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ARTICLE

The European Pesticides Harmonised Risk Indicator HRI_1: A Clarification About Its Displayed Rendering

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Abstract

Since the EU Directive (EC) No 128/2009 (SUD) was approved by the European Parliament, the establishment of a general framework aimed at securing the sustainable use of pesticides was laid down, and European Union (EU) Member States adopted National Action Plans in accordance with this Directive. Specifically, for EU Member States, pesticides, objectives and quantitative targets were created. Therefore, the EU Commission provided a methodology for risk assessment as the derivation of two harmonised risk indicators: HRI_1 and HRI_2. The present study focuses on HRI_1, as this can be implemented at the country level. Each EU Member State delivers annual harmonised risk indicators values to the Commission based on calculations using their own data and results. However, only the EU Commission can derive this HRI_1 (concatenated) indicator at the EU level. Therefore, the present study is an attempt to shed some light on the *modus operandi* used by the EU Commission to compile this HRI_1, and it also aims to clarify these calculations. Data originating from twenty-seven EU Member States were analysed. These data were compared to data published on the EU Commission website over time. Possible virtual developments including the modification and evolution of active substance statuses are envisaged.

Keywords: Active substances; Directive (EC) No 128/2009 (SUD); harmonised risk indicators

I. Introduction

The use of pesticides is evaluated and regulated within the European Union (EU). For example, in 2009, the European Parliament and Council[1] implemented Directive (EC) No 128/2009, which established a general framework to secure the sustainable use of pesticides. EU Member States were expected to adopt National Action Plans (NAPs) to implement this Directive by November 2012. These plans had to include objectives, quantitative targets, measurements and timetables to reduce the risk and impact of pesticide use. A reassessment of these plans is required at least every five years. These action plans, together with an integrated pest management (IPM) plan, all supervised by the EU Commission ("Commission services", the institutional body with civil servants), are to be implemented by the EU Member States in the form of NAPs.[2] The main NAPs concerned the training of users, advisors and distributors, the inspection of pesticide application equipment, the prohibition of aerial spraying, protection of the aquatic

[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" (2009) 309 Official Journal of the European Union 71.

[2] European Commission, "Main Actions, Food Safety" (2019) <https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/main-actions_en> (last accessed 9 June 2023).

environment, limitation of pesticide uses in sensitive areas and informing and raising awareness about pesticide risks. Monitoring of the pesticide risk was introduced by the EU in this last point, and with regard to these objectives a harmonisation of European indexes concerning human health and environmental risks was proposed by the EU Commission[3] and Directive No 128/2009. As a result, many scientists contributed to meeting this objective in different domains, including health,[4] and pesticides were not spared from this initiative.[5] Many injunctions of the European Parliament aimed at protecting populations from the risks associated with pesticide uses (substances of concern, including residues of substances whether approved or not), leading to a report being produced by the Commission for the European Parliament and Council.[6]

Therefore, an EU-wide pesticide risk indicator was developed by the EU Commission: the harmonised risk indicator (HRI).[7] The HRI aims to standardise and monitor pesticide policy across the EU Member States in order to measure the real advances achieved in meeting these objectives at the EU level. These compulsory dispositions trigger Member States to manage the potential risks[8] at a national level and report back to the Commission. In addition, Member States should be able to use the same tools across Europe.[9]

Two types of HRI were defined: HRI_1 is based on the quantity of active substances placed on the market (annual volume of pesticides in weight (usually in tonnes)), while HRI_2 is based on the number of derogations or emergency situations in plant protection

[3] European Commission, "Environment and human health. Joint European Environment Agency (EEA)-JRC Report No 5/2013-EUR 25933 EN" (2013) 11 Publications Office of the European Union 1 <https://www.eea.europa.eu/publications/environment-and-human-health> (last accessed 9 June 2023).

[4] M Calliera, A Finizio, G Azimonti, E Benfenati and M Trevisan "Harmonised pesticide risk trend indicator for food: The methodological approach" (2006) 62 Pest Management Science 1168; World Health Organization (WHO), "Harmonised assessment of risk and risk management for water-related infectious disease: an overview" in L Fewtrell and J Bartram (eds), *Water Quality: Guidelines, Standards and Health* (London, IWA Publishing 2001); F-E Helepciuc and A Todor, "Evaluating the effectiveness of the EU's approach to the sustainable use of pesticides" (2021) 16 PLoS ONE e0256719; F-E Helepciuc and A Todor, "Evaluating the EU's Efforts to Improve Resilience to Health and Environmental Risks Associated with Pesticide Use by Analyzing the National Action Plans of EU Member States from 2009 to 2019" (2022) 19 International Journal of Environmental Research and Public Health 5446; I-C Vasilachi, L Tapciuc, G-M Finaru Chelaru, D-M Asiminicesei, M Rosca, P Cozma et al, "Pesticides in the Environment and Harmonized Risk Indicators" (2020) The 8th IEEE International Conference on E-Health and Bioengineering – EHB 2020 <http://www.ehbconference.ro/2020/Home.aspx> (last accessed 9 June 2023).

[5] J Bridges, "Human health and environmental risk assessment: The need for a more harmonised and integrated approach" (2003) 52 Chemosphere 1347.

[6] European Parliament and Council, Report from the Commission to the European Parliament and the Council. Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, COM/2020/208 final; European Parliament and Council, Commission Staff Working Document Accompanying the document Report from the Commission to the European Parliament and the Council. Evaluation of Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and of Regulation (EC) No 396/2005 on maximum residue levels of pesticides, SWD/2020/87 final; European Parliament and Council, Report from the Commission to the European Parliament and the Council On the experience gained by Member States on the implementation of national targets established in their National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides, COM/2020/204 final.

[7] "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" (2019) 127 Official Journal of the European Union 1.

[8] J Reus, P Leendertse, C Bockstaller, I Fomsgaard, V Gutsche, K Lewis and T Seppälä, "Comparison and evaluation of eight pesticide environmental risk indicators developed in Europe and recommendations for future use" (2002) 90 Agriculture, Ecosystems and Environment 177.

[9] I-C Vasilachi et al, supra, note 4.

defined under Article 53 of Regulation (EC) No 1107/2009[10] and granted by Member States.[11] These Article 53 derogations are market authorisations for specific usages (one to a few crops) for 120 days (four months) at a national level.

1. Definitions

a. Active substances

Basic substances are approved according to Article 23 of Regulation (EC) No 1107/2009 and listed in Part C of Implementing Regulation (EU) No 540/2011.[12]

Low-risk (LR) substances are approved according Article 22 of Regulation (EC) No 1107/2009 and listed in Part D of Implementing Regulation (EU) No 540/2011.[13]

Substances candidates for substitution (CfSs) are approved according to Article 24 of Regulation (EC) No 1107/2009[14] and listed in Part E of Implementing Regulation (EU) No 540/2011.[15] These active substances meet one or more of the additional criteria laid down in point 4 of Annex II of Regulation No 1107/2009.[16]

b. Harmonised risk indicators

HRI_1 is hazard-based HRI based on the quantities of active substances placed on the market in plant protection products (PPPs) under Regulation (EC) No 1107/2009.

HRI_2 is a HRI based on the number of authorisations granted under Article 53 of Regulation (EC) No 1107/2009.

HRI_1 index is the raw HRI-calculated values from Table 1 (of substance × coefficient) without the weighting of quantities (HRI_1 index × mass in tons of the corresponding substance in fields) instead of HRI_1 indicators.

c. Regulatory framework

The EU "Sustainable Use of Pesticides Directive" (SUD; Directive (EC) No 128/2009) was approved by the European Parliament, establishing a framework to achieve the sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of IPM and of alternative approaches or techniques such as non-chemical alternatives to pesticides. Under this Directive, EU Member States shall adopt NAPs in accordance with this Directive to set up their quantitative objectives, targets, measures and timetables to reduce the risks and impacts of pesticide use on human health and the environment and to encourage the development

[10] "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" (2009) 309 Official Journal of the European Union 1.

[11] Eurostat, "Agri-Environmental indicators" (2023) <https://ec.europa.eu/eurostat/web/agriculture/agri-environmental-indicators/information> (last accessed 9 June 2023).

[12] G Romanazzi, Y Orçonneau, M Moumni, Y Davillerd and PA Marchand, "Basic substances, a sustainable tool to complement and eventually replace synthetic pesticides in the management of pre and postharvest diseases: reviewed instructions for users" (2022) 27 Molecules 3484.

[13] DC Robin and PA Marchand, "Expansion of the low-risk substances in the framework of the European Pesticide Regulation (EC) No. 1107/2009" (2022) 13 European Journal of Risk Regulation 514.

[14] DC Robin and PA Marchand, "The slow decrease of the active substances candidates for substitution in the framework of the European Pesticide Regulation (EC) No. 1107/2009" (2021) 13 European Journal of Risk Regulation 1.

[15] DC Robin and PA Marchand, "Evolution of Regulation (EU) No 540/2011 since its entry into force" (2019) 7 Journal of Regulatory Science 1.

[16] European Commission, supra, note 10.

Table 1. HRI_1 index-calculated values from Annex IV of Directive (EC) No 128/2009. Italic text represents ongoing data for 2023. Bold text represents base years.

	Corresponding number of substances					HRI_1 index
2011	0	0	398	0	0	**3184**
2012	0	0	417	0	0	**3336**
2013	0	0	438	0	0	**3504**
2014	0	0	462	0	0	3696
2015	2	3	403	77		4461
2016	4	3	411	73		4463
2017	8	3	420	68		4459
2018	10	4	416	66		4398
2019	13	5	383	61	*880*	4058
2020	17	7	364	66	*890*	3992
2021	22	11	341	56	*931*	3657
2022	24	40	310	53	*942*	3392
2023	*25*	*46*	*304*	*50*	*946*	*3303*
LR	100		275	50		3100
LR+CfS	100		275	0		2300
All LR	425		0	0		425
HRI_1 index						
2011–2013			100			Base 100
			100			
			100			
2014			110.6			> Base
2015			133.5			> Base
2016			133.6			> Base
2017			133.4			> Base
2018			131.6			> Base
2019			121.4			> Base
2020			119.5			> Base
2021			109.4			> Base
2022			101.5			> Base
2023			*94.0*			< *Base*
LR			92.8			> Base
LR+CfS			65.5			< Base
All LR			10.9			< Base

LR = low-risk active substance; CfS = candidate for substitution active substance; All LR = all possible low-risk active substances approved + potential low-risk active substances.

and introduction of IPM and of alternative approaches and techniques in order to reduce dependency on the use of pesticides.

