

Analysis of trends, priority and good practices in the context of harmonised risk indicators under Directive 2009/128/EC
Republic of Bulgaria

Harmonised Risk Indicator 1 (HRI1): The first Harmonised Risk Indicator is based on statistics on the quantities of active substances placed on the market in plant protection products under Regulation (EC) No 1107/2009, belonging to the groups defined in COMMISSION DIRECTIVE (EU) 2019/782 of 15 May 2019 amending Directive 2009/128/EC of the European Parliament and of the Council as regards the establishment of harmonised risk indicators.

Figure 1: Harmonised Risk Indicator 1 – Evolution of the overall weighted index, with a baseline of 100, average in 2011-2013

	2011-2013	2011	2012	2013	2014	2015	2016	2017	2018	2019
BG HRI1, 2011-2019	100	242	34	24	17	27	65	56	83	98

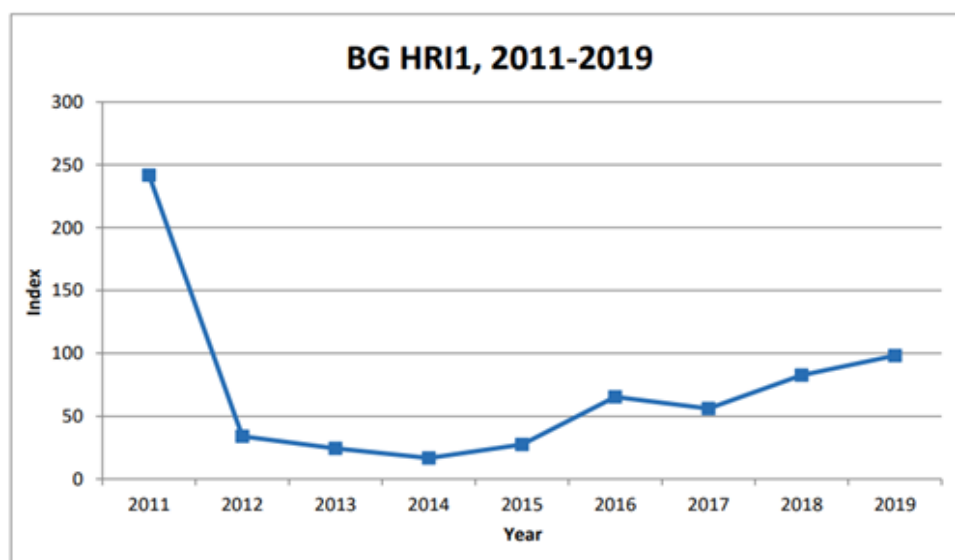
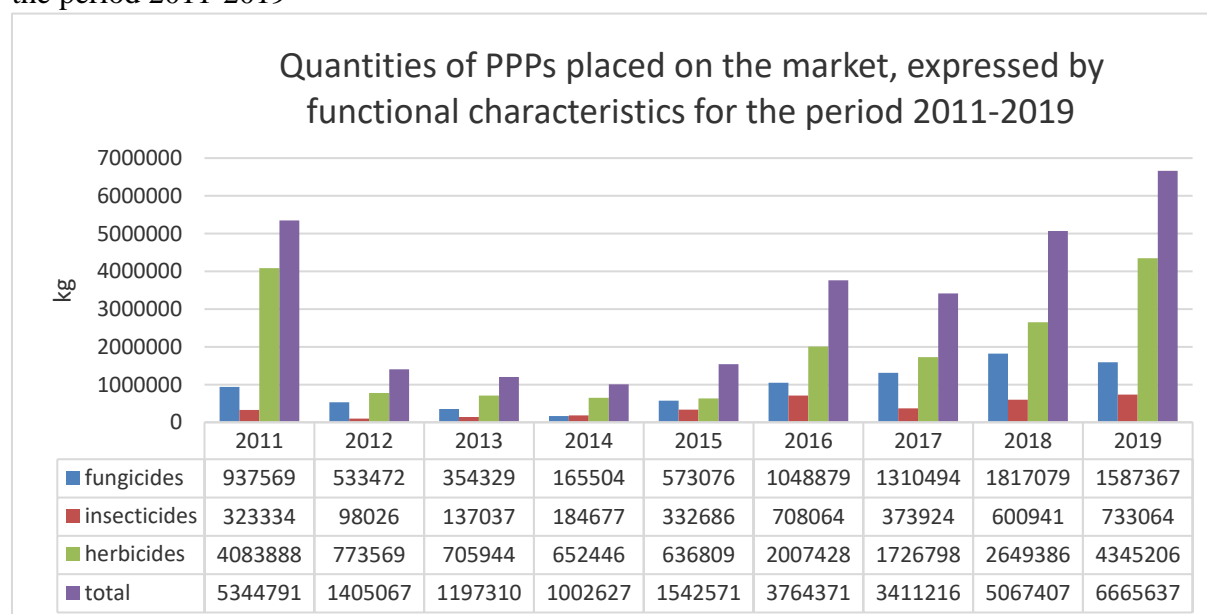


