Appreciation of Harmonised Risk Indicator proposals

Alternatives proposed by Member States Belgium and Denmark for the Harmonised Risk Indicator F2F1

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Contents

Samenvatting

Annex I van de concept versie van de *Sustainable Use Regulation* (SUR) bevat een voorstel voor een aantal geharmoniseerde risico indicatoren. Deze indicatoren zijn bedoeld om de voortgang te volgen richting gemeenschappelijke reductiedoelstellingen voor het jaar 2030. De lidstaten België en Denemarken hebben een alternatief voorstel ingediend voor een van deze geharmoniseerde risico indicatoren (HRI F2F1 SUR). Het Ministerie van Landbouw, Natuur en Voedselkwaliteit heeft WEnR gevraagd om de HRI F2F1 SUR te vergelijken met twee alternatieve voorstellen vanuit Denemarken (HRI F2F1 DK) en vanuit België (HRI F2F1 BE).

HRI F2F1 SUR is gebaseerd op gegevens over de jaarlijkse afzet van chemische actieve stoffen in gewasbeschermingsmiddelen en een wegingsfactor voor het gevaar van stoffen voor mens en milieu. Er zijn vier groepen stoffen benoemd; de wegingsfactor is het laagst voor de groep laag-risico stoffen en het hoogst voor de groep stoffen die niet zijn toegelaten onder verordening (EC) 1107/2009. De alternatieve voorstellen beogen minder nadruk te leggen op de afzetcijfers en meer nadruk op de gevaren van de stoffen voor mens en milieu. Het alternatieve voorstel van Denemarken benoemt een vijfde groep; voor de stoffen die zijn toegelaten met specifieke vermelding van het gevaar voor mens en milieu (CLP classificatie volgens verordening (EC) 1272/2008) of van specifieke restricties die tot doel hebben om het milieurisico te beperken. Het bereik van de wegingsfactor voor het gevaar van groepen stoffen is in HRI F2F1 DK groter ten opzichte van HRI F2F1 SUR. In het alternatieve voorstel van België is een aantal beschermdoelen opgenomen. Voor elk beschermdoel en voor elke stof is een toxwaarde of een intrinsieke eigenschap toegevoegd aan de invoer. Deze worden vertaald naar een wegingsfactor. Het gebruik van deze wegingsfactoren per stof in HRI F2F1 BK is een belangrijk verschil ten opzichte van beide andere indicatoren, die gebruik maken van een wegingsfactor per stofgroep.

De drie indicatoren zijn vergeleken aan de hand van vier criteria: de hoeveelheid middelen die nodig is om de indicator te kunnen berekenen; de mate waarin de indicator bijdraagt aan de harmonisatie tussen lidstaten; de mogelijkheid van de indicator om rekening te houden met de specifieke situatie van de lidstaten; en de consistentie van de indicator met de Europese toelating. Voor deze vergelijking is gebruik gemaakt van EU-documenten en overige bronnen, en van het spreadsheet met de benodigde invoer en de berekening van HRI F2F1 BE - onderdeel van het alternatieve voorstel van België.

HRI F2F1 BE maakt gebruik van een afzetcijfer en van toxwaarden, intrinsieke eigenschappen en een wegingsfactor van elke stof. De benodigde middelen om deze indicator te kunnen berekenen zijn naar verwachting groter dan die voor de twee andere indicatoren. Dit geldt ook voor de opzet en het onderhoud van een database waarin alle benodigde invoergegevens zijn opgeslagen en die toegankelijk is voor de lidstaten.

De eenvoud van de berekeningen van HRI F2F1 SUR en HRI F2F1 DK maakt deze indicatoren bij uitstek geschikt om voor elke lidstaat op dezelfde wijze de voortgang richting de reductiedoel-stellingen te berekenen. Verschillen tussen lidstaten in de waardering van beschermdoelen komen immers niet tot uitdrukking in de invoer. HRI F2F1 BE heeft wel de flexibiliteit om beschermdoelen naar keuze op te nemen en tevens om deze beschermdoelen te wegen ten opzichte van elkaar. Dit maakt deze indicator minder geschikt voor harmonisatie van het gebruik door uiteenlopende lidstaten. In HRI F2F1 SUR en HRI F2F1 DK ontbreekt de flexibiliteit om rekening te houden met de specifieke situatie in de lidstaten. In de HRI F2F1 BE benadering is deze flexibiliteit wel aanwezig.

De drie indicatoren op basis van afzetcijfers en wegingsfactoren voor het gevaar voor mens en milieu kunnen de stoffen met de grootste risico's alleen zeer globaal aanwijzen. De inschatting van de blootstelling van mens en milieu als gevolg van het gebruik van deze stoffen is onderdeel van de risico beoordeling in de toelating. De drie indicatoren houden geen rekening met de blootstelling en de uitkomsten zijn niet geschikt voor gebruik in de beoordeling. De uitkomsten zijn wel geschikt voor het sorteren van stoffen en het globaal afleiden van trends.

In de drie voorstellen voor de geharmoniseerde risico indicator wordt de afzethoeveelheid van een stof vermenigvuldigd met een wegingsfactor waarin de gevaren van een stof voor mens en milieu zijn samengevoegd. Dit levert de bijdrage van de stof aan de indicator score, die vervolgens voor alle stoffen wordt opgeteld. De top5-stoffen met de grootste bijdrage zijn vervolgens in beeld om nadere gegevens te verzamelen over het gebruik en de blootstelling.