The European Green Deal[17] focuses on improving the well-being of people. Making Europe carbon-neutral and protecting our natural habitat will be good for people, planet and economy. Officially, the Farm to Fork Strategy (F2F) is at the heart of the European Green Deal, aiming to make food systems fair, healthy and environmentally friendly and, more specifically, requiring reductions in the uses and risks of chemical pesticides by 50% by 2030.[18]

2. HR indexes

Corresponding HR indexes to be introduced in the calculations of HRI indicators are defined under Commission Directive (EU) No 2019/782, for all Member States,[19] with the implementation of Annex IV regarding HRIs of Directive (EC) No 128/2009.[20] HRI_1 and HRI_2 focus on annual European development surveys,[21] although with full data only available at the national level (number of Article 53 derogations, weight of used pesticides) Member States may thus be compared to each other regarding their arable surface area or crop production. From a risk perspective, the idea of managing these risks through indicators is clearly defined and orientated to decreasing these indicators. This study focuses on the evolution of the displayed HRI_1 levels between 2011 and 2020.

II. Materials and methods

1. Sources of materials

a. Regulatory sources

Raw data were extracted from the European Commission pesticide database website.[22] Information about regulatory documents was drawn from the *Official Journal of the European Union*, especially Directive (EC) No 128/2009 on the sustainable use of pesticides,[23] with Regulation (EC) No 1107/2009 concerning the placing of PPPs on the market,[24] Regulation (EC) No 1185/2009[25] relating to statistics on pesticides, Directive (EU) No 2019/782[26]

[17] European Commission, "A European Green Deal: Striving to be the first climate-neutral continent" (2023) <https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en> (last accessed 9 June 2023).

[18] European Commission, "Farm to Fork strategy: for a fair, healthy and environmentally-friendly food system" (2023) <https://food.ec.europa.eu/horizontal-topics/farm-fork-strategy_en> (last accessed 9 June 2023).

[19] European Commission, supra, note 1.

[20] DC Robin and PA Marchand, "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" (2019) 7 Journal of Regulatory Science 1.

[21] European Commission, "Member States trends in use and risk of chemical pesticides and the use of more hazardous pesticides" (2023) <https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides/farm-fork-targets-progress/member-states-trends_en#member-state-trends> (last accessed 9 June 2023).

[22] European Commission, Pesticides database v3 (2023) <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/active-substances> (last accessed 9 June 2023).

[23] European Commission, supra, note 1.

[24] European Commission, supra, note 10.

[25] "Regulation (EC) No 1185/2009 of the European Parliament and of the council of 25 November 2009 concerning statistics on pesticides" (2009) 324 Official Journal of the European Union 1.

[26] "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" (2009) 127 Official Journal of the European Union 4.

concerning Annex IV of Directive (EC) No 128/2009, Regulation (EC) No 396/2005 concerning maximum residue levels of pesticides[27] and Implementing Regulation (EU) No 540/2011[28] dealing with active substance regulatory movements.

b. HRI_1 indicators at the Member State level

Primarily, data were collected from the EU Member State agriculture ministry and Commission websites.[29] Then, data were collated, and a mean was computed to approximate European trends (Table 2). All data for HRI_1 indicators were provided by the beginning of 2023.

c. HRI evolution graphs

The different regression curves (in Figs 1–6) regarding the development of HRI_1 over time were retrieved from the data extracted from the European Commission pesticide database.[30] The methodology derives from Eurostat.[31] Eurostat is the statistical office of the EU, providing comparable, harmonised and consolidated data that enable comparisons between Member States and regions. Eurostat does not collect such data, however.[32] This is conducted within Member States by their statistical authorities. They verify and analyse national data and send them to Eurostat. The other curves were previously published by our department[33] or derived from data obtained from different European Member States (Fig. 3).[34]

2. Methodology

a. Calculation background

To meet the targets of the NAPs derived from Directive EC No 128/2009, a routine computation of HRIs concerning plant protection substances is important. Thus, the EU published a decision and a report entitled "Trends in Harmonised Risk Indicators for the European Union".[35] The detailed methodology of HRI_1 calculation is available on the EU pesticides website. This methodology demonstrates the computation of HRI_1 and HRI_2 to allow each Member State to estimate these indexes at the national level in a harmonised

[27] "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" (2005) 70 Official Journal of the European Union 1.

[28] "Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances" (2011) 153 Official Journal of the European Union 133.

[29] European Commission, supra, note 4.

[30] European Commission, supra, note 22.

[31] European Commission, "Trends in Harmonised Risk Indicators for the European Union for 2020" (2023) <https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/harmonised-risk-indicators/trends-hri-eu_en> (last accessed 9 June 2023); E Barany, I Barbier, J-C Jeanty and D O'Shea, "Methodology for calculating harmonised risk indicators for pesticides under Directive 2009/128/EC – 2019 edition" (2019) Manuals and Guidelines <https://ec.europa.eu/eurostat/web/products-manuals-and-guidelines/product/-/asset_publisher/Wq1sJK3yM5fP/content/ks-gq-19-009> (last accessed 9 June 2023).

[32] Eurostat, Sales of pesticides in the EU – Product (2023) <https://ec.europa.eu/eurostat/fr/web/products-eurostat-news/-/DDN-20181015-1> (last accessed 9 June 2023).

[33] Robin and Marchand, supra, note 20.

[34] European Commission, "Trends in Harmonised Risk Indicators for Member States. Food Safety" (2023) <https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides/harmonised-risk-indicators/trends-hri-ms_en> (last accessed 9 June 2023).

[35] European Commission, supra, note 21.

Table 2. Gathering of the HRI_1 indicator values calculated by twenty-seven European Union (EU) Member States (number of units, 2011–2013 = baseline 100).

Country	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
AT	102	106	92	95	101	115	116	129	121	135
BE	102	104	94	106	96	93	71	72	66	58
BG	242	34	24	17	27	65	56	83	98	65
CY	105	100	95	93	87	92	92	92	96	93
CZ	122	96	82	75	81	74	65	61	56	49
DE	100	104	96	100	101	97	94	85	85	89
DK	90	123	88	38	51	51	54	52	53	61
EE	88	104	108	116	136	170	156	131	149	153
EL	84	88	128	50	52	55	56	59	57	57
ES	112	90	98	107	107	88	68	78	91	88
FI	97	101	101	109	126	136	130	144	119	144
FR	101	100	100	114	103	99	84	100	63	76
HR	100	100	100	96	88	70	60	62	55	56
HU	112	104	84	96	101	102	99	84	76	85
IE	120	84	96	109	114	105	79	69	77	76
IT	92	106	103	119	128	146	128	140	85	73
LV	92	106	103	119	128	146	128	140	140	161
LT	96	102	102	103	114	138	126	86	94	99
LU	106	95	99	106	101	81	72	62	50	51
MT	90	100	110	92	119	76	91	81	72	87
NL	104	102	93	86	80	89	79	70	68	72
PL	115	94	91	96	98	98	89	78	81	83
PT	115	103	82	106	93	99	72	66	75	71
RO	99	110	91	45	49	48	51	48	38	35
SE	101	117	82	94	88	74	77	67	64	73
SI	111	99	90	99	103	113	103	109	81	80
SK	97	112	91	81	82	78	79	84	78	77
EU (average)	108.0	99.2	92.8	90.3	93.6	94.5	86.8	84. 6	81.0	83.2
EU (SD)	28.5	15.4	17.0	25.1	25.4	28.9	26.4	26.0	26.8	31.5

way. HRI_1 is the result of the multiplication of the calculated index by the quantities of pesticides used.

Firstly, these calculations regarding the evolution of HRI_1 over time represent an extension of our previous work on the HRI_1 index[36] incorporating EU pesticide annual weight sales from 2011 to 2020.

[36] Robin and Marchand, supra, note 20.

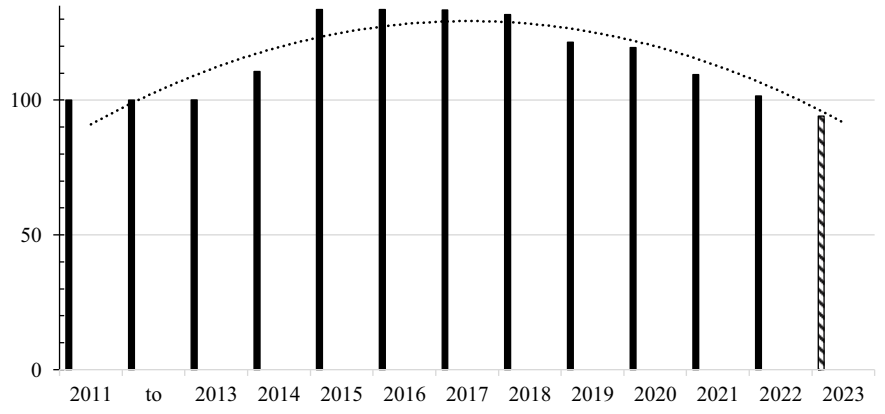

Figure 1: Evolution of the HRI_1 index versus baseline of 100 (2011–2013).
Note: 2011–2013 are baseline averages of 100, values are given for 2014–2021 and an actual transitory value is given for 2022.

