policies and policies on chemicals and biocides?
  - To which extent is the legal framework coherent with international rules and agreements related to trade, food, environment and chemicals?
  - Where coherence is not achieved, what factors or elements have hindered its achievement? Which are the main differences, overlaps and inconsistencies? How do these shortcomings impact the compliance level?
- **EU added value:**
  - What is the added value of setting a legislation on plant protection products and pesticides residues at EU level?
  - To which extent have Regulations (EC) No 396/2005 and 1107/2009 resulted in added value with regards to the objectives pursued that could not be achieved at national/international level?

#### (C.3) Other tasks

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## D. Evidence base

#### (D.1) Evidence from monitoring

According to Article 68 of Regulation (EC) No 1107/2009 the Member States must carry out official controls in



order to enforce compliance with this Regulation. They have to prepare yearly reports to the Commission on the scope and the results of these controls. These reports can provide information on how this Regulation is implemented.

The EU Pesticides database EU (<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>) provides useful data on the status of active substances and MRLs.

This EU Pesticides data base will be complemented for the PPP authorisations by the *Plant protection products authorisations management system*:

([http://ec.europa.eu/food/plant/pesticides/authorisation\\_of\\_ppp/pppams/index\\_en.htm](http://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/pppams/index_en.htm))

Finally, according to article 29 of Regulation (EC) No 396/2005 the Commission shall prepare a coordinated multiannual Community control programme, identifying specific samples to be included in the national control programmes and 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. EFSA prepares an Annual European Union Report on pesticides residues in which monitoring data from national and the EU wide coordinated monitoring programmes are compiled. Member States have an obligation to report these monitoring data annually to EFSA in accordance with Article 30 of Regulation (EC) No 396/2005. The report gives a good overview on the residue situation in foods on the market. The most recent report is the one containing the 2013 monitoring data: <http://www.efsa.europa.eu/en/efsajournal/pub/4038>.

#### (D.2) Previous evaluations and other reports

The Commission's impact assessment for a Regulation replacing Directive 91/414/EEC on plant protection products which preceded the adoption of the Regulation (EC) No 1107/2009 will be taken into account in order to assess whether the objectives have been achieved as a result from the implementation of Regulation (EC) No 1107/2009.

The Commission report COM(2014) 82 on "minor uses"<sup>20</sup> which are uses of PPP on acreages too small for industry to invest in the application for a profitable authorisation of a product. The implementation of the "minor uses" provisions of Regulation (EC) No 1107/2009 can be taken into account to evaluate the effectiveness of the EU pesticides legislation in safeguarding the competitiveness of the European agriculture and the improvement of agricultural production.

For the assessment of the implementation and functioning of the Regulations (EC) No 396/2005 and 1107/2009 the following studies commissioned by the Commission will be taken into account:

- "Trade in illegal and counterfeit pesticides"<sup>21</sup>,
- The Report and the Commission Staff Working Document on the "REACH review"<sup>22</sup>, and
- Interpretation of the WSSD 2020 chemicals - Goal and assessment of EU efforts to meet the WSSD commitment.<sup>23</sup>

During the performance of the evaluation, there should be a close interaction with the following on-going studies:

- Studies on Cumulative Cost Assessment for the Chemical Industry,
- Studies conducted in support of the REACH review of the Commission;
- Studies/projects on cumulative risk assessment funded by EFSA and DG SANTE.

In addition, there will be close interaction with the following evaluations and fitness checks which are ongoing or which are about to be concluded:

- REFIT – Fitness Check on chemical legislation (excluding REACH), in particular the CLP regulation;
- Fitness Check on the General Food Law Regulation.

#### (D.3) Evidence from assessing the implementation and application of legislation (complaints, infringement procedures)

<sup>20</sup> [http://ec.europa.eu/food/plant/pesticides/legislation/docs/com\\_2014\\_82\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/legislation/docs/com_2014_82_en.pdf).

<sup>21</sup> [http://ec.europa.eu/food/plant/pesticides/docs/study\\_on\\_illegal\\_ppps\\_summary\\_en.pdf](http://ec.europa.eu/food/plant/pesticides/docs/study_on_illegal_ppps_summary_en.pdf).

<sup>22</sup> The conclusions of the REACH Review are available at [http://ec.europa.eu/growth/sectors/chemicals/reach/index\\_en.htm](http://ec.europa.eu/growth/sectors/chemicals/reach/index_en.htm). The Report and the Commission Staff Working Document have been published at the links below:

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013DC0049>

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013SC0025>.

<sup>23</sup> <http://bookshop.europa.eu/en/interpretation-of-the-wssd-2020-chemicals-pbKH0113550/>.

<p>The Food and Veterinary Office carries out audits in the Member States for the purpose of verifying the implementation of the rules on pesticides. The FVO audit reports are publicly available at the webpage: <a href="http://ec.europa.eu/food/fvo/audit_reports/">http://ec.europa.eu/food/fvo/audit_reports/</a>. These include:</p> <ul style="list-style-type: none"> <li>- Reports on 19 MS audited from 2012-2014 covering authorisation and controls on marketing and use;</li> <li>- Overview report on the 2012-2014 audit series;</li> <li>- Reports on 13 MS audited from 2015-2016 covering controls on marketing and use (2015 &amp; 2016);</li> <li>- Overview report on the 2015-2016 audit series (not available until (Q4 2016);</li> <li>- Desk study based on MS responses to questionnaire on authorisation of PPPs;</li> <li>- Reports on 5 MS audited in 2016 covering authorisation of PPPs (2016);</li> <li>- Overview report on the 2016 audit series covering authorisation of PPPs (Q4 2016).</li> </ul> <p>The Commission recently commissioned an external study on the trade of illegal and counterfeit pesticides. The report is available at <a href="http://ec.europa.eu/food/plant/pesticides/docs/study_on_illegal_ppps_summary_en.pdf">http://ec.europa.eu/food/plant/pesticides/docs/study_on_illegal_ppps_summary_en.pdf</a>.</p> <p>A large number of guidance documents and a question and answer document were published in order to improve the implementation of Regulation (EC) No 1107/2009.</p> <p>Court cases provided for clarification of certain aspect of the pesticides legislation<sup>24</sup>.</p> <p>Moreover, complaints and infringements (for instance in the areas of mutual recognition and authorisation) provided information on the implementation of the legislation in different Member States.</p>
(D.4) Consultation
<p>A consultation strategy with the following elements will be developed and published:</p> <ul style="list-style-type: none"> <li>- a consultation of the Members of the Advisory group for the food chain <a href="http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/advisory_group_en.htm">http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/advisory_group_en.htm</a></li> <li>- targeted consultation with stakeholders in and outside the EU</li> <li>- an SME survey</li> <li>- targeted consultations of authorities in the Member States and third countries, and</li> <li>- a public consultation to be published on <a href="http://ec.europa.eu/yourvoice/consultations/index_en.htm">http://ec.europa.eu/yourvoice/consultations/index_en.htm</a></li> </ul> <p>These surveys and consultations will start in October 2016 and are aimed at collecting evidences of the implementation of the legislation, data (including economic data), perceptions and opinions. Results of the consultations and surveys will be analysed for the purpose of the evaluation.</p>
(D.5) Further evidence to be gathered
The Commission is planning to conduct from the beginning of January 2017 a study in support of this evaluation.

## E. Other relevant information/ remarks

Annex 1: Intervention Logic for Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005

<sup>24</sup> e.g. T-578/13 on confidentiality.



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

