OVERVIEW REPORT
Authorisation of Plant Protection Products

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OVERVIEW REPORT
ON A SERIES OF AUDITS CARRIED OUT IN EU MEMBER STATES
IN 2016 AND 2017
IN ORDER TO EVALUATE THE SYSTEMS IN PLACE FOR THE
AUTHORISATION OF PLANT PROTECTION PRODUCTS
Executive Summary

This overview report provides a summary on the outcome of audits to Member States carried out in 2016 and 2017 by the Health and Food Safety Directorate General of the European Commission to evaluate the systems in place for the authorisation of plant protection products.

Regulation (EC) No 1107/2009 sets out the requirements, procedure and timeframes for authorisation of plant protection products. To ensure a high level of protection for human and animal health and the environment, plant protection products must undergo a comprehensive evaluation at Member State level. The Regulation also establishes a zonal authorisation system intended to optimise this process.

The majority of Member States fail to use the zonal authorisation system as envisaged in the Regulation and fail to comply with almost all legal deadlines under the Regulation, by significant margins in many cases. As a result, there is delayed or reduced access to new pest control tools for growers. In addition, the re-evaluation of plant protection products already on the market, in light of new scientific and technical knowledge, is delayed. Finally, delays in processing requests for authorisation also contribute to more emergency authorisations being granted by Member States, without a full evaluation being performed.

Co-operation, work-sharing and reliance on the evaluation work conducted by other Member States are the foundations of the zonal authorisation system. The main reasons why Member States fail to use the opportunities for work-sharing is Member States having specific national requirements and the lack of harmonisation in the methodologies used for conducting evaluations.

Good practices have been identified such as fast-tracking applications for low-risk and non-chemical plant protection products, prioritising authorisations for plant protection products on minor crops, and the use of customised information management systems to monitor compliance with deadlines and identify bottlenecks in the process.
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<td>Competent Authority(ies)</td>
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<td>cMS</td>
<td>Concerned Member State</td>
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<td>EU</td>
<td>European Union</td>
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<td>FTE</td>
<td>Full time equivalent</td>
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<td>GAP</td>
<td>Good agricultural practices</td>
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<td>IPM</td>
<td>Integrated Pest Management</td>
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<td>Member State(s)</td>
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1. INTRODUCTION AND OBJECTIVES

In 2016 and 2017, the Health and Food Safety Directorate General of the European Commission undertook a series of audits on the authorisation of Plant Protection Products (PPPs) in seven Member States (MS): Germany, the United Kingdom (UK), Luxembourg, Portugal, France, Lithuania, and Spain. Annex II provides details of the audit dates and reference numbers. The individual audit reports are published at http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm. In parallel to this audit series on authorisation of PPPs, another series of audits was undertaken in eleven Member States (MS) to evaluate the control systems in place for the marketing and use of PPPs under Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of PPPs on the market and repealing Council Directives 79/117/EEC and 91/414/EEC and certain elements of Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides. In three MS, Luxembourg, the UK and Portugal, combined audits were conducted.

The objective of the audit series was to evaluate the systems in place for authorisation of PPPs laid down in Regulation (EC) No 1107/2009 (the Regulation), to improve co-operation and co-ordination of competent authorities evaluating applications of PPPs and to provide information to EU policy makers regarding the implementation of the Regulation on the authorisation of PPPs and to share good practices amongst Member States. The scope of the audits did not include quality aspects of the evaluations of the individual applications for PPP performed by the MS.

The audits were carried out under the general provisions of European Union (EU) legislation, in particular Article 68 of the Regulation. A full list of the legal instruments referred to in this report is provided in Annex I and refers, where applicable, to the last amended version.

This was the first audit series dedicated exclusively to the evaluation of the system for the authorisation of PPPs. In previous audit series carried out in the period January 2012 to June 2014 on controls on marketing and use of PPPs, some aspects of the authorisation process were included, and weaknesses were already identified. The overview report of that series (2014-7567) can be found at http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=79.

The main conclusions of the 2012-2014 series in the area of authorisation were that "many authorised PPP had not been evaluated to EU standards more than 15 years after the principles for evaluation had been established". Similarly, delays and problems with co-operation between MS were identified for the zonal authorisation system under the Regulation. Problems were also identified related to the misuse of emergency authorisations.

In 2015, the Health and Food Safety Directorate General of the European Commission undertook a survey of all MS on the authorisation of PPPs (hereinafter referred to as the "2015 Survey"). The responses to the survey showed that the majority of the MS did not comply with the legal requirements laid down in the Regulation regarding deadlines for the authorisations of PPPs.
PPP, commonly referred to as pesticides, are used to keep crops healthy and prevent them from being damaged by diseases and pests. These include herbicides, fungicides and insecticides. PPPs comprise both active substances, which may be a chemical or a micro-organism, and a range of other ingredients, such as synergists, to help the PPP work effectively.

