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Health and food audits and analysis

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FINAL REPORT OF AN AUDIT
CARRIED OUT IN
LITHUANIA
FROM 14 TO 27 SEPTEMBER 2022
IN ORDER TO
EVALUATE CONTROLS ON THE MARKETING AND USE 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 of Lithuania, carried out from 14 to 27 September 2022 as part of the published Directorate-General for Health and Food Safety work programme for 2022.

The objective of the audit was to evaluate the system of official controls on the marketing and use of plant protection products.

The audit outcome is based on a review of documentation and records pertinent to the audit scope, interviews and discussions with representatives of the competent authorities, via video-conference and on-site verification, and assessment of the operation of official controls.

Lithuania has a relatively low intensity of pesticide use compared to the EU average with its 70,000 professional users accounting for less than 1% of the plant protection products used in the European Union. In addition, there is no manufacturing, and limited re-packing and importation, of plant protection products.

Overall, the control system on the marketing and use of plant protection products is effective. The responsibilities of the respective Competent Authorities are well defined, with high levels of both formal and informal cooperation between Competent Authorities. Controls are risk based, are conducted according to the annual plan, and cover all relevant economic operators with an appropriate frequency.

The system of controls ensures that only appropriately registered products are distributed and that these products are used in accordance with their approved labels. The formulation analysis programme is an integral part of these controls, is effective and is constantly being refined, but uses laboratories which are not officially designated in line with Regulation (EU) 2017/625.

The report contains one recommendation to the competent authorities to address the shortcoming identified.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA(s)	Competent Authority(ies)
CCCs	cross-compliance checks
EPA	Environmental Protection Agency
EU	European Union
ha	Hectare(s)
IKMIS	System of Integrated Plant Protection Information, Consulting and Training
IPM	Integrated Pest Management
MS(s)	Member State(s)
MoA	Ministry of Agriculture
NAP	National Action Plan
NPA	National Paying Agency
PAE	Pesticide Application Equipment
PPP(s)	Plant Protection Product(s)
SFVS	State Food and Veterinary Service
SPS	State Plant Service
SUD	Sustainable Use Directive

1. INTRODUCTION

The audit formed part of the Directorate-General for Health and Food Safety (DG Health and Food Safety) planned work programme for 2022. The audit took place from 14 to 27 September 2022. The audit team comprised three auditors from DG Health and Food Safety. Most of the audit meetings were carried out remotely, with just one face to face meeting in Lithuania, and these meetings were augmented by specific site visits by the audit team.

An opening meeting was held remotely with representatives of the Ministry of Agriculture (MoA), including the State Plant Service (SPS). At this meeting, the audit team confirmed the objectives of, and itinerary for, the audit and information required for the successful completion of the audit was requested. The audit team was accompanied throughout the site visits by representatives of the SPS.

2. OBJECTIVES AND SCOPE

The objective of the audit was to evaluate the system for official controls on the marketing and use of plant protection products (PPPs), in particular:

- the implementation of requirements for official controls of PPPs under Regulation (EU) 2017/625 of the European Parliament and of the Council, performed in order to verify compliance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council,
- the implementation of Articles 5 and 6 of Directive 2009/128/EC of the European Parliament and of the Council (the SUD),
- the actions taken for the follow-up of open recommendations in the area of PPP controls.

In terms of scope, the audit focused on the organisation of the competent authorities (CAs) and on the planning and implementation of official control systems on the marketing and use of PPPs under Regulation (EC) No 1107/2009. Articles 5 and 6 of the SUD are also included in the scope of the audit, given their relevance to controls on the marketing and use of PPPs. On the other hand, other requirements of the SUD, such as control systems on integrated pest management (IPM), the handling and storage of PPPs and treatment of their packaging and remnants are not addressed in this audit. This is because these issues are covered extensively in the series of audits dedicated to assessing the implementation of the SUD.

To meet the above objectives, a series of meetings were held with CAs, and there were four days of site visits in Lithuania, during which the audit team observed inspectors carrying out controls on professional users, distributors, importers and re-packers.

Meetings and Site Visits	
Meetings	**Comments**
Five remote meeting and one physical	Representatives of SPS, MoA, Customs, NPA
4 Locations/Economic operator	A farm, a PPP re-packer, a PPP retailer and the SPS phytosanitary border control point at Klaipėda port

3. LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of EU legislation, in particular Articles 116, 117 and 119 of Regulation (EU) 2017/625.

Full legal references for the relevant EU legal acts are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

4. BACKGROUND

4.1. LEGAL CONTEXT

The 2006 Thematic Strategy on the sustainable use of pesticides[1] led to a new legislative framework for the approval and use of pesticides. This includes a strict framework for the approval of active substances by the European Commission and the authorisation of PPPs by Member States (MSs), introduced by Regulation (EC) No 1107/2009, adopted on 21 October 2009. This Regulation requires for active substances and PPPs to be authorised only if these have no identified harmful effects on human and animal health, and no unacceptable effects on the environment. It also requires that PPPs be applied according to the authorised conditions of use. The SUD was adopted on the same date (21 October 2009) as part of the above mentioned Thematic Strategy.

Article 55 of Regulation (EC) No 1107/2009 requires PPPs to be properly used. This means the application of the principles of good plant protection practice and compliance with the conditions established in accordance with Article 31 of the same Regulation, and specified on the label. In addition, Article 55 also stipulates that proper use includes compliance with the provisions of the SUD and, in particular, with the general principles of IPM, as referred to in Article 14 and Annex III to the SUD. However, given that IPM is addressed extensively in a separate audit series on the SUD, it will not be addressed in this series.

With effect from 14 December 2019, Articles 9 and 10 of Regulation (EU) 2017/625 requires MSs to carry out official controls in order to verify compliance with the rules referred to in its Article 1 (2) (h), which includes requirements for the placing on the market and use of PPPs.