Vanwege de flexibiliteit om verschillende beschermdoelen op te nemen in de berekening, lijkt HRI F2F1 BE de meest geschikte benadering om de voortgang richting de reductiedoelstellingen voor 2030 te volgen. Wij doen aanbeveling om deze indicator te gebruiken voor elk beschermdoel afzonderlijk. Wij ontraden het om de uitkomsten voor verschillende beschermdoelen bij elkaar op te tellen. We doen aanbeveling om de HRI F2F1 BE benadering in te vullen met identificatie van de top-5 stoffen voor elk afzonderlijk beschermdoel met een plek in de berekening van de indicator.

Metabolieten van actieve stoffen zijn niet opgenomen in de invoer van de indicatoren. Bij de afbraak van bepaalde actieve stoffen worden metabolieten gevormd met een relatief grote gevoeligheid voor uitspoeling naar grondwater. Wij doen aanbeveling om deze metabolieten toe te voegen aan het rekenschema volgens de HRI F2F1 BE benadering, die gebruik maakt van wegingsfactoren per stof.

Summary

Under the farm to fork strategy (F2F), part of the European Green Deal, the EU has set targets for a 50% reduction in the overall use and risk from chemical plant protection products, and for a 50% reduction in the use of the most hazardous products by the year 2030. The Commission made a proposal for the regulation which would require Member States to contribute to these EU-wide targets, and would replace the Sustainable Use of Pesticides Directive (SUD; 2009/128/EC). The Sustainable Use Regulation proposal (SUR) includes two Harmonised Risk Indicators (HRI F2F1 and HRI F2F2) to track progress towards these reduction targets. Member States Belgium and Denmark proposed an alternative to the Harmonised Risk Indicator F2F1 in SUR Annex I (HRI F2F1 SUR). The Dutch Ministry of Agriculture, Nature and Food Quality (LNV) requested Wageningen Environmental Research for an appreciation of these proposals from Belgium and Denmark.

Methodology

The HRI F2F1 indicators proposed are based on the annual volume per chemical active substance in the plant protection products put on the market. In HRI F2F1 SUR these chemical active substances are categorised into four groups. A hazard weighting factor is applied which reflects the aims of the farm to fork strategy, with the minimum value for Group 1 low-risk active substances and the maximum value for Group 4 active substances which are not approved under Regulation (EC) 1107/2009. The alternative proposals from Denmark and Belgium aim at less emphasis on the quantities put on the market and at more emphasis on the chemical active substances and their potential risks to human health and the environment. The alternative indicator proposed by Denmark HRI F2F1 DK considers five groups of chemical active substances. The extra group contains the chemical active substances approved with a particular Classification for Labelling and Packaging (CLP) or type of risk mitigation measure. In addition, the range of the hazard weighting factor for these five groups of chemical active substances is increased compared to HRI F2F1 SUR. The alternative indicator proposed by Belgium HRI F2F1 BE incorporates hazard criteria of active substances for human health and different non-target species groups and aspects of environmental fate. In addition to these substance based input, HRI F2F1 BE includes a weighting factor and scoring function for each non-target species group and for each aspect of environmental fate considered.

Discussion

The discussion of the methodology to calculate the harmonised risk indicators focusses on the amount of resources needed to calculate the indicator, the harmonization between Member States, the flexibility to incorporate the specific situation in the Member States, and the consistency with European registration and protection goals.

Feasible amount of resources needed to calculate the indicator

HRI F2F1 BE requires toxicity data and environmental fate properties for each substance with a quantity reported by the Member State to the Commission. For this reason, the amount of resources needed to operate and maintain HRI F2F1 BE is expected to be considerably higher compared to the other indicators. Furthermore, HRI F2F1 DK requires input from EU registration dossiers regarding CLP classifications and risk mitigation measures. For this reason the amount of resources needed to operate and maintain HRI F2F1 DK may be higher compared to HRI F2F1 SUR.

Harmonization between Member States

Both HRI F2F1 SUR and HRI F2F1 DK may contribute to the harmonisation between Member States and may help to keep track of progress towards achieving common targets. The methodology of these two indicators is based on quantities and a weighting factor for groups of substances. Differences between Member States regarding the appreciation of human and environmental protection goals will not affect the outcome of these two indicators.

HRI F2F1 BE has the flexibility to consider multiple protection goals. However, when different environmental protection goals are considered, the outcome of this indicator can't be compared between Member States. In addition, the weighting factor for a substance depends on the dataset with substances, quantities and toxicity values (as explained in Annex A). This makes the HRI F2F1 BE less suitable to contribute to the harmonisation between Member States with different quantities of chemical active substances put on the market.

Flexibility to incorporate the specific situation in Member States

Both HRI F2F1 SUR and HRI F2F1 DK are based on quantities and a hazard weighting factor only; for this reason they lack the flexibility to adapt to the specific situation in the Member State. HRI F2F1 BE weighs for each substance the hazard to human health, and the hazard to different non-target species groups and aspects of environmental fate. To some extent, weighting factors for the human and environmental protection goals considered in HRI F2F1 BE may reflect the specific situation in the Member State. The Belgian proposal includes two options regarding the decision making on which protection goals need to be considered and on the values of the weighting factors: the responsibility for this task can be either with the Member State or with the Commission.

Consistency with European registration and the protection goals

HRI F2F1 indicators provide a general indication of the human and environmental hazards of chemical active substances only. The exposure assessment of human groups and parts of the environment with chemical active substances and their residues is part of a risk assessment. HRI F2F1 indicators take no account of exposure and should not be taken as a substitute for a risk assessment. The outcome of the indicators can be used for deriving trends, ranking substances, and to further investigate the use of substances with the highest contribution to the indicator score. Aggregating risk indicators for different protection goals is not in line with registration procedures. Within the OECD Project on Pesticide Aquatic Risk Indicators, it was recommended to use separate indicators of risk to human health and risk to each compartment of the environment rather than a single indicator of pesticide risks. It was further suggested that specific substances with major contribution to the indicator score be identified for close attention; i.e. to link with use data and with exposure data. After all, the risk is determined by what happens in the field.