PPP are regulated under EU legislation so as to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of PPPs, while improving EU agricultural production. Furthermore, in a broader context, the authorisation of PPP is an important component of the sustainable use of pesticides which is the objective of Directive 2009/128/EC, by providing growers with some of the tools necessary for integrated pest management (IPM), which is a legal requirement for all professional users. IPM promotes a preventive approach and when treatment is unavoidable it entails the use of the most specific PPPs as possible and having the least side effects as well as the implementation of anti-resistance strategies, which involves using products with different modes of action, and prioritises wherever possible, the use of sustainable biological or non-chemical methods rather than chemical PPPs. All PPPs, both chemicals and non-chemicals, must be authorised in line with the requirements of Regulation (EC) No 1107/2009.

This Regulation lays down rules for the authorisation of PPPs and for their placing on the market, use and control within the EU. The Regulation applies from 14 June 2011, and repealed Directive 91/414/EEC. An authorisation can only be issued for a product where the constituent active substance(s) has been approved at EU level. Following approval of the active substance, MS may then authorise PPPs containing this active substance for marketing and use. Authorisation can be granted only following a detailed evaluation covering relevant areas such as operator exposure, toxicology, environmental fate, eco-toxicology and efficacy. Commission Regulation (EU) No 546/2011 sets out the uniform principles required by Article 29(6) of Regulation (EC) No 1107/2009. The uniform principles set out the criteria which PPPs must satisfy in order to be authorised under Regulation (EC) No 1107/2009.

The Regulation aims to minimise the need for MS to conduct stand-alone national evaluations by using the evaluations conducted by another MS on a product to take decisions on authorising the same PPPs. With this in mind, three zones were established, with comparable agricultural and environmental conditions. The Regulation envisages that within each zone, one MS, conducts the evaluation, and other MSs in the same zone, use this evaluation when taking a decision on authorisation for their own territory. The MS responsible for conducting the evaluation is known as the zonal Rapporteur MS (zRMS) and the other MS as concerned MS (cMS). There is also a second, very similar system to the cMS system, where a holder of a PPP authorisation in one MS can apply in another MS with comparable agricultural and environmental conditions, to get the product authorised by Mutual Recognition (MR). By this procedure, the latter MS use the evaluation and decision carried out for the authorisation in the original MS to take decisions related to authorisations.
in their territory. Finally, the Regulation specifies clear deadlines for processing applications in all cases.

For purposes of information and of harmonisation, the European Commission issued a list of test methods and guidance documents for the submission of information according to the data requirements and for evaluations under uniform principles. This is not an exhaustive list, and for some requirements, no method or model is proposed. MSs may use these guidances, or alternative national models, in order to address the data requirements for their evaluations. The audits show that a national requirement is in some cases specified in addition to the EU uniform principles in order to address conditions specific to the MS in question, or that a MS uses a method or model for the evaluation according to uniform principles in the absence a harmonised EU method/model, or superseding models/methods listed by the European Commission.

In conclusion, authorisation is the initial administrative act providing the basis for the legal placing on the market and use of PPPs in each MSs, and the conditions of the authorisation provide the foundation for the implementation of proper use and for effective control systems for the marketing and use of PPPs.

3. OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

3.1. National Legislation

In addition to the Regulation which is directly applicable, in all audited MSs there was complementary national legislation laying down implementing powers and establishing the fees framework for the authorisation of PPPs and PTPs. The Regulation provides that MSs may recover the cost associated with any work they carry out within the scope of the Regulation, by means of fees or charges. Four of the audited MSs have decided not to recover the costs, and in the other three, there were delays or lack of a system to update fees to reflect the actual costs involved.

In one case, there were specific national requirements for re-authorisation of PPPs which had been authorised before Regulation (EC) No 1107/2009 became applicable, with different timelines to those specified by EU legislation meaning that this MS is out of synchronisation with the rest of MSs in this area. This greatly reduces the possibility to co-operate with other MSs.

Good practices:

- All MSs charge reduced fees for authorisation of potential low-risk PPPs, mainly of biological origin such as micro-organisms, which is considered a good practice to encourage applications for these products, as they present generally lower risk than chemical PPPs.
3.2. Competent Authorities, Resources and Planning

In the majority of MSs, all tasks relating to the authorisation of PPPs are under the responsibility of one single entity. However, in two MSs there are multiple independent entities involved in this process. In these two MSs, there were no common IT systems for all bodies, which made it difficult to determine the state of play of each application, and compromised the effectiveness of co-ordination and co-operation between and within CAs.

The evaluator staff in all MSs were suitably qualified and trained, and are therefore capable of conducting evaluations to a high standard. Four MSs identified the lack of resources as a constraint to delivering the work on time mainly due to restrictions on public services in hiring new staff. These restrictions occurred even though MSs may apply fees and charges to recover costs associated with authorisation of PPPs.