4.2. COUNTRY PROFILE AND STATISTICS

DG Health and Food Safety has published a country profile for Lithuania, which can be found on its web-site:
https://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=LT

This 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 audit reports.

The utilised agricultural area of Lithuania is just less than three million hectares with more than two thirds of it dedicated to production of arable crops (EUROSTAT, 2016). In 2020, PPPs containing in excess of 2,500 tonnes of active substances were placed on the market in

[1] COM/2006/0372 final - Not published in the Official Journal

Lithuania accounting for less than 1% of EU sales. At the time of the audit in September 2022, there were nearly 600 authorised PPPs which could be marketed and used in Lithuania, and about a further 50 PPPs which could be sold under parallel trade permits.

4.3. PREVIOUS AUDITS/MISSIONS

This audit is part of a series of audits in EU MSs on controls of PPPs. Prior to the current audit series, DG Health and Food Safety carried out five series of missions/audits to MSs concerning controls of PPPs. The overview reports of these mission/audit series can be found on the DG Health and Food Safety website https://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm.

The most recent audit series concerning controls on the marketing and use of PPPs was carried out in the period January 2015 to June 2016. The overview report of the series (DG(SANTE) 2016-6004 - MR) concluded that control systems on users and retailers were satisfactory. On the other hand, there were significant weaknesses in controlling that the products placed on the market complied with the stringent conditions of their authorisation or parallel trade permit. In the majority of MSs, the risks associated with larger, higher-risk operators, specifically, importers, manufacturers and re-packers of PPPs, had not been sufficiently considered in the planning of controls. Consequently, the frequency and scope of controls at these operators was generally insufficient. Controls at these specialist operators were further weakened by the lack of specific training for inspectors and insufficient formulation analysis programmes. Finally, the majority of MSs did not conduct controls on PPPs intended for use in other MSs or in non-EU countries, a significant weakness that could be easily exploited to place non-compliant products on the market.

The most recent audit of Lithuania dealing at least partially with the marketing and use of PPPs was in September 2005 (DG(SANCO)/7667/2005- MR Final), which was prior to the implementation of the current legislative framework. However, Lithuania was audited for compliance with elements of SUD in 2019 (DG(SANTE) 2019-6722), resulting in a number of recommendations, two of which were followed-up during the course of this audit.

5. FINDINGS AND CONCLUSIONS

5.1. ORGANISATION OF OFFICIAL CONTROLS ON THE MARKETING AND USE OF PLANT PROTECTION PRODUCTS

Legal requirements

Articles 4 to 6, 9 to 14, 28 to 33 and 37 to 42 of Regulation (EU) 2017/625

Article 28 (2) (c) and (d) of Regulation (EC) No 1107/2009

Article 291 (1) of the Treaty on the Functioning of the European Union

Findings

5.1.1. *Competent authorities*

1. The CAs responsible for planning and implementing official controls are described in the Country Profile https://ec.europa.eu/food/audits-analysis/country/profile/details/LT. The CAs confirmed that there had been no changes since the Country Profile was last updated. The CAs responsible for official controls on the importation and the marketing and use of PPPs are clearly defined and designated in line with Article 4 (1) of Regulation (EU) 2017/625.
   In summary;
   - The MoA is the CA responsible for all legislation associated with official controls on the marketing and use of PPPs,
   - The SPS, which is under the auspices of the MoA is the CA responsible for planning, and execution of all non-import related PPP controls,
   - The SPS is the main CA for controlling imports of PPPs into Lithuania and PPPs in transit, in close cooperation with Customs,
   - The SPS is also the CA for authorisation of PPPs and the assessment of active substances, safeners, synergists and co-formulants, which can be used to manufacture PPPs,
   - The National Paying Agency (NPA) is the paying agency for funds under the Common Agricultural Policy (CAP), and is responsible for carrying out controls under Cross Compliance on professional users of PPPs claiming these funds.

2. Coordination between the CAs is defined in cooperation agreements, ensuring an effective and consistent approach to official controls in line with Article 4 (2) of Regulation (EU) 2017/625. Cooperation agreements exist between the SPS and the following:

   - The State Food and Veterinary Service, since 2010 with an update in 2015,
   - The Customs Department, since 2011 and revised 2022,
   - The State Border Guard Service, since 2011,
   - The Lithuanian Agricultural Advisory Service, since 2011 with an update in 2015,
   - Lithuanian Plant Protection Association, since 2011,
   - Agricultural Information and Rural Business Centre, since 2012,
   - National Paying Agency and State enterprise Lithuanian Agricultural and Food Market Regulatory Agency since 2016,
   - Police Department, since 2016.

3. The SPS has several central divisions as well as 10 regional divisions. The SPS is sufficiently staffed with around 290 staff in total, 99 of which work from the regional offices and 54 from border posts. Staff are well educated, with 76% having a university degree in life sciences. While responsibilities extend beyond PPPs, the system of controls is well resourced with currently six people working exclusively on PPP controls at central level and 24 full time equivalents devoted to PPPs at regional level.

4. The Agrochemical division of the SPS uses a defined risk analysis to develop a plan of controls annually and sends it to each of the ten regional divisions. It also issues instructions and guidelines to the regional divisions on what areas and topics should be checked during official controls, providing various control questionnaires, to ensure a harmonised approach across all regional divisions.

5. The Agrochemical division of the SPS also devises annual staff training programmes which are also developed at the beginning of each year and disseminated to the regional divisions. Other actors such as Border Control Coordination Division are also included in these programmes.