Figure 2: Quantities of PPPs placed on the market, expressed by functional characteristics for the period 2011-2019



Analysis of the course of the curve:

For 2011, large quantities of active substances were provided, expressed in kilograms and litres, e.g. glyphosate. The peak of the curve is due to the fact that a number of active substances placed on the market have a high hazard weighting as they were notified in 2011 under Directive 91/414 EEC. In accordance with the legislation in force in 2011, PPPs containing notified active substances were authorised for three years. For this reason, such active substances have been identified as risky.

From 2012 to 2015, the data provided to Eurostat were incomplete and unrepresentative. During this period, data on PPPs placed on the market were submitted only by some companies, with the largest ones not providing them. For this reason, we refrain from analysing for this period.

When voting on Directive 2019/782, the Republic of Bulgaria expressed its position of disagreement with the approach that the basis for calculating the quantities of PPPs placed on the market expressed as the quantity of active substance should be determined on the basis of the data for 2011-2013, for the following reasons:

- According to Regulation (EC) No 1185/2009, the first reference period for submission of the data on the active substances placed on the market shall be the second calendar year after 30-th of December 2009, thus making the information gathered for the first years of the application of this Regulation (i.e. 2011 through 2013) largely incomplete and not corresponding the actual quantities.

- At present, not any harmonized EU approach has been achieved under Regulation (EC) No 1185/2009 not only as regards gathering the reliable statistical data about the actual use of PPPs (as it is mentioned in point 6 of the Preamble of the draft Directive in question), but there is also no such harmonized approach to PPPs placed on the market and, therefore, the absence of reliable data is a real problem.

For this reason, Bulgaria proposes to designate the time period **2016-2018 as a reference period**, taking into account that this is the 3-years period prior to the adoption of the Directive amending Directive 128/2009 on the introduction of harmonized risk indicators.

Data analysis for the period 2016-2019:

1. Explanation of the gradually increasing course of the curve from 2017 to 2019.

➤ In 2017, the certificates for the placing on the market and use of PPPs containing active substances Linuron were withdrawn, which is one of the likely causes of the increased marketing and use of herbicides containing the active substance Pendimethalin in 2018, as both active substances are used in identical crops. This factor is likely to affect the downward trend of the Harmonised Risk Indicator 1 curve in 2017.

➤ Some of the PPPs authorised for use in the National pest control programme for permanent crops (winter sprays) contain active substance Mancozeb, Copper hydroxide, Paraffin oil and are among the active substances placed on the market in the largest quantities during this period. In addition, the areas planted with crops under this programme (apples, pears, peaches, apricots, plums, cherries, raspberries and strawberries) increased gradually during the period 2016-2019, with the exception of the strawberries. These two factors are a prerequisite for the use of larger quantities of these active substances, which underpins the growing curve of Harmonised Risk Indicator 1.