The UK compiled data on the resource requirements for each step in the evaluation process. This information was not available in any of the other audited MS. These data showed that the average evaluation time has increased by 70% from 2007 to 2015. This increase is most pronounced in some areas of evaluation such as efficacy, due to the greater number of crops/uses covered in each application, and to the increasing complexity of environment fate evaluations (see chart No 1).

The UK makes use of the data on the evaluation processes to plan and allocate resources to match the workload. It also allows the UK to monitor and manage staff performance as data can be analysed for each staff member. Other MSs did not have comparable data.

On the other hand, in the majority of the audited MSs, deficiencies in long term planning were identified, which meant that the systems in place were not sufficient to ensure that applications were, or would be, processed within legal deadlines. Regarding the authorisation system, the administrative factors contributing to delays include the lack of a reliable tracking system for ongoing applications and the lack of key performance indicators to manage the actual capacity of the existing resources to deliver the work. Other administrative factors were identified, such as inefficient processes relating to purely administrative tasks and delays in taking risk management decisions.
The difficulties associated with long-term planning were compounded in cases where the approach to the evaluation did not take the opportunity to facilitate the use of relevant available unprotected information from previous assessments. In addition some CAs were not actively promoting practices to reduce the workload, for example by using the "risk envelope" approach. This allows for multiple applications with similar formulations and good agricultural practices (GAP) to be grouped for the purpose of assessment, or, for the identification of a "worst case group" which can be assessed as representative for other similar products.

One important aspect related to the overall management of the authorisation systems, is the difficulties which MSs have to avail of the opportunities to use the work done by others, as provided for in the current legal framework for authorisation of PPPs. Where work-sharing systems are effectively implemented, the workload of repeated evaluations could decrease significantly, releasing resources and allowing MSs to cooperate to ensure a fair division of the workload.

The UK was the only audited MS that could quantify precisely the average time required to complete the full evaluation for PPP applications. According to their data, a full evaluation for UK as zRMS requires around 60 man days. Subsequently, other MSs can use the work done by the zRMS to authorise use of the same PPP on its territory acting either as cMS (under Article 36) or by way of mutual recognition (under Article 41). An example of a MS which makes good use of the MR procedure is Luxembourg which takes, on average, two days to complete a MR authorisation. This shows the benefits, in particular in terms of time saving, of using the provisions of the Regulation for simplified authorisation streams.

In the course of the audit series, the Commission Services and CAs held meetings with representatives of applicants. In their view, there is a lack of predictability on the expected timeframe for CAs to reach decisions in the PPP authorisation process. The failure to implement an effective MR system in the majority of the MSs has led to an increase in the number of applications for full evaluation, which increases the costs and time needed for preparing complete data, and also increases the time the MSs require to conduct the evaluation.

Applicants considered that meetings with the CA prior to submission of applications would be an effective tool to improve the quality of applications, thus helping to make evaluations more efficient.

<table>
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<th>Good practices:</th>
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<tr>
<td>• Having a single body responsible for all aspects of a process leads to an inherently more efficient system than where multiple bodies are involved.</td>
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<tr>
<td>• In the UK, fees are retained by the CA, which means that they have control of staffing. This enhances the capacity of the CA to make the arrangements needed to cope with the workload.</td>
</tr>
<tr>
<td>• The UK's bespoke IT system allows for monitoring and managing staff performance and the use of this data to analyse bottlenecks, blockers and to motivate staff to enhance the system.</td>
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</table>
• The UK trains evaluators on modern farming practices, crop growth habits and other agricultural aspects so as to improve the adequacy of proposed risk mitigation measures in their assessments.
• In the UK, specific training for the industry and through meetings with applicants prior to submission of applications have been identified as a key factor enhancing the quality of applications, and reducing the time required for evaluation, therefore contributing to the effectiveness of the authorisation system.
• The UK policy of systematically seeking out opportunities for more efficient work practices to reduce the time needed for processing applications, e.g. using a "risk-envelope" approach.

3.3. Authorisation of Plant Protection Products

3.3.1. Overview of Authorisation of Plant Protection Products

In the audited MSs, the number of authorised PPPs ranged from 363 to 4100. These PPPs contain between 165 and 402 different active substances as seen in Charts 2 and 3. All audited MSs had in place official electronic registers containing information on the authorised PPPs as required by the Regulation, however in three MSs the information in the electronic register was incomplete, in particular for emergency authorisations of PPPs. The analysis of the responses to the 2015 survey showed that in 40 % of the MSs, the electronic register lacked specific mandatory information related to PPPs such as information on emergency authorisations, toxicity product classification, or the full GAP.

