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Guidance on monitoring and surveying of impacts of pesticide use on human health and the environment under Article 7(3) of Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides (referred to as the Sustainable Use Directive)

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1. GENERAL CONTEXT

1. 1. Purpose

This guidance fulfils the requirement of Article 7 of Directive 2009/128/EC[1]. While this document has been adopted by the European Commission and sets out its views as at the date of publication, it is not legally binding, and only the Court of Justice of the European Union may authoritatively interpret Union law.

1.2. Definition of monitoring and surveillance

For the purpose of this guidance, reference is made to the following broad definitions as defined in http://www.eionet.europa.eu/gemet (by April 28, 2014).

Monitoring is defined as *checking regularly in order to perceive change in some quality or quantity* ("checking" implies a measurement activity and "regularly in order to perceive change" a measurement activity repeated over time). M**onitoring techniques** are techniques employed in the process of checking, observing and measuring events, processes or physical, chemical, biological and environmental phenomena.

Surveillance is defined as a "*system that permits the continuous observation, measurement and evaluation of the progress of a process or phenomenon with the view to taking corrective measures*".

By contrast, **testing** in the context of plant protection product (PPP) authorisation is performed within a limited time period, either under laboratory or field conditions, via a specific study design which involves known exposure level(s) to an active substance or PPPs and an untreated control. The aim of these studies is to answer a specific question (hypothesis) in order to establish the effectiveness of the active substance or PPP under environmental conditions; to assess the possible side effects on animals, plants or humans and to determine the persistence of pesticide residues in the environment.

2. DESIGN OF PPP MONITORING AND SURVEILLANCE PROGRAMMES

2.1. Expected impacts of PPP use to be considered

Monitoring needs to be considered in the context of the authorisation and use cycle of PPPs in the EU (Figure 1), where any PPP use has to be authorised according to Regulation (EC) No 1107/2009[2]. The PPP uses are authorised after comprehensive risk assessments based on harmonised criteria and data requirements indicate that neither immediate or delayed harmful effects on human and animal health nor any unacceptable effects on the environment are expected under the particular conditions of use. Specific conditions and/or restrictions could be imposed (if applicable) and may include the requirement of performing "ad-hoc" monitoring for certain active substances[3].

[1] 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. OJ L 309, 24.11.2009, p. 71–86.
[2] 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. OJ L 309, 24.11.2009, p. 1–50.
[3] Art. 6(i) and 67(2) of Regulation (EC) No 1107/2009.