Recommendations

The intended use of a harmonized risk indicator is to track progress towards reduction targets and to identify substances with the largest contributions to the indicator score. We recommend to use multiple indicators that express a hazard to human health, a species group or aspect of environmental fate, rather than a single indicator of aggregated pesticide risks. We recommend these type of indicators for ranking chemical active substances and for deriving trends in the hazard (potential risk) imposed by plant protection product use. These indicators should not be taken as a substitute for a risk assessment.

HRI F2F1 BE seems to be the indicator most suited to identify (hazard-based) contributions from substances to different protection goals. Since this indicator allows for including the protection goals that are considered of relevance for a Member State we do recommend using this type of approach, and in addition to derive individual top5 chemical active substances for each protection goal considered.

Metabolites are not considered in the indicators proposed. Some active substances degrade into metabolite(s) with a relative high potential for leaching towards groundwater. It is recommended to incorporate the leaching potential towards groundwater into the environmental fate part of HRI F2F1 BE and to add relevant metabolites to the methodology for calculation.

Member State Belgium provided an example dataset with the HRI F2F1 BE proposal. It is recommended to further analyse the behaviour and robustness of the HRI F2F1 BE approach, using additional datasets from other Member States.

In order to warrant consistent operation of the Harmonised Risk Indicator F2F1 by the Commission and the Member States, the Commission is recommended to provide instructions regarding the selection of substance toxicity data and fate properties, and to provide and maintain a single and unique data source which contains all the input required for calculating the harmonised risk indicator. We also recommended to provide a list with metabolites which are mentioned for their leaching potential in EU registration dossiers, including the relevant fate parameters.

Introduction

Under the farm to fork strategy (F2F), part of the European Green Deal, the EU has set targets for a 50% reduction in the overall use and environmental and human risk from chemical plant protection products, and for a 50% reduction in the use of the most hazardous products by the year 2030. The Commission made a proposal for the regulation which would require Member States to contribute to these EU-wide targets, and would replace the Sustainable Use of Pesticides Directive (SUD; 2009/128/EC). The Sustainable Use Regulation proposal (SUR) includes two Harmonised Risk Indicators to track progress towards these reduction targets (HRI F2F1 and HRI F2F2). The indicators should be calculated annually at both EU level and Member State level, based on statistical data collected in accordance with Regulation EC 1185/2009. Member States should also conduct evaluations for five active substances with the most significant contribution to the total score of the indicator.

Member States Belgium and Denmark proposed alternative risk indicators for the HRI F2F1 in SUR proposal Annex I. These alternatives place less emphasis on the quantities put on the market and more emphasis on the chemical active substances and their potential risks to human health and the environment (MS BE 2022; MS DK 2022)[1]. The Dutch Ministry of Agriculture, Nature and Food Quality (LNV) requested Wageningen Environmental Research to deliver the appreciation of these proposals from Belgium and Denmark in this document. The terminology introduced in the Sustainable Use Regulation proposal (SUR) and in the alternative proposals from Denmark and from Belgium is followed in this document.

Methodology for calculating Harmonised Risk Indicator F2F1

According to the Sustainable Use Regulation proposal

The HRI F2F1 in SUR proposal Annex I is based on the annual volume per chemical active substance in the plant protection products put on the market. These chemical active substances are categorised into four groups (Table 1). For each group a hazard weighting factor is applied: 1) approved chemical active substances in low-risk pesticides (factor 1); 2) approved chemical active substances not falling into any other category (factor 8); 3) approved chemical active substances which are candidate for substitution (factor 16); and 4) chemical active substances not approved under Regulation (EC) 1107/2009 (factor 64).

For each chemical active substance, the contribution to the indicator equals the product of the quantity[2] and the hazard weighting factor. The HRI F2F1 score equals the sum of these contributions for all substances (Example in Annex A).

The example dataset provided with the alternative proposal from Belgium (next section) contains 322 chemical active substances with a quantity reported. The number of substances assigned to Group 1, 2, 3 and 4 equals 3, 239, 59 and 21, respectively. Group 2 contains by far the largest number of chemical active substances.

[1] These alternative proposals are described in the documents and the example dataset provided to the Council Working Party on the Commission proposal for a regulation on the sustainable use of plant protection products. These were handed over by the Dutch Ministry of Agriculture, Nature and Food Quality to Wageningen Environmental Research for the appraisal.

[2] The quantity is reported by the Member State to the Commission (Eurostat) under Regulation (EC) No 1185/2009.

Table 1: Categories of chemical active substances and hazard weighting factor in HRI F2F1 in SUR proposal Annex I for calculating progress towards achieving national 2030 reduction target 1.