Regulation (EC) No 1107/2009 sets out the different routes for authorisation of PPPs. The basic procedures for authorisation of PPPs set out in the Regulation are as follows:

• An application is made to the MSs where the PPP is intended to be placed on the market. The applicant proposes one zonal Rapporteur Member State (zRMS) for each zone in which the PPP is intended to be authorised. The MSs agree on a zRMS to carry out an assessment of the application on behalf of all the cMSs in the same zone, which may comment on the zRMS's evaluation. The zRMS makes the final decision on whether to
grant or refuse an authorisation. The zRMS has a maximum of 12 months to complete the evaluation and to issue the registration report, with an additional period of 6 months to allow applicants to provide additional information if required, which in total amounts to 18 months (550 days).

- The Regulation provides that each of the concerned Member State (cMS) must take a decision within a maximum of 120 days, after the zRMS has issued the registration report.

- Active substances contained in PPPs are subject to renewal procedures. Following the renewal of approval of an active substance, all PPPs containing that active substance must also undergo an evaluation to make sure that products comply with the updated assessment of the active substance and with new scientific and technical knowledge. A period of 12 months for re-authorisations was defined in EU legislation. This is shorter than the time allowed for re-registration of existing products, following the inclusion of existing active substances in Annex I of Directive 91/414/EEC.

- If an authorisation is issued and later the applicant wishes to place the same product on the market in another MS (than the zRMS or the cMS), an application is made for "Mutual Recognition" of the product in this Member State, which has a maximum of 120 days to take a decision.

- Parallel trade permits allow a product that is authorised in one MS (origin MS) to be introduced into another MS (introduction MS) if the MS of introduction determines that an identical product is already authorised in its territory. This simplified procedure requires permits to be granted within 45 working days.

- MSs may grant emergency authorisations for a maximum period of 120 days and for limited and controlled use in special circumstances, where such a measure is needed to control a serious danger that cannot be controlled by any other reasonable means.

- A PPP may be placed on the market only if it contains active substance(s) from the source(s) equivalent to the EU reference specification of the active substance(s). Authorisation holders may subsequently seek approval for new sources and CAs must conduct an assessment of its equivalence within 60 days.

The Regulation allows a MS to withdraw or amend an authorisation at any time where there are indications that an authorisation requirement is no longer satisfied.

As already mentioned in the previous chapter, the Regulation provides for opportunities to use the work done by others. However, despite some CAs' initiatives to promote work-sharing, these have not generally succeeded and as a consequence a huge duplication of work was observed in the audited MSs. In the majority of MSs, the main impediments to relying on the work of others were the lack of use of harmonised methodology and models to conduct the evaluations or the existence of additional national requirements to address conditions particular to the MS concerned. This lack of harmonisation makes MSs reluctant to accept the evaluation outcomes of other MSs obtained by using different methodology and models. The existence of additional national requirements gives rise to the need for evaluation of compliance with these requirements.
In order to achieve a higher degree of harmonisation, the Commission has listed the guidance documents and test methods to be used for evaluation of requirements. However, this Commission guidance is not legally binding on MSs to use these methods or models. Therefore there is flexibility for MSs to decide what methodology to apply. When receiving applications for PPPs that have been evaluated in another MSs with a different methodology, MSs may apply the precautionary approach and decide to re-evaluate applications based on their own accepted models and methods.

Six of the seven audited MSs have specific national requirements. The CAs in these MSs explained that these specific requirements better reflect the reality of some specific environmental, working or agricultural conditions, which in the MSs' opinions, are not fully covered by the common agreed standards. This constrains the possibility of relying on the work done by others.

The 2015 survey showed that half of the MSs do not apply additional national requirements, which facilitates compliance with legal deadlines. In the case of the other half of MS, their national requirements fall into the evaluation categories described in chart No. 4. In 70% of these MSs, there were specific requirements on eco-toxicity; in 60% there were specific national requirements on operator safety and environmental fate and in 50% there were national requirements on efficacy.

The audit series focussed on an analysis of the processing of applications received by MS in the period 1 January 2013 to the end of 2015. The following chapters of this report describe the different authorisation routes and outline the main results of the performance of the authorisation systems.

3.3.2. Authorisation as zonal Rapporteur Member State

When MSs act as zRMS, there were significant differences between the MSs in the number of decisions that have been taken relative to applications received. Information on authorisation shown in this report comprises both positive and negative decisions. Chart No. 5 shows the number of applications as zRMS received between 2013 and 2014 and the number of decisions taken at the time of the audit. In this analysis, applications received in 2015 have been excluded for statistical purposes, to ensure that for all considered applications, the legal deadline had elapsed at the time of the audit.
The analysis of this information identifies an imbalance in the number of applications between some MSs of the same zone and of similar size and agricultural conditions. The comparison between two audited MSs from the Southern zone clearly illustrates this situation, where applicants choose France as zRMS for evaluation 15 times more than Spain. This imbalance in the pattern of applications, and the difficulties which MSs have to cooperate and to share the work, undermine the aim of the Regulation to ensure a fair division of the workload.