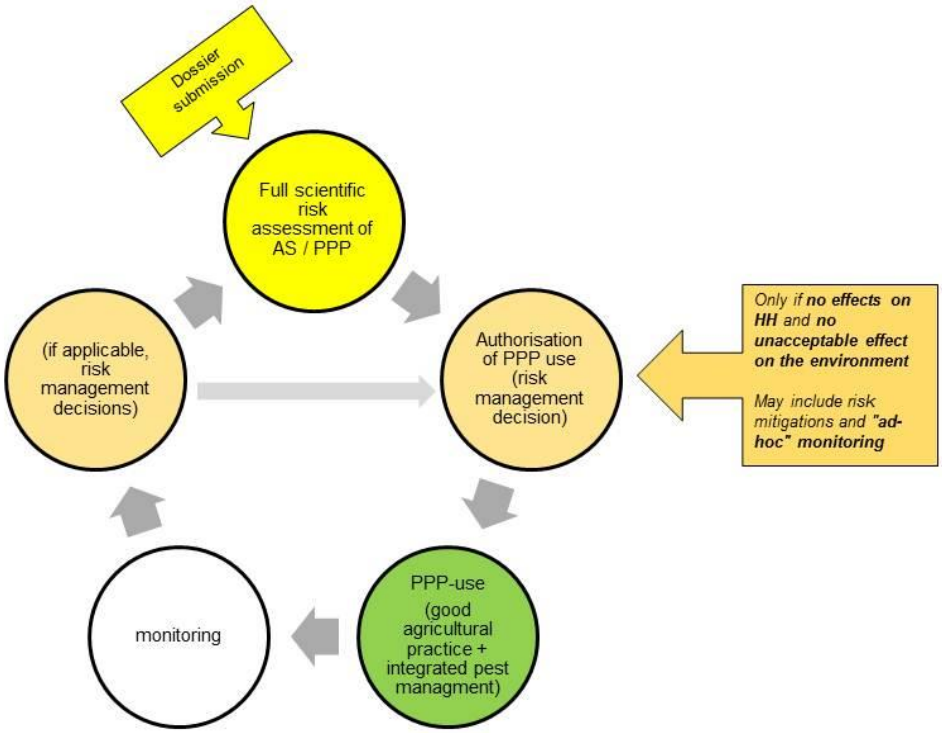

Figure 1: Monitoring and surveillance in the context of the authorisation and use cycle of PPPs in the EU (Regulation (EC) No 1107/2009 and Regulations (EU) No 283/2013 and 284/2013).

For the design of any monitoring or surveillance programme, it is essential to know what impacts or effects are expected. In other words, potential answers to the question "what are we looking for?" are needed in order to design a monitoring/ surveillance programme. Considering that, as mentioned above, a PPP use is only authorised if neither harmful effects on human and animal health nor any unacceptable effects on the environment are expected, the main objectives for monitoring and surveillance of PPP use are to confirm the absence of these effects by:

1. Monitoring of specific active substances in cases required according to Art. 6(i) and 67(2) of Regulation (EC) No 1107/2009,

2. Surveillance monitoring providing for a system that complements the pre-authorisation scientific risk assessment.

Article 68 of Regulation (EC) No 1107/2009, in conjunction with Article 55 of the same Regulation, requires Member States to control and verify that PPPs are used in accordance with the conditions of authorisation and the labelling. Data collected in the context of these requirements can be considered as complementary and are often collected using similar techniques. Moreover, monitoring and surveillance programmes are mentioned in Regulation (EC) No 882/2004 as one of the potential subject areas for control procedures[4].

[4] Article 10 and Annex II of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. OJ L 165, 30.4.2004.

2.2. Follow-up of monitoring results: what happens after monitoring data are available?

Monitoring and surveillance data will indicate if the risk management measures put in place are effective and thus legal requirements are met. Based on monitoring data, further actions may be needed. Monitoring and surveillance data will inform consumers and general public on the quality of their food and/or environment.

Available monitoring data may be used for 1) any renewal, withdrawal or amendment of authorisation as requested by Regulations No 1107/2009 (Articles 43 and 44), 283/2013[5] and 284/2013[6] and 2) to trigger a review of an active substance approval pursuant to Article 21 of Regulation (EC) No 1107/2009.

In the case unexpected effects are reported as a result of monitoring and surveillance programmes, potential risk management actions are recommended, within the framework of the above legislation, to follow the rationale below:

1. **Causality link** between the PPP use and the observed unexpected effect: the plausibility of a causal relationship between a PPP use and the observed effect needs to be assessed. The effects observed may refer either to direct measurements of residues in matrices (e.g. biomonitoring) or indirect effects on, e.g., populations of organisms. During this assessment other factors which may cause adverse events should also be considered (i.e., repeated cut of grass, bees deprived of pollen as food).

2. **Significance of identified effects**: It needs to be demonstrated that the observed effects are statistically significant. Making use of additional available data may be needed.

3. If both 1 and 2 apply, an understanding of the **reasons for the observed effect** is important for taking appropriate measures at risk manager level (e.g. has the PPP been used correctly, or could the observed effect be associated with overdose or misuse?).

2.3. Proportionality and cost efficiency of monitoring and surveillance of PPP-use

In general terms, it is considered essential that measures proposed are necessary, cost-effective and of high quality[7]. This is also applicable to the monitoring and surveillance activities described in this document.