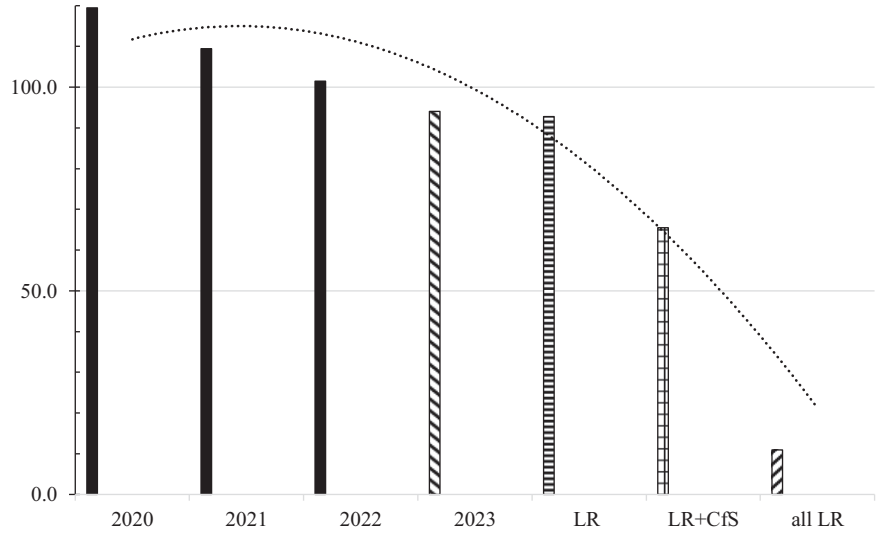

Figure 2: Possible evolution of the HRI_1 index based on hypotheses.
Note: 2011–2013 are averaged at 100, values are given for 2014–2021 and an actual value is given for 2022.
LR = low-risk active substance; CfS = candidate for substitution active substance; all LR = all possible low-risk active substances approved + potential low-risk active substances.

Four groups are presented: Group 1, which contains LR substances approved under Article 22[37] of Regulation (EC) No 1107/2009[38]; Group 2, which represents other approved active substances; Group 3, which refers to CfSs[39] also under Article 24 of Regulation (EC) No 1107/2009[40]; and finally Group 4, which refers to non-approved substances that are nevertheless possible to use via a derogation. The category G value does not affect the

[37] European Commission, supra, note 10.

[38] European Commission, "Commission notice concerning a list of potentially low-risk active substances approved for use in plant protection" (2018) C265 Official Journal of the European Union 8.

[39] Robin and Marchand, supra, note 14.

[40] "Commission Regulation (EU) 2017/1432 of 7 August 2017 amending Regulation (EC) No 1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market as

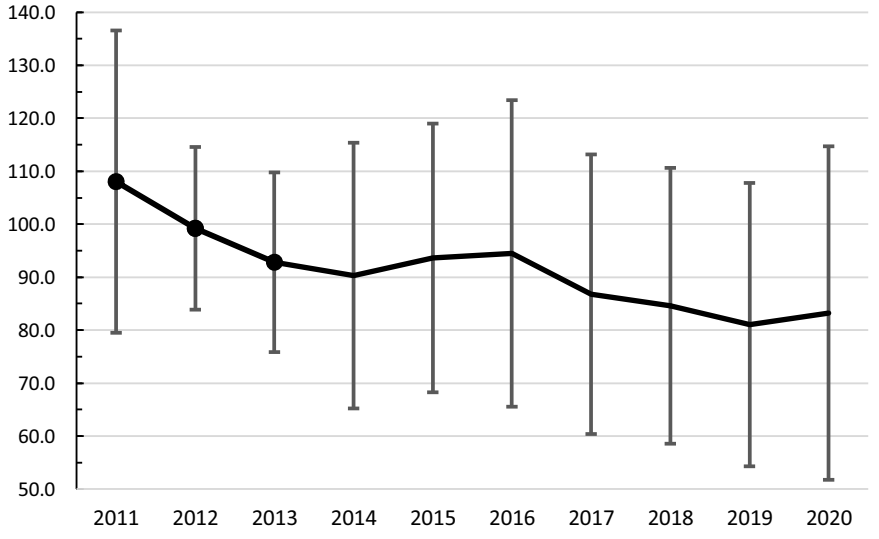

Figure 3: Evolution of the re-calculated European Union-wide HRI_1 indicator trend average based on the data from the twenty-seven Member States with standard deviations (points represent the baseline of 100 for the years 2011–2013).

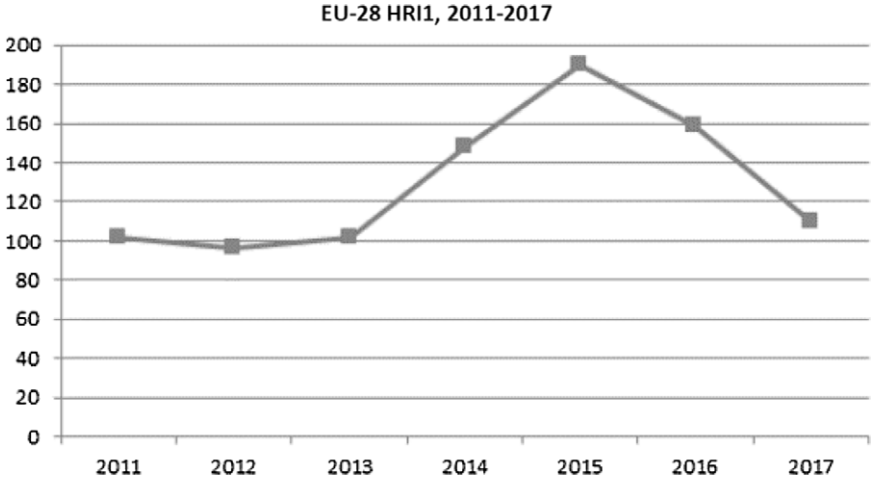

Figure 4: Evolution of overall weighted HRI_1 index over time presented in the methodology of Barany et al (2019).
Note: 2011–2013 are baseline averages of 100; values are unitless.

HRI_1 index nor HRI_1 values, but only affects HRI_2. The different groups (1–4) are then granted different arbitrary weighting values (wv): (1) wv = 1; (2) wv = 8; (3) wv = 16; and (4) wv = 64. (i) to (vi) represent, respectively, the row numbers in Table 3 from Commission Directive (EU) No 2019/782.[41] Groups 1–3 are each divided into two categories: (1) groups A + B; (2) groups C + D; and (3) groups E + F. However, Group 4 has only one category: G. The first categories for each group (A, C, E) are accounting for microorganisms,

regards the criteria for the approval of low-risk active substances" (2017) 205 Official Journal of the European Union 59.

[41] European Commission, supra, note 26.

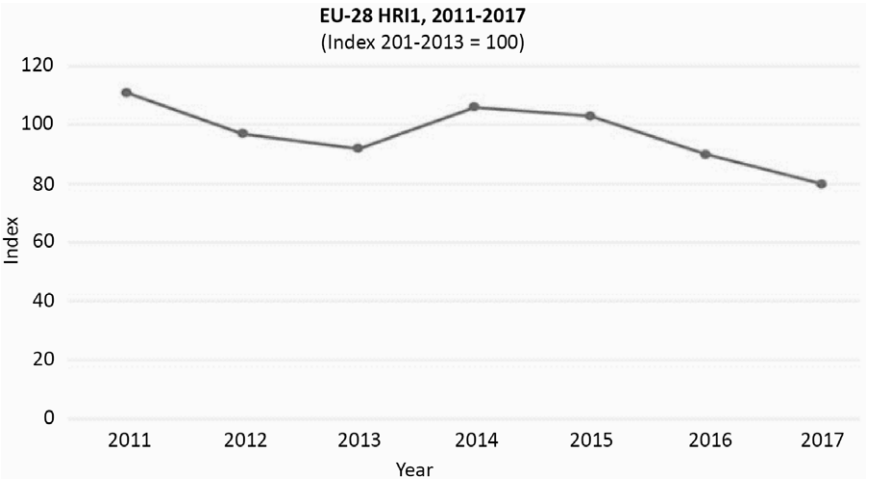

Figure 5: Evolution of the HRI_1 indicator over time presented by the European Union online (2019).
Note: 2011–2013 are baseline averages of 100; values are unitless.

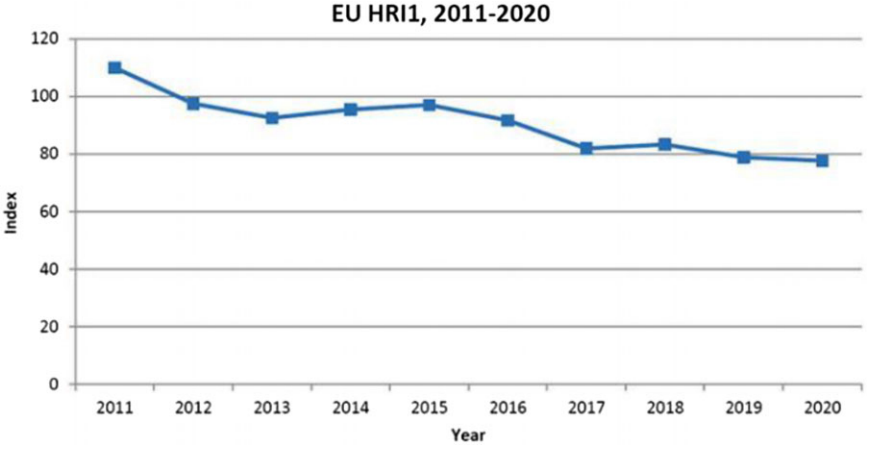

Figure 6: Evolution of the HRI_1 indicator over time presented by the European Union online (2023).
Note: 2011–2013 are baseline averages of 100; values are unitless.

while the second categories for each group (B, D, F) are accounting for non-microorganisms (chemicals, substances of natural origin or semiochemicals). Despite these two categories per group, the same weight is assigned to them. These respective wv for Group 3 were set to disadvantage and put pressure on those substances perceived as being the most dangerous, with the ultimate intention of removing/replacing them. However, the attribution of the same wv in each group for microorganisms, substances of natural origin or semiochemicals is debatable. Indeed, while the characteristics of the substances from Group 1 (LR substances) or from Group 3 (CfSs) may be homogeneous, with regards to Group 2 ("other approved active substances"), the same wv being assigned to exogenous chemicals or residue-generating exogenous agrochemicals[42] and natural

[42] PA Marchand, "EU chemical plant protection products in 2023: current state and perspectives" (2023) 2 Agrochemicals 106.

