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Health and food audits and analysis

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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
GERMANY
FROM 29 FEBRUARY 2016 TO 04 MARCH 2016
IN ORDER TO
EVALUATE THE SYSTEM FOR AUTHORISATION OF PLANT PROTECTION PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of an audit in Germany, carried out from 29 February to 4 March 2016 as part of the published Directorate- General for Health and Food Safety audit programme.

The objective of the audit was to evaluate the control systems in place for plant protection products, in particular those rules laid down in Regulation (EC) No 1107/2009 which relate to the authorisation of plant protection products.

Overall, the report concludes that significant delays in granting authorisations of plant protection products are commonplace. These delays exceed the legal deadlines set out in European Union (EU) legislation for both new products and re-authorisation of those already on the market. This is primarily caused by a lack of EU harmonisation in the standards which Member States use for evaluations, particularly in the environmental area. Consequently, all applications received by Germany are evaluated to satisfy German requirements, even when other Member States have already conducted evaluations based on EU agreed principles. Further evaluation delays result as a consequence of the policy of routinely accepting additional studies and clarifications from applicants in cases where the initial evaluation has a negative outcome. Finally, delays in evaluation are compounded by further delays in determining appropriate risk mitigation measures, due to a policy of achieving consensus between the two competent authorities responsible for risk management.

The national requirements and procedures to implement Regulation (EC) No 1107/2009 are particularly onerous for the German competent authorities. This burden is largely due to working to German rather than EU timelines (which makes it more difficult to achieve synergies across Member States), not seeking synergies and avoiding duplicating evaluation work, and by having an extensive range of national requirements. All these practices make work-sharing with other Member States very difficult. As a consequence, applicants are incentivised to seek authorisation in Germany based on a stand-alone evaluation, rather than Mutual Recognition, leading to an even greater evaluation workload which constrains the capacity of the authorisation system to efficiently carry out the obligations laid down in the Regulation. The lack of reliable forecasting regarding the number of future applications makes for an ineffective system of long term planning necessary to ensure compliance with EU legal deadlines.

There are significant market access issues arising from weaknesses in the system of authorisation of plant protection products. Delays in the authorisation process and slow access to the market for new products increase the regulatory burden on applicants. Applicants for generic authorisations have particular difficulties in gaining authorisations, thus reducing choice for growers and access to the market for applicants.

The report makes recommendations to the competent authorities, aimed at rectifying the shortcomings identified and improving the plant protection products authorisation system.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AIR	Annex I Renewal
BfR	Federal Institute for Risk Assessment
BVL	Federal Office for Consumer Protection
CA(s)	Competent authority(ies)
cMS	Concerned Member State
E-fate	Environmental fate
EPPO	European and Mediterranean Plant Protection Organisation
EU	European Union
FME	Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety
FMFA	Federal Ministry of Food and Agriculture
FTE	Full time equivalent
JKI	Federal Biological Research Centre for Agriculture and Forestry Julius Kuhn Institute
MR	Mutual Recognition
MS	Member State
NR	National Requirement
PEC	Predicted environmental concentration
PPP	Plant protection product
PTP	Parallel trade permit
UBA	Federal Environmental Agency
zRMS	Zonal Rapporteur Member State

1. INTRODUCTION

The audit formed part of the Directorate-General for Health and Food Safety (DG Health and Food Safety) planned audit programme. The audit took place from 29 February to 4 March 2016. The team comprised three auditors from DG Health and Food Safety and one expert from a European Union (EU) Member State (MS).

An opening meeting was held with the Federal Ministry of Food and Agriculture (FMFA), the Federal Office for Consumer Protection (BVL), the Federal Institute for Risk Assessment (BfR), the Federal Biological Research Centre for Agriculture and Forestry Julius Kuhn Institute (JKI) and the Federal Environmental Agency (UBA). At this meeting, the audit team confirmed the objectives of, and itinerary for the audit, and requested additional information required for the satisfactory completion of the audit.

2. OBJECTIVES AND SCOPE

The objective of the audit was to evaluate the control systems in place for plant protection products (PPPs), in particular those rules laid down in Regulation (EC) No 1107/2009 which relate to the authorisation of PPPs; and to identify good practices implemented in the authorisation process. In terms of scope, the audit reviewed the designation of Competent Authorities (CAs), their resources, the systems employed to authorise PPPs and their co-operation and co-ordination with other relevant CAs and with applicants.

In pursuit of these objectives, the following meetings were held:

Table 1: Mission meetings

Meetings		**Comments**
Competent Authorities		
Central	1	Opening and closing meeting with FMFA, BVL, BfR, JKI and UBA.
Applicants' Representatives		
Meetings with applicants' representatives	1	Representatives of research and development applicants Representatives of generic PPP applicants Representatives of applicants of parallel trade permits Representative of applicants grower's associations

3. LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of EU legislation, and in particular, Article 68 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council. EU legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the EU acts quoted in this report are given in Annex 1.

4. BACKGROUND

Regulation (EC) No 1107/2009 concerning the placing of PPPs on the market lays down rules for the authorisation of PPP and for the placing on the market, use and control within the EU. The Regulation applies from 14 June 2011, and repealed Directive 91/414/EEC. The purpose of the Regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of EU agriculture.

Under the Regulation, active substances are approved at EU level and PPPs are authorised at MS level. The Regulation lays down the requirements that PPPs must satisfy to be authorised, and sets out the legal basis for the establishment of uniform principles to be used when conducting the evaluation. The uniform principles are defined in Commission Regulation (EU) No 546/2011. As part of the process for the approval of an active substance, the European Food Safety Authority (EFSA) conducts a peer review of the pesticide risk assessment for the active substance and concludes on endpoints for use in the national evaluations of PPPs. Endpoints describe the toxicological, eco-toxicological and other properties of active substances, e.g. the Acute Reference Dose.

For purposes of information and of harmonisation, the European Commission has issued a list of test methods and guidance documents for the evaluation under uniform principles. This is not an exhaustive list, and for some requirements no method or model is proposed. MS should use these published test methods and guidelines for evaluation purposes or additional national models may be used if no higher-level models/methods are listed. A National Requirement may either take the form of an additional requirement corresponding to the agreed uniform EU principles or may also refer to a specific method or model to be used for evaluation according to uniform principles in the absence of a harmonised one at EU level, or superseding models/methods listed by the European Commission.