For keeping monitoring of PPPs use **proportionate**, it should be considered in the context of other (environmental and agricultural) factors which may influence human health, animal health or the environment. Proportionality is also indicated in Directive 2009/128/EC (Article 15.2.c) where MS are requested to identify priority items based on active substances, crops, regions or practices that require particular attention. Other legislation, such as the Regulation (EC) No 882/2004 on official controls, also defines that the measures taken should be proportionate to the risks and provides for appropriate coordination among competent authorities.

[5] Annex of Commission Regulation (EU) No 283/2013, Sections 5.9.1, 7.3.1, 7.5, 8.9.
[6] Annex of Commission Regulation (EU) No 284/2013, Section 10.8.
[7] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. Smart Regulation in the European Union COM/2010/0543 final.

Cost efficiency is achieved making best use of health, environmental and/or agronomic data already collected either in the context of PPP use or in the context of other related monitoring activities (e.g. under Regulation (EC) No 396/2005[8], Water Framework Directive 2000/60/EC[9]). For maximising the efficient use of resources, the recorded monitoring or surveillance **data shall be interoperable and available to risk managers of different authorities**. Directive 2007/2/EC[10] establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) applies to data which could be used in the context of environmental policies or policies which may have an impact on the environment, and is thus also applicable to monitoring activities. Other European initiatives, in particular the development of the Information Platform for Chemical Monitoring (IPCheM)[11] should be considered in this context.

3. "AD-HOC"MONITORING: ACTIVE SUBSTANCE MONITORING REQUESTED FOR SPECIFIC AUTHORISATIONS (ART. 6(I) AND/OR ART. 67(2) OF REGULATION (EC) NO 1107/2009)

Active substance specific monitoring may be requested according to Art. 6(i) and/or Art. 67(2) of Regulation (EC) No 1107/2009. It shall be performed mainly by the PPP producers on the request of competent authorities.

This monitoring is designed on a case by case basis depending on the specific active substances. Therefore, no further guidance can be provided in this document for these situations. However, it should be considered if and how the data collected could be made interoperable, e.g. via IPCheM.

It is the responsibility of authorisation holders of a PPP to immediately notify the MS that granted the authorisation of any new information concerning the PPP which could suggest it does not comply anymore with the criteria set out in the Regulation (Art. 56 of Regulation (EC) No 1107/2009). This includes reporting suspected adverse reactions in humans, animals and the environment related to the use of the PPP's. Monitoring data may be useful for this purpose.

4. SURVEILLANCE AND MONITORING OF PPP EFFECTS ON HUMAN HEALTH AND ENVIRONMENT AS AN ADDITIONAL "EARLY WARNING"

In the EU any PPP use is authorised after a comprehensive risk assessment which indicates that neither immediate or delayed harmful effects on human and animal health nor any unacceptable effects on the environment are expected. However, PPPs may still be a potential source of risk to humans or of pollution of the environment if not used appropriately or in the case of unpredicted

[8] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

[9] Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy.

[10] Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE). OJ L 108, 25.4.2007, p. 1–14.

[11] The Information Platform for Chemical Monitoring (IPCheM) is a single access point for discovering chemical monitoring data collections managed and available to European Commission bodies, Member States, international and national organisations and researchers. The Platform aims to support a more coordinated approach for collecting, storing, accessing and assessing data related to the occurrence of chemicals and chemical mixtures, in relation to humans and the environment. IPCheM is designed and implemented as de-centralised system, providing remote access to existing information systems and data providers. https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html

events. Surveillance monitoring is intended to provide for an additional early warning system for detecting, in particular:

- Potential harmful effects or risks for human health, in particular as a result of the exposure of consumers to residues of PPPs and chronic exposure of operators, workers and residents.
- Potential unacceptable effects or risks for the environment, e.g. water pollution; potential effects on biodiversity.

Any monitoring or surveillance programme is based on collected data. A variety of data relevant to assess the potential impacts of PPPs is already collected by different national authorities, in particular related to EU legislation and national requirements (for an overview refer to Figure 2, for more details to Arcadia, 2012[12]). Additional actions and surveys are carried out at EU level (CEH et al, 2014[13]). However, so far it is not always possible to link these data easily (Arcadia, 2012), in particular between different competent authorities or between data collected with different objectives.