6. The SPS, including the 10 Regional divisions and 13 Border Inspection Posts, cooperate closely with Customs and there exists within SPS a dedicated division to facilitate such cooperation, the Border Control Coordination division. This cooperation allows for the sharing of intelligence, staff training and most importantly provides the basis for joint controls in cases where PPP consignments are identified as high-risk.

7. The SPS cooperates with the State Food and Veterinary Service in the context of follow up controls on users of PPPs identified as a result of maximum residue level (MRL) exceedances.

8. The CAP NPA cross reports the results of its PPP related inspections to the SPS and vice versa.

9. The Regional divisions, the Agrochemical division and the Border Control Coordination division of SPS have access to the SPS databases and the expertise from the PPP Registration units specialists, which enhances the effectiveness of their controls.

10. All staff performing official controls receive appropriate initial and additional annual training on PPPs, ensuring that everybody remains competent and up to date as required by Article 5 (4) of Regulation (EU) 2017/625. The training provided to SPS inspectors is at least one session per year, but more can be arranged if required. Sessions tend to concentrate on updates in legislation, results of the previous control programmes and emerging issues. Historically, all training sessions took place in person but in recent years some sessions also take place online, in response to the Covid-19 pandemic.

11. The ten Regional divisions report the outcomes of official controls to the headquarters of the SPS and the Agrochemcial division quarterly, an example of which can be found using this link http://www.vatzum.lt/lt/administracine-informacija/ukio-subjektu-prieziura/informacija-apie-veiklos-vertinimo-kriterijus-rodiklius/ with more serious issues reported immediately. In addition, using the SPS electronic platform VATIS, the central authorities can access real time information in relation to individual inspections, or more general information such as progress with the annual plan of inspections.

12. Customs together with SPS participate in the annual Silver Axe operations coordinated by the European Union's Law Enforcement Agency (Europol) since 2017. These

operations enhance cooperation between enforcement authorities in MSs with the aim of improving detections of illegal PPPs.

13. In accordance with Article 5 (1) (a) and (b) of Regulation (EU) 2017/625, the SPS systems and procedures in place ensure high quality, impartial, effective and appropriate controls. The VATIS platform is an efficient mechanism for recording inspection details and results in real time. In addition, it provides heads of regional divisions real time oversight on progress achieved with the plan of inspections. Furthermore, as required by Article 5 (1) (e) of Regulation (EU) 2017/625, the staff in pertinent SPS divisions and Customs are suitably qualified and sufficiently experienced to ensure efficient and effective execution of official controls.

14. The processes and procedures in SPS are constantly being refined, and to enhance the effectiveness of this practice, there is an internal system of audit. This audit process helps identify practices which could be inefficient or unnecessary or indeed practices that are missing or lacking. An internal audit covering PPP controls took place earlier in 2022. The internal audit process is further complemented by a further level of audit which is carried out periodically by the MoA, the last one taking place in September and October of 2020.

Conclusions on the competent authorities

15. All relevant CAs and their responsibilities are clearly defined, with good cooperation between CAs, which forms a firm basis for execution of official controls on the marketing and use of PPPs.

16. Staff are competent and well trained, which ensures that the programme of controls can be carried out effectively and efficiently.

5.1.2. *Planning of official controls*

Findings

Planning of official controls (SPS)

17. There is no manufacturing and limited repackaging of PPPs in Lithuania. The repackaging of PPPs tends to be solely for the purpose of providing smaller pack sizes for non-professional users (home and garden) and smaller, less intensive farmers/professional users.

18. The Agrochemical division of the SPS is responsible for formulating an annual plan of controls on the marketing and use of PPPs. This plan is devised using an agreed methodology using a weighting system to categorise economic operators into risk categories. The weighting system considers the size of the economic operator, size of storage, type of products etc. as well as results from previous controls. This results in economic operators being divided into three categories - low, medium and high-risk.

19. The methodology requires up to 10% of low-risk operators, at least 10% of medium-risk operators, and at least 50% of high-risk operators be inspected annually. In addition, up to 15% of economic operators not inspected in the previous ten years, should be inspected irrespective of their risk category. Further controls, based on complaints and information from other CAs are also possible, as are follow up inspections to confirm rectification of issues identified in previous inspections.

20. The SPS has lists of the various types of economic operators identified. While there is some overlap in some instances, e.g., a wholesaler may also be a re-packer or retailer, this does not detract from the efficiency of the process. In fact, it enhances the likelihood of an economic operator who is engaged in many different types of trade of being inspected. There are 12 importers, three re-packers, 368 distributors and 696 sale points of PPPs in Lithuania.

21. The number of professional users in 2021 was 63 772. This figure is made up of both agricultural and non-agricultural economic operators. The primary sources of information are the pesticide application equipment (PAE) register, the professional user training register, the list of applicants for various CAP related payments, as well as information gathered through the inspection programme and general operations.

22. The annual control plan is issued from central level and is distributed using an electronic networking platform (VATIS). The plan takes the form of a document which outlines the economic operators to be inspected in each region. The plan provides for a window of up to three weeks for regional divisions to perform each inspection. The head of each regional division may refine based on resources when exactly the inspections are carried out. If a planned inspection is postponed, a report is completed and a justification is provided through VATIS. Each regional division issues quarterly progress reports on the delivery of the planned inspections through VATIS, even though the central CA is able to follow the plan's evolution in real time again via VATIS.

23. The VATIS platform provides inspectors with their weekly plan of inspections. As they are aware of the identity of the economic operator, they can prepare for the inspection by consulting previous inspection reports, as well being able to pre-populate the appropriate control questionnaire with data available from relevant internal resources, such as the lists of certified users of PPPs or PAE certificates of compliance.

24. Five per-cent of all planned inspections are carried out by inspectors from neighbouring regions, to ensure harmonised application of the requirements and to ensure overall consistency, uniformity and impartiality during the performance of these inspections.