In order to remove as far as possible obstacles to trade in plant protection products, Regulation (EC) No 1107/2009 lays down harmonised rules for the placing on the market of PPPs. The Regulation divides the EU into three zones with comparable agricultural and environmental conditions in order to facilitate mutual recognition between MS. For the zonal evaluation of applications for authorisation of PPPs, the zonal rapporteur MS (zRMS)[1] is responsible for examining the application, while other MS in the same zone to which an application has been submitted, so called concerned MS (cMS) rely on the evaluation of the zRMS when taking a decision on authorisation. The Regulation also lays down the rules on

[1] In principle, the MS proposed by the applicant as zRMS will act as zonal rapporteur unless another MS in the same zone agrees to examine it.

the mutual recognition of authorisations to ensure free movement of goods within the EU, and avoid a duplication of work. Authorisations granted by one MS should be accepted by other MSs where agricultural, plant health and environmental (including climatic) conditions are comparable.

Under Regulation (EC) No 1107/2009, PPPs may only be marketed and used in a MS if they are authorised or have a parallel trade permit (PTP). When PPPs are authorised, the quantity of the each co-formulant and the quantity and specific source(s) of each active substance that must be included in the PPP are defined. PTPs are granted for a PPP that is authorised in one MS (MS of origin) and may be introduced, placed on the market or used in another MS (MS of introduction), if this other MS determines that the PPP is identical in composition to a PPP already authorised in its territory. Any deviation from these very detailed requirements means that the PPP does not comply with its condition of authorisation/PTP.

Germany is allocated to the central zone with another twelve MS.

4.1. AUDIT SERIES

This was the first of six audits planned in Member States to evaluate the authorisation system for PPPs.
The overview reports of previous audit series on PPPs can be found on the DG Health and Food Safety website, http://ec.europa.eu/food/audits-analysis/specialreports/index_en.htm.
The most recent audit series, carried out in the period January 2012 – June 2014, had focused mainly on controls relating to the marketing and use of PPPs, but also covered some aspects of the authorisation process where weaknesses relating to the authorisation of PPPs were also identified. These included *"delays with re-authorisations of PPPs under Directive 91/414/EEC, and with mutual recognitions under Regulation (EC) No 1107/2009. It was found that many authorised PPPs had not been evaluated to EU standards more than 15 years after the uniform principles for evaluation had been established. Similarly, delays, and problems with co-operation between MS, were identified for the zonal authorisation system as envisaged under Regulation (EC) No 1107/2009."* (See overview report 2015-7567 http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=79).

4.2. COUNTRY PROFILE

DG Health and Food Safety has published a country profile for Germany, located at http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm, which summarises the control systems for food and feed, animal health and welfare, and plant health, and gives an overview on the implementation of recommendations of previous audit reports.

5. FINDINGS AND CONCLUSIONS

5.1. RELEVANT NATIONAL LEGISLATION

Legal Requirements

Article 291 of the Treaty on the Functioning of the EU

Findings

1. In relation to Regulation (EC) No 1107/2009, implementing powers in Germany are laid down in the "Plant Protection Act" of 6 February 2012 and the "Regulation on the authorisation and permit procedure for plant protection products" of 15 January 2013. The "Regulation on Plant Protection" of 22 October 2013 establishes the fees relating to applications for authorisations and PTPs.
2. The Plant Protection Act refers to National Requirements (NRs). These are specific requirements that applicants must satisfy for PPP authorisations to be granted. BVL stated that all NRs are publicly available in the Official Gazette, located at http://www1.bgbl.de/.

Conclusions

3. Relevant legislation within the scope of the audit is in place, and national legislation establishes a legal basis both for EU requirements and for additional NRs for the authorisation of PPPs.

5.2. COMPETENT AUTHORITIES: DESIGNATION, RESOURCES AND PLANNING.

Legal Requirements

Article 75(1) and, (2) and (3) of Regulation (EC) No 1107/2009 on designation of CAs and co-ordinating national authority

Findings

5.2.1. Designation of Competent Authorities:

4. The Plant Protection Act designates the CAs for the authorisation of PPPs. Three of these, the BVL, BfR and JKI are under the aegis of the FMFA, while the UBA is under the aegis of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (FME). All CAs are funded directly from the federal budget and not from the fees received from applicants seeking for authorisation of PPPs or approval of active substances which go directly to the Federal Finance Ministry, rather than being ring-fenced within the four CAs. BVL is the CA responsible for co-ordinating the evaluation of active substances under the EU review process and the evaluation and

authorisation of PPPs. All four CAs conduct evaluations on both active substances and PPPs.

5. In the PPP authorisation process, BVL is responsible for evaluating the identity, physical, chemical and technical properties, and analysis methods (formulation), JKI is responsible for evaluation of efficacy, phyto-toxicity and ecotoxicology issues relating to honey bees and BfR is responsible for the evaluation of health risks, residue analysis procedures and maximum limits. Finally, UBA is responsible for the evaluation relating to environmental fate (E-fate) and ecotoxicology, with the exception of honey bees, but including other pollinators.

6. The Plant Protection Act requires BVL to make the decision on PPP authorisation, in consultation with JKI and BfR, and in agreement with UBA. The BVL and UBA interpretation of this requirement has resulted in shared competence in the area of risk management, resulting in decision making by consensus. BVL is solely responsible for granting emergency authorisations and PTPs, with no obligation to consult other CAs.

Conclusions

7. CAs have been designated for all tasks relating to the evaluation and authorisation of PPPs.

5.2.2. Resources

8. BVL has 99 full time equivalents (FTEs) dealing with PPP related administration/co-ordination issues and evaluation work, of which 45 have a relevant university degree. Four FTE (two technical assistants and two degree holders) are responsible for evaluation in the area of responsibility of BVL (see paragraph 5). Beyond this, BVL were not able to quantify the FTE responsible for dealing with active substances as distinct from PPPs, or those having administration/co-ordination roles, as distinct from risk management.

9. BfR have 20 FTE dedicated to evaluating PPPs and approximately 12 FTE evaluating active substances (AS). Eighty percent of staff have a relevant university degree, with the remainder having a technical qualification. Relevant BfR staff dedicate an average of 40 % of their time to the evaluation of PPP applications. There is no specific training programme for evaluator staff, but they participate in relevant events, e.g. contributing to development of specific guidance in international fora, and participating in specific ad-hoc training on toxicology. Evaluations are conducted in teams and an in-house peer review system is used with the objective of ensuring consistently high quality work.