Row	Groups			
	1	**2**	**3**	**4**
(i)	Low-risk chemical active substances which are approved or deemed to be approved under Article 22 of Regulation (EC) No 1107/2009, and which are listed in Part D of the Annex to Implementing Regulation (EU) No 540/2011	Chemical active substances approved or deemed to be approved under Regulation (EC) No 1107/2009, and not falling in other categories, and which are listed in Parts A and B of the Annex to Implementing Regulation (EU) No 540/2011	Chemical active substances that are approved as candidates for substitution in accordance with Article 24 of Regulation (EC) No 1107/2009 and listed in Part E of the Annex to Implementing Regulation (EU) No 540/2011, or that are listed in the Annex to Implementing Regulation (EU) 2015/408.	Chemical active substances which are not approved under Regulation (EC) No 1107/2009, and therefore which are not listed in the Annex to Implementing Regulation (EU) No 540/2011
(ii)	Hazard weighting factor applicable to quantities of chemical active substance placed on the market			
(iii)	**1**	**8**	**16**	**64**

The alternative proposal from Belgium

According to the Belgian proposal (MS BE, 2022) there is lack of evidence that HRI F2F1 adequately addresses the objective to reduce the risks to human health and the environment resulting from the agricultural use of plant protection products based on chemical active substances. The alternative indicator HRI F2F1 BE is based on the Pesticide Load approach (Kudsk et al., 2018). It incorporates the hazard of chemical active substances to human health and it differentiates between substances regarding the hazard to different non-target species groups and environmental compartments. The input includes separate hazard weighting factors and scoring functions for each non-target species group and each aspect of environmental fate. Two options are described:

1. without subsidiarity: the Commission chooses the non-target species (groups) and the environmental compartments to be considered.
2. with subsidiarity: the Member State chooses the non-target species and the environmental compartments to be considered.

The hazard weighting factors for Group 1, 2, 3 chemical active substances in the ecotoxicity part and the environmental fate part of the indicator are calculated to express the potential risks (Table 2). The hazard weighting factors for all chemical active substances in the human health part of the indicator, and the hazard weighting factors for Group 4 chemical active substances in the ecotoxicity part and the environmental fate part of the indicator, are similar to the ones used in HRI F2F1 SUR.

Multiple non-target species groups can be included in the ecotoxicity part of the indicator (e.g. bees, birds, aquatic species, earthworms). For each non-target species group, the weighting factor of the

chemical active substance is obtained from a toxicity value (e.g. LD50 for birds, in mg / kg body weight) and a scoring function. The scoring function distributes the toxicity values for the chemical active substances in the dataset among 16 classes. The procedure is described in detail in Annex A. In addition to these hazard weighting factors per substance, a non-target species group weighting factor[3] determines the contribution of the species group relative to the other species groups considered in the ecotoxicity part of the indicator.

At least two parameters determining the persistence and mobility of the chemical active substance must be considered in the environmental fate part of the indicator proposed. Degradation half-life determines the persistence in soil, whereas the sorption coefficient to organic matter or the octanol-water partition coefficient indicates the tendency to adsorb to soil or living organisms, and mobility in soil. Similar to the calculations for the non-target species groups in the toxicity part of the indicator, the weighting factor of the chemical active substance is obtained from a scoring function. The environmental fate weighting factor[4] determines the relative contribution of the aspect (e.g. persistence, mobility) to the environmental fate part of the indicator. The overall hazard weighting factor of a chemical active substance is calculated from the weighting factors for human health, ecotoxicity and environmental fate (Table 3).

For each chemical active substance, the contribution to the indicator equals the product of the quantity and the overall hazard weighting factor. The HRI F2F1 BE score equals the sum of these contributions for all substances.

Table 2: Categories of active substances and separate hazard weighting factors for human health, ecotoxicity and environmental fate in HRI F2F1 BE for calculating progress towards achieving national 2030 reduction target 1.

Row	Indicator part	Groups			
		1	**2**	**3**	**4**
(i)		*Similar to Table 1*	*Similar to Table 1*	*Similar to Table 1*	*Similar to Table 1*
		Hazard weighting factor applicable to quantities of chemical active substance placed on the market			
(ii)	**Human health**	**1**	**8**	**16**	**64**
(iii)	**Ecotoxicity**	A score from 1 to 16 from a scoring function of the ecotoxicity for non-target species			**64**
(iv)	**Environmental fate**	A score from 1 to 16 from a scoring function of specific endpoints for environmental fate			**64**

[3] The range of the non-target species group weighting factor = 0-1. The sum of the non-target species group weighting factors must be equal to 1.

[4] The range of the environmental fate weighting factor = 0-1. The sum of the environmental fate weighting factors must be equal to 1.

Member State Belgium provided example calculations using a dataset with national average annual quantities for 322 chemical active substances in the years 2011-2013, 2015-2017, and 2018-2020[5]. The example considers toxicity to aquatic species, bees, birds and earthworms, and persistence in soil. The major part of the toxicity values and fate parameters was obtained from the Pesticide Properties Database (MS BE, 2022; referring to Lewis et al., 2016). The responsibility for providing the input according to both options for the alternative indicator is summarised in Table 3.

Table 3: Responsibility for deciding on the input required by HRI F2F1 BE according to Option 1 without subsidiarity and according to Option 2 with subsidiarity.

Input	Option 1 without subsidiarity	Option 2 with subsidiarity
Non-target organisms	bees, birds and aquatic	MS chooses at least 2 non-target organisms
Contribution of each non-target organism to the ecotoxicity weighting factor	Determined by COM	Determined by the MS
Distribution function for each non-target organism (range 1 – 16)		Determined by the MS; at least 4 classes
Aspects of environmental fate (e.g. persistence in soil, leaching towards groundwater)	persistence and mobility	Determined by the MS; at least 2 properties
Contribution of each aspect of environmental fate / parameter to the environmental fate weighting factor	Determined by COM	Determined by the MS
Distribution function for each aspect of environmental fate (range 1 – 16)		Determined by the MS; at least 4 classes
Contribution of the hazard weighting factors for human health, ecotoxicity and environmental fate to the overall hazard weighting factor	Equal weight (3 x 1/3)	

The alternative proposal from Denmark

The alternative proposal from Denmark aims at less emphasis on the quantities put on the market in HRI F2F1 in SUR proposal Annex I. The intent is to better reflect the potential effects to human health and the environment resulting from the agricultural use of chemical active substances. For example, compared to HRI F2F1 SUR it will show a further decrease of the total HRI score when a Group 2 or Group 3 chemical active substance is replaced with a categorized Group 1 chemical active substance.