➤ The active substance Cypermethrin is among those placed on the market in the largest quantity. Plant protection products containing this active substances are authorised for use in the national programme of control measures against soil pests of potatoes of the family of *Wireworms*, which is one of the prerequisites for its increased use in the recent years, also underpin the growing curve of Harmonised Risk Indicator 1.

➤ *Meligethes aeneus* is an enemy of rapeseed, against which the highest proportion of the areas cultivated with this crop are treated annually. In 2016 and 2017, there was a mass multiplication of *Meligethes aeneus* in crops in all regions of the country where the rapeseed is grown.

In the spring of 2017, there was an increase in infested areas of *Tanymecus dilaticollis* compared to the previous year for areas planted with maize and sunflower.

An attack of *Aphidoidea* in 2017, 2018 and 2019 was found ubiquitously and in all fruit crops. Mass harmful activity and high population density were reported.

In 2018, a harmful activity of adults and larvae of the enemy *Schizotetranychus viticola* was detected throughout the country in the vineyards.

In 2019, there was a massive hatching and harmful activity from the larvae of *Oulema melanopus* across the country, which is twice as high as the previous year.

The emergence and development of the above pests necessitates an increased use of PPPs containing active substances Chlorpyrifos-ethyl and Cypermethrin, including PPPs in which they are combined together, which explains the smooth increase of the curve of the Harmonised Risk Indicator 1 since 2017.

➤ In the Crop Sector in 2018 and 2019, crisis situations caused by unfavorable climatic conditions and natural disasters – frost /shelter, flood / overwetting of agricultural land, hail and drought - have been announced on almost the entire territory of the country. Prolonged drought during the autumn period hinders the development of the autumn crops, which requires plowing and re-sowing of areas and is a prerequisite for additional plant protection measures.

➤ Unstable and wet weather, alternating cool and hot periods in spring 2018 and 2019, which has created the conditions for the development of a number of fungal diseases and, consequently, determines the increased marketing and use of PPPs containing the active substances Mancozeb and Thiophanate-methyl.

➤ In 2019, there was another increase in areas under maize, wheat, sunflower, potatoes and vegetables. This trend, combined with changing climatic conditions, is a prerequisite for increased use of PPPs controlling weeds containing some of the active substances placed on the market, such as S-metolachlor and Terbutylazine.

➤ There is an increase in the sown areas since 2018 with:

- Barley, which leads to increased use of insecticides and fungicides;
- Maize, which leads to increased use of fungicides;
- Sunflower, which leads to increased use of insecticides and fungicides.

➤ The decrease in the trajectory in 2017 is due to lower quantities for widely applied pesticides as a result of legislative changes and follow-up of withdrawals of authorisations and uses:

- For the period from 2016 to 2019, the active substance placed on the market in the largest quantity is Glyphosate. The amount of active substance Glyphosate placed on the market in 2017 was 2 times lower than in 2016, as the renewal of its approval was questioned. After a long discussion with Regulation (EU) 2017/2324, the approval of the active substance Glyphosate was renewed in December 2017. Therefore, and given its extensive use, the quantity of the active substance placed on the market has increased significantly between 2 and 5 times in 2018 and 2019.

- In 2016, the quantity of active substance Lambda-cyhalothrin, placed on the market was very high. In the following years, there was a significant decrease for 2017 as opposed to 2016. The decline continued in 2018 and 2019.

Regulation (EU) 2016/146 renewed the approval of active substance Lambda-cyhalothrin, as a candidate for substitution, with reduced toxicological reference values. Regulation 2018/960 subsequently reduced the MRL of active substance Lambda-cyhalothrin, leading to the elimination of uses in pomegranates, brassicas, lettuce, etc., pulses, soybeans, sugar beet, etc.

-In 2017 there was:

2 times less active substance Chlorpyrifos placed on the market than in the previous year and 3.3 times less than in 2018.