Table 3. HRI_1 groups, categories and hazard weightings values in Annex IV of Directive (EC) No 128/2009.

Row							
(i)		1		2		3	*4*
(ii)				Categories			
(iii)	A	B	C	D	E	F	*G*
(v)				Hazard weightings			
(vi)		1		8		16	*64*

Categories A and B are low-risk active substances, C and D are regular active substances, E and F are candidate for substitution active substances and G is non-approved (highlighted with italics).

substances, microorganisms or semiochemicals (as some of these may not have maximum residue limits; MRLs[43]), can be criticised.

Greater danger is being indiscriminately linked to toxicology data for humans and/or ecotoxicology data for non-target organisms and the environment, as demonstrated during the European Food Safety Authority (EFSA) evaluation.[44] Hazard was also taken into consideration during this evaluation, contributing to the attribution of a regulatory status; LR, normal active substance, CfSs and non-approved substances, the latter affecting only HRI_2. The baseline was also required to be fixed at 100 for the average of 2011–2013 values (Equation 1).

b. Calculations in our work

During the first calculation step, the HRI_1 index is a fixed number per year for each column depending on the number of LR substances, active substances (chemicals or microorganisms) and CfSs, each weighted respectively by the corresponding published values 1, 8 and 16 (non-approved substances and basic substances[45] are not included in HRI_1). Values were first updated from previous work[46] for the years 2019 and 2020 and ongoing values from 2021. The second step is to add all column values and divide the row sum by the average of the years 2011, 2012 and 2013 (3341.3). This average was designated to represent a base value of 100, which is then used to calculate the HRI_1 index for each year. Thus, although it is possible to calculate the HRI_1 index when all of the quantities of all substances are known for each category each year, this is only the first part of the analysis. For each category, chemicals or microorganisms are equivalent in terms of weight.

Determination of the HRI_1 indexes for a year 20XX[47] is derived[48] using the following equations.[49] Equation 1 focuses on the baseline for the years 2011–2013, Equation 2 on the HRI_1 index for each year from 2014 to now and Equation 3 on comparing index results to the baseline of 100 (from 2011–2013).

[43] European Commission, supra, note 27.

[44] "OpenEFSA portal: the single public interface for all information related to EFSA's scientific work" (2023) <https://open.efsa.europa.eu/> (last accessed 9 June 2023); European Food Safety Authority (EFSA) Journal (2023) <https://efsa.onlinelibrary.wiley.com/> (last accessed 9 June 2023).

[45] PA Marchand, "Basic Substances: An Approval Opportunity for Low Concern Natural Products under EU Pesticide Regulation" (2015) 71 Pest Management Science 1197.

[46] Robin and Marchand, supra, note 20.

[47] European Commission, supra, note 11.

[48] European Commission, supra, note 26.

[49] Robin and Marchand, supra, note 20.

Equation 1. HRI_1 index baseline for the years 2011–2013 fixed at 100 for each Member State.

$$\frac{\sum \text{HRI\_1 index 2011} + \text{HRI\_1 index 2012} + \text{HRI\_1 index 2013}}{3} \equiv 100 \quad (1)$$

Equation 2. HRI_1 index values for years 20XX.

$$\text{HRI\_1 index of 20XX} = \sum \text{nb(LR) in 20XX} + \text{nb(a.s.) in 20XX}*8 + \text{nb(CfS) in 20XX} * 16 \quad (2)$$

where "nb" refers to "number of" and "a.s." refers to "active substances". Concretely, CfSs and LR substances are only included in Equation 2[50] from 2015.[51] Finally, in order to describe the HRI_1 index for a year 20XX with a baseline of 100 from the years 2011–2013, Equation 3 is necessary.

Equation 3. HRI_1 index values for years 20XX with a baseline of 100 from the years 2011–2013.

$$\text{HRI\_1 index of 20XX} = \frac{\sum \text{nb(LR) in 20XX} + \text{nb(a.s.) in 20XX}*8 + \text{nb(CfS) in 20XX} * 16}{\sum \frac{\text{HRI\_1index 2011}+\text{HRI\_1 index 2012}+\text{HRI\_1 index 2013}}{3}} * 100 \quad (3)$$

c. Calculations from the Commission[52]

The calculations regarding the data from the Commission are obtained according to Equation 4.

Equation 4. HRI_1 indicator values for years 20XX with a baseline of 100 from the years 2011–2013.

$$\text{HRI\_1 indicators of 20XX} = \text{HRI\_1 index of 20XX} * \text{mass (tonnes) of corresponding pesticides} \quad (4)$$

Again, these calculations are adjusted to be reported to a baseline of 100 from the years 2011–2013.[53]

III. Results

1. Background and update of previous work

Using this approach, Robin and Marchand[54] studied the evolution of the HRI_1 index at the European level. In fact, the HRI_1 index curve (in Figs 1 & 2) is a virtual evolution outcome since it is only based on the number of active substances and their relative weight, whereas the EU HRI_1 indicator is a product of the HRI_1 index factor for the actual amounts of pesticides used.

[50] Robin and Marchand, supra, note 14.

[51] Robin and Marchand, supra, note 13.

[52] European Commission, supra, note 11.

[53] European Commission, "Methodology for calculating harmonized risk indicators for pesticides under Directive 2009/128/EC 2021 edition" (2023) <https://ec.europa.eu/eurostat/documents/3859598/12727554/KS-GQ-21-008-EN.pdf/d3b02348-3277-a1cd-e7cf-e8ae4367257d?t=1619684530876> (last accessed 9 June 2023).

[54] Robin and Marchand, supra, note 20.

a. Update of HRI_1 index data

An update of our previous work is provided in this work (Fig. 1 & Table 1). Real and definitive values and the evolution of the HRI_1 index are now reported for 2019–2022 and are extended with ongoing values for 2023 shown in Table 1. The G column is shown in italics in Table 3, since the number of non-approved substance is not taken into consideration for the HRI_1 index and the HRI_1 indicator. Later, this HRI_1 index will be multiplied by pesticide quantities to obtain the corresponding HRI_1 indicators for each year.

b. Update of the HRI_1 index curve

In contrast to the results presented by the European Commission (Figs 5 & 6),[55] the results from Robin and Marchand[56] do not illustrate the HRI_1, but instead the overall index without quantities (annual sold masses). This deserves some clarification: the rules of calculation used by the European Commission[57] include different instructions.[58] The first rule implies that the indicator shall be based on statistics on the quantity of active substances, described broadly at the EU level,[59] sold on the market as PPPs under Regulation (EC) No 1107/2009[60] and provided by the Commission (Eurostat) under Annex I of Regulation (EC) No 1185/2009.[61] These data are characterised into four groups divided into seven categories. The HRI_1 indicator should be calculated by multiplying the annual quantity of active substances put on the market for each group by the relevant hazard weighting index.[62] As a result, the estimates in Robin and Marchand were incomplete, as it was not possible to take the annual quantities sold into consideration, which explains most of the observed differences between the published graphs and curves (see Figs 1–7). Nevertheless, the graph in Fig. 1 produced using the calculation of our index was relatively easy to constitute and compute, and it provides a background that allows for easier reading of the HRI_1 indicator and for the visualisation of the impact of the quantities (masses in tonnes) sold by comparing them.[63]

2. Evolution of the HRI_1 index

The updated data shown in Fig. 1 and Table 1 based on our previous work take into account the full stabilised data of 2019 and 2021 and the ongoing developments for 2022. The possible evolution of the HRI_1 index (Fig. 2) has continued to be investigated with the same background (all potential LR substances validated) and the suppression of CfSs (CfSs removed from the approved substances listing; see the "LR+CfS" bar). Another situation was envisaged as an ultimate case ("All LR"), when all of the PPPs would be LR substances there would be no more CfSs and so no more simple "active" substances, in order to calculate the minimum level of the HRI_1 index. Therefore, the results presented in these

[55] European Commission, "Trends in Harmonised Risk Indicators for the European Union" (2023) <https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides/harmonised-risk-indicators/trends-eu_en#fig1> (last accessed 9 June 2023).

[56] Robin and Marchand, supra, note 20.

[57] European Commission, supra, note 1.

[58] European Commission, supra, note 26.

[59] European Court of Auditors, "Sustainable use of plant protection products: limited progress in measuring and reducing risks" (2020) Special Report 05/2020 1 <https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=53001> (last accessed 9 June 2023).

[60] European Commission, supra, note 24.

[61] European Commission, supra, note 25.

[62] Robin and Marchand, supra, note 20.

[63] European Commission, "Food Safety. Sustainable Use of Pesticides" (2023) <https://webgate.ec.europa.eu/europhyt/cgi-bin/sud_europa.cgi#/> (last accessed 9 June 2023).