The Danish propose to modify the hazard weighting factor in the HRI F2F1: 1) approved chemical active substances in low-risk pesticides (factor decreases from 1 according to HRI F2F1 SUR to 0.1 according to HRI F2F1 DK); 2) approved chemical active substances not falling into any other category (factor remains 8 for the new Group 2a and increases from 8 to 24 for the new Group 2b); 3) approved chemical active substances which are candidate for substitution (factor increases from 16 to 48); and 4) not approved chemical active substances (factor increases from 64 to 96).

Group 2 is considered too large and is divided in groups 2a, 2b by incorporating two additional data sources: Regulation (EC) No 1272/2008 for Classification, Labeling and Packaging (CLP) and risk mitigation measures (RMM). The Danish propose to assign greater weight (increase from 8 to 24) to

[5] In the example dataset provided by Member State Belgium the alternative indicator HRI F2F1 BE is calculated based on the annual average sales volume in the period 2011-2013, 2015-2017 and 2018-2020 (quantities in kg).

a Group 2 chemical active substance if it is approved with one or more of these labels from CLP and/or these types of risk mitigation measures:

- Toxicity: H300 Acute toxicity (oral), H310 Acute toxicity (dermal), H330 (inhale)
- Carcinogenic: H351 (suspected)
- Reproductive toxicity: H361 (suspected)
- Toxic to aquatic life: H400 (Hazardous to the aquatic environment), H410 (Hazardous to the aquatic environment with long lasting effects)
- RMM mentioning mammals or birds
- RMM mentioning groundwater

These chemical active substances are categorized in the new Group 2b. The other chemical active substances in Group 2 are approved without any of the CLP classifications or risk mitigation measures mentioned above and these are categorized in Group 2a.

Table 4: Categories of active substances and a hazard weighting factor in HRI F2F1 SUR DK for calculating progress towards achieving national 2030 reduction target 1.

Row	**Groups**				
	1	**2a**	**2b**	**3**	**4**
(i)	*Similar to Table 1*	*Similar to Table 1, Group 2, row (i)* Substances without any of the CLP classifications or RMMs mentioned (see text)	*Similar to Table 1, Group 2, row (i)* Substances with one or more of the CLP classifications or RMMs mentioned (see text)	*Similar to Table 1*	*Similar to Table 1*
(ii)	Hazard weighting factor applicable to quantities of chemical active substance placed on the market				
(iii)	**0.1**	**8**	**24**	**48**	**96**

For each chemical active substance, the contribution to the indicator equals the product of the quantity and the hazard weighting factor. The HRI F2F1 DK score equals the sum of these contributions for all substances (Example in Annex A).

Discussion

In a meeting with LNV the criteria for comparing the methodologies to calculate the Harmonised Risk Indicator F2F1 were selected:

1. feasible amount of resources needed to calculate the indicator
2. harmonization between Member States
3. flexibility to incorporate the specific situation in the Member States
4. consistency with European registration and the protection goals

Feasible amount of resources needed to calculate the indicator

All HRI F2F1 indicators use annual quantities of chemical active substances which are reported by the Member States to the Commission. HRI F2F1 SUR uses a hazard weighting factor for four groups of substances, and HRI F2F1 DK uses the same type of hazard weighting factor for five groups of substances. HRI F2F1 BE uses for each chemical active substance in Group 1, 2, 3 additional input regarding the ecotoxicity for non-target species groups and environmental fate properties. HRI F2F1 BE also uses a scoring function and a weighting factor for each non-target species group and for each aspect of environmental fate considered.

In the course of time, new substances will appear in the dataset. Also, the group number assigned to a chemical active substance may change according to the latest registration decision. These inputs have to remain up to date with the EU registration status and the same applies to the toxicity values and fate parameters and the scoring functions used in HRI F2F1 BE. The amount of resources needed to operate and maintain HRI F2F1 BE will increase with the number of species groups and aspects of environmental fate considered. It is foreseen that the amount of resources needed to operate and maintain HRI F2F1 BE is higher compared to HRI F2F1 SUR and HRI F2F1 DK.

Harmonization between Member States

Both HRI F2F1 SUR and HRI F2F1 DK may contribute to the harmonisation between Member States and may help to keep track of progress towards achieving common targets. Differences between Member States regarding the appreciation of human and environmental protection goals will not affect the outcomes of these two indicators. The HRI F2F1 BE allows for including protection goals that are considered of relevance for a Member State. On the other hand, a protection goal considered in EU and national registration may be irrelevant for particular Member States. Such differences between Member States can't be considered in HRI F2F1 SUR and HRI F2F1 DK.

In order to warrant harmonisation in the sense of a consistent operation of the indicator, it is recommended to provide and maintain a single and unique database which contains all input required (e.g. from Eurostat, EU Pesticides Database, Pesticide Properties Database PPDB). The HRI F2F1 BE proposal suggests that the Commission provides detailed instructions regarding the selection of toxicity values and fate parameters. In addition, the range of the HRI F2F1 BE non-target species group hazard weighting factors and the environmental fate hazard weighting factors needs to be defined. Also, datasets with quantities of chemical active substances put on the market may contain missing values for toxicity values and fate parameters. A procedure for the replacement of these missing values is needed in order to be able to calculate the contribution of these substances to the HRI F2F1 BE score. In addition, instructions are needed for handling of lower limits (the character '>') in the data source.