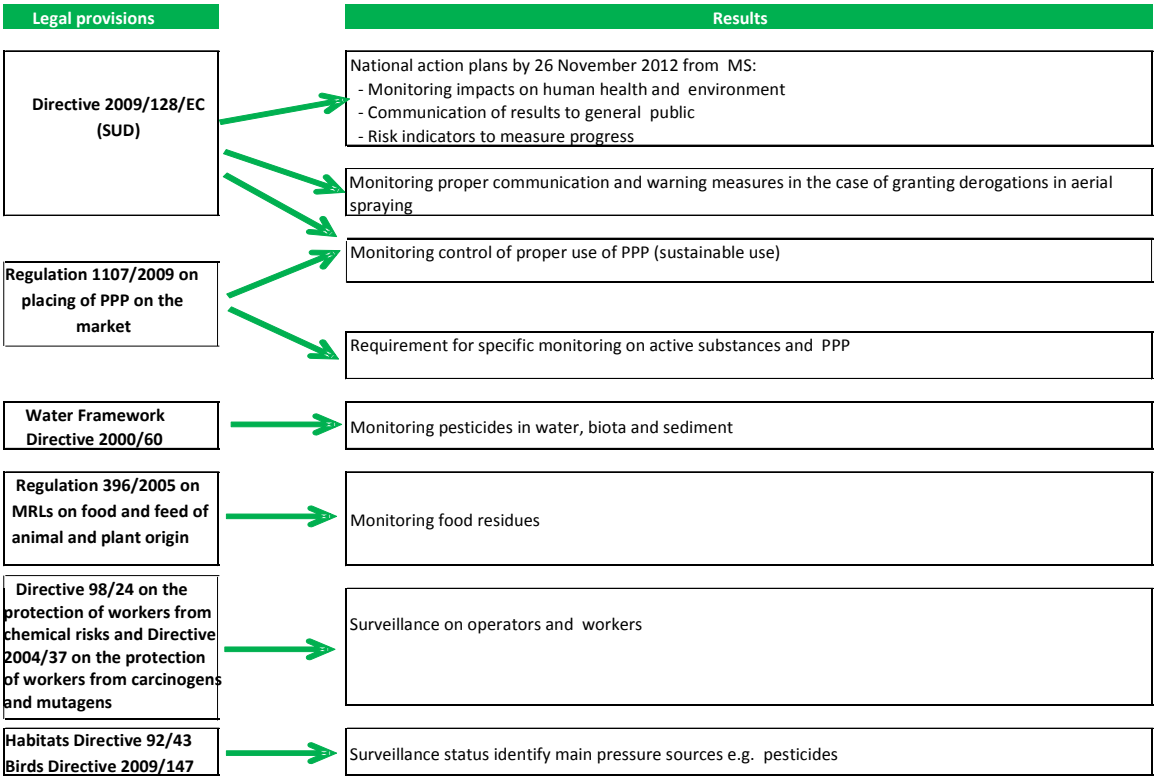

Figure 2: Overview on monitoring and surveillance on impacts of pesticide use on human health and on the environment in accordance with EU provisions

[12] Arcadia International. 2012. Study on existing monitoring and surveillance activities, communication of the results of these activities to the public and awareness raising programmes put in place by MS on the impacts of use of plant protection products on human health and the environment. Final report prepared by the Food Chain Evaluation Consortium (FCEC), Civic Consulting, Bureau van Dijk, Arcadia International, Agra CEAS. Framework Contract for evaluation and evaluation related services - Lot 3: Food Chain (Awarded through tender No SANCO/2008/01/055).

[13] Centre for Ecology and Hydrology, Perseus, Rijksinstituut voor Volksgezondheid en Milieu; Review of statistical methods and data requirements to support post market environmental monitoring of agro ecosystems. Supporting Publications 20YY:EN-NNNN. [16 pp.]. www.efsa.europa.eu/publications.