10. JKI have a total of 50 staff dealing with PPPs. On average, staff dedicate 25 % (range 10 - 60 %) of their time to evaluation work. This equates to twelve FTE responsible for efficacy (five technical assistants and seven degree holders) and 3.5 FTE responsible for ecotoxicology (two degree holders and 1.5 technical assistants). JKI stated that while there is no formal in-house training programme, staff participate in European and Mediterranean Plant Protection Organisation (EPPO) meetings and in-house training is

organised to disseminate new EPPO guidance to all staff. Work is organised by product type (herbicides, fungicides, insecticides etc.) to make the best use of staff expertise. The CA stated that there was an internal system for supervising the observance of legal deadlines and a staggered peer review process to ensure the quality of input for the evaluation of PPPs.

11. Within UBA, there are 13 FTE dedicated to ecotoxicology (11 degree holders), and 9.5 FTE (7.5 degree holders), dedicated to E-fate evaluations. UBA stated that, in general, staff dedicate two thirds of their time to evaluation work. UBA estimate that up to two years is required to train new staff. This is based on one-to-one training and a mentoring system where new staff are supervised by more experienced staff. Some UBA staff undertake relevant post-graduate courses and UBA also has a programme of in-house training using external experts. Systems are in place to monitor compliance with deadlines for completion of work and to assess the quality of work via an internal peer review process.

12. In all CAs, the scientific staff (degree holders) do the evaluation work, while the technical staff provide administrative support. BVL, BfR and JKI only employ permanent staff to conduct work in this area, whereas UBA employ both permanent and contract staff in an attempt to respond promptly to variations in workload.

13. There is no clear demarcation regarding risk management and risk assessment between BVL and UBA. As described in paragraph 6, the decision on authorisation of PPPs requires the agreement between BVL and UBA, which confers to both CAs risk management responsibilities. During the audit, the CAs informed the audit team that, as part of the risk assessment, UBA staff also propose risk mitigation measures. BVL stated that they are only responsible for risk management, with the exception of special areas such as the evaluation of physical-chemical data. Regulation (EC) 178/2002 laying down the general principles and requirements of food law, defines risk management as "*the process, distinct from risk assessment, of weighing policy alternatives considering risk assessment and other factors and if need be, selecting appropriate prevention and control options*" and the Food and Agriculture Organisation (FAO) has published the working principles for risk analysis which states that "*there should be a functional separation of risk assessment and risk management, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest*". (http://www.fao.org/docrep/006/y4800e/y4800e0o.htm#bm24)

Conclusions

14. There are suitably qualified and trained staff in all CAs, capable of conducting evaluations to a high standard.

5.2.3. Planning

15. BVL stated that, under national legislation, it is mandatory to accept all applications received. In 2013, BVL hired a consulting company to conduct a survey among known applicants to determine future resource requirements, based on a projected 100 applications per year. The assessment of the survey concluded that just five additional FTE in the scientific area would be required to process these applications and authorise the relevant PPPs in compliance with the prescribed deadlines, and that positions should be cut in the technical area. The other CAs used the BVL projections to determine their future resources needs. BVL have no formal process to engage with applicants to estimate future workloads and no official projections on the number of future applications, which would be critical information for future planning. BVL stated, in response to questions from the audit team, that they expect the number of applications to increase each year and to reach approximately 280 applications per year by 2021.

16. There are a number of reasons for the high, and increasing, number of applications. Mainly because, Germany is a relatively large PPP market in an EU context, so it attracts a high number of applications.

17. The number of applications will increase due to Article 43 of Regulation (EC) No 1107/2009. This Article requires the re-authorisation of PPPs after the re-approval of each active substance in the product, rather than after the approval of the last active substance, as was previously the case under Directive 91/414/EEC. Therefore, PPPs containing two active substances must be re-evaluated twice as often and PPPs with three active substances must be re-evaluated three times more frequently under Regulation (EC) No 1107/2009 compared to Directive 91/414/EEC.

18. The high number of applications is accompanied by a relatively high evaluation workload for each product, for various reasons. Under both Directive 91/414/EEC and Regulation (EC) No 1107/2009, active substances are reviewed at EU level, and when first approved or re-approved, PPPs containing these active substances must be evaluated/re-evaluated and authorised/re-authorised at MS level, in line with defined EU deadlines. MS may engage in voluntary work-sharing to reduce this evaluation workload. Voluntary work-sharing is a system MS can use, most commonly for re-evaluation and re-authorisation of existing PPPs. Under the system, each MS voluntarily agrees to evaluate a relatively small number of PPPs, share the evaluation reports, and re-authorise a larger pool of products based on their own evaluation reports, and those of the other participating MS. On the other hand, Germany has historically authorised all PPPs for ten years in line with national legislation, with a re-evaluation and re-authorisation needed to remain on the market. In order to satisfy the EU requirement of re-authorising the PPP following re-approval of the active substance, the German CAs stated that they conduct a brief review of the conditions of authorisation which had been granted under the re-evaluation conducted to National timelines with the objective of ensuring compliance with any additional requirements arising from the review of the active substance as required under the decision to approve the active substance at EU level. Germany performs complete reviews of the products at different points in time than in

the 27 other MS, meaning that the possibility to use voluntary work-sharing for evaluation work in conjunction with other MS is greatly reduced.

19. Looking forward, MS may conduct partial evaluations and/or combined evaluations in order to comply with the requirements of Article 43 of Regulation (EC) No 1107/2009 (on renewal of authorisations) for PPPs with multiple active substances, in line with the "Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009" (SANCO/2010/13170 rev. 13). During the audit, BVL initially stated that it was their intention to harmonise their re-authorisation system with EU deadlines in future. However, BVL subsequently clarified that the Guidance is only applicable in case of active substances which had been approved under the Regulation (EC) 1107/2009. Therefore, for authorisations granted under Directive 91/414/EEC, which comprise the majority of authorised PPPs in Germany, and/or for PPPs containing more than one active substance, a full re-evaluation of the PPP focussing on the critical areas will be performed following approval of the first active substance. Other MS, considering the applicability of the guidance document also for active substances approved under Directive 91/414/EC, will only perform a partial evaluation at this point in time and a full re-evaluation once the last active substance contained in the PPP is re-approved. These differences in the interpretation of the Guidance Document would lead to impede the synchronisation to evaluate PPPs with other MSs. Therefore Germany will not be able to avail of voluntary work-sharing opportunities with other MS, which could greatly reduce the evaluation workload. BVL stated that at the time of the audit, no applications had yet been received for renewal of a PPP under Article 43 of Regulation (EC) No 1107/2009.