25. The bulk of professional user inspections are conducted during the main PPP use period of April to October to ensure as broad a scope of inspection is covered including field visits but also to facilitate sampling of crop, vegetation, water or soil, when considered necessary. While distributer and re-packer inspections are planned to take place throughout the year.

26. In addition, the ten regional divisions conduct controls in a more ad-hoc basis, as a result of complaints or intelligence related to local markets and internet sales. Checks are also carried out in relation to advertising both as part of routine official controls on distributors, but also in a more general way so as to detect traders not registered with SPS to sell PPPs.

27. The SPS confirmed that official controls are performed without prior notice as required by Article 9 (4) of Regulation (EU) 2017/625, except where particular circumstances require that notice is given. This was further confirmed by the inspectors from the regional divisions. Official controls are carried out in a way that minimises disruption or administrative burden to the economic operator as required by Article 9 (5) of Regulation (EU) 2017/625.

28. In 2020, 2 556 inspections were planned, of which 2 255 were carried out, and in addition 294 unscheduled inspections were carried out. In 2021, 2872 inspections were planned, of which 2 508 were carried out, and an additional 396 unscheduled inspections were also carried out.

Planning of official controls (National Paying Agency)

29. The NPA selects operators for inspection based on a detailed risk profiling document, considering in excess of 50 parameters, such as number of crops, cultivation of pollinator attractive crops, size of economic operator etc. The NPA typically completes over 1 200 inspections per year.

30. The cooperation agreement between the SPS and the NPA helps to avoid where possible, duplication of inspection.

31. The NPA possesses a list of economic operators who make application for CAP funds annually. Not all of these applicants are professional users of PPPs. In 2020, the number of applicants for CAP funds was 124 482 with 738 being chosen for PPP related inspection and for 2021 the number of applicants for CAP funds was 120 901 with 665 being chosen for PPP related inspections. The number of inspections for these years was 50% of the usual number due to pandemic related restrictions.

Planning of official controls (Customs)

32. The SPS in conjunction with Customs authorities conduct routine documentary controls on all imports of both PPPs authorised for use in EU and in third countries. They examine the ships manifest and other transport documents to detect words/phrases as well as combined nomenclature (CN) codes to determine if a physical inspection is necessary.

33. Customs do not have a predetermined control plan established at the start of each year as the information available to them on incoming shipments is simply insufficient. There is a useful procedure whereby an economic operator wishing to import PPPs into Lithuania for use in the national territory, must first apply to the SPS for permission.

Where approval is granted by SPS, the SPS informs Customs and the economic operator has 45 days to import the PPP consignment. Such pre-notification is useful to both SPS border posts and Customs, and gives an early indication of possible quantity and timing of consignments and allows for planning of controls. Customs and SPS confirm that 100% of PPP imports for Lithuanian or other EU market are subject to both documentary and physical controls. Furthermore, 100% of consignments from third countries in transit to other third countries are subject to documentary checks with physical checks only being triggered on a risk basis, if suspicions are raised from documents accompanying the consignment.

34. The official controls conducted by the CAs at points of entry into the country cover plant protection products, active substances, safeners, synergists, adjuvants and co-formulants as required by Article 24 (1) of Regulation (EU) 2017/625.

35. The SPS conduct controls on the storage and movement of PPPs intended for use in other MSs and non-EU countries to ensure that these PPPs are not used in Lithuania and are exported as required in line with Article 28 (2) (c) and (d) of Regulation (EC) No 1107/2009. Each consignment identified as "in transit" is subjected to a documentary check, and if any anomalies or suspicions result, a physical inspection ensues.

36. The CAs provided data demonstrating the relatively insignificant scale of PPP imports (2021, 106 356 litres of formulated product) and also the amount of which was declared as "in transit" to a third country (2021, 152 consignments). Each consignment declared as being "in transit" is given a maximum of 8 days to exit the territory via a nominated border control post. Any issue or deviation is noted centrally and investigated. These cases involve close cooperation between SPS and Customs and importantly between SPS and counterparts in other MSs.

Planning of Official Controls (Formulation analyses)

37. There are nearly 600 PPPs authorised for marketing and use in Lithuania, with about a further 50 products with parallel trade permits which can also be marketed and used. Samples for formulation analyses are chosen on the basis of risks posed within the supply chain and volume in which they are placed on the market. The average number of products chosen for sampling and analyses from 2019 to 2021 was about eight *per annum*. 2022 saw an increase in the number of PPPs to be sampled, nearly doubling the number to 15.

38. When a sample is taken for analysis and a laboratory is chosen, the specification of the PPP is obtained from the PPP Registration division and sent with the sample to the analytical laboratory. This ensures that the laboratory can commence its work immediately and does not have to engage in any correspondence requesting such information.

Conclusions on planning of official controls

39. The CAs consider all relevant risks when developing the plan of controls on the

marketing and use of PPPs.

40. The scope and frequency of inspections, coupled with the PPP formulation analysis programme, provides a firm basis for an effective system of controls on PPPs for use in Lithuania.

41. Official controls are performed without prior notice and in a consistent manner thereby ensuring all economic operators are treated fairly and that controls are effective.

42. The CAs have up to date lists for all economic operators marketing and using PPPs, thereby having the necessary information on which to base controls.

43. Controls on both imports and consignments in transit from third countries are efficient and effective.

5.1.3. *Delegation of certain tasks*

Findings

44. The CAs confirmed that all aspects of the planning and implementation of controls on the marketing and use of PPPs are undertaken by the CAs, rather than being delegated to other bodies or natural persons in accordance with the conditions provided for in Articles 29 and 30 of Regulation (EU) 2017/625.