4. 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
EU-27 HRI1, 2011-2019	100	99	94	106	124	81	86	107	81	79

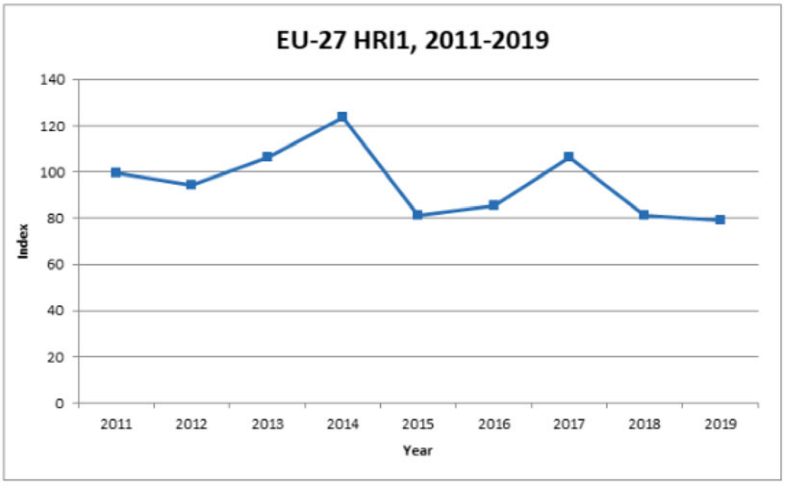

Figure 7: Evolution of the HRI_1 indicator over time presented by the European Union online (2021).
Note: 2011–2013 are baseline averages of 100; values are unitless.

bars in Fig. 2 show that the decrease of the curve will plateau. Indeed, this decrease will be hindered mechanically once all substances accepted by the EU have been considered (approved or renewed) as LR substances. For example, if all of the approved substances would fall under the LR criteria, then the lower limit will be 425, which corresponds to the total number of currently approved substances minus twenty-four (the number of basic substances not taken in consideration for HRI_1 indicator),[64] with the overall weighted index equal to 10.9 (Fig. 2).

a. Effect of the LR substances

The "LR" situation corresponds to all of the potential LR substances converted to this status. Since most of the LR substances are already converted or non-renewed, the difference from the 2021 situation is not greatly significant, since they are increasing very slowly and the qualification of all possible LR substances is feasible.[65] The corresponding gain for the HRI_1 index is not expected to be greatly important either. In fact, the residual reserve in LR substances weak because the list of initial potential LR substances drawn up in 2018 has been largely exploited.[66] Only some active substances (fifteen from the fifty-seven listed as "potential") were renewed as LR substances from 2015 to 2023, but the process is quite slow, while already eight potentially LR active substances were abandoned during this time, such as pepper dust extraction residue, fenugreek seed powder, ammonium acetate and seaweed. Moreover, five potentially LR active substances listed in Table 1 (microorganisms and substances of natural origin) were not renewed as LR

[64] Marchand, supra, note 45.

[65] DC Robin and PA Marchand, "Low-risk substances, new effective category of biocontrol agents as lever for durable crop protection products" (2021) 5 Chronicle of Bioresource Management 9.

[66] PA Marchand, "Basic and Low Risk Substances under EU Pesticide Regulation: A New Choice for Biorationals Portfolio of Small and Medium-Sized Enterprises" (2017) 57 Journal of Plant Protection Research 433.

substances. It should be noted that many potential LR substances had already been taken off the market before 2003 (the deadline for submitting dossiers for active substances under Directive 91/414), and many were not included in the corresponding Annex I by the EU,[67] thereby reducing the actual "LR" effect, although some substances were LR active substance candidates later. That is reflected by the last rows of Table 1. Indeed, these rows give the value of the index in three cases: in the "LR" row, all substances accepted potentially as LR substances[68] would be assigned LR status. Instead, this status is only delivered during individual renewal of the substances following the conclusion of the risk assessment of each active substance; thus, the full status modification may take a long time, since the last substance will not be renewed before 2024 at the earliest. Thus, the "LR" row in Table 1 shows a small reduction for the 2023 ongoing calculations compared to 2022 due to the slow implementation of LR substance assignment.[69]

b. Effect of the CfSs

The number of CfSs results from the loss of candidates by non-renewal (eleven substances) deriving from the newly approved list of active substances as CfSs and the approved active substances characterised as CfSs (seven substances: carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron methyl, ipconazole and tembotrione).[70] This recent qualification as CfSs for seven active substances negatively affects the curve and the HRI_1 index by 7 × 8 points (ie 56 points), when active substances migrate from the D column to the E or F columns, increasing the HRI_1 index value. By contrast, the removal of CfS qualification for propoxycarbazone changed the amount of CfSs to sixty-six and then to fifty-six.[71] These changes are again responsible for the decrease in the values shown in Table 3 and in curves shown in Figs 1 & 2.

c. Ultimate possible evolution

The "LR+CfS" situation corresponds to all potential LR substances being assigned this LR status and the disappearance of CfSs, both of which positively affect the curve. The gain is high but hypothetical because the CfSs do not disappear very quickly and only during the renewal process, but the total amount of CfSs is not just decreasing as new substances are constantly qualified as CfSs.[72]

The "All LR" situation corresponds to the theoretical situation of all active substances, except for basic substances, being qualified with as having LR status.

4. Evolution of the HRI_1 indicators

a. HRI_1 indicators at the Member State level

We studied the trends of the HRI_1 indicator at the EU level based on the data published by the twenty-seven EU Member States.

[67] Commission Decision of 21 June 2007 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances (notified under document number C(2007) 2576). JO L 166 of 28.6.2007, p 16.

[68] European Commission, supra, note 38.

[69] European Court of Auditors, supra, note 59.

[70] "Commission Implementing Regulation (EU) 2020/1295 of 16 September 2020 amending Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substances carbetamide, emamectin, flurochloridone, gamma-cyhalothrin, halosulfuron-methyl, ipconazole and tembotrione in the list of candidates for substitution" (2020) 303 Official Journal of the European Union 18.

[71] Robin and Marchand, supra, note 13.

[72] Robin and Marchand, supra, note 14.

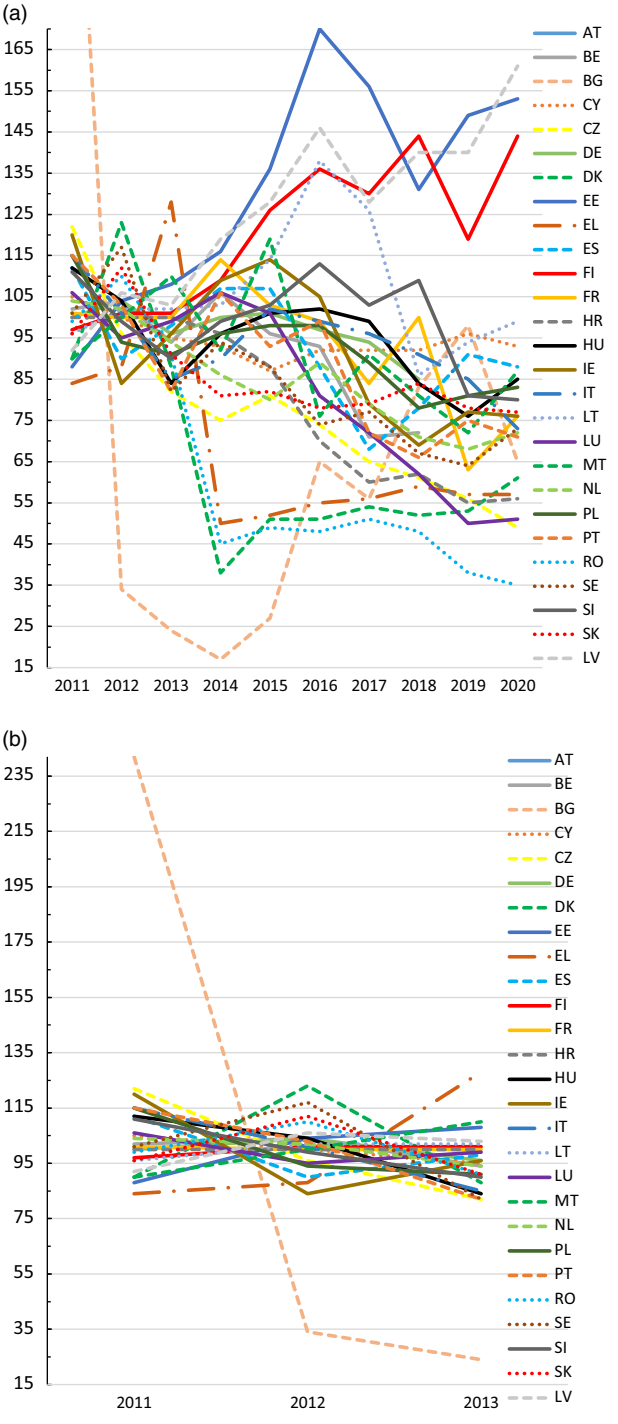

Figure 8: Evolution of national HRI_1 indicators over time in twenty-seven European Union Member States: (a) from 2011 to 2020, (b) from 2011 to 2013 and (c) from 2014 to 2020.

Individual Member State results were illustrated using a curve that is easily comparable to the one provided by the EU. Figure 8 exhibits the evolution of national HRI_1 indicators over time at the Member State level obtained directly from Table 2. The results are shown in Figs 3–5 & 7. Figure 5 exhibits the national variation in the HRI_1 indicator since 2011,

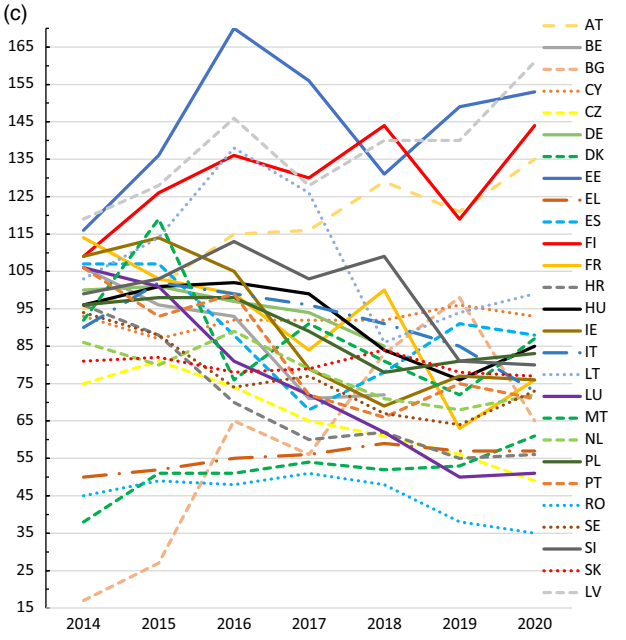

Figure 8: (Continued).

whereas Fig. 3 shows the HRI_1 indicator calculation with pesticide sale volumes (tonnes). Each country conducts its computations for its own market as no specific European data can be found on Eurostat.[73]

b. HRI_1 indicators at the EU level

The average of the twenty-seven EU Member State HRI_1 indicators for each year permit us to draw a global EU HRI_1 indicator that can be compared to the officially published one.