For those applications received in 2013 and 2014 on which decisions had been taken, in five of the audited MSs the average time taken exceeded the 18 months (550 days) deadline, and in three of these MSs, the percentage of compliance with deadlines was below 5%.

The data in the individual reports showed the position for applications received from 2013 to 2015 which are summarised in the following charts No 6-7.

Although the UK complies with deadlines for only 26 % of the applications, it received a high number of applications and was still able to take a decision on almost 70 % of the cases.
with an average of just one month above the deadline. The UK is the MS with by far the highest number of decisions taken when acting as zRMS. This contributes very positively to the situation in the central zone, by allowing applicants to apply for mutual recognition of the authorisations in other MSs.

The analysis of both the responses to the 2015 survey and the data gathered in the course of the audit series indicate that delays are commonplace, and also that the number of decisions compared to the number of applications is very low in the majority of MSs, with exceptions such as the UK and Lithuania. In the case of Lithuania, a MS with lower resources than larger MSs, the CA’s policy to prioritise zRMS applications has allowed for the delivery of decisions on all applications, and in the majority of the cases, within the deadlines.

As regards the evaluations carried out by the zRMS, assessments are conducted by using models or methodology covering different scenarios representing actual different agricultural, plant health and environmental conditions. All the audited MSs grant authorisations when the PPP is suitable for the entire country. Therefore, PPPs must satisfy all models for all different scenarios in order to be authorised. Thus, a product which might be accepted for use on a specific crop in the dry climate conditions of a region could not be authorised because evaluations show a negative behaviour in the wetter regions of the same MS. Therefore, in MSs with wide variations in climate and environmental conditions, it is more difficult for applicants to get products authorised.

In addition to possible root causes that have been already identified in previous chapters, another factor contributing to delays was the situation where, following an initial negative conclusion on an evaluation, applicants were allowed multiple opportunities to submit further studies to satisfy the requirements.

Although the majority of MSs conduct the assessment of applications based on guidance documents available at the time of application as provided in the Regulation, there are other MSs which base their evaluation on the latest scientific and technological knowledge at the time of evaluation. The latter case generally requires applicants to submit further information and studies to satisfy any new requirements which were not applicable at the time of the original application, leading to delays.

The lengthy delays in processing applications have direct consequences in areas such as:

- Access to market for new products is delayed, resulting in lack of predictability for applicants.
- Delays in processing applications for PPPs containing new active substances recently approved to the latest more stringent EU standards, reduce the range of pest management tools available to growers.
- The consequence of delays in the authorisation process by the zRMS is that applications are also delayed in cMS and any subsequent MR applications.
3.3.3. Authorisation as a concerned Member State

Once the zRMS has conducted the assessments, a draft Registration Report is provided to all other concerned MSs for them to make comments to be considered by the zRMS when finalising the Registration Report. Based on the final registration report including the copy of the PPP authorisation of the zRMS, each cMS shall decide on their corresponding PPP applications within 120 days.

In all audited MS, when acting as cMS, the average time for processing these applications exceeded the 120 day deadline. This highlights a lost opportunity for MS to process applications based on the work done by the zRMS.

Charts No 8-9 show the information gathered during the audits:

In addition to some possible root causes identified in previous chapters and generally applicable to all authorisation routes, the analysis of the information gathered during the audits indicates that the main reasons for delays were:

- The zRMS had not taken into consideration the comments from cMS, which resulted in the latter conducting further evaluations once the Registration Report is received. Should the zRMS fully address the comments from cMS, the authorisation for cMS is an administrative action manageable within the deadlines provided by the Regulation.

- Lack of resources allocated to this task. Staff resources are used for other authorisation routes.

3.3.4. Re-Registration of Plant Protection Products

The current Regulation requires the re-authorisation of PPPs after the re-approval of each active substance in the product, rather than after the re-approval of the last active substance, as was previously the case under Directive 91/414/EEC. This applies from 2016 onwards, and therefore, implementation of this requirement could not be evaluated during the present audit series. Nevertheless, this requirement is very likely to increase the workload in this area in the future, and all audited MSs consider that timelines set out for the re-authorisation are difficult to comply with.
In relation to re-registration of PPPs, MSs are also experiencing difficulties in cooperating in order to achieve a fair distribution of work. After re-approval of active substances at EU level, MSs must re-evaluate the PPPs containing these substances within the specified deadlines. The portfolio of authorised PPPs is very similar between some MSs with the same climatic and agricultural conditions. However, there were difficulties to achieve a balanced share of the work. Effective work-sharing could have helped MSs to comply with these deadlines and to optimise the use of their resources.