Conclusions on delegation of certain tasks

45. All aspects of the planning and implementation are undertaken by the CAs.

5.1.4. *Laboratories used for formulation analysis of plant protection products as part of official controls*

Findings

46. The CA has used a number of laboratories outside Lithuania to carry out formulation analyses. These laboratories are all accredited in accordance with the EN ISO/IEC 17025 standard by their respective national accreditation body operating in accordance with Regulation (EC) No 765/2008 as required by Article 37 (4) (e) of Regulation (EU) 2017/625. The CAs instructions to the laboratories include a description of the tasks required in line with Article 37 (3) of Regulation (EU) 2017/625, and the laboratories used in each case satisfy the requirements set out in Article 37 (4) of the same Regulation.

47. The majority of laboratories used by the SPS participate in annual proficiency tests in line with Article 38 (2) of Regulation (EU) 2017/625, while other laboratories participate in additional inter-laboratory comparative testing.

48. The CA has not designated any laboratory as an official laboratory to carry out PPP formulation analysis. This is not in line with Article 37 (1) of Regulation (EU) 2017/625.

49. As required by Article 38 (1) of Regulation (EU) 2017/625, the analytical results of sampled formulations, including both compliant and non-compliant samples, when finalised, are immediately forwarded to the CA, who in turn inform the regional division responsible for the sampling, who take action as necessary.

50. Where non-compliant samples are identified and communicated by the laboratory, immediate action is taken involving participation from many divisions of the SPS, including the regional divisions, the Agrochemical division and the PPP Registration division.

51. From 2019 to 2021, 5 out of 24 samples were deemed not to be compliant with specifications authorised by the PPP Registration division and all had their authorisations revoked. The high rate of non-compliance reflects the fact that the majority of the samples taken were based on intelligence, including both observations and reports. Where a non-compliance is identified, SPS issue a revocation notice to the authorisation holder, followed by a recall notice to all levels of distribution and use. All economic operators including end users have to provide proof of rendering/destruction of hazardous waste any unused quantities of a recalled PPP.

Conclusions on laboratories used for formulation analysis of plant protection products as part of official controls

52. While the laboratories utilised by the CA are accredited, participate in inter-laboratory testing and standardised proficiency tests, and are capable of conducting the wide range of analysis required, the laboratories used for formulation analysis are not officially designated, as required by Article 37 of Regulation (EU) 2017/625.

5.2. Implementation of Official Controls on the Marketing and Use of Plant Protection Products

5.2.1. *Controls on the marketing of plant protection products*

Legal Requirements

Articles 11 to 14, 24, and 138 to 139 of Regulation (EU) 2017/625

Article 28, 29, 31, 52, 65, 67 (1) and 68 of Regulation (EC) No 1107/2009

Articles 5 and 6 of Directive 2009/128/EC

Findings

53. The list of PPPs which can be marketed and used in Lithuania is available at *https://vatis.vatzum.lt/aapSarasas* and the approved labels for all these PPPs are available by following the appropriate links. Inspectors use this website to determine if PPPs are authorised, and to check the conditions of use approved by the CA. Such conditions of use include details of the crops on which the PPPs are approved, the maximum individual dose and maximum number of doses, the times of permitted use, and any risk mitigation measures required.

54. The Agrochemical division of SPS operate a system that requires all distributors of PPPs to be licensed by them.

55. In 2020, 388 economic operators had at least one infringement identified during inspections, resulting in 122 administrative offence protocols being drawn up (one for storage practices, six for issues on placing on the market and 115 for non-compliances relating to PPP use).
56. In 2021, 435 economic operators had at least one infringement identified during inspections, resulting in 207 administrative offence protocols being drawn up (four for storage practices, 18 for issues on placing on the market and 185 for non-compliances relating to PPP use).
57. Official controls are carried out in teams comprising of two or more inspectors following documented procedures and using control questionnaires provided by the Agrochemical division of SPS available on the VATIS web platform.

Importation of PPPs for use in other MSs or third countries

58. The main entry point for imports of PPPs is the port of Klaipėda, which is the largest sea port in Lithuania. SPS based control activities on PPPs, supported by the Customs, also take place at airports and on border crossings of both railway and roads. Lithuania borders two non-EU countries - Belarus and Russia. However, in practice, land border routes are not used for importation of PPPs.

59. A three-tiered approach is followed by SPS for all PPP consignments involving: documentation checks, verification checks and physical inspections. After SPS perform their checks, the consignments are forwarded with the necessary documents to customs for further processing. Customs procedures are facilitated by dedicated IT systems: 'KIPIS' (Freight and Goods Information System) (Klaipėda port only), RIKS (Risk Assessment and Control System) and NTKS (National transit Control System).

60. SPS are the CA responsible for PPP import controls and Customs are responsible for further procedures such as releasing for free circulation. Customs acknowledge the key role of SPS border inspectors as experts (as described in bilateral cooperation agreement). This cooperation and coordination occurs at all levels and on a day-to-day basis. This incorporates the inclusion of Customs personnel in SPS organised PPP

training events and other multi-disciplinary seminars organised both in person and remotely.

61. Increasingly, cooperation with other MSs, and resulting intelligence gathered, helps determine which PPP consignments merit physical inspection. To that end, participation in the Silver Axe project has enhanced Customs ability to identify suspicious CN codes and other anomalies. Customs and SPS did indicate that in some instances economic operators may actually request an inspection on a voluntary basis.

62. PPP consignments specifically designated for use in third countries are considered as being "in transit" and consequently undergo a routine documentary check in 100% of cases. These consignments are "sealed" by Customs to prevent such consignments being opened whilst in the territory. Further verification and physical checks are carried out only if there are issues or anomalies identified. However, each consignment is required to leave the territory of Lithuania within a minimum period of eight days. Progress of consignments "in transit" is tracked by border inspection post staff using the NTKS platform and central Customs are made aware if a consignment fails to leave the territory or if container seals have been tampered with. Customs seals may only be opened with Customs permission and Customs staff present. In 2021 there were 152 such consignments.