2. Evolution of the HRI_1 curves: characteristics and slope

a. Description of the evolution: a virtual decrease

The HRI_1 indicator has the goal of illustrating the level of risk from the substances for the user, as well as for the environment and biodiversity in terms of the quantity of uses. In fact, since risk = danger/hazard × exposure, the HRI_1 index may be considered as the risk and pesticide sales as the "exposure". The present study aims to shed some light on the expression of HRI_1 and to contribute to a better understanding of the actual development of pesticide use in Europe correlated to the corresponding danger and therefore risk. Even though the regression curves obtained by Robin and Marchand[74] on the HRI_1 index reviewed in this study and of Barany et al[75] using this methodology were in agreement, somewhat surprisingly the curves posted on the European Commission website do not reflect the same trend. The shapes of the Commission curves were not only different, but also showed a continuous decrease, whereas the figures from Robin and Marchand and Barany et al exhibited a Gaussian shape. This difference in shape shows that the HRI_1 indicator has decreased over time since 2013 – a positive and welcome trend. Yet this interesting observation cannot be confirmed mathematically as the required data are

[73] Eurostat, supra, note 32.
[74] Robin and Marchand, supra, note 20.
[75] Barany et al, supra, note 31.

not shared by the European Commission. The calculations require data on the quantity of each substance sold on the market in each country, which are confidential and not fully accessible. Secondly, the curves published in 2020 (Fig. 6) are always under the 100 baseline (2011–2013), while the curves published in 2019 (Fig. 5) exhibit points above the 100 baseline. This differences six years after the official uses (2013 data) is quite anomalous since no explanation nor comparison between these curves was provided by the Commission.

b. Review of the different HRI_1 curves

Similar work is undertaken by all EU Member States each year, the results of which are then published. The results presented in Fig. 1 represent an update (2019–2023) to those obtained by Robin and Marchand[76] in 2019 with the same parameters. These values must be weighted with the quantities (tonnes) of pesticides used in the different groups[77] to obtain the actual HRI_1 indicator values. The data and results are displayed and presented in Figs 1, 2 & 8 and Tables 1–3. In addition, the results concerning the evolution of the weighted indicators are presented in the methodology section from EU (Fig. 4). From our work, the resulting curve calculated only with the HRI_1 index is exhibited in Fig. 1, and this approximately fits with the published results shown in Fig. 2[78] and the first curve published using the EU methodology,[79] which determined the overall weighted index (Figs 5 & 6). Surprisingly, the curve in Fig. 4, focusing on the data from the twenty-seven Member States published in 2020, is very similar or even identical to Fig. 1.

The initial increase observed after the 2011–2013 baseline is similar to our HRI_1 index, although the increase is higher, but the subsequent rapid decrease is surprising since we observe a plateau in our data (Fig. 1). This may be attributed to reductions in the volume (tonnes) of pesticides sold globally or specifically for CfSs used, although this is not clearly confirmed by data on sales. Secondly, a European trend for the HRI_1 curve was derived using the results obtained from twenty-seven European Member States. Finally, a comparison between the different curves obtained was performed. However, the results presented by the European Commission also differ from those obtained by others (see Figs 5–7).

A slow but continuous decrease from the baseline (2011–2013) calculation is shown, whereas Barany et al[80] described a curve with a peak. The EU curve showed a peak in 2014, which is in agreement with our previous[81] and ongoing (Fig. 1) calculations of the HRI_1 index, but this then decreased after 2015, while our HRI_1 index is quite stable and always higher than the baseline of 100. Although the appearance of CfSs in 2015 in the total substance panel/list can explain the HRI_1 index increase (by approximately +20%),[93] no rapid decrease of CfSs can explain the significant reduction in pesticide sales targeted at CfSs seen in the official data (Fig. 6). In the same way, the F2F programme neither mentions nor specifically targets the CfSs, since only "chemicals" are cited. To our view, this CfS reduction is the only way to obtain such a reducing curve (Fig. 2) and the resulting risk reduction.

Together, the pesticide sales data and the communications regarding NAPs are not sufficient to explain the steady reduction over time of the curve derived from EU data since 2020 (Fig. 6). The corresponding information or explanation from the EU about the modification of the curves *a posteriori* (2023) to be always under the baseline 100, after a

[76] Robin and Marchand, supra, note 20.
[77] European Commission, supra, note 53.
[78] Barany et al, supra, note 31.
[79] European Commission, supra, note 53.
[80] Barany et al, supra, note 31.
[81] Robin and Marchand, supra, note 20.

published "bump" in Fig. 5 (in 2014 and 2015), is missing. By contrast, Barany et al's curve[82] even went up to 190 and is closer to the HRI_1 index that we calculated.

IV. Discussion

1. Evolution of the HRI_1 index

a. Weighting values

As mentioned, the wv are the same in each group (for Groups 1–3) among both categories, which means that microorganisms without a MRL are more easily placed at the same level of wv (same value) without advantage than chemical substances with residues.[83] The only advantage for biocontrol agent (BCA) microorganisms under this accounting system is that they are more easily described as LR, but this is not always the case, even during renewal (eg *Streptomyces* K61) and even with no MRL. Thus, if the separation of the groups and the corresponding wv are legitimate, a boost could have been given to the microorganisms approved as regular active substances. A similar boost could have been given to all active substances without a MRL by having distinctions within the same group, so as to boost and promote the use of BCAs.[84]

b. HRI_1 index

The first observation from Figs 1 & 2 that can be made is that, ten years after its creation, this HRI_1 index has always had a value greater than the baseline of 100 (2011–2013 years), except for the current year 2023 (Fig. 1). Indeed, 2023 is the first year to see a potential decrease under the baseline of 100, although any CfS qualifications for an approved active substance would negate this positive evolution. Furthermore, with the HRI_1 index displaying such a bell curve, it is strange to observe a continuous decrease of HRI_1 over time. A heavy decrease in pesticide sales in the E and F categories (Group 3) or pesticides from Group 4 may be at the core of this, but individual Member State sales[85] and EU data[86] do not show a drop strong enough to compensate for the increase in the HRI_1 index and the slight reduction in CfSs or even the new CfS entries in 2020. It is necessary to specify here that the CfS classification is in no way linked to the SUD Directive or the F2F project since it derives from the new (more demanding) requirements for the evaluation or re-evaluation of pesticides (more specifically the publication of criteria for endocrine-disrupting properties and their application).[87]

c. HRI_1 indicator

Figure 5 shows a divergence of the points soon after the baseline of 100 (2011–2013), with higher points at +142% (242) and lower points at −83% (17), without any specific climatic explanation for these data, nor obvious geographical coherence. The baseline of 100 itself

[82] Barany et al, supra, note 31.

[83] M Charon, D Robin and PA Marchand, "The major interest for crop protection of agrochemical substances without maximum residue limit (MRL)" (2019) 23 Biotechnologie, Agronomie, Société et Environnement 22.

[84] DC Robin and PA Marchand, "Biocontrol active substances: evolution since the entry in vigour of Reg. 1107/2009" (2019) 75 Pest Management Science 950.

[85] Eurostat, "Sales of pesticides in the EU" (2020) <https://ec.europa.eu/eurostat/fr/web/products-eurostat-news/-/ddn-20200603-1> (last accessed 9 June 2023).

[86] European Environment Agency, "Pesticide sales" (2019) <https://www.eea.europa.eu/airs/2018/environment-and-health/pesticides-sales> (last accessed 9 June 2023).

[87] "Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties" (2018) 101 Official Journal of the European Union 33.

shows higher points at +142% (242) and lower points at −65% (34), with diverse and divergent slopes between 2011 and 2013 (Fig. 8). These observations show its artificial value with a high standard deviation of more than 15% and up to 28% for these three years. Later, after the relatively stable baseline, the extreme divergence of the values after 2013, with a standard deviation dispersed between 25.1% and 31.5%, after the relatively stable baseline is not explained by Member States' public data used to calculate the curves.

The work conducted by the EU is not easy to evaluate in the light of the literature[88] and especially when comparing the evolution through the years of publication (Fig. 4 vs Fig. 5 vs Fig. 6). Another curve (Fig. 7) published in 2021[89] even shows a global curve with two recovery peaks in 2014 and 2017 that can no longer be found in the latest published data (Fig. 3).

Indeed, computations require data on the sales of each plant protection substance type. Thus, for each substance it is necessary to extract the amount sold on the market for each group to perform the actual calculations, but this does not explain the evolution of the published curves. In addition, data on pesticide sales were patchy for a number of Member States, are often very slow to be published online (eg data for 2018 may not be provided until the end of 2020) and are still not yet published for 2021. Finally, these data are difficult to control, especially when they are decreasing over time. For instance, how can the quantities of sold pesticides validated five years before decrease and correspond to a lowered HRI_1 indicator in the published Table 2?[90] Moreover, the correlations within the groups and categories of pesticides (A–F) are impossible to determine. In addition, the regulatory status of the active substances is time-varying: first through the transition from unapproved to approved with the reduction of wv (from slight (wv divided by 4) to significant (wv divided by 64)), then through the acquisition of LR status and the reduction of wv (wv divided by 4) and the acquisition of CfS status and the increase of wv (wv multiplied by 4) or, more striking, their loss (wv divided by 4). Finally, ongoing F2F policy, targeting the reduction of chemical pesticides, should still produce serious effects on this curve, since chemical pesticides are very predominant in Group 3.

2. *Evolution of the HRI_1: a review of the published curves*

An initial comparison of Figs 5–7, initiated by the EU, shows changes in the values since the more recent ones were published (Fig. 3). The latter show all data points under 100, in contrast with Fig. 5, which was previously published in 2018. No information about a later refinement or new data from Member States was furnished along with the second and third curves that were published. Therefore, the HRI_1 index is unchallengeable for any one year, since it is not linked to pesticide sales and only depends on the number of substances in each category. Then, since the sales of pesticides could not possibly change to lesser amounts after the values are published, it seems *a priori* valid to multiply these sales by the HRI_1 index. Therefore, since the EU-published curves exhibit an almost consistent decrease and moreover turn out to be below 100, it is curious that no explanation was given to explain these modifications of the curves over the time. In addition, if changes are introduced corresponding to changes in the status of substances, as described above, they do not necessarily lead to a reduction, as clearly shown in the more realistic Fig. 7.

[88] Helepciuc & Todor (2021), supra, note 4; Helepciuc & Todor (2022), supra, note 4.
[89] European Commission, supra, note 53, p 16.
[90] European Commission, supra, note 53.

3. Impact of Directive (EC) No 128/2009

The second observation as to the shape of the figures is that although the multiplications are necessary to obtain the final HRI_1 indicator, in no case does the slope result in a curve showing a strong decrease. The gradually decreasing slopes of the HRI_1 indicator produced by the EU analysis (Figs 5–7) could be explained by the transfers of sales volumes from the most dangerous substances including CfSs (wv coefficient = 16) to substances with a lower coefficient (wv = 8 or 1 with LR substances) encouraged by NAPs. However, if in fact the amounts of chemical substances used are indeed rapidly decreasing (especially from 2018), a constant increase in CfSs since 2015 should negatively impact the HRI_1 indicator. Clearly, the new active substances have mainly been BCA substances since 2018 (and exclusively so since 2019), including a large portion in the LR categories,[91] although some categories (ie botanicals[92]) are difficult to get approved.[93] These changes in the global panel of active substances in the EU, which are symmetrically opposed (ie a decrease of chemicals sees an increase of BCA substances), new entries/qualifications of CfSs and the implementation of LR substances are clearly not sufficient in Fig. 1 to claim a definitive and irreversible decrease in the HRI_1 indicator as show in Fig. 7. In addition, Figs 3 & 8 show the probable diminishing use of highly dangerous pesticides in most European countries. Nevertheless, it appears that the variability of pesticide use in Europe has tended to increase as each country aims at developing its own preferred cocktail of pesticides. This is well illustrated in Fig. 8. In addition, the decreasing curve presented by the European Commission does not necessary reflect a reduction in the use of highly dangerous pesticides. Firstly, it may be the result of a switch from a small number of very toxic pesticides (CfSs) to a greater variety and volume of moderately toxic ones, demonstrating that the wv coefficient is not the ultimate tool for discriminating between substances with different properties. Indeed, the opportunity of having a higher number of LR substances is not being pursued, since potential LR substances from the 2015 list[94] have been neither fully validated (substances renewed without this status) nor completely exploited (substances abandoned). This issue has also been pointed out by the European Court of Auditors (Points 36–43) in 2020, especially in Point 39.[95] Another specific argument has been exhibited by the European Court of Auditors in Point 40, highlighting "the low number of low-risk PPPs" due to the low number of LR active substances and the smaller number of low-risk PPPs. This situation is highly complex as "not all low-risk [active substances] are giving rise to low-risk PPPs" due to some co-formulants being "of concern". However, recent[96] and ongoing[97] implementations of rules for unacceptable co-formulants in Annex III of the PPP Regulation may improve this situation. This market authorisation decision will not change the LR status of the substance, nor the multiplier of the substance for the HRI_1 index calculation (ie ×1) for Group 1 (categories A or B), but it disqualifies the corresponding product for a certain number of prerogatives due to its

[91] Robin and Marchand, supra, note 15; Robin and Marchand, supra, note 20; Robin and Marchand, supra note 84.

[92] M-C Vekemans and PA Marchand, "The fate of the biocontrol agents under the European Phytopharmaceutical Regulation: a hindering for approval botanicals as new active substances?" (2020) 27 Environmental Science and Pollution Research 39879.

[93] I Sundh and J Eilenberg, "Why has the authorization of microbial biological control agents been slower in the EU than in comparable jurisdictions?" (2021) 77 Pest Management Science 2170.

[94] European Commission, supra, note 38.

[95] European Court of Auditors, supra, note 59.

[96] "Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products" (2021) 74 Official Journal of the European Union 7.

[97] "Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council" (2023) 75 Official Journal of the European Union 7.

initial LR status. These entitlements listed in Article 47 of the PPP Regulation and their variations at the Member State level (market authorisation delays, pollution charges and fees or taxes or the possibility of promotion in the press) de facto reduce interest in the substance. Questions are also asked regarding the allocation of the quantities (masses) of these products used in the field in the HRI_1 indicator calculation: will they be affected by a classic active substance product coefficient of 8 or still by a factor of 1?

a. Mechanism of evolution of the curve

A decrease in the curve reflects either the effective removal of the most dangerous substances and hypothetical moves to a lower-weighted group or their suppression. It also illustrates an increase in the use of LR substances. Therefore, there is a desire and corresponding will to decrease this curve within the European Commission; however, the increasing toxicological findings on substances due to generally increased expectations of safety regarding active substances leads to a higher number of tests being required.[98] These stricter provisions and increased evaluations or re-evaluations of active substances are further factors that maintain the values/curves at a high level. As a proof of this, seven approved active substances have been added to the CfS list due to the emergence of new toxicology data in 2020. The goal of pointing out targets may be satisfied in this case, but the HRI is negatively impacted. Without calling this indicator into question, it therefore strongly depends on regulations (eg criteria for endocrine disruptors for CfSs and safety for LR substances) that apply to pesticides and requalify them as active substances, modifying the HRI_1 indicator in particular and challenging the usefulness of the indicators (European Court of Auditors, Point 53).[99] This is what prompted us to calculate the HRI_1 index.

However, our results are broadly similar to those obtained by the EU. Therefore, these results might be interpreted as a positive outcome for the implementation of Directive No 128 and a real demonstration of the desire to decrease the use of high-risk substances. Indeed, the EU has recently implemented a wish-list for the decrease in use of approved high-risk substances, meaning that an approval of new toxic substances is more and more difficult to obtain. For example, only 455 substances are approved, whereas 943 are not, including non-renewed toxic substances.[100] The HRI_1 index can be easily calculated, but since the quantities of pesticide sales are not fully available, this means that the HRI_1 indicator cannot be fully verified, so we tried to re-calculate this HRI_1 indicator from the available data (Fig. 3). Analysis of the curve shows a similarity with the published HRI_1 indicator from the European Commission, but any decrease over the years (slope) is more difficult to validate, especially when the modifications regarding some points (years) decrease over time (ie the curve from 2020 compared to the curve published in 2018).

3. An unwelcome flashback

These indicators relate to both the agricultural and food industry domains linked to consumer concerns more than ten years after the implementation of Directive (EC) No 128/2009, and while the results (reduction of risks) are as expected, they do not appear to support the European Green Deal that is now being invoked to solve the problem and obtain desired outcomes. Many of the regulatory, legal and easy means of obtaining a real inflection of the curve have in fact not been implemented. The slow implementation of LR substances and the renewal of CfSs are indeed symptomatic of the tardiness of enforcing the European Green Deal approach. For instance, we highlight the renewal of

[98] Commission Regulation, supra, note 87.
[99] European Court of Auditors, supra, note 59.
[100] European Commission, supra, note 22.

semiochemical straight-chain lepidopteran pheromones (SCLPs; encompassing acetate, aldehyde and alcohol families), of which only a part (the alcohol family) has been granted LR status, even though all of these molecules are used in traps, possibly leaving residues on the crops they protect, the environment and the users/applicators. Indeed, after a few years of debate, the lack of MRLs for these SCLPs has now been resolved.

a. EFSA statement

Specifically, the EFSA follows this scheme, and its executive director, Dr Bernhard Url, claimed in 2020 in Euractiv[101] that "pesticides will be more targeted in what we would call 'sustainable use of pesticides', which would mean replacement of higher risk pesticides with low-risk pesticides under the Green Deal", although Directive (EC) No 128/2009 had already aimed at achieving this goal ten years ago.

In fact, under the European Green Deal, the European Commission wants to reduce the use of chemical pesticides in the EU by 50% over the next seven years (therefore twenty years after the SUD's implementation) in a benchmark established by the new F2F Strategy and Biodiversity Strategy. However, the definitive targets for the "reduction of the risks/pesticide use" will be subjected to the implementation of the soon-to-arrive "Sustainable Use of Pesticides" Regulation (SUR), starting fifteen years at best after the SUD.

To achieve this "new" monitoring, Dr Url also mentioned the necessity of IPM,[102] again as already required by the SUD,[103] which means that methods other than chemical pesticides will need to be adopted to control pests, such as crop rotation, managing soil fertility and using cultivars that are resistant to certain pests, although we showed that chemicals used in traps are compatible with IPM and BCAs.[104] Nevertheless, the European Commission claims that the SUD has (already) resulted in a "significant reduction" in risks from pesticides, whereas Dr Url from EFSA states that risk reduction will be achieved by the European Green Deal: "the Green Deal will do it", although undoubtedly there is a "later" implied in this statement, which is antithetical to the Commission's position. However, the study of the HRI_1 development shown here (Fig. 3) as well as the HRI_1 index (Fig. 1) already substantiates this trend. Clearly, it will be difficult to distinguish what is achieved by the SUD and what is the impact of the European Green Deal, although both are acting in the same direction. The HRI_1 indicators, notwithstanding the criticisms regarding their curves, through the SUD, are triggering efforts that are leading to substantial rearrangements and modifications of the plant protection fingerprint, especially regarding LR active substances. This observation raises questions regarding the complete validation, in 2018, of the list of all potentially LR substances.

b. Organic sector point of view

Again, most BCAs and LR substances are compatible with organic farming principles,[105] including chemicals used in traps. LR substances are all on the way towards being included

[101] Euractiv, "EFSA chief: Assessing fast-changing agrifood innovation is key challenge" (n.d.) <https://www.euractiv.com/section/agriculture-food/interview/efsa-chief-assessing-fast-changing-agrifood-innovation-is-key-challenge-part-i/> (last accessed 9 June 2023).

[102] European Commission, "Farmer's Toolbox for Integrated Pest Management" (2023) <https://datam.jrc.ec.europa.eu/datam/mashup/IPM/index.html> (last accessed 9 June 2023).

[103] European Commission, supra, note 1.

[104] N Bakthatvatsalam, K Subharan and M Mani, "Semiochemicals and Their Potential Use in Pest Management in Horticultural Crops" in M Mani (ed.), *Trends in Horticultural Entomology* (Singapore, Springer 2022); PA Marchand, "Synthetic agrochemicals: a necessary clarification about their use exposure and impact in crop protection" (2019) 26 Environmental Science and Pollution Research 17996.

[105] PA Marchand, "Novel plant protection regulation: new perspectives for organic production?" (2018) 4 Organic Farming 3.

in Annex I of the new organic production regulation[106] within a distinguishable and dedicated subcategory. Interestingly, the pressure to increase the use of BCAs and LR substances for IPM will continue to be profitable for organic production crop protection, whereas any reduction of controversial active substances may only slightly affect the number of substances available for organic production,[107] although some are of importance and may be negatively impacted (eg copper, spinosad, pyrethrums) and few are chemicals used in traps (eg deltamethrin and lambda-cyhalothrin).[108] However, the increase in the choice of BCA active substances available for organic production certainly requires that alternative non-chemical plant protection methods are actively developed and implemented in the organic sector. Conversely, the work on natural substances typical used in organic farming can offer solutions and could guide approaches within conventional agriculture.

V. Conclusions

The analysis of HRIs, in addition to monitoring the reduction of risk from pesticides, may also have another impact on the retrofitting of the PPP Regulation, including the ongoing SUD revision for the SUR, in order to improve subsequent approvals of less toxic compounds, although it was not designed for these objectives and aims. However, the rollout of the SUD and these indicators, with the first results only being obtained ten years after its entry into force, has been extremely slow. Moreover, these risk indicators are only linked to the HRI_1 index, weights and sales volumes within broad classes. Some recent proposals with more of a focus on triggering action may be better designed for achieving the goal of reducing the use of the most toxic agrochemicals[109] and for more concrete risk reduction in the field (applicators, operators) as well as for consumers. The F2F Strategy goes even further with the "environmentally friendly food system", which commits to going so far as to "have a neutral or positive environmental impact", "help to mitigate climate change and adapt to its impacts" and "reverse the loss of biodiversity".

We believe that this curve is primarily a communication tool regarding the positive developments in the pesticide panel. Nevertheless, it could also represent a trap facing the European Commission for when they are no longer able to decrease this curve due to its lower ceiling. In addition, mobility from one group to another can easily change the trend of the curve. Indeed, this observed for the three theoretical cases of "LR", "LR+CfS" and "All LR", with "All LR" having a the lowest possible ceiling for the HRI_1 indicator/index. The instability of the HRI_1 indicator is therefore a "Sword of Damocles" with regards to the objective of mandatory decreases of pesticides to enable positive communication, but data that could lead to such variations (plateaus as in 2020 or rises as in 2015) are extremely difficult to manage for EU institutions. In fact, after positive communication regarding a 20% reduction of the HRI_1 indicator in Fig. 5[110] followed by a greater reduction in Fig. 3 but

[106] "Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007" (2018) 150 Official Journal of the European Union 1.

[107] "Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists" (2021) 253 Official Journal of the European Union 13.

[108] Marchand, supra, note 104.

[109] N Möhring, K Ingold, P Kudsk, F Martin-Laurent, U Niggli, M Siegrist et al, "Pathways for advancing pesticide policies" (2020) 1 Nature Food 535; F Dedieu, "Organized denial at work: The difficult search for consistencies in French pesticide regulation" (2022) 16 Regulation & Governance 951; VC Schreiner, M Link, S Kunz, E Szöcs, A Scharmüller, B Vogler et al, "Paradise lost? Pesticide pollution in a European region with considerable amount of traditional agriculture" (2021) 188 Water research 116528.

[110] European Parliament and Council, supra, note 6.

without a drastic reduction in the number and amount of CfSs since 2021, there is a risk that the downward trend will stabilise in 2020 or, in the worst case, even increase. The significant reduction of sales of the more harmful PPPs happened more as a result of the loss of chemical active substances, without counting the derogations granted to products no longer approved at all. To illustrate this fact, a study by the European Parliament in 2021[111] showed no significant reduction of sales between 2011 and 2018, but we have shown that chemical pesticides have since started to decrease sharply. It is therefore the changes in the EU approval requirements (approvals and renewals) that led to the decline in HRI_1.

Only EU-wide data and curves are presented unilaterally by the Commission and also by Member States, sometimes without showing values. The necessary study of the HRI_1 index at the European level proposed here cannot be fully undertaken by any other stakeholder except the EU itself, since information about the annual quantities of pesticides consumed is not freely available. Even with these data sorted by function (eg herbicides, insecticides, etc.), there is no way of knowing the precise numbers of every substance sold in Europe nor to link these with their status and thus with the corresponding multiplying factor for HRI_1. Data regarding the more precise product categories (A–F) are also inaccessible. The EU pesticide database[112] even supresses the function display (eg herbicides, insecticides, etc.) in its third revision.

Therefore, the lack of the necessary information needed to properly calculate HRI_1 leads to the impossibility of control. This leads to a computational dead-end as the whole system cannot be modelled independently. This makes our HRI_1 index the next most reliable alternative and an essential intermediary for measuring the real evolution of the desired effective decline. In fact, the European Green Deal may contribute to a further reduction in HRI_1 values since one target of the F2F 2030 global action is to reduce the use of chemical and more hazardous pesticides by 50%. However, this goal is being implemented and achieved through the tightening of the regulations themselves.[113] Clearly, when taken into consideration, a new baseline 100 for the years 2015–2017, representing the worst years in our HRI_1 index (Fig. 1), for the future SUR will lead to confusion as well as the inability to rapidly compare later HRI_1 indicators from the SUD over time since 2011.

Towards this objective, ongoing research for organic and IPM alternative inputs for more sustainable plant protection may also be a triggering factor for the inclusion of basic substances and LR approved substances, although implementation of the PPP Regulation for natural substances is not straightforward.[114] However, we show, especially in Fig. 2, that great change in the HRI_1 cannot be achieved without a massive switch from *potential* LR substances to substances an *actual* LR status and a drastic reduction in CfSs. A better differentiation between active substances in categories B (microorganisms) and c (chemicals) in terms of their weighting coefficients may also result in improved risk reduction.

The first lever can be quite easily activated, and the number of LR substances is increasing strongly (renewals and approvals), although a lot of potential LR substances have been abandoned since 2015 by their initial applicants[115] and some listed potential LR substances are not being renewed as being LR substances (eg the renewal on garlic).[116] However, the current situation shows that the second lever does not work, with only

[111] European Parliament, "The future of crop protection in Europe: Appendix 1 – Overview of current and emerging crop protection practices" (2021) <https://www.europarl.europa.eu/RegData/etudes/STUD/2021/656330/EPRS_STU(2021)656330_EN.pdf > (last accessed 9 June 2023).

[112] European Commission, supra, note 22.

[113] Marchand, supra, note 42.

[114] Vekemans and Marchand, supra, note 92.

[115] European Commission, supra, note 38.

[116] "Commission Implementing Regulation (EU) 2021/129 of 3 February 2021 renewing the approval of the active substance garlic extract in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to

thirty-six CfSs being removed while the total amount has also been added to, meaning that there are only twenty-one fewer CfSs (56 vs 77) since 2015.[117] This is proof that the actual withdrawal of CfS uses has not worked as intended, even if the comparative evaluation can block certain marketing authorisations in practice. Substitution appears to be very difficult in practice, as we have shown that BCAs are definitely not substitute active substances.[118]

In addition, the poor results of the evolution of the HRI_1 values may induce further pressure against pesticides from civil society, as already observed in recent publications on the subject.[119] Ultimately, we show that regulatory pressure on pesticides and pesticide approval pathways mainly leads to a reduction in the number of substances (data not shown) and secondarily their risks. For example, knowing that the risk here is almost entirely incremented by the mass of pesticides in terms of the overall exposure to each class, no other exposure factors (eg persistence, volatility, solubility, type of hazard) are actually taken into account in the risk assessment, with the respective danger of the substances being reduced to a single factor: 1 to 64.

Finally, the very different shapes of the curve between 2019 and 2021 (Figs 5–7) requires some serious explanation, as such differences cannot be linked to a drop in sales during this time because they had already been made and counted in 2019. This significant variety in the curves is representative of the HRI_1 being a public relations statement of intent rather than representing a genuine risk management process. Further work is necessary to define the development of all of the specific entries for the HRI_1 index, which gives rise to the HRI_1 indicator, as LR substances and CfSs, but this class transfer cannot be the main way to reduce pesticide risk. Finally, an IPM transfer, switching from biotic to abiotic action, switching from pesticides to other regulatory compartments such as biostimulants or the breeding of more disease-resistant plant varieties will be the major changes in the coming years. Furthermore, the full implementation of the fourth pilar of biocontrol, namely macroorganisms,[120] is another essential element to compensate for the inevitable global reduction of chemical pesticides. When all of these IPM tools, mainly but not wholly dependent on the PPP Regulation, are completely implemented, the necessity for and interest in the HRI_1 indicator will undoubtedly drop, even if it is necessary to pursue it as a survey tool.

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Commission Implementing Regulation (EU) No 540/2011" (2021) 40 Official Journal of the European Union 11; Robin and Marchand, supra, note 20; Robin and Marchand, supra, note 65; Robin and Marchand, supra, note 84.

[117] Robin and Marchand, supra, note 14.

[118] PA Marchand, "Biocontrol agents in Europe: substitution plant protection active substances or a new paradigm?" (2023) Environmental Science & Policy (submitted).

[119] Möhring et al, supra, note 109.

[120] DC Robin, L Merlet and PA Marchand, "Regulatory aspects of biocontrol" in C Prigent-Combaret and B Dumas (eds), *Biocontrol of Plant Disease: Recent Advances and prospects in Plant Protection* (London, ISTE 2023) pp 1–17.

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