6 times less active substance Chlorpyrifos-methyl placed on the market than in the previous year. In the following years, the declining trend continued.

Regulation (EU) 2016/60 of 19 January 2016 accepts a reduction in MRLs for Chlorpyrifos-ethyl and Chlorpyrifos-methyl, leading to the elimination of a number of uses (seed, stone, tomatoes, pepper, cabbage, vineyards).

2. The active substances placed on the market in the largest quantities for the period 2016-2019 are glyphosate (herbicide), mancozeb (fungicide), chlorpyrifos-ethyl (insecticide), s-metolachlor (herbicide), pendimethalin (herbicide), tebuconazole (fungicide), thiophanate-methyl (fungicide), sulphur (fungicide), copper compounds (fungicide), chlorothalonil (fungicide), dimethenamid-P (herbicide), terbutylazine (herbicide), cypermethrin (insecticide).

Figure 3: Quantities of PPPs placed on the market in the highest quantity expressed in active substances and crops for which they apply for the period 2016-2019

PLACED ON THE MARKET IN THE LARGEST QUANTITY (KG), EXPRESSED IN THE ACTIVE SUBSTANCE AND CULTURES IN WHICH THEY APPLY FOR THE PERIOD 2016-2019								
	ACTIVE SUBSTANCE	Type	2016	2017	2018	2019	Average amount	Cultures
1	GLYPHOSATE	herbicide	1227689	601120	1304728	3099823	1558340	fruit species, vines, cereals, vegetables
2	CHLORPYRIFOS-ETHYL	insecticide	154461	82674	275287	423344	233941	cereals, tobacco, vegetables, vines
3	S-METOLACHLOR	herbicide	353407	37392	54163	275184	180037	cereals, potatoes, tobacco, vegetables, vines, apples
4	PENDIMETHALIN	herbicide	86415	7516	300486	207061	150369	cereals, potatoes, tobacco, vegetables, vines, apples
5	COPPER COMPOUNDS	fungicide	103061	105181	198631	175649	145630	vines, potatoes, fruit crops, vegetables
6	TEBUCONAZOLE	fungicide	115941	152680	128079	125590	130572	vines, cereals
7	MANCOZEB	fungicide	78974	70498	190417	165160	126262	cereals, tobacco, vegetables, vines
8	SULPHUR	fungicide	*	124676	102376	105000	110684	vines, potatoes, tobacco, vegetables, cereals
9	TERBUTYLAZINE	herbicide	*	66333	97575	155053	106320	maize sunflower
10	DIMETHENAMID-P	herbicide	*	15700	143623	158890	106071	cereals, potatoes
11	THIOPHANATE-METHYL	fungicide	72400	59788	121302	139106	98149	vines, cereals, sugar beet, vegetables, fruit species
12	CHLOROTHALONIL	fungicide	10000	70015	111984	149015	85254	cereals, vines, potatoes

* no data

- Among the active substances with the largest amount on the market are Sulfur and Copper compounds, which are also used in the organic farming.