20. Finally, all applications received in Germany are evaluated to satisfy NRs, in addition to EU requirements, which greatly increase the workload. This is even more relevant for PPPs which are already authorised in other MS of the same zone, where evaluation could be solely based on the evaluation completed in other MS according to uniform principles for the EU requirements. Due to the requirement to satisfy NRs, it is easier for applicants to submit additional studies for on-going applications to address them in cases where Germany is the zRMS rather than where Germany is cMS. Therefore applicants often apply to Germany as zRMS, which significantly increases the evaluation workload, compared to other authorisation systems, as summarised in Paragraph 23. Indeed, the audit team noted a number of applications where Germany was the zRMS and there were no cMS, where the product had been already authorised in other central zone MS to uniform principle standards.

21. In line with internal procedures, BVL implements a "first in first out" policy for managing applications, with exceptions only possible in cases of public interest. There is no fast-track system for relatively simple applications e.g. applications for extending the range of approved crops for an existing authorised PPP. There is no methodical approach and no flexibility within the system to seek opportunities to reduce the evaluation workload. For example, the audit team noted a number of applications where Germany was the zRMS, but the PPP was already authorised to uniform principles standards in

other central zone MS. The uniform principles for evaluation and authorisation of plant protection products are defined under Regulation (EU) No 546/2011. The Regulation defines at an EU level the areas under which MS must evaluate PPPs so as to ensure that authorised PPPs pose no unacceptable risk to human, animal and the environment. However, in these cases where the products are already authorised to uniform principles standards in other central zone MS, the German CAs continue to conduct an evaluation to satisfy national requirements, rather than seeking to use the evaluation work already undertaken by the other MS[2].

22. In regards to possible actions to reduce the evaluation workload, all four CAs stated that a "risk-envelope" approach is not routinely taken when evaluating similar products. The risk envelope approach is described in the Guidance Document SANCO/11244/2011 rev5 and also in the guidance document SANCO/13169/2010 rev. 9 on zonal evaluation and mutual recognition and the main principle for this approach consists in conducting an evaluation on the "worst-case" scenario to cover a range of products. This approach can greatly reduce workload by. BVL stated that they cannot suggest this practise for other CAs in their role as a co-ordinator. Other CAs have no forecast regarding future workload and therefore take each evaluation file as a stand-alone project. The audit team noted a number of cases of very similar products, or groups of products, which the CAs stated were all being evaluated separately as individual applications.

23. The CAs provided an estimate of the average number of days required to conduct the necessary evaluation in each area and for each application type. The following table clearly demonstrates the huge range in evaluation resources required for different types of applications, with a 300-600% increase in evaluation work, depending on the area involved, when acting as the zRMS compared to granting authorisation by mutual recognition (MR).

Evaluation time (FTE/days)				
CA	**Area of evaluation**	**zRMS**	**cMS**	**MR**
BVL	**Physical and Chemical properties**	4	0.8	0.3
BfR	**Toxicology, residues and analysis methods**	50	20	8
JKI	**Efficacy + Ecotoxicology (honey bees)**	44	16.5	10.3
UBA	**Ecotoxicology**	33.7	13.5	10.1
	E-Fate	22.5	9	6.7

Conclusions

24. The German policy of conducting re-authorisations of PPPs according to national rather than EU timelines has made co-operation and work-sharing with other MS very difficult,

[2]In their response to the draft report the Competent Authority noted that they could not use the evaluation work already undertaken by the other Member State. The CA stated that this is partly due to the fact that the risk evaluation by the other Member State, e.g. in the environmental sector, in its opinion, does not reflect current scientific and technical knowledge as laid down in Article 36(1).

thereby increasing the evaluation workload. Germany's position concerning the renewal of authorisations under Article 43 of Regulation (EC) No 1107/2009 means that they are likely to remain out of line with other MS, resulting in an increased evaluation workload in the foreseeable future.

25. The failure to use opportunities for more efficient work practices, e.g. using a "risk-envelope" approach in line with EU Guidance Documents, or a fast-track system for extensions in use or seeking to use evaluations conducted in other MS, results in a cumbersome system of authorisation. This contributes to delays which result in the failure to comply with legal deadlines, as described in paragraph 41.

5.2.4. Co-ordination and co-operation between and within Competent Authorities

26. BVL use a customised, computer-based application to track all applications including authorisations, emergency authorisations and PTP. All documents are logged, and all activities are recorded, in the system. This allows detailed reports to be generated to determine compliance with prescribed deadlines. BVL allocate work to other CAs using this system on a case by case basis, who then record when the work is completed. Evaluating CAs do not have access to the entire system and therefore do not have the possibility to look forward and use a risk-envelope approach, where possible. Applicants also have restricted access to the system in order to monitor progress on their applications.

27. BVL is the designated, national co-ordinating authority and is solely responsible for communication with applicants, other MS and the Commission. BVL stated that in all cases where applications for authorisation are refused, the Commission is informed as required by Article 36(3) of the Regulation. BVL also stated that all evaluation reports are uploaded to the common EU platform, CIRCABC, thus facilitating access for other MS. Communication with other relevant bodies, such as extension services, takes place as required, particularly when granting emergency authorisations. There is open communication between BVL and applicants regarding specific applications, with applicants given multiple opportunities to provide additional data, argumentation etc. to demonstrate safe use at the proposed use pattern. While applicants appreciated this communication, they expressed frustration at the difficulties in communicating directly with other relevant CAs.

Conclusions

28. BVL uses a sophisticated electronic system to administer the authorisation and the PTP application process.

29. On an individual product level, BVL engage with applicants to deliver the widest possible range of approved uses for each authorisation application. However, the current systems for co-ordination between BVL and the other CAs limit the potential for the routine use of more efficient work practices.

5.3. AUTHORISATION OF PLANT PROTECTION PRODUCTS

Legal Requirements

Articles 28 to 32 of Regulation (EC) No 1107/2009 on requirements, contents, and duration of authorisation of PPPs

Commission Regulation (EU) No 546/2011 setting out uniform principles for the evaluation and authorisation of PPPs (hereafter the Uniform Principles)

Articles 33 to 39 of Regulation (EC) No 1107/2009 on the procedure for the authorisation of PPPs, and in particular Article 37 on period of examination

Articles 40 to 42 of Regulation (EC) No 1107/2009 on mutual recognition of authorisations

Articles 43 to 46 of Regulation (EC) No 1107/2009 on renewal, withdrawal and amendment of authorisations of PPPs

Article 52 of Regulation (EC) No 1107/2009 on parallel trade of PPPs

Article 53 of Regulation (EC) No 1107/2009 on emergency situations in plant protection

Article 59 and 60 of Regulation (EC) No 1107/2009 on data protection and data sharing

Article 80 of Regulation (EC) No 1107/2009 on transitional measures

Findings

5.3.1. General information

30. At the time of the audit, there were 739 PPPs authorised in Germany, marketed under 1 432 trade names, of which 84 % were for professional use only. These PPPs contain 232 different active substances. BVL stated that 80 % of authorised PPPs are commercially available. There are a further 3 745 products marketed under PTPs. BVL stated that all products currently authorised in Germany have been evaluated to UP standards. The official product register is located at http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/02_ZulassungPSM/01_ZugelPSM/01_OnlineDatenbank/psm_onlineDB_node.html.