Significant delays were commonplace for the re-registration of PPPs. In the course of the audits, it was noted that in three MSs, there were PPPs still authorised which had not been evaluated to EU agreed uniform principles, i.e. PPPs that were authorised prior to the adoption of Directive 91/414 in 1993. The percentage of authorised PPPs that had not been evaluated to uniform principles ranged from 9% to 33% of the total number of authorised PPPs. Examples of delays were seen during the audit, ranging from 8 months to 5 years. The need to satisfy specific national requirements, or lack of harmonisation of the specific models and thresholds used for evaluation, were the main factors preventing the implementation of effective work-sharing strategies that could have helped to reduce delays.

When the conclusion of an evaluation shows that some risks could not be mitigated for some or all uses, the product authorisation must be amended or withdrawn to prevent harmful effects on human healths or the environment. In these cases, the failure to comply with legal deadlines meant that the risk of any potential harmful effects remains in place beyond the date set for expiry of the authorisation. Delays in reviewing PPP authorisations after the re-assessments of active substances undermine the implementation of EU standards.

3.3.5. Authorisation by Mutual Recognition

The holder of an authorisation granted in one MS may apply for an authorisation for the same PPP, with the same use and comparable agricultural practices in another MS under the mutual recognition procedure. The MS receiving the mutual recognition application, shall take a decision, within 120 days, based on the evaluation and the assessment carried out for the authorisation in the original MS.

The responses to the 2015 survey already showed that MS had difficulties in meeting deadlines. The average time taken for a decision was within the deadline in the case of only 5 MSs. Althought these MSs are among the smaller in the EU with fewer resources dedicated the authorisation process, they were capable of examining the applications received within the deadlines. At the other end of the scale, 33 % of the MSs had an average time exceeding 240 days (twice the legal deadline).

The outcome of the audits conducted in the seven MS confirmed the picture from the 2015 survey. The average time for processing MR applications in four of the seven visited MS, significantly exceeded the deadline. Luxembourg fully relies on mutual recognition of authorisations granted in other MS, and all applications were dealt within the deadline,
In the course of the audits, it was noted that some MSs re-evaluate fully or partially, applications for MR, to satisfy specific national requirements or their own evaluation models. These evaluations were conducted in the light of current scientific and technological knowledge at the time when the MR application is received, which may differ from that available at the time when the reference PPP was authorised. This requires applicants to invest in new studies to satisfy new requirements not applicable at the time of application, leads to delays and limits the incentive to use the MR authorisation route.

The 2015 survey also asked MS to provide information on the authorisation outcome after re-evaluating the MR applications. In 56 % of cases, the authorisation remained identical to that granted in the MS of origin, and in 27 % of cases, PPPs were authorised with different risk mitigation measures. This means that in the majority of the cases, the outcome of the evaluation is either the same or very similar to the original authorisation, however the authorisation is delayed beyond the deadlines. Chart No 12 shows the different outcomes to authorisations granted, detailing any changes relative to the original authorisation.

For those applications which were refused, the survey responses indicated that the main reasons were that the registration report or the complete data package had not been provided by the applicant. The next most common reason for refusals was the failure to satisfy additional national requirements (see chart 13).
According to the Regulation, MSs may refuse a MR authorisation only when, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question poses an unacceptable risk to human health or animal health or the environment that cannot be controlled by the establishment of national risk mitigation measures. In such cases, it should be noted that refusals of MR applications do not trigger an automatic review of the conditions of authorisation for other similar authorised PPPs on the market which could equally be considered to pose unacceptable risks on the same grounds.

3.3.6. Authorisation of "generic" products

When a PPP is first placed on the market in a MS, all data associated with the product is protected for at least ten years. This means that Research and Development companies have exclusive market access for their new PPPs for a defined period of time, thus encouraging them to invest in developing new PPPs. Once the period of data protection has lapsed, other companies may seek authorisation for equivalent, commonly known as generic PPP, which also facilitates price competition.

The audit series revealed differences in how MSs evaluate applications for authorisation of PPPs equivalent to existing authorised PPPs, resulting in significant variation in the number of generic PPPs on the market across MSs.

The Regulation requires that the MSs shall make an assessment in the light of current scientific and technical knowledge at the time of application. In the case of generic products equivalent to existing products authorised at least 10 years before, this criterion requires applicants to provide studies to satisfy new requirements arising since then. Therefore applications for generic PPPs are refused unless new studies are provided to satisfy the new requirements.

Where evaluators reach a conclusion on a "generic" application which differs from that made on the original reference product, applications are refused. However, in such cases, MSs do not avail of their discretionary powers under Article 44(1) of the regulation to proceed to review the reference authorised PPPs in order to amend or withdraw these authorisations. As a consequence of this policy, the reference product remains on the market, and access to equivalent products is limited, which affects the price structure of the PPP market.
3.3.7. Parallel Trade Permits

Authorised PPPs may be marketed under a PTP. Under this system, PPPs may be placed on the market and purchased in one MS and used in another, provided that the product is authorised in both MSs. In this way, PTPs facilitate trade between MSs. In order to be granted a PTP, the PPP has to be identical to the reference product and the MS has 45 working days to take a decision on applications for PTP.