Flexibility to incorporate the specific situation in the Member States

Both HRI F2F1 SUR and HRI F2F1 DK lack the flexibility to adapt to the specific situation in the Member State. These indicators can't incorporate differences between Member States regarding the appreciation of human health and environmental protection goals. To some extent, HRI F2F1 BE can incorporate the specific situation in the Member States. It can weigh the contribution of protection goals within the ecotoxicity part and within the environmental fate part, and it can weigh the contribution of the ecotoxicity part, the environmental fate part, and the human health part of the indicator to the overall hazard weighting factor. The product of the quantity and the overall hazard weighting factor equals the contribution of the substance to HRI F2F1 BE.

Risk assessment procedures as used in the authorisation of plant protection products may take the national specific situation into account within the exposure concentrations. Climate, soil and hydrological conditions and agricultural practices may require specific assessment methodologies. For example, in the Netherlands national specific procedures were developed for calculating the exposure concentration in surface water and in groundwater. Also mitigation measures such as drift reduction are regulated at the member state level. Since exposure is not considered in these hazard-based indicators, the incorporation of the specific situation in the Member States is limited (BE) or non-existent (COM, DK).

Consistency with European registration and the protection goals

The exposure to human groups and the environment with chemical active substances and their residues depends on multiple factors; such as the crop system, the area of use, the local environmental conditions, the application method and object treated, the application rate, the crop stage, the application timing, the formulation of the plant protection product. HRI F2F1 indicators provide a general indication of the hazards of chemical active substances only. They don't account for exposure routes or environmental fate and should not be taken as a substitute for a risk assessment. The outcome of the indicators can be used for ranking substances and for deriving trends.

HRI F2F1 SUR incorporates a hazard weighting factor for four groups of chemical active substances. Classification is based on the EU registration status and the hazard weighting factor reflects the aims of the farm to fork strategy – with the minimum value for low-risk chemical active substances and the maximum value for chemical active substances which are not approved under Regulation (EC) 1107/2009. HRI F2F1 DK incorporates a hazard weighting factor for five groups of chemical active substances and the range of the hazard weighting factor is increased compared to HRI F2F1 SUR. The extra group contains those chemical active substances with a specific CLP classification or with a specific type of risk mitigation measure mentioned in the EU registration dossier.

HRI F2F1 BE incorporates protection goals based on toxicity values and properties determining persistence and transport in soil, weighting factors for individual substances, and additional weighting factors for the non-target species groups and aspect of environmental fate considered. Aggregating risk indicator output for different species groups, for parts of the environmental and for human health, is not in line with registration procedures and neither with OECD recommendations. Within the OECD Project on Pesticide Aquatic Risk Indicators, it was recommended to use separate indicators of risk to human health and of risk to each compartment of the environment rather than a single indicator of pesticide risks. It was further suggested that specific substances with the major contribution to the indicator score for a particular risk could be identified for close attention (Pesticides Risk Indicators - OECD; ARI Summary Report). This comprises the use data and exposure data available. After all, the risk is determined by what happens in the field.

The example dataset contains instances of chemical active substances with a single non-target species group or a single aspect of environmental fate dominating the overall hazard weighting factor for that substance in HRI F2F1 BE (see also Annex A). In view of the flexibility of HRI F2F1 BE to incorporate separate hazards to species groups and aspects of environmental fate, we suggest to further analyse the behaviour and the robustness of HRI F2F1 BE. In order to improve transparency of the methodology and to prevent substances of high potential risk remain unidentified, it is further suggested to report the five chemical active substances with the largest contributions to the potential risk for each species group and for each aspect of environmental fate separately.

Recommendations

The intended use of a harmonized risk indicator is to track progress towards reduction targets and to identify substances with the largest contributions to the indicator score. We recommend to use an indicator that can express a hazard to human health, a species groups or aspect of environmental fate, rather than a single indicator of aggregated pesticide risks. We recommend these type of indicators for ranking chemical active substances and for deriving trends in the potential risk that is imposed by plant protection product use. These indicators should not be taken as a substitute for a risk assessment.

HRI F2F1 BE seems to be the indicator most suited to identify (hazard-based) contributions from substances to different protection goals to the overall hazard weighing factor. Because this indicator allows for including the protection goals that are considered of relevance for a Member State we do recommend using this type of approach, and in addition to derive individual top5 chemical active substances for each protection goal considered.

Metabolites are not considered in the indicators proposed. Some active substances (mainly herbicides) degrade into metabolite(s) with a relative high potential for leaching towards groundwater. It is recommended to incorporate the leaching potential towards groundwater into the environmental fate part of HRI F2F1 BE and to add relevant metabolites to the methodology for calculating the indicator. It is further recommended to provide a list with the metabolites mentioned for their leaching potential in the EU registration dossiers, including the values for degradation half-life and coefficient for sorption to organic matter.

Member State Belgium provided an example dataset with the HRI F2F1 BE proposal. It is recommended to further analyse the behaviour and robustness of the HRI F2F1 BE approach and to use additional datasets from other Member States as well. In order to warrant consistent operation of the Harmonised Risk Indicator F2F1 by the Commission and the Member States, the Commission is recommended to provide instructions regarding the selection of the substance toxicity data and fate properties, and to provide and maintain a single and unique data source which contains all the input required for calculating the harmonised risk indicator.

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EU Pesticides Database

Pesticide Properties Database (PPDB)

Annex A – Example dataset

In this annex, the alternative HRI F2F1 BE score is compared with HRI F2F1 SUR using the example dataset provided with the Belgian proposal. Five chemical active substances are selected from this dataset in order to explain the results in terms of the contribution to the total indicator score for HRI F2F1 SUR and for both the alternative indicators. These five substances represent the categories / groups defined in HRI F2F1 DK (laminarin, ethofumesate, beta-cyfluthrin, aclonifen and asulam).