31. In the 2013-2105 period, 178, 155 and 229 applications for authorisation were received, 43 % for Germany as the zRMS, 46% for Germany as a cMS and 10 % for MR. In addition, at the time of the audit there were 75 applications which had been received prior to 1 January 2013 for which a decision had not yet been taken. BVL stated that on average 65 applications for authorisation are processed annually, some 33% less than the projected inflow based on the 2013 survey (see paragraph 15). BVL have not formally tried to determine why current output does not match the projected output, or to determine the bottleneck, if any, in the system. At the time of the audit, there were a total of 601 applications for authorisation under, or awaiting, evaluation, and a final decision as summarised in the following table.

Application type	No. of ongoing applications	Average time from application (days)	Range (No. of days from application)
zRMS	271	617	51 to 1732
cMS	286	639	65 to 1677
MR	44	416	57 to 1122

32. In addition, 521, 804 and 572 applications for PTPs were received in 2013, 2014 and 2015 respectively. Finally, from 1 January 2013, BVL has received 24 applications for the evaluation of new sources of active substance, and 79 applications for recognition of an active substance source approved by another MS.

33. The following table summarises the situation for applications received after 1 January 2013 at the time of the audit. Regulation (EC) No 1107/2009 sets out the deadlines for processing of applications for the different types of applications. The specified deadlines are as follows:
    - A maximum of 18 months for the zRMS to complete the evaluation under Article 37 (1).
    - A maximum of 120 days, after the zRMS has issued the registration report, for the cMS to take a decision under Article 37 (4).
    - A maximum of 120 days to take a decision on applications for MR under Article 42 (2).

		2013	2014	2015	Total
zRMS	**No of applications received**	75	65	96	236
	No of decisions taken at the time of the audit	2	1	0	3
	Percentage of decisions taken within the 18 month deadline under Article 37(1)	0%	0%	N/A	
cMS	**No of applications received**	75	73	105	253
	No of decisions taken at the time of the audit	5	1	0	6
	Percentage of decisions taken within the 120 day deadline under Article 37(4)	0%	0%	N/A	
MR	**No of applications received**	15	14	28	57
	No of decisions taken at the time of the audit	10	3	0	
	Percentage of decisions taken within the 120 day deadline under Article 42(2)	0%	0%	N/A	
All	**Total No of applications received**	165	152	229	

34. For applications received since 1 January 2013 where Germany was the zRMS, the final decision has been made in just three cases, of which all were positive. The average time to make the final decision was 732 days, with a range of 646 – 789 days from date of application. The final decision was made for six applications where Germany was the cMS, of which all were positive. The average time to the final decision was 757 days, with a range of 527 – 964 days from date of application. Finally, thirteen final decisions were taken (resulting in seven authorisations and six refusals) where MR was sought.

The average time to grant these authorisations was 405 days, with a range of 133 – 833 days from date of application. This data demonstrates the consistent failure to comply with deadlines, with significant delays on a routine basis. In the case of re-authorisations, in all cases where BVL fail to conduct evaluations by the prescribed deadlines, the existing product remains on the market. Therefore, applicants and PPPs users are not disadvantaged for delays relating to existing products. Indeed in many cases, increased restrictions are placed on PPPs following re-evaluation e.g. reduced range of crops, so applicants and PPPs users may unduly benefit from delays in re-authorisation of existing products which remain on the market and are used for an additional period of time beyond the legal deadlines.

35. These figures show a systemic failure to comply with the deadlines set out in Article 37 (1) and (4) for zRMS (18 months) and cMS (120 days) and Article 42 (3) for MR (120 days) under Regulation (EC) No 1107/2009. Furthermore, based on the number of applications on hand, the projected number of applications, the current working procedures and resources, Germany is, and will, in the foreseeable future, remain, unable to meet any of the deadlines established under Article 37 (1) and (4) and 42 (3) of Regulation (EC) No 1107/2009.

36. The audit team met representatives of applicants in the course of the audit. They expressed frustration regarding the significant delays in authorising PPPs, but they acknowledged that some of the delays are due to the BVL policy of allowing additional information to be submitted to clarify issues raised in the initial evaluation where Germany is the zRMS. They confirmed that this policy has encouraged applicants to use Germany as a zRMS to a greater extent than initially envisaged. Specifically, they identified the failure to use the MR system, the practice of using German specific endpoints (as opposed to EU endpoints) and modelling in some cases and the practice of using guidance documents agreed after the submission of the application as significant problem areas. The applicants highlighted that these policies, coupled with the Regulation (EC) No 1107/2009 re-authorisation procedures described in Paragraph 17, leads to an increased regulatory burden on their members, makes planning very difficult, deprives German growers of newer and environmentally more benign PPPs and can result in significant loss of earnings for applicants. Examples were provided of projected losses in sales due to delays in granting authorisations, ranging from 2-21 million €/season for products intended for use on widely grown field crops.

37. The audit team also met growers' associations in their role as applicants for PPP authorisations. These associations highlighted the difficulties for German growers in gaining access to some PPPs available to growers in neighbouring MS. These PPPs are not yet authorised in Germany which, in the view of the association was due to the lack of harmonisation in the EU PPP authorisation process. They highlighted minor uses and minor crops as a particular problem area, giving the example of hops to illustrate the point. Germany has 33% of global, and 60 % of EU, hop production. Seventeen thousand hectares is dedicated to this crop in Germany, and 34 000 tonnes, with an approximate value of 140 M€, is produced annually, and exported to 120 countries. However, due to

the relatively small area grown, there is a very limited range of PPPs available for this high value, culturally significant crop. Furthermore they stated that there are delays of many years in authorising some PPPs for use on hops in Germany compared to some neighbouring MS and provided an example to the audit team to support this point.