The analysis of the responses to the 2015 survey showed that the number of PTP applications varied widely between MSs, and even between MS of similar size and agricultural conditions. The information gathered in the audit series confirmed this analysis. The wide variation in the number of PTPs granted may be illustrated by the fact that, at the time of the audits, in Germany there were more than 3 500 PTP granted while in Spain there were less than 210. Information is detailed in chart No 14.

![Chart 14 Total number of PTPs granted in the audited MSs](chart)

The information gathered during the audits showed that, in three MSs, the average time taken to take a decision was within the deadline. In the other four MSs, the systems in place for processing PTPs applications, which is largely an administrative task, were not effective, resulting in significant delays for alternative operators in gaining access to the market.

![Chart 15 Average time for decisions on PTP applications](chart)
3.3.8. Emergency Authorisations

In special circumstances, a MS may authorise for a period not exceeding 120 days, the placing on the market of PPPs where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. Authorities must assess the critical need for these emergency authorisations, however without any requirement for a full evaluation to EU standards. The Regulation requires MSs to notify any emergency authorisation to the Commission.

The 2015 survey gathered information regarding the number, and the repetition, of emergency authorisations. The number of emergency authorisations per year in MS ranged from two to 123 and the analysis of the information showed that in some MSs there was a high number of repeated emergency authorisations. Several MSs indicated in their responses that the repetition of emergency authorisations was due to the absence of effective and economically viable alternatives for controlling of pests.

In the audited MSs, the assessment of emergency authorisations concluded that the systems were effective in evaluating the critical need to grant this type of authorisation for limited and controlled use. In the majority of the audited MSs, repeat applications were subject to an enhanced degree of scrutiny and applicants were encouraged to apply for other types of authorisation. In some cases, repeated applications involved PPPs which were awaiting a final decision for regular authorisation. This might indicate that there are weaknesses in the authorisation processes which make it difficult to achieve longer term solutions to plant health problems.

The audit series outcome confirms that delays in granting regular authorisation, especially for minor uses, lead to an increased number of emergency authorisation applications. The majority of the MSs are taking steps to address the lack of authorised PPPs for minor uses, where profitability for applicants is limited due to the limited demand for such products. To the extent that these efforts facilitate authorisations of PPPs for minor uses, this has a positive effect in reducing the number of emergency authorisations.

On the other hand, information on emergency authorisations communicated to the Commission in recent years, shows a clear upward trend since 2007. Chart No 16 shows the total number of emergency authorisations granted in the EU in the last four years.
The emergency authorisation process does not cover certain aspects that would be assessed in a full evaluation of the PPP, in particular in relation to potential harmful effects. Therefore, this upward trend in the number of emergency authorisation, where attributable to delays in regular authorisations, affects the fulfilment of the health protection objective of the Regulation.

**Good practices:**

- The pro-active approach taken to address critical gaps in PPPs for minor crops in France. There is an annual programme of residue and efficacy trials, designed to address crop/pest specific problems, by generating data to facilitate full authorisation of relevant PPPs on these crops, as a more sustainable alternative to emergency authorisations.

- The policy of the majority of MSs to subject any repeated application for an emergency authorisation to an enhanced degree of scrutiny and encouraging applicants to apply for other types of authorisation.

### 3.3.9. Assessment of equivalence of new sources of active substances for already authorised Plant Protection Products

At the time when an authorisation for a PPP is granted, the source of the active substance(s) is specified in the conditions of its authorisation. Authorisation holders may subsequently seek approval for new sources of active substances. A functioning system for the evaluation and approval of new active substance sources is important to facilitate authorisation holders seeking to make changes in their PPP manufacturing and supply chain.

In three audited MSs, the system for acceptance of new sources of active substances, involving a limited evaluation workload, and the evaluation of new sources, consistently failed to deliver timely responses to applicants, thus restricting authorisation holders seeking to change, or expand, their range of active substance sources.

### 3.4. Main Conclusions

The main conclusions highlighted in this report:

- Member States are not generally availing of the opportunities to cooperate in order to ensure a fair division of the workload by relying on the evaluation work done by other MSs. The main reasons for this are the lack of harmonisation of evaluation methodologies, and the existence of additional national requirements.

- With the increasing complexity of evaluations, worsening delays can only be avoided through better cooperation or increased evaluation resources at national level.

- The evaluating staff are suitably qualified and trained, and therefore capable of conducting evaluations to a high standard.

- Delays and/or refusal decisions on MR authorisations, or in cases where MS acts as cMS, reduce the range of pest management tools available to growers which are available in neighbouring MSs for the same crops.
Delays in taking decisions on re-registration of PPPs, defer the re-evaluation of these plant protection products in light of new scientific and technical knowledge, weakening the objective of the Regulation to ensure a high level of protection of human and animal health and the environment.