Member State Belgium calculated the alternative indicator based on the average annual sales volume in the period 2011-2013, 2015-2017, 2018-2020 (quantities in kg). The example dataset includes: 322 chemical active substances with a quantity; toxicity to aquatic species, bees, birds and earthworms; degradation half-life and index for persistence in soil; scoring functions; and hazard weighting factors. The major part of the toxicity and fate parameters was obtained from the Pesticide Properties Database (MS BE, 2022; referring to Lewis at al., 2016).

In order to calculate HRI F2F1 SUR, the category / group number according to the indicator definition was assigned to the substances in the example dataset (MS BE, 2022; EU Pesticides Database). Next, the quantities were multiplied with the appropriate hazard weighting factor. The HRI F2F1 SUR score equals the sum of these contributions for all substances. The result is given in Table 5. They indicate a reduction in the use of chemical active substances: the total quantity in 2018-2020 is reduced with 100 – 93 = 7% compared to the base 2015-2017. The HRI F2F1 SUR score in 2018-2020 is reduced with 100 – 74 = 26%, indicating a shift towards chemical active substances with lower hazard. Table 5 also gives the example substances with the quantity, the hazard weighting factor and the contribution to the HRI F2F1 SUR score in each period.

Table 5: Example substances with the annual quantity, the hazard weighting factor and their contribution to the HRI F2F1 SUR score in three periods. Totals are based on the dataset from MS Belgium with 322 active substances.

Group			1	2	2	3	4
Substance name			laminarin	Ethofumesate	beta-cyfluthrin	aclonifen	asulam
CAS nr.			9008-22-4	26225-79-6	1820573-27-0	74070-46-5	3337-71-1
Code EUROSTAT			F06_02_05	H99_02_01	I01_01_03	H99_08_01	H04_02_01
	quantity						
period	total (kg)	(%)	(kg)	(kg)	(kg)	(kg)	(kg)
2011-2013	6338584	98	89	57994	1092	72001	10694
2015-2017 #	6446063	100	144	42598	904	81248	11693
2018-2020	6021464	93	92	43628	268	109639	15309
			hazard weighting factor				
			1	8	8	16	64
	HRI score						
period	total (-)	(%)	(-)	(-)	(-)	(-)	(-)
2011-2013	76754390	103	89	463950	8735	1152016	684416
2015-2017 #	74674364	100	144	340787	7233	1299960	748331
2018-2020	54892354	74	92	349027	2141	1754229	979776

base year

Table 6 shows the example substances with the input to calculate their contribution to HRI F2F1 BE: toxicity values and hazard weighting factors (wf) for species groups; degradation half-life and index for persistence in soil; weighting factors for the ecotoxicity, environmental fate, and human health parts of the indicator.

The calculation of the contribution to HRI F2F1 BE is explained for the low-risk chemical active substance laminarin. The maximum permissible concentration (MPC) in surface water, LD50 for bees, LD50 for birds, and LC50 for earthworms for this substance and the scoring functions result in hazard weighting factors 3, 3, 6 and 1, respectively. With equal hazard weighting factors for these four species groups, the hazard weighting factor for ecotoxicity equals (3 x 0,25 + 3 x 0.25 + 6 x 0.25 + 1 x 0.25) = 3.25. Due to the relatively long half-life in soil for laminarin, RI persistence = 7.7 (Figure 2). The scoring function for persistence returns the class number 8. Since only one aspect of environmental fate is considered, the hazard weighting factor for persistence in soil = 1.0. The hazard weighting factor for environmental fate equals 8 x 1.0 = 8.

According to HRI F2F1 SUR, the human health hazard weighting factor = 1. The resulting overall hazard weighting factor for laminarin equals (3.25 x 0.33 + 8 x 0.33 + 1 x 0.33) = 4.1.

Table 6: Example substances with the toxicity values and weighting factors (wf) for four species groups; degradation half-life and index for persistence in soil; and weighting factors for toxicity, environmental fate and human health. These are input to calculate the contribution to HRI F2F1 BE. The quantities are given in Table 5.

	species group wf	Substance group				
		1	2	2	3	4
Substance name →		laminarin	ethofumesate	beta-cyfluthrin	aclonifen	asulam
Toxicity values and weighting factors per species group → feeds into weighting factor for ecotoxicity						
MPC# AqOrg (mg/L)$	-	0.88	0.0156	0.0000032	0.0005	0.64
LD50 bees (µg/bee)	-	100	50	0.012	100	100
LD50 birds (mg/kg bw)	-	1700	2000	170	2000	1827
LC50 earthworms (mg/kg bw)	-	na	134	0.565	150	1000
wf Aquatic organisms (-)	0.25	3	6	13	9	3
wf Bees (-)	0.25	3	4	13	3	3
wf Birds (-)	0.25	6	6	9	6	6
wf Earthworms (-)	0.25	1	7	16	7	4
Soil persistence parameter and weighting factor → feeds into weighting factor for environmental fate						
DT50 in soil (d)	-	130	37.8	93.3	80.4	9
RI persistence% (-)	1.00	7.7	1	1.2	1	1
Hazard weighting factor for ecotoxicity, for environmental fate, and for human health						
wf ecotoxicity (-)	0.33	3.25	5.75	12.8	6.25	64
wf environmental fate (-)	0.33	8	1	2	1	64
wf human health (-)	0.33	1	8	8	16	64
Overall hazard weighting factor						
Overall hazard wf (-)	-	4.1	4.9	7.6	7.8	64
Contribution to HRI score						
Score 2011-2013	-	362	285136	8280	558008	684416
Score 2015-2017	-	590	209442	6856	629668	748331
Score 2018-2020	-	375	214506	2029	849705	979776

MPC = maximum permissible concentration; $ dimensions to be confirmed; % RI = Risk Index persistence in soil. RI = 1 for substances with DT50 <= 90 d and RI = 100 for substances with DT50 > 180 d. For substances with 90 < DT50 < 180, RI is a power function of DT50 (Vercruysse and Steurbaut, 2002). These boundary values for DT50 were taken from EC 91/414 (Council Directive 94/93/EC) and from the Dutch registration procedure.