5.3.2. National requirements for Assessment of Applications of PPPs

38. Regulation (EC) No 1107/2009 lays down the common rules for the authorisation of PPPs within the Community. However, this Regulation does not establish the specific models and tools to be used to ensure that PPP satisfy the agreed uniform principles defined in Commission Regulation (EU) No 546/2011. For this reason, MS may request specific requirements at a national level. The guidance document on zonal evaluation and mutual recognition SANCO/13169/2010 rev9 of 11 July 2014 acknowledges that "given the large number of national assessment requirements, further work is necessary to harmonise national requirements at EU level". This guidance document also recommends that MS should consider making their national requirements available, so that they can be taken into account by the applicants, as is the case for Germany (see paragraph 2).

39. Germany has a range of NRs. BVL stated that there are no NRs relating to physical and chemical properties. In the toxicology area, BfR stated that there are no specific NRs, however in cases where there are no harmonised EU models, German specific models are used. To evaluate ecotoxicology and E-fate, UBA deviates from existing EU guidance documents, referring to four national requirements or specific models. JKI have just one NR relating to dust levels in treated seeds. All four CAs stated that evaluations are generally conducted using the guidance documents available at the time of the application, as distinct from at time of evaluation, but they reserve the right to use newer versions where they consider these to be more appropriate. Finally, BVL, BfR and JKI stated that EU agreed endpoints are always used, whereas UBA stated that EU agreed endpoints are generally, but not always, used. UBA added that they had recently introduced an internal procedure to clarify which endpoint should be used in each case.

40. The Commission communication 2013/C 95/02, for the purposes of information and of harmonisation, provides the list of test methods and guidance documents relevant to the implementation of Regulation (EU) No 284/2013 setting out the data requirements for the evaluation and authorisation of PPPs to uniform principle standards. Despite this initiative for harmonisation, there are data requirements for which a test method/guidance document has not yet been agreed, and in these cases, the German CAs have adopted their own test methods and guidance documents. Consequently, Germany follows different, in some cases more conservative guidance, than that used by other MS. The CAs identified these German specific models, data requirements and interpretation of EFSA guidance documents as one of the main reasons for refusing applications, and for arriving at different conclusions when conducting evaluations compared to other MS. In some cases, where German standards exist, the CAs are not willing to accept evaluations conducted using other models in other MS. BfR provided examples of joint initiatives between EFSA and MS, which have resulted in two new harmonised models now being used in the toxicology area, where previously there were a number of broadly

similar models. UBA stated that they are involved in EU or central zone wide process to work towards harmonisation of the models used for evaluation in the ecotoxicology and E-fate areas.

Conclusions

41. Inefficiencies in current work practices and procedures, combined with the level of existing resources are such that the CAs have been and continue to be, unless drastic measures are taken, unable to process more than half the applications received in each of the last three years. This results in a considerable and growing backlog of applications and ongoing, consistent failure to meet legal deadlines.
42. Inefficiencies in the current procedures and systems mean that the CAs are not able to process, within the legal deadlines, the projected minimum number of applications based on the BVL in-house review of future demands on the authorisation system. Furthermore, BVL have not determined the root cause of this discrepancy and therefore have not, to date, taken appropriate remedial action.
43. Weaknesses in long term planning in BVL and the other CAs mean that there is no systematic approach to ensure compliance with defined authorisation deadlines in the foreseeable future.
44. The consistent failure to achieve the authorisation deadlines specified under Regulation 1107/2009 slows access to market for new products, increases the regulatory burden on applicants, acts as a barrier to entry for new entrants, and results in lost earnings for applicants. Finally, it restricts the range of available PPPs and thus limits the range of Integrated Pest Management tools available to growers.
45. Delays in the re-authorisation of existing PPPs mean that some PPPs/uses remain authorised and used at national level after the prescribed legal deadline, until such time as the decision on the re-authorisation is actually taken. There are also delays in introduction of justified restrictions.

5.3.3. Applications for authorisation by evaluation

46. In the 2013-2015 period, a total of 236 applications were received for authorisation of PPPs with Germany as the zRMS, resulting in just three decisions on authorisations being taken at the time of the audit.
47. The audit team examined a number of these applications. It was clear that the initial evaluation was conducted promptly in most cases, however often with a negative outcome, usually in the environmental area, due to difficulties in satisfying relevant NRs. Delays result as BVL routinely requests additional studies/justification from the applicant, which must then be evaluated. There are further significant delays, of up to one year in some cases, in achieving consensus between BVL and UBA on appropriate risk mitigation measures. While this process shows the CAs work with applicants to grant authorisations with the widest possible range of uses, this causes significant delays

in the evaluation and authorisation process. The consequence is that both Germany, and the cMS, systematically fail to comply with the deadlines set out in Regulation (EC) No 1107/2009.

48. Among the applications examined, a number were, or were about to be, refused as the applicant failed to satisfy a NR relating to earthworms. In all cases, these products are authorised to uniform principles standards in other MS. Germany requires that no negative effects be demonstrated on earthworms at 2.5 cm soil depth, rather than at 5 cm, as used by other MS. UBA stated that they believe that this more conservative model is appropriate as they consider that earthworm populations are not sufficiently protected in certain German soil types, due to a range of factors including soil type, organic matter levels and cultivation practices. During the audit, no information was provided related to the existence of any peer reviewed scientific studies linking the health status of the earth worm population in these specific soil types with the use of PPPs.

49. Also among the applications examined, a number were, or were about to be, refused as the applicant failed to satisfy a NR relating to the predicted levels of metabolites of a specific commonly used active substance in ground water, based on the model used by UBA. In this case, a number of commonly used PPPs containing this active substance in various formulations have been authorised in Germany, and other MS, for many years and the specific products under evaluation are authorised to uniform principle standards in other MS. Although the German model has been used for many years, UBA have not validated it by comparing the output of the model to real monitoring data.

50. In both cases, relating to earthworms and groundwater metabolites, these applications were, or were about to be, refused under Article 36.3 of Regulation (EC) No 1107/2009 as the CA could find any means to mitigate environmental concerns. In both cases, equivalent PPPs (same concentration, same AS, same conditions of use) are currently authorised for use and remain on the market. Although Article 44(1) of the Regulation provides that MS may review an authorisation under certain conditions, BVL has chosen not to conduct a review of these existing authorisations. BVL stated that, on the basis of national administrative legislation, it is much more complex to withdraw an existing authorisation than to refuse new applications. In two cases examined by the audit team, both dealing with widely used PPPs, one existing product in each case remains on the market, while in each case three new applications for authorisation of equivalent products were, or were about to be, refused.