MSs who decide to conduct further evaluations for MR applications reduce the incentive to use the MR route. Although in the majority of the cases the further evaluation does not involve significant changes to the conditions of authorisation, this procedure causes delays in the decision process and increase the burden for both applicants and CAs. This may result in a diversion to authorisation via other routes which are more resource intensive for CAs.

The difficulties faced by applicants of "generic" products in obtaining authorisation, affects the price structure of the PPP market.

In some MSs, PTP has become an effective tool to facilitate trade between MS. However delays in some MS in taking decisions on PTP applications limit trade between MSs, which in turn prevents users benefiting from a better price structure.

In the audited MSs, systems for emergency authorisations are effective in evaluating the justification for granting this type of authorisation for limited and controlled use. The delays in the regular authorisation system give rise to higher numbers of emergency authorisation applications. As this process does not involve a full evaluation of the PPP and only requires a compliance check with the legal maximum residue limits, this situation compromises the objective of the Regulation to ensure high protection levels.

Overall, the zonal system laid down in the Regulation is not working effectively. MSs do not avail of the opportunities to use the work done by other MSs and they have not taken measures to compensate for this lack of work sharing. As a consequence, delays in processing applications for authorisation of PPPs reduce the range of pest management tools available to growers. Such delays also mean that some products, which had been authorised prior to entry into force of the common EU regulatory framework, remain on the market without re-authorisation to EU standards. Such delays defer the re-evaluation of these plant protection products in light of new scientific and technical knowledge.
4. **Matters for Consideration by Member States**

The individual audit reports contained recommendations made to the CAs of the MS visited. MSs should take actions to address the main weaknesses described in this overview report so as to:

- Ensure that their system for processing applications for authorisation is reviewed, and the necessary changes implemented, so as to consistently meet the deadlines laid down in Regulation (EC) No 1107/2009 when acting as zRMS, as cMS, for mutual recognition applications and for parallel trade permits, and for assessing equivalence of new sources of active substances, and to meet the deadlines laid down in the relevant Commission Implementing Regulations or Directives for re-authorisation of PPPs.

While recommendations have been addressed to the audited MSs, the 2015 survey showed that most MSs are facing similar problems, and therefore all MS are invited to review and improve their authorisation systems.

5. **Actions Taken, or Planned, by Commission Services**

5.1. **Follow–up of Audit Recommendations**

Following each audit, a copy of the draft audit report is sent to the national CA, with a request for an action plan to specify the actions to be undertaken, and the deadlines for their completion, to address each recommendation.

The actions taken to address recommendations are followed up through correspondence, dialogue and in subsequent audits to verify their implementation. In cases where the actions are insufficient to rectify the weakness, the Commission services actively pursue the matter with the authorities concerned.

Progress on the actions undertaken by MS to address recommendations is summarised in Country Profiles, which can be found at [http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm](http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm).

5.2. **Additional actions by Commission Services**

The analysis of the responses to the 2015 survey on authorisation of PPP was presented to MS at the Standing Committee for Plants, Animals, Food and Feed meeting in January 2016 and the key messages from the audit series were also presented at the Standing Committee in December 2016. This overview report will be presented at a future Standing Committee meeting.

The Commission Services are committed to actively communicate to all MSs the conclusions of this overview report and will closely monitor the evolution of compliance by MSs with the legal deadlines for authorisation.
The Commission services will continue to promote a harmonised evaluation and decision making of PPP applications through different actions such as workshops on specific evaluation issues.

The Commission services will also continue to facilitate and contribute to the harmonisation of the authorisation of PPP mainly through the development of guidance. Numerous guidance documents are already available on topics such as renewal of authorisations, mutual recognition, parallel trade and data protection. Commission services will continue to support exchanges between MS authorities such as exchanges in the working group on post-approval issues of the Standing Committee on Plants, Animals, Food and Feed.

Finally the setting of the plant protection products authorisations management system (PPAMS) will facilitate the follow up of applications for authorisation which should help MS management of authorisation. It will also bring more transparency and as a consequence facilitate mutual recognitions.

6. **ACKNOWLEDGEMENTS**

The European Commission would like to acknowledge the contribution of the National Experts who gave of both their time and their expertise in contributing to the success of this audit series. National Experts are CA officials that work in the specific area being audited, and work with Commission officials as part of the audit team for the duration of the specific audit in a country other than their own. Their detailed knowledge of technical aspects of the legislation and control systems contributed greatly to the value-added component of the audit series.

Finally, the European Commission would like to thank all the CA officials and applicants' representatives met during the audit series for their co-operation and positive approach, which greatly facilitated our work.
## ANNEX 1 – LEGAL REFERENCES

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<tr>
<th>Legal Reference</th>
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## ANNEX II: DETAILS OF AUDITS UNDERTAKEN

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The individual audit reports, Competent Authority comments on draft reports and Competent Authority responses to the recommendations made are at [http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm](http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm).
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