63. Where a PPP consignment is designated as being "in transit" to another MS, no permit is required to allow the importation. However, the consignments are checked and if necessary communication is made with MSs to which the consignment is in transit. In 2021, there were only two such consignments.

64. The PPP import controls described in the preceding paragraphs verify that:
    - PPPs intended for use in other MSs are authorised in that MS and that they are not used in Lithuania in line with Article 28 (2) (c) of Regulation (EC) No 1107/2009,
    - PPPs intended for use non-EU countries are exported in line with Article 28 (2) (d) of Regulation (EC) No 1107/2009.

Importation of PPPs authorised for use in Lithuania

65. The annual importation of PPPs countries is insignificant and in 2020 was just 17 600 kg and 206 388 L and in 2021, 22 consignments containing 106 356 L of formulated product were subject to documentary and physical controls. Consequently, it is not considered a major issue in Lithuania, nevertheless both documentary and physical controls are carried out on 100% of such importations at the point of Customs clearance.

Re-packers of PPPs

66. Re-packaging of PPPs currently takes place in Lithuania primarily to facilitate the marketing of PPPs in smaller pack sizes, where the authorisation holder is not prepared to place such smaller pack sizes on the market. As pack sizes are approved as part of the PPP authorisation process, no repackaging into smaller pack sizes can take place without prior approval from SPS. The re-packaging companies receive products that are in

already approved larger pack sizes but also in some instances in larger containers such as two hundred litre and one thousand litre containers. Material from these containers is then decanted into smaller containers sizes using specialised equipment and processes. The processes used are usually developed in conjunction with the main authorisation holder(s).

67. In Lithuania, products sold under parallel trade permits cannot be re-packaged, either inside or outside Lithuania.

68. The controls carried out at economic operators engaged in re-packaging, includes;
    - A mass balance type analyses of the records of purchases and sales, with an allowance made for a percentage of waste depending on the particular formulation.
    - A check that all PPPs present and intended for use within Lithuania are authorised in Lithuania in line with Article 29 of Regulation (EC) No 1107/2009 or have a parallel trade permit in line with Article 52 of Regulation (EC) No 1107/2009.

Distributors (Wholesale and retail)

69. There is no differentiation in Lithuania between PPP retailers or wholesalers of professional use and amateur use PPPs. Official controls on distributors involves both documentary and physical checks. The procedure entails some background work which can be completed in the inspectors office, checking details such as training certificates and checking if there are any online sales etc. This is followed by the physical checks on the economic operators premises, which involves checks on storage, verifying that training certificates are present as required by Article 5(2) of Directive 2009/128/EC, that PPPs in storage are authorised and within their expiry dates etc. Finally, there is a documentary check whereby the inspector confirms that sales of professional use products are only to professional users as required by Article 6(2) of Directive 2009/128/EC and further documentary checks on a selection of products chosen while in the storage area or alternatively whiles in the display area. The audit team observed the following documentary checks;
    - a "mass balance" type examination on three selected products, where three years records were examined for purchases. Opening and closing stocks are considered as well as other types of disposals, i.e., expired product for destruction etc.,
    - Examination of the authorisation status of all products present
    - Examination of expiry status of all products present,
    - Examination of labelling of the selected products for compliance with Articles 29, 52, 64 and 65 of Regulation (EC) No 1107/2009,

Formulation Analysis

70. Between 2019 and 2021 there were 24 PPPs sampled for analysis. The PPPs were chosen in a very targeted way using risk and volume as the two main parameters. Each sample was analysed for compliance with the authorised specification and the non-compliance rate for this period was approximately 21%. As none of these samples chosen were truly random samples, the non-compliance figure does not reflect the true

level of non-compliance in the market place in Lithuania. The CA has increased considerably the number of PPPs to be sampled and the programme for 2022 involves analyses of 15 formulations.

71. The analyses carried out is tailored in each case. In all instances the level of active substance is determined and in some cases the physical-chemical properties and/ or relevant impurities etc. Where PPPs are marketed under parallel trade permits, a comparison is made with the reference PPP.

72. For the 2019 to 2021 period, the sample turnaround time varied between 13 days and 160 days, with an average of 45 days. When you exclude the 3 samples with extended turnaround time (147, 147 & 160 days) a more acceptable but also a more reflective average of 30 days results.

Outcomes of controls and sanctions

73. Lithuania documents and submits the outcome of the official controls on the marketing and use of PPPs carried out, to verify compliance with Regulation (EC) No 1107/2009, to the Commission by 31 August each year as required by Article 68 of the Regulation.

74. In addition, and as required by Article 11 (1) of Regulation (EU) 2017/625, SPS confirmed that Lithuania publishes information on the outcome of the official controls on the marketing and use of PPPs annually. These reports contain information on the type, number and outcome of official controls and, the type and number of cases of non-compliance detected. An example of such a publication can be found using this link, *https://vmvt.lt/veikla/veiklos-ataskaitos/daugiamecio-nacionalinio-kontroles-plano-2021-m-veiklos-ataskaita*

75. While conducting official controls on the marketing and use of PPPs, SPS staff from each of the regional divisions use the methodology and control questionnaires provided by the Agrochemical division in accordance with Article 12 (1) of Regulation (EU) 2017/625.