5.3.4. Applications for authorisation as a concerned Member State or by Mutual Recognition

51. In the 2013-2015 period, 253 applications were received for the authorisation of PPPs with Germany as cMS, and 57 by MR with a final decision made in just six and thirteen cases, respectively. For applications where Germany is a cMS, BVL stated that problems arise due to the frequent failure by the zRMS to evaluate German specific uses and the failure to consider the comments from Germany as a cMS related to German specific NRs. The audit team also noted numerous cases where the zRMS was late in finalising

the Registration Report, which is needed by cMS to complete their authorisation processes. The German, as distinct from EU, policy is that MR is only possible for PPPs authorised under Regulation (EC) No 1107/2009. Therefore, MR applications for PPPs authorised according to uniform principles under the Directive 91/414/EEC are automatically refused. The Guidance Document on zonal evaluation and mutual recognition" (SANCO/13169/2010 rev9 of 11 July 2014) states that "MR applies to all authorisations in MS, which were either granted under Directive 91/414/EEC in compliance with Annexes II, III and VI of that Directive or under Regulation (EC) No 1107/2009". [3]

52. For PPPs authorised by another MS under Regulation (EC) No 1107/2009 in the German cMS or MR application stream, an evaluation is conducted by the German CAs to satisfy specific NRs in the areas of toxicology, E-fate, ecotoxicology and efficacy. As with the zRMS system, delays in granting authorisations result from both the evaluation to satisfy NRs and a lengthy risk mitigation process. Refusals are due to a failure to satisfy NRs, mainly in the environmental area.

Conclusions

53. When acting as zRMS, applications are delayed due to the practice of accepting additional data and conducting additional evaluations to satisfy NRs. This is compounded by further delays in the risk management process and as a consequence, authorisations are also delayed in cMS. As a consequence of these delays, the deadlines set out in Regulation (EC) No 1107/2009 are not complied with.

54. In many cases, other MS acting as zRMS do not evaluate all uses sought in Germany and are routinely late in finalising the RR, thus contributing to delays in the German authorisation process. In addition, applications as cMS and for MR are routinely evaluated to satisfy numerous NRs, mainly in the environmental area which also contributes to delays in the process and the lack of compliance with the deadlines set out in Regulation (EC) No 1107/2009.

55. The German policy of not accepting applications for MR for PPPs authorised by other MS under Directive 91/414/EEC, and the difficulties for applicants to get PPPs authorised using the cMS/MR systems, incentivises them to use Germany as a zRMS, thus increasing the evaluation workload and reducing the efficiency of the authorisation system, the result being that the deadlines set out in Regulation (EC) No 1107/2009 are not complied with.

56. Although some significant NRs have been in place for many years, CAs have not thoroughly sought systems to validate the models used, for example with the experience gained from the actual use of PPPs, thus providing little justification for the imposition of

[3] In their response to the draft report the Competent Authority noted that they consider Article 40 of Regulation (EC) No 1107/2009 to be binding, expressly providing for mutual recognition, only for authorisations granted under Article 29 of this Regulation. In their opinion, a guidance document cannot change the provisions of this Regulation.

these onerous requirements on both applicants and the CAs. Experience gained from the actual use of plant protection products containing the substances concerned and any developments in science and technology should be taken into account.[4]

57. Where non-mitigatable adverse consequences of PPP use are identified in the course of PPP evaluations, the application is refused. However, CAs do not review equivalent existing authorised PPPs, as provided for under Article 44 of Regulation (EC) No 1107/2009. Therefore, the existing PPPs continue to remain on the market, thus creating a system that favours incumbents over new entrants, with significant market access, and therefore, economic consequences for applicants.

5.3.5. Generic plant protection products

58. Under both Directive 91/414/EEC and Regulation (EC) No 1107/2009, when a PPP is first placed on the market in a MS, all data associated with the product is protected for ten years, with some additional data protection possible associated with approval on minor-use crops under Regulation (EC) No 1107/2009. This encourages research and development companies to invest in developing new PPPs and after the ten year period facilitates price competition by allowing other companies to use the unprotected data to authorise equivalent PPPs. The audit team noted that while BVL receive applications for authorisation of generic PPPs, (13% of 2015 applications), there are relatively few generic PPPs on the market compared to some other central zone MS. For example, for one widely used fungicide, first marketed over 20 years ago, Germany has just one authorised PPP, whereas four other central zone MS, have over 30, 6, 5 and 2 equivalent authorised PPPs respectively, including a number of generic products. In the case of a relatively old herbicide formulation, Germany has just one authorised PPP, whereas in the same four central zone MS have 20, 13, 3 and 2 equivalent authorised PPPs, including generic products. While all of the authorisation holders in this other central zone MS may not have sought authorisation in Germany, the audit team noted that such authorisations had been sought in a number of cases and were refused in Germany for a number of these generic PPPs authorised in the other central zone MS.

Conclusions

59. Applicants for generic authorisations have difficulties in gaining authorisations compared to some other MS, thus restricting access to the market for applicants and choice for users.

5.3.6. Emergency authorisations

60. Approximately forty emergency authorisations are granted per year. These are granted only when BVL, in consultation with relevant stakeholders, are satisfied that there are no other viable pest control options. This is reflected in the fact that some 35 % of all

[4] In their response to the draft report the Competent Authority noted that the experience gained from the actual use should be taken into consideration for the development of all evaluation models used in the EU.

applications for emergency authorisations are refused. Emergency authorisations are published at http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/02_ZulassungPSM/01_ZugelPSM/02_Genehmigungen/psm_ZugelPSM_genehmigungen_node.html, rather than on the main PPP register. However, contrary to the requirements of Article 57 of Regulation (EC) No 1107/2009, all relevant information is not made publicly available, in particular the description of use or uses (dosage, application methods and conditions, risk mitigation measures) for which these PPP are authorised. The significant delays in authorising PPPs, and the absence of a fast-track system for extensions in use, compound the problem of a lack of products for minor uses. This has led users to apply for repeated emergency authorisations for some minor use crops e.g. hops. In some cases, these emergency authorisations were sought, and granted, in consecutive years while applications for authorisation of the PPPs/extension in use was in the evaluation/authorisation process, and the PPP was authorised, and the use on the specific crop permitted, in other central zone MS.

Conclusions

61. Emergency authorisations for PPPs are granted only where a critical need has been established and while they are made publicly available, some specific information for their safe use is not available as required, information which is critical to ensure a high level of protection of both human and animal health and the environment.

62. Delays in granting regular authorisations leads to an increased number of emergency authorisations being requested, and granted, to control pests, particularly on minor use crops.