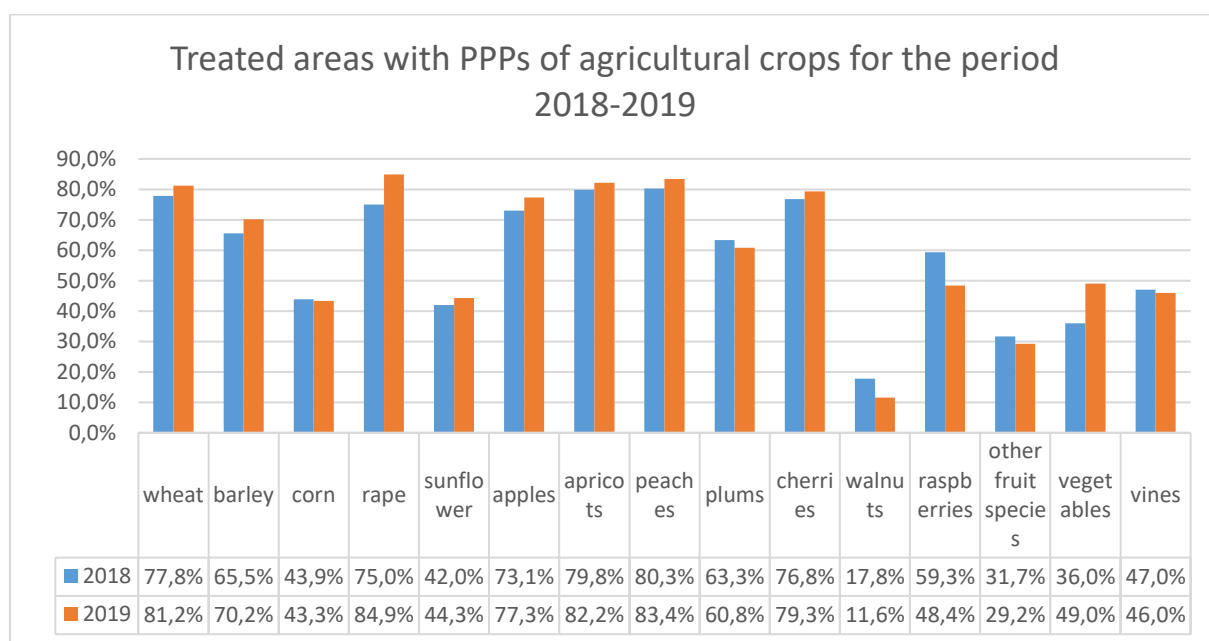
Sulphur does not present a risk due to its low toxicity. It is on the list of substances for which MRLs need not be set according to Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

PPPs containing Copper compounds are used to combat a wide range of fungal and bacterial diseases and are also used in the organic farming to combat these diseases. In cases of bacterial diseases, the Copper compounds are often the only solution, whether in the organic or in the conventional agriculture. Plant protection products containing Copper compounds are used in a higher doses and in a large number of crops, which is a prerequisite for the use of higher amounts of these active substances.

A correspondence is established between the active substances placed on the market in the largest quantities and the most used active substances in 2018 in cereals according to the statistical data.

Treated areas with PPPs by crops.

Figure 4: Treated areas with PPPs of agricultural crops for the period 2018-2019 in %

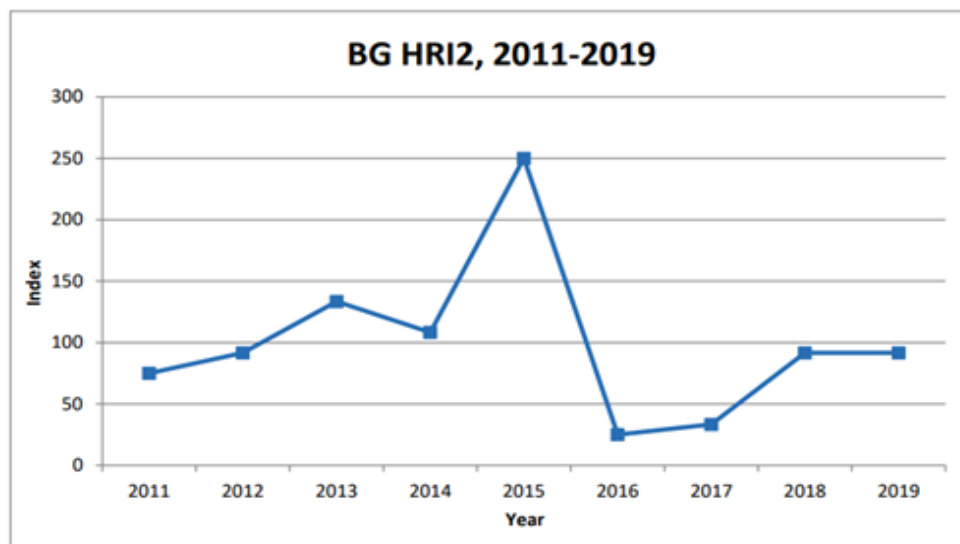


The percentage of treated areas is different for crops. There is a relatively constant trend of area treatment for 2018 and 2019 for the respective crops.