76. The inspections are carried out using control questionnaires which are completed using electronic equipment. While notes are taken to collect initial data when in PPP stores or in the field etc., these handwritten notes are then transferred directly into the electronic control questionnaires which feed directly into the VATIS platform fulfilling the requirement of Article 13 (1) of Regulation (EU) 2017/625. The control questionnaires are quite detailed and have free text boxes in which to place additional information. Most inspections incorporate physical checks (PPP storage, PAE), documentary checks (PPP use records, purchase records etc.) as well as the possibility of sampling (PPP, soil, water etc.). The final document provides a complete record of the inspection, describing the control activity carried out, as well as the final outcome and remedial measures required by the economic operator. The economic operator is required to electronically sign the inspection report and may be provided with an electronic copy of the report.

77. Where a non-compliance is identified during the course of an inspection, the CAs have a range of sanctions they can apply in line with Article 138 (1) of Regulation (EU) 2017/625. Financial penalties and sanctions are defined in Articles 213 and 342 of Code of Administrative Offences of and implementing arrangements law 25 June 2015, No XII-1869, which was amended last in May 2021. Whereas an order to recall or render/destroy a consignment of PPPs or withdrawing the authorisation or parallel trade permit is detailed in the Lithuanian Plant Protection Law https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.21793/asr amended by Order Nos 3D-52 and 3D-53 of the Minister for Agriculture of the Republic of Lithuania of 1 February 2018.

78. Administrative penalties can be applied to both the economic operator but also can be applied directly the person in charge i.e., a manager of a company. Another important feature is that repeat offences attract a more substantial fine. Fines or penalties under the code of administrative offences for PPP related infringements range from €300 to €9000, depending on the gravity of the offence and whether it is a repeat offence or not. It is generally the case that infringements resulting from routine controls use the code of administrative offences as a means of penalty. Article 213 of the administrative code of offences allows for confiscation of a PPP consignment as well as imposing an administrative fine.

79. For more serious offences such as fraud, counterfeit or illegal PPPs being placed on the market, the Plant Protection Law allows for penalties ranging from 8% to 14% of the annual gross income of the economic operator, but only if it is a legal person. If the gross income of the economic operator cannot be calculated or is considered to be below €200 000 p.a., a fine of between €10 000 and €20 000 can be applied to the economic operator, instead. The amount of the fine to be imposed is determined taking into account the mitigating and aggravating circumstances, such as, the nature, the duration, the extent of the infringement as well as cooperation and preventing other harmful consequences etc. An offence is considered a repeat offence only if it is detected within one calendar year of the original offence.

80. The level of non-compliances detected in the distribution chain in 2020 was about 3% and was about 10% in 2021. The most frequent non-compliances related to the sale of PPPs which were revoked or had expired (more than two years from the date of manufacture).

81. The CAs are satisfied that the penalties applicable to the infringements detected for the marketing of PPPs in Lithuania are effective, proportionate and dissuasive as is required by Article 139 (1) of Regulation (EU) 2017/625.

Conclusions on controls on the marketing of plant protection products

82. The system of controls on PPPs intended for use in Lithuania, other MSs and non-EU countries, the frequent controls at higher-risk economic operators coupled with the formulation analysis programme, ensures that the PPPs placed on the market are safe

and that illegal and counterfeit PPPs are likely to be detected.

83. The documented procedures which incorporate detailed control questionnaires for performing official controls, ensure a consistent approach is taken across the regional divisions when inspecting every economic operator.

84. The outcome of controls on the marketing and use of PPPs are made publicly available annually and reported to the Commission by 31 August of the following year, ensuring transparency of operation and that relevant information is made available to all stakeholders.

85. Penalties for infringements relating to the marketing of PPPs are effective, proportionate and dissuasive, thus being an effective deterrent to operating in illegal and fraudulent trade of PPPs.

5.2.2. *Controls on the use of plant protection products*

Legal Requirements

Articles 11 to 14 and 138 to 139 of Regulation (EU) 2017/625

Articles 28, 31, 55 (first and second sentences) and 67 (1) of Regulation (EC) No 1107/2009 on the proper use of PPPs

Article 5 of Directive 2009/128/EC

Article 67 (1) of Regulation (EC) No 1107/2009, Article 4 (1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council, and Annex I, Part A.III of the same Regulation on keeping records of the PPP use

Findings

Professional user controls carried out by SPS

86. The list of professional users includes both agricultural and non-agricultural users of PPPs and is largely compiled using the professional user training register, the register of pesticide application equipment and the list of applicants for various CAP related payments. This list includes any person who uses PPPs during the course of their daily work as defined under Article 12 (a) of the SUD. It includes farmers, seed treatment specialists, municipal authorities, PPP contractors, and landscape contractors etc. The total number of professional users for 2020 and 2021 was 68 173 and 63 772 respectively.

87. In 2020 there were 1961 inspections conducted on professional users, with 2 037 inspections carried out in 2021. Despite difficulties presented by the Covid-19 pandemic, the vast majority of planned inspections in both years took place. However,

additional unscheduled controls took place in both years, resulting in the 80-90% of the planned number of inspections being carried out.

88. Official controls carried out by SPS on professional users takes place across all 10 regional divisions, with all divisions using identical control questionnaires, ensuring a uniform approach is taken across all inspections. For inspections of professional users, two control questionnaires are used. The first control questionnaires incorporates PPP use and storage elements and the second concentrates on compliance with the general principles of IPM. Areas for scrutiny included in the control questionnaires ensures that;
    - Professional users use only PPPs that are authorised or are approved as parallel trade permits,
    - Professional users keep appropriate records of use of PPPs for the preceding three years as required by Article 67 (1) of Regulation (EC) No 1107/2009,
    - Professional users keep records and are operating to the general principles of IPM,
    - Professional users use PPPs in accordance with the SPS approved product label, i.e. on the permitted crops/areas and adhering to the maximum individual and total doses, the maximum number of treatments and the pre-harvest interval (through examining records of use and residue analysis),
    - Professional users are appropriately trained and have obtained the necessary certificate of competence,
    - Professional users apply PPPs using only equipment that has successfully passed the testing process in the national PAE testing scheme.