The data collected may be either "**direct measurements"** of active substances or residues in different matrices (e.g. agricultural food commodities, water bodies), or the data may describe the status of individuals, populations or ecosystems ("**indirect measurements"**). For both kinds of data, a **link to the actual PPP use** (exposure) needs to be made in order to be able to take action once undesirable effects or impacts are detected via monitoring: it is crucial to understand if the particular effect is a consequence of a correct PPP use (and thus a consequence of an unpredicted event) or a consequence of misuse. Only then it would be possible to take informed actions at regulatory level where applicable (see also Section 2.2).

In the sections below this outline is explained in more detail for each particular sector.

4.1. Surveillance monitoring linked to human health

4.1.1. Direct surveillance monitoring on residues in food and feed

Direct monitoring of residues in food and feed matrices is legally required in the EU (Regulation (EC) No 396/2005) and provides data for evaluating potential dietary exposure of consumers to residues. The data collection on direct measurements of residues of active substances (maximum residue levels, MRLs) is implemented and coordinated at EU level. Articles 29 to 33 of Regulation (EC) No 396/2005 provide for annual monitoring control programmes in each Member State with a coordinated programme at European level including transmission of the data to the European Food Safety Authority (EFSA) which reports annually on pesticides residues. In addition, the monitoring of the presence of PPP in drinking water is linked to obligations of the Drinking Water Directive (Council Directive 98/83/EC[14]), as amended by Commission Directive (EU) 2015/1787.

MRLs are established based on an assessment of the conditions of use of the pesticide (i.e. the quantities used and the time period between the final application and harvest) and an assessment of potential consumer risk, taking into account highest food consumption values and vulnerable groups. MRLs are set at levels far below those which may lead to negative health effects. Therefore, in the very limited number of cases where MRL exceedances occur, the levels of residues are unlikely to pose health concerns to consumers in the vast majority of cases.

Besides the direct measurement data on residues of active substances and, if applicable, metabolites, also other kind of data may be needed, e.g. exceedance of agreed thresholds, such as MRLs and acute reference dose (ARfD), data on food consumption, diets. Recent EFSA reports include an acute and chronic dietary exposure assessment for consumers[15].

4.1.2. Surveillance of chronic health effects potentially caused by exposure to PPPs

The difficulty to link results from epidemiological studies, e.g. potential toxicological effects, with the exposure to single substances is recognised (e.g. Ntzani et al, 2013[16]) and needs to be considered. Therefore, efficient surveillance programmes are recommended to focus on epidemiological data of populations with a higher level of exposure, and thus potentially subject to higher risks.

[14] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

[15] For example: European Food Safety Authority; The 2010 European Union Report on Pesticide Residues in Food. EFSA Journal 2013;11(3):3130. [808 pp.] doi:10.2903/j.efsa.2013.3130. www.efsa.europa.eu/efsajournal.

[16] Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E, Tzoulaki I, 2013. Literature review on epidemiological studies linking exposure to pesticides and health effects. EFSA supporting publication 2013:EN-497, 159 pp.

Directive 2009/128/EC (Article 7.2) requires Member States to put in place systems for gathering information on *"chronic poisoning developments where available, among groups that may be exposed regularly to pesticides such as operators, agricultural workers or persons living close to pesticides application areas*". Agriculture in general is identified as a risk sector by Directive 89/391/EEC[17] (Annex). A Guidance document[18], addressed to farmers, was issued by the European Commission in 2012, where handling of chemicals in the agricultural sector was also covered. Commission Communication on Safer and Healthier Work for All[19] identifies fighting occupational cancer and dealing with dangerous chemicals among the top three actions in this area and emphasizes the need for better availability and sharing of data.

Health surveillance activities are foreseen in the context of Directive 98/24/EC[20]. In addition, Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009 provides for a medical surveillance of manufacturing plants personnel and monitoring studies (Annex, point 5.9.1). The reports submitted shall be supported by information on the design of the programmes and exposure to the substance and other chemicals.

Furthermore, an EU Strategic Framework on Health and Safety at Work 2014-2020[21] has been adopted, with one of its strategic objectives being the improvement of statistical data collection to have better evidence and for developing monitoring tools. Several related activities are on-going at the EU, among them the recently finalised definition of priorities for occupational safety and health research in Europe by the EU Agency for safety and health at work (OSHA). Toxicological and epidemiological research to assess health risks from occupational exposure to multiple substances is becoming more important and includes PPPs as one of the possible elements of the exposure to chemical mixtures.

Progress has been also made in the EU in the area of harmonising human bio-monitoring in Europe (COPHES and DEMOCOPHES projects[22] and HBM4EU initiative[23]), which should be considered too when designing surveillance of human health.

Based on this situation and the recent developments, it is recommended to develop in first instance systems for gathering information on chronic poisoning among agricultural operators and/ or workers, who are exposed regularly to PPPs during their professional life. Once these systems are

[17] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.

[18] European Commission, 2012. Protecting health and safety of workers in agriculture, livestock farming, horticulture and forestry. A non-binding guide to best practice with a view to improving the application of related directives. ISBN 978-92-79-22673-1.

[19] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safer and Healthier Work for All – Modernisation of the EU Occupational Safety and Health Legislation and Policy". COM (2017) 12 final.

[20] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). OJ L 131, 5.5.1998, p. 11–23.

[21] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an EU Strategic Framework on Health and Safety at Work 2014-2020. COM (2014) 332 final.

[22] http://www.eu-hbm.info/

[23] www.hbm4eu.eu

implemented, they might be expanded in a second step to other population groups that may be exposed regularly to PPPs, e.g. residents.

In any case, for the surveillance programmes based on epidemiological data of populations, a **link to the actual PPP use** (exposure) is crucial in order to be able to make use of the collected data and to take action based on monitoring data.

4.1.3. Reporting of poisoning incidents (Art. 68 of Regulation (EC) No 1107/2009)

Article 68 of Regulation (EC) No 1107/2009 requires the European Commission to adopt provisions for detailed rules on monitoring and controls by Member States. Any such provisions shall also include collection of information and reporting of suspected poisonings. However, Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls, once applicable, amends this article and provides instead that the Commission may, by means of implementing acts, lay down detailed rules on uniform practical arrangements for the performance of official controls, including on the collection of information, monitoring and reporting on suspected poisonings from plant protection products. Furthermore, Directive 2009/128/EC requires Member States to "… put in place systems for gathering information on pesticide acute poisoning incidents…". So far, the corresponding implementation of these systems and the following up of acute poisoning incidents varies between the different Member States (Arcadia, 2012).

Harmonisation of the information collected by the Poisoning Centres[24] in order to formulate preventive and curative measures in the event of emerging health responses is promoted via the actions foreseen in Article 45 of Regulation (EC) No 1272/2008[25] on classification, labelling and packaging of substances and mixtures, as amended by Regulation (EU) No 2017/542[26]. The scope of this Regulation also includes PPPs. Information centres (e.g. help desks) that could be contacted in case of an incident in agriculture could be integrated with information centres covering also other hazard and chemicals. Proper follow up of the reported acute poisoning incidents are important for detecting the reasons and for considering, if applicable, risk management measures. Particularly important is to understand and record if the reported poisoning incident was a consequence of a correct PPP use, or a consequence of overdose or misuse.

4.2. Environmental surveillance monitoring

Environmental surveillance monitoring is intended to confirm to risk managers the absence of any unacceptable effect or risks for animal health and the environment as a consequence of PPP use by providing an additional "early warning" system that complements the pre-authorisation scientific risk assessment. In addition, it may inform the general public addressing directly their potential concerns on environmental issues.

[24] European Commission, DG ENTR. Harmonisation of Information for Poison Centres. Review according to Article 45(4) of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. http://ec.europa.eu/enterprise/sectors/chemicals/classification/poison-centres/index_en.htm.

[25] Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006. OJ L353, 31.12.2008.

[26] Regulation (EU) 2017/542 of 22 March 2017 amending Regulation No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response.

The environment is complex and subject to a wide variety of natural (e.g. climate) and anthropogenic (e.g. any kind of farming) influences. Therefore, monitoring of potential unexpected effects of PPPs on environmental compartments which go beyond Articles 6 and 67 of Regulation (EC) No 1107/2009 shall be considered in a general environmental monitoring context. As already mentioned, for a proportionate and cost-efficient environmental monitoring it is essential to make best use of data already collected, for instance data collected also for other (agro-) environmental monitoring and/or surveillance purposes.

Data collected in the context of a wide range of environmental EU legislation may be also used for environmental monitoring of potential impacts of PPP use. This includes both direct and indirect environmental surveillance monitoring and is explained in the sub-sections below. Further data collected at national or EU level may also be relevant as a data basis for environmental monitoring and are summarized in Figure 2, Arcadia (2012) and CEH et al (2014).

4.2.1. Direct environmental PPP monitoring

Surface water and ground water are monitored as legally required by the Water Framework Directive (Directive 2000/60/EC[27]) and its daughter directives, Directive 2008/105/EC[28] (priority substances in surface water), as amended by Directive 2013/39/EU and the Groundwater Directive (Directive 2006/118/EC[29]), as amended by Directive 2014/80/EU. In addition, guidance documents were developed and published under the Water Framework Directive[30] (in particular, guidance documents No 7, 15, 19 and 25 on monitoring) to assist Member States to implement the Directive. These are intended to provide an overall methodological approach, but will need to be tailored to the specific circumstances of each EU Member State. Under the Water Framework Directive Member States are required to monitor concentrations of priority substances and substances discharged in significant quantities (river basin specific pollutants) in the water bodies, including pesticides. Member States should take the necessary measures to ensure that concentrations identified do not exceed the relevant environmental quality standards in all waterbodies, by designing and implementing appropriate measures.

With regard to protected areas, monitoring and surveillance are performed as required by the Habitats Directive. If effects are observed under the monitoring and surveillance programmes, these indicate that corrective measures are needed and should be implemented.

4.2.2. Environmental monitoring of populations and /or communities

In light of the need of proportionality and cost efficiency, activities are expected to focus on specific biological entities, some of which have been previously identified as vulnerable. Some areas have been already identified in European legislation and monitoring or surveillance activities are on-going, e.g.:

[27] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. OJ L 327, 22.12.2000, p. 1-72.

[28] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council. OJ L 348, 24.12.2008, p. 84-97.

[29] Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration. OJ L 372, 27.12.2006, p. 19-31.

[30] Common Implementation Strategy guidance documents, available at: http://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm.

1. Bees: Regulation (EU) No 415/2013[31]

2. Biodiversity: Habitats Directive 92/43/EEC[32], Birds Directive 2009/147/EC[33] and Water Framework Directive 2000/60/EC

If effects are observed in any of the monitored populations or communities, these will serve as an indication that corrective measures may need to be considered. As mentioned in Section 2.2, the link to the actual PPP-use (exposure) needs to be made in order to be able to make use of the collected data and to take action based on monitoring data.

5. HORIZONTAL ASPECTS

5.1. Availability of PPP use data

Any monitoring or surveillance programme is based on collected data, which may be **direct measurements** of active substance or PPP residues in different matrices (e.g. agricultural food commodities, water bodies), or measurements linked to the status of individuals, populations or ecosystems (**indirect measurements**). For both kinds of measurement data, a **link to the actual PPP use** (as a proxy for exposure) needs to be made in order to be able to take, if applicable, further risk management decisions.

It is important to understand whether the particular monitoring data are a consequence of a correct PPP use (and thus a consequence of an unpredicted event) or a consequence of misuse (Section 2.2).

Professional users of PPPs have the obligation to keep records on the use of PPPs for at least 3 years (Art. 67 of Regulation (EC) No 1107/2009). The information recorded shall contain:

- the name of the PPP,
- the time and dose of the application,
- the area where the PPP was used,
- the crop on which the PPP was used.

With this information, aimed at increasing the efficiency of monitoring and control (Recital 44 of Regulation (EC) No 1107/2009), it should be possible to assess environmental exposure. Human exposure can be also assessed, provided it is known if and how many individuals (operators, bystanders, residents) were exposed during the use of the PPP and afterwards (during the re-entry period). In addition, Art. 67 of Regulation (EC) No 1107/2009 also requires that these records are made available to the competent authority on request.

[31] Commission Regulation (EU) No 87/2011 of 2 February 2011 designating the EU reference laboratory for bee health, laying down additional responsibilities and tasks for that laboratory and amending Annex VII to Regulation (EC) No 882/2004 of the European Parliament and of the Council. OJ L 29, 3.2.2011, p. 1–4.
[32] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora. OJ L 206, 22.7.1992, p. 7–50.
[33] Directive 2009/147/EC of the European Parliament and of the Council of 30 November 2009 on the conservation of wild birds. OJ L 20, 26.1.2010, p. 7–25.

Regulation (EC) No 1185/2009[34] concerning statistics on pesticides establishes a framework for the systematic production of statistics on the placing on the market and use of PPPs at national level, specifying that Member States shall collect the necessary data and transmit to the European Commission (Eurostat) the statistical results in accordance with specified schedules and periodicities. However, since the geographical location is a key element to determine the exposure to PPPs, data on pesticide use on geographical areas are in particular important in the context of human health and environment monitoring and surveillance. It would thus be appropriate that Member States further develop pesticide use statistics with the aim of improving the availability of data on pesticide use at regional level, where possible by using existing data sources, such as the records kept by professional users mentioned above.

5.2. Availability of other complementary data

Complementary data (e.g. diet, geographical distribution of different population groups, environmental conditions, land use data, additional monitoring and environmental data) may be needed in some cases in order to assess a specific case or to identify e. g. population groups which were particularly exposed. Other (agri-) environmental data like those linked to the Communication[35] on development of agri-environmental indicators could be also considered as a potential source of complementary information for the monitoring and surveillance of PPP-use.

Besides the information on the monitoring data themselves and the PPP-use data, other information related to policy enforcement may be relevant. For example, some data and information collected in the context of monitoring and control as required by Art. 68 of Regulation (EC) No 1107/2009 may provide additional information, in particular in the phase of potential decisions regarding regulatory actions. Furthermore, the proper use of PPPs considering the principles of good plant protection practice and in compliance with the conditions reported in the label (Art. 31 and 55 of Regulation (EC) No 1107/2009) might be relevant. In addition, proper use refers also to the compliance with the provisions of Directive 2009/128/EC, for instance regarding inspections of pesticide application equipment (Art. 8) or the general principles of Integrated Pest Management (Art. 14).

5.3. Interoperability of data

Data which could be used for monitoring or surveillance purposes are being collected by different competent authorities due to the wide spectrum of monitoring activities covered (Arcadia, 2012) and the variety of data (direct measurements on residues in a matrix, indirect measurements of populations or communities, PPP-use data, etc.). For a maximal efficiency of resources, the compiled monitoring or surveillance data shall be interoperable and available to risk managers of different authorities. Thus, coordination is needed for a better integration of the monitoring results obtained in different areas.

[34] Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides. OJ L 324, 10.12.2009, p. 1–22.

[35] COM(2006) 508. Communication from the Commission to the Council and the European Parliament Development of agri-environmental indicators for monitoring the integration of environmental concerns into the common agricultural policy. 15.9.2006.

Directive 2007/2/EC establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) is applicable to data related to environmental policies or policies which may have an impact on the environment, and is thus applicable to the data recorded in the context of monitoring and surveillance of PPP-use.

The INSPIRE Directive ensures that the spatial data infrastructures of the Member States are compatible and that the data collected can be used in a European Union and transboundary context. Common Implementing Rules are adopted in a number of specific areas (Metadata, Data Specifications, Network Services, Data and Service Sharing and Monitoring and Reporting). Detailed information is available under http://inspire.jrc.ec.europa.eu/index.cfm, and covers already some aspects relevant to the monitoring and surveillance activities mentioned in this document. The development of specific use-case studies may need to be further developed.