Harmonised Risk Indicator 2 (HRI2)

Figure 5: Harmonised Risk Indicator 2 – Evolution of the overall weighted index, with a baseline of 100, average in 2011-2013

	2011-2013	2011	2012	2013	2014	2015	2016	2017	2018	2019
BG HRI2, 2011-2019	100	75	92	133	108	250	25	33	92	92



When voting on Directive 2019/782, the Republic of Bulgaria expressed its position that the Harmonized Risk Indicator 2, which is based on the number of the PPP authorisations issued under Article 53 of Regulation 1107/2009, does not reflect the real risk of using the PPPs authorized under this procedure. Such an indicator is irrelevant taking into account that the quantities placed on the market for restricted and controlled use of PPPs will be counted as quantities of the corresponding weight in Harmonized Risk Indicator 1 no matter the procedure, under which their authorisations has been granted.

Curve analysis for emergency uses:

For 2011, 7 authorisations were granted for emergency use of PPPs containing the following active substances: abamectin — approved; tau-fluvalinate — approved since June 2011; bifenox — approved; imidachloprid — approved in 2011; chlorpyrifos — approved in 2011; difenoconazole — approved; tebuconazole — approved.

In 2012, 3 authorisations were granted for emergency use of PPPs containing the following active substances: zinc phosphide — approved; abamectin — approved; chlorantraniliprole — approved since 2014, chlormequat — approved.

For 2013, 6 authorisations for emergency use of PPP were issued, containing the following active substances: zinc phosphide - approved; alpha-cypermethrin - approved in 2013 with validity until 2021; metaflumizone - approved from 2015; lambda-cyhalothrin - approved from 2016; thiacloprid – approved with validity until 2020; propanil - an unapproved active substance.

For 2014, 5 authorisations for for emergency use of PPPs containing the following active substances were granted: picoxystrobin — approved by 2017; azoxystrobin — approved;

cooper hydroxide — approved AB since 2019; chlorpyrifos — approved with validity for the year 2020; chlormequat — approved.

In 2015, 10 authorisations for emergency use of PPPs containing the following active substances were granted: picoxystrobin — approved by 2017; azoxystrobin — approved; cooper hydroxide — approved since 2019; fipronil — approved by 2017; pyraclostrobin — approved; trefloxystrobin — approved since 2018; copper hydroxide — approved; thiamethoxam — approved by 2019; clothianidin — approved by 2019.

For 2016, 3 authorisations for emergency use of PPPs containing the following active substances were granted: zinc phosphide — approved; thiamethoxam — approved by 2019; imidacloprid — approved by 2020.

For 2017, 4 authorisations for emergency use of PPPs containing the following active substances were granted: zinc phosphide — approved; thiamethoxam — approved by 2019; imidacloprid — approved by 2020; clothianidin — approved by 2019.

For 2018, 4 authorisations for emergency use of PPPs containing the following active substances were granted: *zinc phosphide — approved; emamectin — approved; quinclorac — not approved; pyridate — approved.*

For 2019, 5 authorisations for emergency use of PPPs containing the following active substances were granted: oxadiazon — not approved; oxathiapiprolin — approved; quinclorac — not approved; pyridate — approved.

For 2020, 3 authorisations for emergency use of PPPs containing the following active substances were granted: oxathiapiprolin — approved; oxadiazon — not approved; quinclorac — not approved.

For the period 2011-2020, the trend of increasing the number of issues when issuing a permit for emergency use of PPPs as for 2015 is monitored, where it marks a peak, and then the number decreases. The reason is the prohibition of neonicotinoids pursuant to Article 2 of Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, seeds of crops listed in Annex II which have been treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid shall not be used or placed on the market, except seeds used in greenhouses. Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing clothianidin, thiamethoxam or imidacloprid as active substances by 30 September 2013.

