



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate F - Food and Veterinary Office

DG(SANTE) 2015-7566 - MR

FINAL REPORT OF A MISSION
CARRIED OUT IN
ROMANIA
FROM 04 MAY 2015 TO 08 MAY 2015
IN ORDER TO
GATHER INFORMATION ON BEE HEALTH AND RESTRICTION ON USE OF
CERTAIN 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 a fact-finding mission carried out by the Food and Veterinary Office in Romania, from 4 to 8 May 2015.

The overall objectives of the fact-finding mission were to:

- gather information on the state of implementation of EU legislation on bee diseases, and possible additional legislation on the same topic;*
- better understand the monitoring, surveillance and control systems in place for bee health;*
- check the system to ensure effective and adequate restriction of uses of plant protection products;*
- determine possible gaps and difficult areas in existing EU legislation, and scope for possible improvements for a better protection of bee health.*

Overall, the report concludes that:

The importance of the bee sector in Romania is evidenced by the ample national legislation supporting the sanitary controls of bees. Many elements are formally in place to support an elaborate system for monitoring, surveillance and controls for bee health. This system involves various competent authorities, the task of which has been clearly established. However, insufficient organised coordination between authorities led to the development of a system which lacks at times rationalisation, improvement and simplification.

Emergency authorisations delivered by the Competent Authorities for treatment of seeds with neonicotinoids are accompanied by measures aimed at restricting and monitoring their use. Although real exposure of bees is not subject to a monitoring programme, a system has been developed to mitigate this risk. The lack of transparency and of clear criteria for restriction of use of neonicotinoids hinders clear implementation of related risk mitigation measures.

This report contains no recommendations due to the fact-finding nature of the mission.

Table of Contents

1	Introduction	1
2	Objectives and scope	1
3	Legal Basis	2
4	Background	2
4.1	Overview of the bee sector in Romania	2
4.2	Organisation of the official control systems.....	3
5	Findings and Conclusions	3
5.1	Registration of operators, control of movements	3
5.1.1	<i>Registration of operators, identification of holdings and hives</i>	3
5.1.2	<i>Record of movements</i>	5
5.1.3	<i>Trade and import</i>	6
5.2	Bee diseases	7
5.2.1	<i>Diseases subject to notification and official control</i>	7
5.2.2	<i>General surveillance</i>	7
5.2.3	<i>Varroa</i>	8
5.2.4	<i>American foulbrood</i>	9
5.2.5	<i>Veterinary medicinal products</i>	10
5.2.6	<i>Laboratory capacity</i>	10
5.3	authorisation and control of neonicotinoid plant protection products	12
5.4	Mitigation measures	14
5.4.1	<i>Seed coating facilities and seed drilling equipment</i>	14
5.4.2	<i>Monitoring programme</i>	15
6	Overall Conclusions	17
7	Closing Meeting	17

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CA	Competent Authority
CPU	County phytosanitary unit
CSVFSD	County Sanitary Veterinary and Food Safety Directorate
EU	European Union
FVO	Food and veterinary office
NAZ	National agency for Zootechnics
NPA	National phytosanitary agency
NRL	National Reference laboratory
NSVFSA	National Sanitary Veterinary and Food Safety Authority
TRACES	Trade Control and Expert System, a trans-European network for veterinary health which notifies, certifies and monitors imports, exports and trade in animals.
<i>Varroa</i>	<i>Varroa destructor</i>

1 INTRODUCTION

This fact-finding mission took place in Romania from 04 to 08 May 2015 and was undertaken as part of the planned programme of the Food and Veterinary Office (FVO) for 2015. The mission team comprised two inspectors from the FVO, one National Expert from a Member State, and was accompanied during the whole mission by a representative of the central competent authority, either the National Sanitary Veterinary and Food Safety Authority (NSVFSA - for the animal health part) or the National Phytosanitary Agency (NPA) (for the phytosanitary part).

2 OBJECTIVES AND SCOPE

The objective of the mission was to:

- Gather information on the state of implementation of European Union (EU) legislation on bee diseases, and possible additional legislation on the same topic;
- Better understand the monitoring, surveillance and control systems in place for bee health;
- Check the system to ensure effective and adequate restriction of uses of plant protection products;
- Determine possible gaps and difficult areas in existing EU legislation, and scope for possible improvements for a better protection of bee health.

The scope of the mission included health control systems and activities in relation to honeybees and bumble bees, and controls in relation to authorisation, distribution and use of plant protection products containing fipronil, clothianidin, imidacloprid and thiamethoxam (including risk mitigation measures and monitoring programmes).

In pursuit of this objective, the following meetings were held and sites visited:

Visits/Meeting	Nb	Comment
Central Competent Authorities	3	NSVFSA, CPA, NAZ
Regional Competent Authorities	2	CSVFSD, CPU in Prahova and Ialomita
Local Competent Authorities	1	Local Council
Honey bee holdings	2	
Beekeepers associations	5	3 regional, 2 national associations
Veterinary pharmacy	1	Manufacturer and pharmacy
Seed-coating facilities	2	
Farmers sowing seeds treated with neonicotinoids	2	

3 LEGAL BASIS

The mission was carried out under the general provisions of EU legislation, and, in particular:

- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Article 68 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

4 BACKGROUND

Honeybees (*Apis mellifera*) play an important role in both pollination and the production of honey and other apiculture products. Following the report of increase in honey bees mortality by several countries both within and outside the EU, the European Commission made a communication to the European Parliament and the Council¹, outlining its strategy to protect bee health proactively.

The European Union has established certain harmonised rules to protect and maintain the health of bees, among which are health standards for importation and intra-Union trade of for honeybees and bumble bees (*Bombus spp.*), as these latter, bred and traded for pollination, can carry diseases transmissible to the former.

In response to the European Food Safety Authority's scientific reports which indicated or could not exclude a "high risk" for bees as regards exposure to dust in several crops such as maize, cereals and sunflower, to residue in pollen and nectar in crops like oilseed rape and sunflower and to guttation in maize¹, the European Commission has adopted in 2013 two Regulations to severely restrict the use of fipronil (Regulation (EU) No 781/2013) and 3 further pesticides belonging to the neonicotinoids family (clothianidin, imidacloprid and thiamethoxam – Regulation (EU) No 485/2013). Treatment of corn, sunflower and rape is not allowed, except for seeds sown in greenhouses.

4.1 OVERVIEW OF THE BEE SECTOR IN ROMANIA

According to the 2014-2016 national honey programme, Romania has more than 1.2 million bee colonies registered and approximately 42,000 beekeepers. Romania is the fourth Member State in terms of number of bee colonies, representing 10% of the EU census. 40% of the apiaries are constituted of less than 50 hives. According to the data provided by the National institute of statistics, there has been an average annual increase of 4% of the number of colonies since 2006.

Three counties of the 42 of the country host each 10% of the hives registered by the veterinary services: Alba, Salaj and Mehedinti. According to the veterinary services, no bumble bee holding is registered in Romania.

¹ <http://www.efsa.europa.eu/en/topics/topic/beehealth.htm>

4.2 ORGANISATION OF THE OFFICIAL CONTROL SYSTEMS

The organisation of the official control systems is described in the Country profile for Romania, published on the FVO website². The relevant systems for the current missions are the control systems for animal health, for food of animal origin, for veterinary medicinal products, and for plant protection products.

5 FINDINGS AND CONCLUSIONS

5.1 REGISTRATION OF OPERATORS, CONTROL OF MOVEMENTS

5.1.1 *Registration of operators, identification of holdings and hives*

1. EU legislation has not defined standards for registration of beekeepers or apiaries for animal health purpose; Regulation (EC) No 852/2004 requires the primary food producers to be registered (except those producing for private domestic use, or those producing small quantities of primary products sold to final consumer or small retail establishments).
2. The NVSFSA issued two Orders for sanitary registration of apiaries:
 - Order No 111/2008 requires registration of beekeepers selling honey (to collecting or processing plants, or to consumers). These units must meet food safety standards, which are verified by officials before registration at County level by the County Sanitary Veterinary and Food Safety Directorates (CSVFSD).
 - Order No 16/2010 requires registration of family apiculture farms (not engaged in trade), and of beekeeping units selling animals. The first category of holdings is registered on the basis of declaration by their keepers; both categories are registered at County level after documentary checks by the CSVFSD.
3. Sanitary registration of beekeepers is kept at County level in spreadsheets, which are transmitted and compiled at national level on an ad-hoc basis.
4. Order No 119/2011 of the Ministry of Agriculture has given the National Agency for Zootechnics (NAZ) the responsibility for identification of beehives. The system foresees the attribution of unique identifier number for each beehive, which must be displayed on the hive using an identification tag of specified characteristics. The system is mainly dealt through associations of beekeepers (there are around 300 such beekeeping associations in Romania). NAZ developed a database registering the apiaries and the attributed identification of hives for each of them. Beekeepers are required to notify within 5 days any change in the number of hives they keep (death, swarming, combining colonies...).

² http://ec.europa.eu/food/fvo/country_profiles/details.cfm?co_id=RO

5. NAZ also manages a register of beekeepers involved in breeding of bees (selection of queen bees), according to Ministry of Agriculture's Order 413/2008.
6. Apiaries must be registered on Rural Land Registers kept by Local Councils. Beekeepers must update the number of beehives kept on territory of the local Council at least annually.

Observations:

7. The national spreadsheet compiling registration of beekeepers contained more than 12,000 beekeepers for a total of more than 900,000 bee colonies. Another national register was available, with geographical coordinates of holdings of beekeepers and included 3,476 beekeepers. In this second register, in addition to a registration number, each beekeeper was allocated a holding identification number.
8. One County visited by the mission team indicated that they had 3 registered holdings and 1 approved holding under Order 16/2010, and 513 holdings registered under Order 111/2008. Data available at national level showed only 298 registered beekeepers for this County.
9. There is no upper limit of number of hives in order to be considered as a family apiculture farm: a beekeeper with 220 hives was registered as such (i.e. not engaged in trade). One County visited indicated that they could register a same holding under both Orders, which was not the intention of the NSVFSA.
10. Registrations under Order 111/2008 or 16/2010 were managed by different sections at County level (Public health or Animal Health). One CSVFSD confirmed that in case of non-compliance for hygiene purpose, the authorisation to sell could be suspended or withdrawn, and the registration stricken off.
11. Registration documents observed at both apiaries visited by the mission team did not indicate under which Order they were registered.
12. Representatives of an association indicated that it was not necessary for beekeepers to be registered if they were not requiring subsidies. In practice, they considered that it would apply to beekeepers with less than 15 hives.
13. The NAZ database was still under development and was only available at central level. Associations were required to send quarterly updates of their identification activities to County representations of NAZ, which had to forward them to the central level, where the database was updated. Location of apiaries was not recorded.
14. The registration spreadsheets kept at a County office of the NAZ showed that, contrary to the system requirement, beekeepers were attributed beehive identification numbers without having a sanitary registration (around 20% of members of two associations checked by the mission team). NAZ representatives explained that this was due to the fact that until July 2014, associations were in charge of adding each new beekeeper to be

attributed hives identification numbers. Since then, NAZ staff are required to review each new application (including their sanitary registration), and perform a site visit.

15. Representatives of associations complained about the unclear responsibilities for providing identification devices (between associations and beekeepers), and the additional burden for registration. They complained also that the requirement of reporting any changes in the number of active hives within five days was too burdensome and was not adapted to the beekeeping practices. The NAZ representative pointed out that the system had been developed after consultation of beekeepers associations.

5.1.2 Record of movements

16. The beekeeping Law 383/2013 requires each beekeeper to keep an apiary register, where treatments, sales and purchases of hives, and movements (transhumance or any other movements) must be recorded. Beekeepers must notify the relevant Local Council within 24 hours of installation of hives in a new location, and put a signpost with contact details. The Law also details the responsibilities for enforcement. These are spread among veterinary services (responsible for the presence of apiary register), NAZ (for correct completion of apiary register, identification of hives and constitution of associations), Local Councils and forestry agents (for lack of notification of installation of hives in a new location).
17. A NSVFSO Order pre-dating the beekeeping Law required the beekeepers to notify in advance any movement of hives for their sanitary inspection. This Order being overruled by the beekeeping Law, there was no longer any legal requirement for notification of the veterinary services of movements.

Observations:

18. The mission team asked but did not receive an overview of the organisation of control activities and sanctions taken in the framework of the beekeeping Law. The veterinary services presented anecdotal evidence of sanction for lack of register. NAZ indicated that they perform random checks (but did not give indications on the frequency, number and outcome of such checks).
19. Some beekeepers keep informing the veterinary services of their intention to move hives; in such cases, an official sanitary visit was performed in the County visited. Private veterinarians are required to send to the CSVFSD a monthly update of the number of hives under their responsibility. These numbers are compiled and forwarded at national level.
20. The mission team visited a beekeeper who had his hives temporarily posted several hundreds of kilometres away from his registered apiary basis. He claimed that he had 350 hives, but information passed over to NAZ recorded only 150 hives. The holding register was not available, and he explained that by norm the register had to remain at the actual location of the bees. The officials could not explain how should a beekeeper

deal with the location of his register when he kept hives in various locations at the same time, or what the practical arrangements could be when hives are kept in remote areas with no shelter to keep the register.

5.1.3 Trade and import

21. Directive 92/65/EEC requires that bees subject to intra-Union trade do not come from an area which is subject of a prohibition order associated with an occurrence of American foulbrood (or 30 days in which all hives in a radius of three km are checked, and infected hives are burnt or treated and inspected). Directive 82/894/EEC requires each Member State to notify the Commission within 24 hours of the occurrence of *Tropilaelaps* or small hive beetle infestation. Regulation (EC) No 206/2010 requires that final destination of consignments of bees imported from third countries be placed under official supervision, that the queen bees be transferred to new cages before being introduced to local colonies, and that the cages, attendants and other material be sent to a laboratory for investigation for *Tropilaelaps* and small hive beetle, before their destruction.
22. Romania certifies very few consignments of bees to other Member States (two consignments in 2013 and two in 2014 reported in TRACES); other (nine) Member States certified 32 consignments of honeybees to Romania in 2014, the majority of them being for breeding (and two consignments for transhumance). In addition, 37 consignments of bumble bees were introduced in 2014 from three different Member States. No import of bees occurred in Romania since the rules of Regulation (EC) No 26/2010 are in place.

Observations:

23. No formal procedure is in place for verification of elements to be certified for intra-Union trade certification of bees. Practically, an official veterinarian from the CSVFSD signs the certificate on the basis of an inspection of the apiary. CSVFSD can also access information related to cases of American foulbrood and official control activities in their County (see chapter 5.2.4).
24. A couple of certificates checked by the mission team had health statement regarding American foulbrood incorrectly crossed, because of an error during the creation of the certificate in TRACES.
25. Following the occurrence of small hive beetle in Italy, the NSVFSA reminded stakeholders (CSVFSD, college of Romanian Veterinarians, Beekeeping associations) of the legislation applying to intra-union trade and imports.

Conclusions on registration of operators and control of movements

26. Elaborate systems for registration of beekeepers and apiaries and for record of movements of hives are in place, giving a very good basis for bee health controls in Romania. These systems are run by several authorities, lack integration and sometime clarity, making them cumbersome to update and multiplying the risk of partial or incorrect data being recorded.
27. Responsibility of controls of application of the requirements of registration and identification are clearly defined, but the authorities responsible could not demonstrate that they had developed effective systems for these controls.
28. In the absence of effective controls on identification and movements of hives, it is not possible to conclude whether the very few cases of EU trade reported, along the lines of EU requirements, represent a fair picture of the movements from Romania.

5.2 BEE DISEASES

5.2.1 Diseases subject to notification and official control

29. NSVFSA order 79 of 2008 lists the diseases subject to notification at national level. These include for bees, in addition to diseases listed in Council directive 82/894/EEC (American foulbrood, small hive beetle and *Tropilaelaps*) the following diseases: acarapiosis, European foulbrood and varroosis.
30. No legal basis sets specific official control measures for bee diseases. Nevertheless, Governmental Decision 1214 of 2009 foresees that for American foulbrood, varroosis, noseiosis and viral diseases, compensation can be attributed to the affected beekeepers when official measures are applied to control the disease.

5.2.2 General surveillance

31. Official surveillance and control measures are revised by the CA on an annual basis. For 2015, NSVFSA Order 29 of 2014 sets passive a surveillance programme for acarapiosis, European foulbrood, *Tropilaelaps* and small hive beetle, and active surveillance for American foulbrood, varroosis and noseiosis. This surveillance encompasses both non-professional and professional apiaries. This programme is similar to the one carried out previous year.
32. In case of report of suspicion of a disease subject to passive surveillance the Order defines the samples to be taken and the laboratory to receive the samples.
33. The same level of active surveillance is foreseen for the three bee diseases: 15% of the breeding apiaries (producing queen bees) and 5% of the production apiaries must be sampled by an official veterinarian or a private veterinarian habilitated.

34. Following the detection of small hive beetle in Italy mid-2014, the NVSFSA decided to implement an active surveillance programme on this pest. A specific document was produced, indicating the standards of surveillance³.
35. The CSVFSD organise active surveillance in their territory: they may attribute a number of visits to contracted private veterinarians or official veterinarians, who select the apiaries to be visited. The epidemiological department of the National reference laboratory (NRL) collects on a quarterly basis data on the implementation of the programme.
36. NSVFSA indicated that they initially applied to participate to the pan-European study on honeybee colony mortality⁴ organised between 2012 and 2014 by the EU reference laboratory on bee diseases, but that their application was not pursued due to administrative issues. No other programme has been set in order to monitor bee mortality in Romania.

Observations:

37. Data on implementation of surveillance of bee diseases provided from 2013 and 2014 at central and regional level showed a very partial implementation of the objectives and variations of implementation among diseases within a same County.
38. Both Counties visited indicated that despite training offered to private and official veterinarians, they had very few veterinarians properly skilled to perform inspection and sampling in apiaries. They also indicated that priorities were given to other activities compared to bee health surveillance.
39. No active monitoring of the completion of the surveillance programme was performed at central level. No programme for validation and epidemiological analysis of data gathered from the surveillance programme was in place either.
40. The selection criteria for active surveillance of small hive beetle are the same as for other active surveillance programmes. The surveillance programme did not link the selection of apiaries subject to surveillance with recent introduction of bees from Italy.

5.2.3 *Varroa*

41. The national beekeeping programme 2014-2016, managed by the Ministry of Agriculture according to Government Decision 1050 of 2013, and co-funded by the European Union, includes elements for control of *Varroa*.
42. Control measures include treatments with veterinary medicinal products registered in Romania, according to a schedule defined by the beekeeper, and purchase of screened bottom boards for the hives. In order to be eligible for co-funding, qualified beekeepers must be part of an association, be registered both by the veterinary services and in the

³ http://www.ansvsa.ro/documente/admin/GHID%20Aethina%20tumida_43516ro.pdf

⁴ http://ec.europa.eu/food/animals/live_animals/bees/study_on_mortality/index_en.htm

rural land register, have their hives identified according to the NAZ system, and hold an apiary register.

43. Veterinary services are not involved in the coordination of this programme. The active surveillance programme on *Varroa* is managed independently. In 2014, more than 20,000 samples were examined: in only 2% of the cases *Varroa* were detected and 22 outbreaks were declared.

Observations:

44. Representatives of associations met by the mission team were satisfied that *Varroa* was a manageable problem with the means at their disposal. The mission team saw documentation of official control measures and compensation applied in a case of heavy infestation with *Varroa*.
45. The active surveillance programme does not determine the period of sampling in function of possible treatment against *Varroa*. Although sampling form recorded possible treatment, information was limited (no information on the date of treatment, no information regarding the use of anti-*Varroa* devices). No analysis was done on the results (see section 5.2.2).
46. In 34 counties out of 42, representing 90% of the samples, no mite was detected; on the other hand, one county found mites in 100% of its 266 samples.

5.2.4 American foulbrood

47. NSVFSA implements control measures when outbreaks of American foulbrood are detected. Measures described include destruction of affected colonies, cleaning and disinfection, movement restriction from the affected apiary, examination of the hives in a radius of three km around the outbreak.
48. The veterinary services identified eight American foulbrood outbreaks in 2013 and 30 in 2014.

Observations:

49. Surveillance data on American foulbrood were not available at national level.
50. Documentation of the actions implemented was available in the cases reviewed by the Mission team. The official control activities are not required by any specific legal basis, and guidelines were available.
51. The CSVFSD indicated that they developed a list of hives present in a radius of three kilometres based on their registers and local knowledge. They did not contact the Local Councils to identify possible additional hives that could be in the vicinity on temporary basis. The visit of apiaries was evidenced by signature of beekeepers visited.

5.2.5 *Veterinary medicinal products*

52. Eleven veterinary medicinal products are registered for bees in Romania; nine of them are to be delivered under prescription only, the remaining two, containing essential oils, can be purchased without prescription.

Observations:

53. The list of veterinary medicinal products for bees can be accessed on the internet-published page by the competent authority⁵. The page obtained by selecting product for bees lists products whose status is unclear, as they are indicated with an expired authorisation, while they are still listed with an authorisation number. Most products with authorisation still valid are to be found on a second page.
54. The mission team visited a pharmacy which was also a manufacturer and distributor of a veterinary medicinal product for bees. The operator could not explain the distribution channels for such products (in particular whether these products could be distributed to associations). Prescriptions for bee medicines distributed by the pharmacy were not available.
55. Despite being prohibited to do so by Romanian legislation⁶, several Romanian internet sites distribute veterinary medicinal products for bees. Some were offering products not registered in Romania, and products for which no maximum residue limit has been set (e.g. fumagillin for treatment of nosemosis). Representatives of a beekeeper association acknowledged that fumagillin was used to treat nosemosis in severe cases.
56. According to the national apiculture programme, the eligibility conditions for subsidies for *Varroa* control include the use of products in Romania, but not the presentation of a prescription.
57. Distribution of veterinary medicinal products for bees has not been subject to specific official controls. An internet distributor of veterinary medicinal products was inspected by an official veterinarian during the mission, and subject to a fine of 1,500 Lei.

5.2.6 *Laboratory capacity*

58. Official analyses for bee diseases are carried out in the the national animal health institute of Bucharest, nominated as NRL for diseases of bees and other useful insects (Order 205/2007), or in one of the 40 County laboratories.
59. The NRL collaborates actively with the EU reference laboratory and carries out the tasks of confirmation of diagnosis, coordination of diagnostic methodology, organisation of proficiency tests for other laboratories performing official analyses for bee diseases, development of diagnostic manuals and training. Staff of the NRL acts also as technical

⁵ <http://www.icbmv.ro/ro/nomenclator-produse>

⁶ Art 6 point 2 of NSVFSA President order No 83/2014

experts for the veterinary services, for specific investigations, training, awareness campaigns, or input in the development of legislation and surveillance programmes.

60. The NRL is accredited according to ISO 17025 norm, and the scope includes detection of *Acarapis*, *Nosema*, *Varroa*, *Tropilaelaps*, small hive beetle, bacteriological and PCR determination of American and European foulbrood. The NRL also performs diagnostic tests on various viral bee diseases, for which accreditation is pending.
61. Each of the 40 County veterinary laboratories may perform diagnostic tests for bee diseases if they are accredited. In practice, up to 37 laboratories may detect *Varroa*, 33 may detect American foulbrood by microscopic examination and 18 laboratories may isolate it from broods. For this latter disease, confirmation by PCR is required, and is only performed by the NRL. Four County laboratories are also authorised to analyse for exotic pests (*Tropilaelaps* and small hive beetle). In case of positive result, they need also to send samples to the NRL for confirmation.
62. Two annual sessions of training are organised by the NRL for six specialists from County laboratories each time, so that each specialist is trained about once every three years.
63. The NRL also has the capacity to analyse the presence of pesticides in bees in case of suspicion of intoxication (Gas and liquid chromatography/Mass spectrometry), and includes detection of neonicotinoids (except clothianidin) and fipronil. Tests are done either within a general eco-toxicological surveillance programme or following request. In 2014, 13 samples were analysed in the surveillance framework, and 37 following request. Around half of samples from each category were analysed for the presence of neonicotinoids, and six were positive.

Observations:

64. The NRL participated successfully to the last two proficiency tests organised by the EU reference laboratory on American foulbrood.
65. The NRL organised proficiency testing for the County laboratories in 2013 and 2014 on nose-mosis and American foulbrood (microscopic examination). Twenty three laboratories had satisfactory results from the proficiency test on the latter disease (three good results out of three samples).
66. The very high variations of disease incidence reported by the various Counties (e.g., in 2013, one laboratory reported 100% positive samples for nose-mosis, while all other laboratories reported 0% incidence; see also section 5.2.5 for *Varroa*) did not prompt the NRL to review possible quality issues among laboratories.
67. The NRL received training on identification of small hive beetle (measurement key) and reference material from the EU reference laboratory, and found it to be very useful. All County laboratories have received a diagnostic manual for small hive beetle from the NRL, but none have received reference material. The NRL indicated that CSVFSD

would also submit them suspect samples dismissed at County level, but data provided did not support this allegation: in 2013, the NRL analysed five suspect cases of small hive beetle, while 17 samples were reported as having been examined in Romania, suggesting that 12 suspect samples were discarded at County level only. The diagnostic manual does not require County laboratories to submit negative suspect samples to the NRL.

68. Fipronil was not included in any test performed in 2014, despite the fact that two bee samples from surveillance were positive to this pesticide in 2013. The NRL indicated that they had limited funding for toxicological analyses in bees.

Conclusions on bee diseases

69. The developed official surveillance programme, the control measures applied to some diseases, including American foulbrood, and the compensation scheme in place give a very good basis for effective surveillance and control of bee health (and for certification for trade).
70. The surveillance programme was recently adapted to include the new threat represented by the apparition of small hive beetle into the EU, raising the awareness of the stakeholders.
71. The partial implementation and lack of monitoring of the application of the surveillance programme, the absence of analysis, and the poor design of the surveillance programme for *Varroa* reduces significantly the output of the investment of the veterinary services in this field.
72. Substantial laboratory diagnostic capacity supports bee health controls, both for bee diseases and for pesticide intoxication. While the good quality standard of the NRL is well documented, various elements suggest a variation of quality among County laboratories. In this context, the responsibility for identification of small hive beetle in case of suspicion represents a risk for early detection of possible introduction of this exotic pest into Romania.
73. Distribution of veterinary medicinal products was insufficiently organised and controlled to promote and ensure adequate and safe use of these products in the bee sector.

5.3 AUTHORISATION AND CONTROL OF NEONICOTINOID PLANT PROTECTION PRODUCTS

74. Notwithstanding the disposition of Regulation (EU) No 485/2013, Article 53 of Regulation (EC) No 1107/2009 allows, in emergency situations, the placing on the market of plant protection products, for limited and controlled use, because of a danger which cannot be contained by any other reasonable means. In such cases, the other Member States and the European Commission have to be informed immediately, providing detailed information.

75. In 2014, Romania notified the European Commission of emergency authorisations for seeds of corn and sunflower treated with four products containing clothianidin, thiamethoxam and imidacloprid (valid from end of February to end of June); Romania also notified later in 2014 emergency authorisations for seeds of rape (from end of June to end of October). In March 2015, Romania notified again authorisations for seeds of corn and sunflower treated with neonicotinoids (valid from 2 March to 20 May 2015). The NPA was not sure at the time of the mission whether they would also issue emergency authorisation for treatment of rapeseed.
76. The authorisation certificates for the emergency uses state that the use of treated seeds is only allowed in areas and places with very high infestation of *Agriotes spp* and *Tanymecus dilaticollis*.
77. The Romanian authorities indicated that as a result of the restrictions of use, the areas sown with seeds of corn and sunflower treated with neonicotinoids have been significantly reduced to approximately 584 000 ha in 2014, compared to 1.5 million hectares sown with neonicotinoid-treated seeds previously. The Romanian authorities also indicated that “following the measures taken, the area sown in monoculture during the spring campaign of 2015, which will require chemical treatment, will be further reduced to only the most affected areas in the South and South-East of the country, to about 200,000 hectares”. The authorities stated that without treatment, farmers can face production losses of 20-30 %.

Observations:

78. All persons met by the mission team confirmed that seed treatment with neonicotinoids was the only reasonable means to control *Tanymecus dilaticollis*, a soil pest, which occurs in countries bordering the Black Sea. The crop losses were confirmed by reports from the National Agricultural Research and Development Institute and the National Institute for Agricultural Economy. Farmers stated that strong infestation of corn can cause the complete loss of the young plants, and re-sowing is necessary. The mission team visited fields of corn in Ialomita County, where the infestation and damage were shown by a farmer. A farmer met in Prahova County stated that he uses crop rotation as an effective means to control *Tanymecus dilaticollis* in maize. Another farmer met in Ialomita County stated that he does not rotate the maize fields.
79. Staff from the large seed treatment company visited and from a County phytosanitary unit (CPU) stated that alternative control measures for *Agriotes spp* are available.
80. There was no evidence of research activities, initiated or concluded, to control *Tanymecus dilaticollis* and *Agriotes spp* by other means than use of seeds treated with neonicotinoids. Instead, the available research reports focus on the damages caused by the pest.
81. There is no geographic restriction for the use of treated seeds, and the authorisation certificate does not clarify what constitutes a very high infestation. The NPA provided

the mission team with a table containing data on infestation and uses of treated seeds from 2012 to 2014. The table states that in the Prahova County, where 19 operators were recorded as using treated corn seeds, there were no heavily infested areas.

82. Emergency authorisations were not published, contrary to requirement of Article 57 of Regulation (EC) No 1107/2009. A beekeeper association met by the mission team complained about the lack of information on the conditions of the authorised emergency uses.
83. The NPA stated that there were 29 plant protection products authorised in Romania containing the restricted substances (3 with thiamethoxam, 3 with clothianidin and 23 with imidacloprid). They are approved for crops permitted by Regulation (EU) No 485/2013. No substance containing fipronil is approved.

Conclusions on authorisation and control of neonicotinoids plant protection products

84. While there was evidence of crop losses caused by *Tanymecus dilaticollis* in some untreated corn and sunflower areas, no research was undertaken to identify alternative control measures. This means that there is no plan on how the emergency situation could be resolved.
85. As the emergency authorisations are not published, and as there are no clear criteria to select areas where the use of treated seeds is allowed, there is a lack of transparency about the restrictions in place. More clarity on the restrictions could substantiate the information notified to the European Commission.

5.4 MITIGATION MEASURES

5.4.1 Seed coating facilities and seed drilling equipment

86. Annex Part B of Regulation (EU) No 485/2013 requires that the seed coating with neonicotinoid pesticides shall only be performed in professional facilities with best available techniques, to ensure that the release of dust during application, transport and storage can be minimised. Similarly, the seed drilling equipment shall ensure a high degree of incorporation in soil and minimisation of dust emissions. The EU legislation does not set any limits for dust emission by seeds coated with pesticides or by seed drilling equipment.
87. A European association of seed producers established a private standard and certification scheme for dust emissions. The Heubach test is an established physical method for the assessment of free floating dust and abrasion particles of treated seeds. Similarly, the dust emission by seed drilling equipment is reduced by reconstructed vents, and such equipment is commercially available.

Observations:

88. Operators providing seed treatment and seed drilling are approved by the NPA. For the approval, the operators need to demonstrate training on the sustainable use of pesticides. 389 seed treatment stations were approved.
89. No criteria regarding dust emission of seeds have been established by the NPA, which stated that dust emission of seed treatment facilities falls under the responsibility of the Environmental Agency. The Law Nr 104 of 15 June 2011 on the quality of air, and the Romanian Standard STAS 12574 of 1987 apply. This legislation, however, does not provide any limits for dust emission by the seeds, or related criteria for seed treatment facilities or seed drilling equipment.
90. The mission team visited a large producer of seeds meeting private standards for dust reduction. They stated that in the 2015 season the emergency authorisation came too late to arrange seed treatment of maize or sunflower for the 2015 growing season. The mission team observed that instead, seed treatment was performed by local or mobile equipment, which was not tested for dust reduction.
91. Two farmers met by the mission team had seed drilling equipment with reduced dust emissions in place.
92. In 2014, CPUs performed 1,074 inspections and NPA 22 on users and traders of neonicotinoid pesticides; in 2015, 500 inspections had been performed by CPU, without identifying any non-conformity.

5.4.2 Monitoring programme

93. Annex Part B of Regulation (EU) No 485/2013 requires that monitoring programmes are initiated to verify the real exposure of bees to the restricted neonicotinoids. The EU legislation does not specify the requirements for such programmes.
94. Only authorised professional operators who have received training on sustainable use of pesticides are allowed to treat and drill seeds in Romania. The NPA introduced a comprehensive traceability system for the treatment of seeds with clothianidin, thiamethoxam or imidacloprid, and for their sale and use. Quantities of plant protection products used and seeds traded or sown must be communicated weekly to the CPU. The NPA introduced templates in March 2015 to collect comprehensive information on the location of plots and fields where treated seeds are sown (while in 2014 they recorded only the farmers using such seeds).
95. The beekeeping Law 383/2013 stipulates also obligations for farmers or forestry operators performing chemical treatments. They must notify the relevant Local Council of their intention to perform a treatment at least 48 hours before its implementation, indicating the product used. The Local Council must then inform the beekeepers on its territory within 24 hours. The Law foresees compensations for beekeepers in case of bee mortality linked to treatments non-notified.

96. The NPA indicated that farmers using neonicotinoid treated seeds must also contact directly local beekeepers, and they have to put up signposts in fields informing of the use of neonicotinoids. CPUs were required to hold awareness meetings in their county.
97. A federation of beekeepers association requested information collected by NPA on the location of areas where neonicotinoid-rape seeds were sown in 2014, and uploaded it on its website in order to inform beekeepers.
98. The NPA signed a collaboration protocol with a national association of beekeepers, reminding the obligations of each party in relation to the beekeeping Law.

Observations:

99. The mission team saw evidence of implementation of the traceability system in the Counties visited. At the time of the mission, the emergency authorisations were still valid, and no consolidated statistical data were available as to the number of operators involved.
100. The mission team saw evidence of signposts put up in fields of Counties visited. The beekeepers associations confirmed they received at times information related to field treatments, and indicated that they organise meetings with crop farmers associations. However, they stated that due to the widespread use of treated seeds in Southern Romania the information does not help stationary beekeepers, as they would have to move beehives out of the regions concerned to avoid contact with treated fields.
101. Farmer associations indicated that Local Councils failed to pass on information in many cases. The mission team did not receive information on the operation and monitoring of Local Councils in relation to their duties related to the beekeeping Law. The Local Council visited was not representative, as it had only two beekeepers and no temporary location for hives.
102. Anecdotal evidence of enforcement of the beekeeping Law was available. Local committees were established in cases where bee mortalities were reported, under the responsibility of a zonal veterinarian. Based on the result of the investigations, if beekeepers and farmers did not settle an agreement, cases were deferred to justice.
103. The NPA indicated that they recommended their CPU to invite representative of Local Councils at their awareness meetings.
104. No coordination structure was in place to monitor the correct implementation of the Law.

Conclusions on mitigation measures

105. The NPA restricted the treatment and sowing of seeds to trained operators, and developed an initiative to obtain traceability data on the remaining uses of treated seeds.
106. The absence of established criteria for dust emission by equipment for seed treatment

and seed drilling hinders clear implementation of risk mitigation measures to protect bees from dust.

107. Elements are put in place in a structured way to limit exposure of bees to neonicotinoids (as for other plant protection products), and to investigate and compensate claims of bee intoxication. However, all pieces of information are not pulled together into a monitoring programme to investigate the real exposure of bees to neonicotinoid pesticides.

6 OVERALL CONCLUSIONS

The importance of the bee sector in Romania is evidenced by the ample national legislation supporting the sanitary controls of bees. Many elements are formally in place to support an elaborate system for monitoring, surveillance and controls for bee health. This system involves various competent authorities, the task of which has been clearly established. However, insufficient organised coordination between authorities led to the development of a system which lacks at times rationalisation, improvement and simplification.

Emergency authorisations delivered by the Competent Authorities for treatment of seeds with neonicotinoids are accompanied by measures aimed at restricting and monitoring their use. Although real exposure of bees is not subject to a monitoring programme, a system has been developed to mitigate this risk. The lack of transparency and of clear criteria for restriction of use of neonicotinoids hinders clear implementation of related risk mitigation measures.

7 CLOSING MEETING

A closing meeting was held on 8 May 2015 with representatives of the competent authorities. At this meeting the FVO team presented the main findings and preliminary conclusions of the mission. The CA did not express any major disagreement.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 82/894/EEC	OJ L 378, 31.12.1982, p. 58-62	Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community
Dir. 92/65/EEC	OJ L 268, 14.9.1992, p. 54-72	Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Reg. 206/2010	OJ L 73, 20.3.2010, p. 1–121	Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements

Reg. 485/2013	OJ L 139, 25.5.2013, p. 12-26	Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances
---------------	----------------------------------	---