5.3.7. Parallel Trade Permits

63. PTPs are an important part of the EU PPP market by facilitating intra-EU trade in authorised PPPs, therefore increasing competition and reducing price discrepancies between MS. Since 1 January 2013, more than 1 800 applications for PTPs were received in Germany, of which 90 % were granted and 10 % refused. The average time to take a decision was 38 working days, in compliance with the deadline of 45 working days set out in Article 52 of the Regulation. However, in more than 150 cases (8.5 % of the total applications) the deadline was exceeded, of which 50 applications took over 135 days to process. These delays were mainly due to the large number of applications and sample analyses required to confirm that PPP are identical to the reference products.

64. In 1 000 cases, additional information was required of the originating MS regarding the reference PPP. The average time to receive the additional information was 26 working days, significantly exceeding the 10 working day deadline established under Article 52 of the Regulation. It is notable that in 35 % of the cases, the time to receive an answer from another MS was over 20 days, reflecting the need for greater EU co-operation in this area.

Conclusions

65. The system for granting PTPs is reasonably effective, with more than 90 % of all applications processed within the legal deadline. Delays in the system are generally linked to the large number of applications.

5.3.8. New sources of active substances

66. PPPs may only be placed on the market containing active substance from the source(s) specified in the conditions of authorisation. Authorisation holders may subsequently seek approval for new sources of active substance. 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. There are no defined deadlines for approval of new sources of active substance prescribed in EU legislation.

67. BVL received 24 applications since 1 January 2013 for the evaluation of new sources of active substance as described in Article 38 of Regulation (EC) No 1107/2009. The time to evaluate this type of applications ranges from 29 to 523 days with an average of 166 days. In addition, a further 79 applications were received in the same period for acceptance of active substance sources which had been evaluated by another MS. The average time to process this type of applications is 58 days.

Conclusions

68. The system for approval of new sources of active substance is effective, thereby facilitating authorisation holders to ensure that they only market PPPs containing active substance from approved sources.

6. OVERALL CONCLUSION

Significant delays in granting authorisations of plant protection products are commonplace. These delays exceed the legal deadlines set out in EU legislation for both new products and re-authorisation of those already in the market. This is primarily caused by a lack of EU harmonisation in the standards which Member States use for evaluations, particularly in the environmental area. Consequently, all applications received by Germany are evaluated to satisfy German requirements, even when other Member States have already conducted evaluations based in EU agreed principles. Further evaluation delays result as a consequence of the policy of routinely accepting additional studies and clarifications from applicants in cases where the initial evaluation has a negative outcome. Finally, delays in evaluation are compounded by further delays in determining appropriate risk mitigation measures, due to a policy of achieving consensus between the two CAs responsible for risk management.

The national requirements and procedures to implement Regulation (EC) No 1107/2009 are particularly onerous for the German Competent Authorities. This burden is largely due to

working to German rather than EU timelines (which makes it more difficult to achieve efficiencies across Member States), not seeking synergies and avoiding duplicating evaluation work, and by having an extensive range of national requirements. All these practices make work-sharing with other Member States very difficult. As a consequence, applicants are incentivised to seek authorisation in Germany based on evaluation, rather than Mutual Recognition, leading to an even greater evaluation workload which constrains the capacity of the authorisation system to efficiently carry out the obligations laid down in the Regulation. The lack of reliable forecasting regarding the inflow of future applications makes for an ineffective system of long term planning necessary to ensure compliance with EU legal deadlines.

There are significant market access issues arising from weaknesses in the system of authorisation of plant protection products. Delays in the authorisation process and slow access to the market for new products increase the regulatory burden on applicants. Applicants for generic authorisations have particular difficulties in gaining authorisations, thus reducing choice and access to the market.

7. CLOSING MEETING

A closing meeting was held in Braunschweig on 4 March 2016 with representatives of FMAF, BVL, UBA, BfR and JKI. At this meeting, the audit team presented the preliminary findings and conclusions of the audit and the CAs provided initial comments on these findings and conclusions.

8. RECOMMENDATIONS

The Competent Authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this audit report. The CA should:

No.	Recommendations
1.	Ensure that the authorisation system is reviewed so as to meet the deadlines laid down in Articles 37 (1) of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 41, 42, 43, 44, 53* *Associated findings upon which this recommendation is based: 31, 33, 34, 35*
2.	Ensure that the authorisation system is reviewed so as to meet the deadlines laid down in Articles 37 (4) of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 41, 42, 43, 44* *Associated findings upon which this recommendation is based: 31, 33, 34, 35*
3.	Ensure that the authorisation system is reviewed so as to meet the deadlines laid down in Article 42 (2), of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 41, 42, 43, 44* *Associated findings upon which this recommendation is based: 31, 33, 34, 35*
4.	Ensure that the authorisation system is reviewed so as to meet the deadlines laid down in Article 52 of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 65* *Associated findings upon which this recommendation is based: 64*
5.	Ensure that for emergency authorisations, the information on the use or uses for which the plant protection products are authorised is kept electronically available to the public, as required by Article 57 of Regulation (EC) No 1107/2009. *Conclusions upon which this recommendation is based: 61* *Associated findings upon which this recommendation is based: 60*
6.	Consider reviewing existing authorisations for relevant PPPs under Article 44 of Regulation (EC) No 1107/2009 when applications for generic PPPs have been refused due to the concerns that cannot be controlled by national risk mitigation measures as set out in Article 36 (3), so as to address safety/environmental concerns identified in the refusal decision and to ensure equal treatment of all applicants. *Conclusions upon which this recommendation is based: 57* *Associated findings upon which this recommendation is based: 50*

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2016-8780

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 1107/2009	OJ L 309, 24.11.2009, p. 1-50	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
Reg. 546/2011	OJ L 155, 11.6.2011, p. 127-175	Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products
Reg. 284/2013	OJ L 93, 3.4.2013, p. 85–152	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

Annex 2 – Standard Quoted in the report

Reference number	Full title	Publication details
SANCO/2010/13170	Guidance Document on the Renewal of Authorisations according to Article 43 of Regulation (EC) No 1107/2009	http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents/docs/gd_renewal_1107-2009_rev_13.pdf
SANCO/11244/2011	Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"	http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/risk_envelope_gd_rev_14032011_en.pdf
SANCO/13169/2010	Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009	http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/gd_mut_rec_en.pdf
Codex Alimentarius Commission – Report of the 26th Session Rome, 30 June – 7 July 2003	Appendix IV. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius	http://www.fao.org/docrep/006/y4800e/y4800e0o.htm#bm24