A review of the data reveals that most active substances for which authorisations for emergency use of PPPs have been granted are currently approved or approved during the authorisation period. This is due to the fact that the PPP authorisation process does not coincide with the time of approval of the active substance, which required authorisation for emergency use of PPPs or the active substance was approved, but an authorisation shall be granted for a emergency use which is not in the authorised uses of this active substance.

The highest number of authorisations for emergency use of PPPs between 2011 and 2020 were granted for the active substances: zinc phosphide (5 authorisations), which was approved active substance rodenticide against striped field mouse and forest voles; thiamethoxam (3 authorisations) neonicotinoid against sunflower and maize pests;

imidacloprid (3 authorisations) neonicotinoid used against potato pests, sunflower and maize; quinclorac (3 authorisations) herbicide against annual cereal weeds in rice.

Ways to reduce the identified trends:

1. Increasing the number of the trained farmers.

Training of farmers is essential for the proper use of PPPs and the primary application of integrated pest management (IPM) or other alternative non-chemical methods. In order to take account of progress under this measure, a new indicator has been introduced in the updated National Action Plan for Sustainable Use of Pesticides in the Republic of Bulgaria: ‘Annual increase of 5 % of the number of trained farmer in comparison with the total number of registered to up to 100 % of trained farmers using plant protection products of a professional category of use’.

2. Implementation of good agricultural practices.

Regulation № 14 of 19 September 2016 on the protection of plants and plant products from economically important pests regulates the development and the approval of rules for good plant protection practice, described in manuals.

In order to measure progress under the integrated pest management (IPM) measure, the updated National Action Plan for Sustainable Use of Pesticides in the Republic of Bulgaria requires that the guidelines for integrated pest management be updated within one year after the entry into force of the Ordinance on Integrated Production.

Since Ordinance № 9 of 26 February 2021 on integrated production of plants and plant products and the control of integrated production was adopted in 2021, the Agricultural Academy develops up-to-date IPM guides for the following crops: vegetable, fruit, berries, essential oil, technical, grain legumes, cereals and vines.

The updated guides make it possible to apply good plant protection practices in the modern agriculture under the current conditions.

3. Effective inspections of pesticide application equipment.

Effective inspections and use of precise and reliable equipment is a prerequisite to reduce the drift and protect the water bodies.

4. Establishment and use of a web-based platform for the coverage of plant protection and fertilisation activities carried out by the farmers (keeping electronic logbooks) and for tracking the movement of plant protection products and fertilisers placed on the market to the end user.

The development and the use of a web-based platform will allow for the full traceability of PPPs from placing on the market to end-user use, for the generation of statistical information for the calculation of harmonised risk indicators, for the identification of trends in the use of certain active substances and priority sites or good practices, in accordance with 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.

The system will enable the control authorities to systematically control the use of plant protection products and fertilisers, including farmers’ electronic logbooks.

5. Limited the use of PPPs that are candidates for replacement and reducing the use of chemical plant protection products.

6. Promoting the use of specialised scientific units and consultants on the proper use of plant protection products and fertilisers and the integrated pest management.
7. Prioritising the use of low-risk plant protection products, non-chemical alternatives, integrated production and organic farming.
8. Implementation and use of advisory systems and mathematical models for predicting the development of key pests in strategic agricultural crops for the country.
9. Financial incentives for farmers applying the integrated production.
10. The withdrawal of the authorisations for non-renewed active substance in 2018 (thiram, propiconazole and diquat) and in 2019 (chlorothalonil, clothianidin and dimethoate) should lead to a retention of the trajectory level in 2020. In addition, given the non-renewal of thiophanate-methyl, chlorpyrifos, chlorpyrifos-methyl, epoxiconazole, imidacloprid and thiacloprid in 2020 and mancozeb and carboxin in 2021, the retention should continue to be observed in 2021.