89. The audit team observed a routine inspection of a professional user of PPPs which incorporated the use of both control questionnaires mentioned in the preceding paragraph. This inspection involved a professional user who uses both a boom sprayer and seed treatment equipment. The inspector sought evidence that both pieces of equipment had been certified as compliant, as required by Article 8 of Directive 2009/128/EC. The CA confirmed that the PAE testing scheme is testing all required PAE and that any exemptions are in accordance with Article 8 (3) of Directive 2009/128/EC.

Professional user controls carried out by the National Payment Agency

90. The NPA carries out annual planned Cross Compliance inspections on applicants of CAP funds, however, not all applicants are professional users of PPPs. In 2020, of the 124 482 applicants for CAP funds, 738 were inspected for PPP related issues. In 2021, of the 120 901 applicants for CAP funds, 665 were inspected. The number of inspections carried out in both years is about 50% less than usual due to pandemic related restrictions.

91. The NPA carry out inspections over the course of the year. The inspectors use a checklist which is less detailed than the control questionnaires used by the SPS, however, it does incorporate the core elements necessary to check that the economic

operator is compliant on all matters relating to PPPs, e.g., checks on record keeping, PPPs used and stored, storage conditions, pre-harvest intervals, aquatic buffer zones, certificate of training and certificate of compliance for pesticide application equipment.

Outcomes of controls and sanctions

92. As previously described in paragraphs 77 and 78, there exists a code of administrative offences and this forms the basis for the range of penalties applied where infringements associated with the use of PPPs are detected. In addition, where there is an infringement by an economic operator who is also a recipient of CAP funds, they may be subject to a percentage disallowance of those payments, in addition to any fine imposed.

93. In 2020, the SPS performed 1961 inspections on professional users of PPPs, with 115 infringements. In 2021, of the 2 037 professional user inspections carried out, there were 187 use related infringements detected. The main issues identified during these inspections related to deficiencies in record keeping, use of uncertified PAE, inappropriate storage of PPPs or treated seeds and absence of a professional user training certificate. The most frequently applied penalty is a €500 administrative penalty which is routinely reduced by 50% unless it is a repeat offence.

94. Disallowances applied by the NPA for infringements detected during inspections of economic operators include the following:

- 1% of basic payment applied where records of PPP usage are not maintained,
- 5% of basic payment where use was not in accordance with the approved label,
- 21% of basic payment where infringement is related to inadequate storage of PPPs or treated seeds.

Additional percentage disallowances may be applied in the case of repeat or intentional infringements.

95. In 2020, of the 738 inspections carried by the NPA on economic operators who are professional PPP users, two operators were identified as having at least one infringement. In 2021, of 665 economic operators inspected, seven had infringements. The main infringements found during these inspections related to record keeping, storage of PPPs or treated seeds, use of illegal products etc.

Conclusions on controls on the use of plant protection products

96. The SPS operate an effective system of controls on the use of PPPs, which is augmented by the inspections carried out by the NPA, thereby providing assurances that PPPs are used safely and in line with the product label.

5.3. FOLLOW-UP OF PREVIOUS RECOMMENDATIONS

Findings

The table below summarises the follow-up to the relevant recommendations made in report DG SANTE 2019/6722-MR Final

No	*Previous recommendation*	*Assessment*
2	Ensure that (a) only pesticide application equipment that has successfully passed the required inspection is used, as required by Article 8(2) of Directive 2009/128/EC and (b) exemptions from mandatory inspections are allowed only for pesticide application equipment items listed in Article 8(3)(a) and (b), in conjunction with Article 3(4), of the Directive.	Considered addressed. See finding 89.
4	Ensure that implementation of the eight general principles of IPM set out in Annex III of Directive 2009/128/EC is subject to official controls as per Article 14 (4) of Directive 2009/128/EC, in conjunction with Article 55 of Regulation (EC) No 1107/2009.	Considered addressed. See findings 88 and 89.

6. OVERALL CONCLUSION

Lithuania has a relatively low intensity of pesticide use compared to the EU average with its 70,000 professional users accounting for less than 1% of the plant protection products used in the EU. In addition, there is no manufacturing, and limited re-packing and importation, of plant protection products.

Overall, the control system on the marketing and use of plant protection products is effective. Respective Competent Authorities responsibilities are well defined, with high levels of both formal and informal cooperation between Competent Authorities. Controls are risk based, are conducted according to the annual plan, and cover all relevant economic operators with an appropriate frequency.

The system of controls ensures that only appropriately registered products are distributed and that these products are used in accordance with their approved labels. The formulation analysis programme is an integral part of these controls, is effective and is constantly being refined, but uses laboratories which are not officially designated in line with Regulation (EU) 2017/625.

7. CLOSING MEETING

A closing meeting was held on 27 September 2022 with representatives of all relevant CAs. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit and CAs provided initial comments on these findings and preliminary conclusions.

The CAs thanked the audit team for the thorough examination and audit of their system of controls, acknowledged the shortcomings identified, and committed to take the required remedial actions.

8. RECOMMENDATIONS

The CAs are requested to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendation set out below, within 25 working days of receipt of this audit report. The CA should:

No.	Recommendation
1.	Designate an official laboratory for the analysis of PPPs as required by Article 37 (1) of Regulation (EU) 2017/625. *Recommendation based on conclusion No 52* *Associated finding No 48*

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

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=2022-7475

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)Text with EEA relevance.
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
Dir. 2009/128/EC	OJ L 309, 24.11.2009, p. 71-86	Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides