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Evolution of Directive (EC) No 128/2009 of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve the Sustainable Use of Pesticides

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Abstract

The EC Directive No 128/2009 established a regulatory framework for Community action to achieve the sustainable use of pesticides (phytopharmaceuticals) that entered into force in 2011. The Directive manages all aspect of pesticides approved under Regulation (EC) No 1107/2009 and listed in implementing Regulation (EU) No 540/2011 outside the approval and approval procedure, including all relevant National Action Plans (NAP), training, sales of pesticides, information awareness-raising, pesticides storage, application and equipment (i.e. inspection of equipment in use), specific practices and uses (i.e. aerial spraying), indicators and reporting on pesticide uses. This study examines the evolution of these dispositions framing the use of pesticides in Europe and the recent implementation of the harmonized risk indicators (HRI), which are expected to diminish in numbers over time. Calculation of the annual HRI values, and analysis of their evolution through the years is, therefore, for the first time, a method to quantify the evolution of the theoretical impact of pesticides at the pan-European level and to measure the progress against the original purpose of the directive, and therefore, its success.

Keywords: European Union, phytopharmaceuticals, integrated pest management, sustainable use, Sustainable Use Directive (EC) No 128/2009, Regulation (EC) No 1107/2009

1. Introduction

The term "pesticides" generally refers to crop or plant protection products (PPP) and post-harvest treatments or products. These are sometimes also referred to as phytopharmaceuticals products (or PPPs) and consist of chemicals, single molecules or mixtures, microorganisms, semiochemicals and natural substances from animal, mineral, microbial or plant origin.

In the European Union (EU), the sustainable use of pesticides is managed by Directive (EC) No 128/2009, which established a framework for Community action to achieve a sustainable use of pesticides [10]. The directive was approved in 2009 and includes a total of 25 Articles; it entered into force on December 14, 2011. The full text embraced all aspects needed to achieve a sustainable use of pesticides (Art. 2 and Art. 3) managed by PPP Regulation (EC) No 1107/2009 [22] and Implementing Regulation (EU) No 540/2011 [4, 26], by reducing the risks and impacts of pesticide use on human health and the environment, and promoting the use of Integrated Pest Management (IPM) and alternative approaches or techniques, such as non-chemical alternatives to pesticides (Art. 1). The aim of the present study is to examine the development and the modification of relevant directives and regulation impacted by Directive (EC) No 128/2009 since its entry into force 10 years ago. The results of this quantitative evaluation can provide conclusions as to usefulness, efficiency, correct implementation, and goals achievement of Directive 128 after 10 years of existence.

2. Materials and Methods

The raw data were recovered from the website EUR-Lex [14] for the Implementing Regulation (EU) No 540/2011 [4]. Other relevant Directives were followed in the Official Journal of the European Union. Previous Databases [26] built for biocontrol agent (BCA) evolution analyses, such as microorganisms, natural substances, and semiochemicals, managed by PPP Regulation (EC) No 1107/2009, were also examined. These databases provide the current status of concerned PPP active substances (approval and date of approval, low risk, natural substance or microorganism).

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Chapters					
I	II	III	IV	V	VI
General provision	Training, sales of pesticides, information awareness-raising	Pesticide application and equipment	Specific practices and uses	Indicators, reporting and information exchange	Final provisions
Corresponding Articles					
Art. 1 Subject matter Art. 2 Scope Art. 3 Definitions Art. 4 National Action Plans	Art. 5 Training Art. 6 Requirements for sales of pesticides Art. 7 Information and awareness-raising	Art. 8 Inspection of equipment in use	Art. 9 Aerial spraying Art. 10 Information to the public Art. 11 Specific measures to protect the aquatic environment and drinking water Art. 12 Reduction of pesticide use or risks in specific areas Art. 13 Handling and storage of pesticides and treatment of their packaging and remnants Art. 14 Integrated pest management	Art. 15 Indicator Art. 16 Reporting	Art. 17 Penalties Art. 18 Exchange of information and best practice Art. 19 Fees and charges Art. 20 Standardization Art. 21 Committee procedure ~~Art. 22~~ Art. 23 Transposition Art. 24 Entry into force Art. 25 Addressees
Annexes					
	I	*II*	*III*	*IV*	
	Training subjects referred to in Art. 5	Health and safety and environmental requirements relating to the inspection of pesticide application equipment	General principles of integrated pest management	Harmonized risk indicators	

Table 1: Structure of Directive (EC) No 128/2009.

3. Results

The Directive (EC) No 128/2009 is currently composed of 6 chapters, 24 articles, and 4 annexes (Table 1).

The chapters consider: I. General provisions, including National Action Plans (NAPs); II. Training, sales of pesticides, information awareness-raising, pesticides storage; III. Pesticide application and equipment (i.e. inspection of equipment in use); IV. Specific practices and uses (i.e. aerial spraying); V. Indicators, reporting and information exchange; and VI. Final provisions. The Annexes deal with: *I*. Training subjects referred to in Article 5 of §II.; *II*. Health and safety and environmental requirements relating to the inspection of pesticide application equipment; *III*. General principles of integrated pest management; and *IV*. Harmonized risk indicators. Annex *IV* was empty until 2019.

The scope of the Directive is the PPPs and not Biocides (managed by Directive (EC) No 98/8 or later Regulation (EU) No 528/2012) or Biostimulants (managed by Regulation (EU) 2019/1009), and the definitions of all terms are given by the complete PPP regulation [22, 4] in Art. 3. The general principles of integrated pest management (IPM) are described in Annex *III*. The directive also highlights the necessity of training for all actors (professional users, distributors, and advisors) involved in plant protection in Art. 5, and describes ways to achieve it in Annex *I*.

3.1. Development of the Directive 128/2009

Directive 128, as published, was a general text introducing general concepts and ideas on the sustainable use of pesticides, but required the publication of operational details. Fol-

lowing approval, Directive (EC) No 128/2009 was consolidated by additional regulatory texts, especially Regulation (EC) No 1185/2009 [23], which added further detailed instructions concerning statistics on pesticides.

The first regulatory modifications, such as minor date changes, were made to the directive by means of a corrigendum [9] regarding submission dates for reports. Later, major changes were introduced by Regulation (EU) No 652/2014 [24] presenting the financial implementation of the Directive regarding animal and plant health. In practice, the management cost of Directive 128 to meet the needs of controls for foodstuffs and feedstuffs at all stages of production, processing, distribution, and disposal of these products, as well as actions for the health and welfare of animals, and protection against pests of plants or plant products, is approximately € 2 billion for the period 2014-2020. The general objective of Directive 128 is to to contribute to a high level of human, animal, and plant health protection throughout the food production chain and in related fields, through the prevention and eradication of diseases and pests and ensuring a high level of protection for consumers and the environment. Under the National Action Plans (NAPs), all requirements defined in the chapters of the Directive can be implemented, controlled and surveyed. National Action Plans included in the Directive 128 and initially reviewed every five years, are now evaluated every year by the Standing Committee on Plants, Animals, Food and Feed.

Ongoing and post-evaluation of the effect of the implementation of the Directive are described in Art. 42 of the Regulation, and many old legal texts were repealed [Decisions No 66/399/EEC, No 76/894/EEC and (EC) No 470/2009] or amended [Directive (EC) No 98/56, Directive (EC) No 29/2000, Regulation (EC) No 178/2002 (food law), Regulation (EC) No 396/2005 (MRL) [2], and Directive (EC) No 90/2008]. Initially, the Directive (EC) No 128/2009 [10] and Regulation (EC) No 1107/2009 [22] were also amended, with deletion of some articles (22 and 76, respectively).

The most recent amendment to Directive (EC) No 128/2009 was introduced by the Commission Directive (EU) No 2019/782 [3], with the implementation of Annex *IV* regarding harmonized risk indicators (HRIs).

3.2. Impact of the evolution

The most visible impact and input for relevant professional users, distributors and advisors was the implementation of National Action Plans (NAP) only [12]. Following initial implementation, delays between renewals, checks and training were sometimes shortened from five to three years (i.e., inspection of spraying equipment in use).

Together with the implementation of the new categories of active substances ["positive" (low-risk "LR", basic) [17, 18, 19] and "negative" (candidate for substitution) [26]] under Regulation (EC) No 1107/2009, are the visible tools to promote integrated pest management as a better solution, as described in Art. 14 of the Directive. Specifically, the implementation of these measures contributed to the reduction of the number of approved active substances [25, 26] (obviously, those of concern).

The recent implementation by the Directive (EU) No 2019/782 [3] of Annex *IV* of the Directive (EC) No 128/2009 has been the harmonized risk indicator (HRI) settings for calculations. These hazard-based HRIs are necessary to monitor trends in risk reduction from pesticide use at European Union level [3], and to measure the progress achieved in meeting those objectives, including targets, measures, and timetables to reduce risks and impacts of pesticide use on human health and the environment, development and introduction of integrated pest management and of alternative approaches or techniques. This significant addition will definitively strengthen not only the full process under Regulation (EC) No 1107/2009 (Table 2a) to conduct to an approval (section 2), but also (section 3) the temporary authorizations (derogations) granted under Article 53 of Regulation (EC) No 1107/2009 (Figure 1) [22, 3].

3.3. Risk indicators

Risk indicators are detailed at two levels: #1, based on the quantities of active substances placed on the market in PPP under [10], and #2, based on the number of authorizations granted under Art. 53 of [10]. Both indicators exhibit the same number of groups (4), categories (7), criteria, and hazard weighings (1; 8; 16; 64) (Table 2a). Harmonized Risk Indicator 1 (HRI 1) shall be calculated by multiplying the annual quantities of active substances placed on the market for each Group in Table 1, by the relevant hazard weighing set out in Row (vi), followed by the aggregation of the results of these calculations [3]. Sections 2 and 3 show the table for calculating these indicator.

Using all data in Annex *IV* and the databank numbers for each row, we were able to calculate the corresponding annual risk indicators knowing the defined base at 100 for the average of 2011 to 2013.

4. Discussion

One of the major purposes of Directive (EC) No 128/2009 is "*to achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides*" [10]. Only few reports or analyses of the results of the initial implementation of Directive (EC) No 128/2009 [11, 28, 1] are available, since the initial qualitative objectives and goals did not mention organized numerical indicators. Moreover, even though the NAP's obligation was written, their national transcripts were very diverse regarding their coverage and requirements.

Now, with the implementation of Annex *IV*, the Directive is fully operational, with the corresponding harmonized risk indicators (Table 2a). This will influence the pan-European management of active substances in all compartments (approval, renewal, withdrawal, and emergency situations in plant protection (derogations) under Art. 53) (Figure 1).

Since the Institut Technique de l'Agriculture Biologique (ITAB) manages and keeps up to date an analytical scalable databank of the evolution of the full EU pesticide database [25],

Row	Groups						
	1		2		3		4
(i)	Low-risk active substances which are approved or deemed to be approved (Art. 22) of [21], and which are listed in Part D of [4]		Active substances approved or deemed to be approved under [21], and not falling in other categories, and which are listed in Parts A and B of [4]		Active substances approved or deemed to be approved under Art. 24 of [21], which are candidates for substitution, and which are listed in Part E of [4]		Active substances which are not approved under [21], and therefore are not listed in [4]
(ii)	Categories						
(iii)	A	B	C	D	E	F	G
(iv)	Micro-organisms	Chemical active substances	Micro-organisms	Chemical active substances	Which are classified as not: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors	Which are classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors, where exposure of humans is negligible	
(v)	Hazard Weighings applicable to quantities of active substances placed on the market in products authorized under [21]						
(vi)	1		8		16		64

Table 2a: Annex *IV* of Directive (EC) No 128/2009.

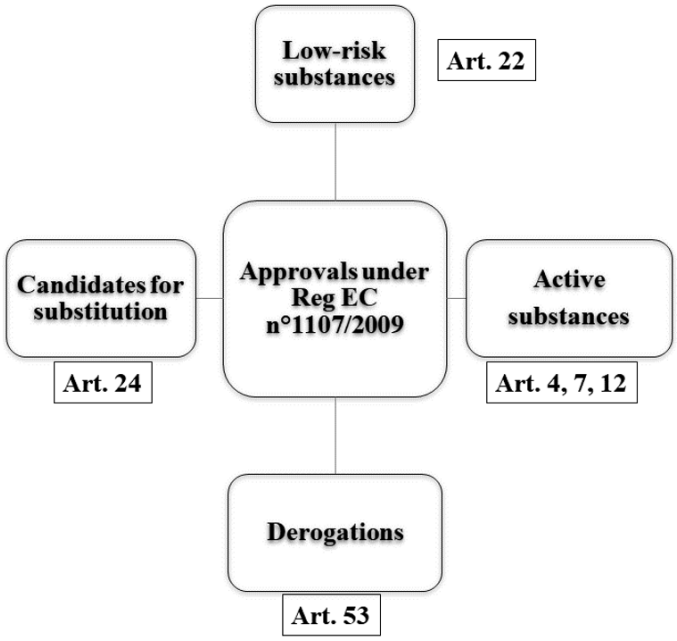

Figure 1: Articles of the PPP Regulation linked to Directive (EC) No 128/2009.

together with corresponding Parts [26, 19, 1, 27] since 2011, we linked this databank to hazard weighings (Table 2a). In order to estimate the corresponding annual values of these harmonized risk indicators (Table 2b) and their evolution at EU level, calculations (with base at 100 for 2011-2013) were conducted using the instructions given in Directive (EU) No 2019/782.

At first glance, both groups, categories, baseline, criteria and calculations are identical in sections 2 and 3; however, a question was first raised concerning group 4 and category G. The harmonized risk indicator 1 is defined at EU level in section 2; however, section 3 regarding harmonized risk indicator 2 is only to be reported by each EU Member State (MS). Although the delivery of a derogation (Art. 53) for a non-approved substance is rare, but possible, and the corresponding full cal-

(iii)	A	B	C	D	E	F	G
(v)	Hazard Weighings						
(vi)	1		8		16		64
Years	Corresponding number of substances						
2011	0	0	398		0	0	
2012	0	0	417		0	0	
2013	0	0	438		0	0	
2014	0	0	462		0	0	
2015	2	3	403		77		
2016	4	3	411		73		
2017	8	3	420		68		
2018	10	4	416		64		
2019	13	5	364		64		868
	Harmonized Risk Indicator 1						
2011 to 2013	100						
2014	110.6						
2015	133.5						
2016	133.6						
2017	133.4						
2018	131.6						
2019	118.3 [a]						
LR [b]	106.3						

Table 2b: Annex *IV* of Directive (EC) No 128/2009.

[a] Ongoing year.
[b] Corresponding to 73 low-risk substances.

culation for section 3 is possible, the calculation of the same result for section 2 is quite inconsistent because the number of non-approved substances is steadily increasing.

4.1. Risk indicator 1

In section 2, the filling of columns A to F for the years 2011 to 2019 is possible by having the databank on hand [26, 19, 25]. For column G in section 2, the number of non-approved substances in 2019 is 851, but it appears to be quite difficult to identify the number of non-approved substances for each year. Therefore, it is difficult to implement the G category, especially because of the high hazard weighing of 64, without artificially destabilizing the harmonized risk indicator 1. The increase in the number of substances mechanically increases the HRI 1; thus, HRI 1 increases until 2017. Low-risk (LR) substances (for column A-B) and candidate for substitution (for column E-F) only appeared in 2015, but the reduction of HRI 1 is only dependent on the total number of active substances (except the basic substance [17]). Therefore, the reduction of this total from 502 (peak substance in 2017 [4]) to 466 (ongoing year 2019) is the only way to reduce HRI 1, since candidates for substitution are still numerous (from the initial list [5] and directly included in Part D [26] during new approvals). The evolution of HRI 1 in the last few years is the bar in Figure 2.

4.2. Analysis of the Risk indicator 1

At first glance, the major point noted is that the HRI 1 coefficient is always above the base 100 established on the three years (2011 to 2012), although an increase of 5 percent each year is already noticeable during the three years included in the average “base 100”. Secondly, we notice an additional increase of HRI 1 of 20 percent the next year (2015), when candidates for substitution were set [5]. Then, there is a stabilization to a plateau around 130 observable for three years from 2015 to 2018. Finally, only a slow decrease of the HRI 1 appears; -1.4 percent in 2018 and -10 percent in 2019 (ongoing year).

Advances in the definition of endocrine disruptors [8] may also increase the number of candidates for substitution and thus the HRI 1, due to a doubling of the hazard weighing (from 8 to 16). However, the implementation of the low-risk criteria [6] would have a positive impact on this indicator, especially if the list of potential low-risk substances is legalized [13], reducing

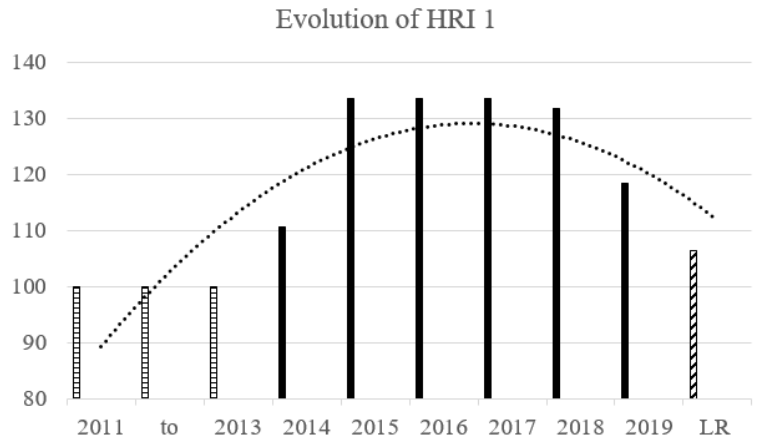

Figure 2: Evolution of HRI 1defined by Annex *IV* of Directive (EC) No 128/2009 with polynomial regression curve.

the corresponding hazard weighing from 8 to 1 for these active substances (57 substances); HRI 1 would therefore be reduced by 399 (57 by 8) mechanically. This result is shown as "LR" bar in Figure 2. However, even if this decision is taken, the HRI 1 would be always greater than 100. This coefficient is, therefore, an undeniable means of calculating the overall risk, but in detail, it highlights that this risk has progressed until 2018 and is still high compared to the base 100 in all cases, including the best hypotheses. Another possible notion on pesticides impact like Maximum Residue Limits (MRL) of active substances [2] and specific non-sprayed substances on crops, is that usage [21] is not considered or differentiated for the calculation of harmonized risk indicators.

5. Conclusions

The implementation of Directive (EC) No 128/2009 was deeply affected by consideration of the sustainability of pesticide use through the National Action Plans (NAP). Consequently, the expansion of integrated pest management (IPM) is triggered by the decrease in the use of chemical PPP agents or molecules and the increase of biocontrol agents (BCA) at PPP Regulation (EC) No 1107/2009. It can be seen that since 2011, the number of BCA increased from 123 to 180, with a maximum of 185 since 2011, while the number of chemicals on the list are relatively stable, from 275 to 285, with a maximum of 319 over the same period.

Recent implementation of the harmonized risk indicators for managing pesticide approvals and renewal as well as derogations (Art. 53), will be a way to drive the development of low-risk substances and a reduction of candidates for substitution. However, the first input in the table did not make it possible to measure a real decrease in harmonized risk indicators between 2014 and 2019 as expected from the Directive. This can be explained by the small number of low-risk substances and the relatively high number of candidates for substitution [26]. It should be noted that other aspects concerning pesticides are not considered in the calculation of harmonized risk indicator 1 [2, 21].

Further positive impacts that may be relevant to the success of implementing NAPs for meeting Directive (EC) No 128/2009 [12] are broader and increasing IPM deployment [16], with 18 approvals given already of low-risk substances [7, 27], together with large-scale withdrawal of candidates for substitution [26]. A broader impact is still possible if the list of potentially low-risk active substances [13] were converted into low-risk status. Even if some actions of this sort were already in force in some Member States (M.S.), the EU M.S. could maintain or amplify success factors of the implementation of Directive (EC) No 128 by encouraging the applications of natural products and microorganisms of low concern through incentives (i.e. reduced fees, fast evaluation, and reduced or removed dossier parts) for active substances, or early zonal market authorizations for plant protection products, while maintaining the same levels of safety. Future hypothetical calculation of harmonized risk indicators for organic production plant protection substances may also be of importance [20] to maintain confidence among customers. However, Directive (EC) No 128 and Reg. (EC) No 1107/2009 only address the durability of pesticide use and plant protection, while other parameters also play a role in the EU's agricultural concerns [15].

5.1. Highlights

- Directive (EC) No 128/2009 was initiated in 2009 with sustainability of pesticide use goals;
- Directive (EC) No 128/2009 was impacted with the successive implementation and inclusion of all Annexes; and
- Directive (EC) No 128/2009 currently manages National Action Plans results and harmonized risk indicator outcomes.

6. Declaration of Conflicting Interest

The authors declare no conflict of interest.

7. Disclaimer

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9. Article Information

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