As an example the scoring function for the bees toxicity data is shown in Figure 1. The values for this toxicity value in the example dataset range from 0.0008 to 1474 µg/bee (n = 304). The scoring function defines the upper class boundary for 16 classes. Class 1 contains the substance with the lowest toxicity value (the substance most toxic to bees; emamectin; LD50 = 0.0008 µg/bee). The

weighting factor for this class equals 16. Class 16 contains the substances with the highest toxicity value (the least toxic to bees; plant oils / rape seed oil, aluminum silicate and paraffin oil). The weighting factor for this class equals 1. In Figure 1 the number of substances (frequency) is plotted at the vertical axis, and the upper class boundary (LD50 in µg/bee) is plotted at the horizontal axis. The label above the bars shows the hazard weighting factor. Group 1 substance laminarin has the toxicity value LD50 = 100 µg/bee and fits in the class with weighting factor 3 (with upper class boundary 215 µg/bee).

It should be noted that the result of the distribution function depends on the substances present in the dataset. The scoring function in Figure 1 is calculated from the population of 304 chemical active substances with a quantity and a value for toxicity to bees available. The hazard weighting factor for a particular substance may change when a single substance is added to or removed from the dataset.

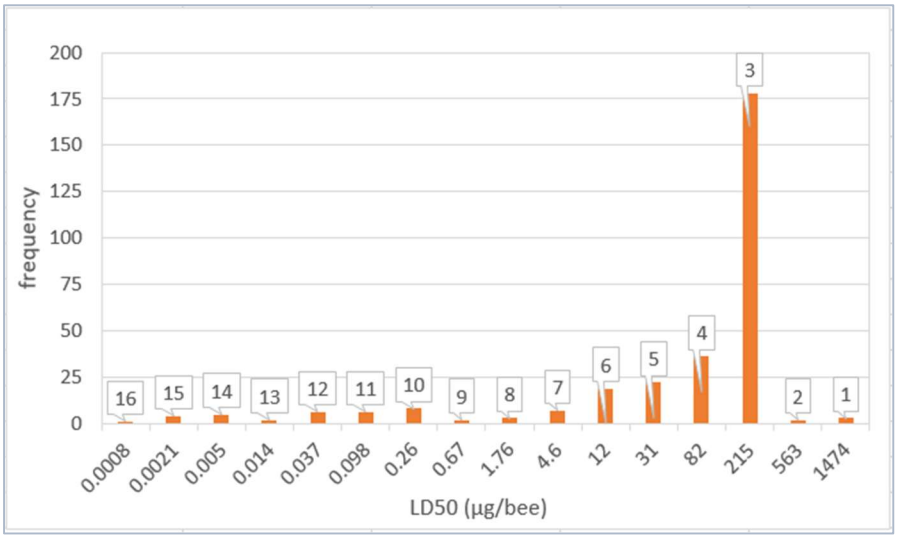

Figure 1: Scoring function for toxicity to bees (Example dataset HRI F2F1 BE; PPDB). Toxicity values in the example dataset are distributed among 16 classes. The number of substances (frequency) is plotted at the vertical axis. The upper class boundary (LD50 in µg/bee) is plotted at the horizontal axis. The label above the bars shows the weighting factor. Example substance laminarin, with LD50 = 100 µg/bee, fits in the class with weighting factor 3 (with upper boundary 215 µg/bee).

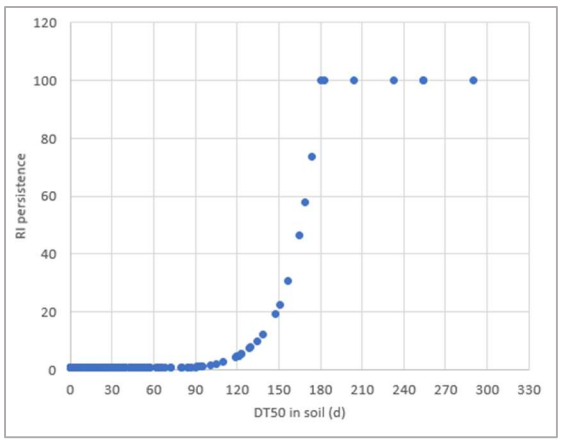

Figure 2: Risk Index persistence in soil according to POCER (Vercruysse and Steurbaut, 2002; HRI F2F1 BE). RI = 1 for substances with DT50 <= 90 d and RI = 100 for substances with DT50 > 180 d. For substances with 90 < DT50 < 180, RI is a power function of DT50.

The overall hazard weighting factor for laminarin in HRI F2F1 BE is high compared to the hazard weighting factor 1 for this substance in HRI F2F1 SUR. This is explained by the large contribution of the environmental fate part (persistence in soil), which dominates the toxicity part and the human health part of this indicator for laminarin. Note that, for the other example substances ethofumesate, beta-cyfluthrin and aclonifen, the environmental fate part has a minor contribution to the overall hazard weighting factor (Table 6).

Figure 3 shows the frequency (number of substances) of the overall hazard weighting factor in HRI F2F1 BE. The range in values of this factor results from the incorporation of several species groups and environmental fate in the HRI F2F1 BE. For Group 1 chemical active substances (weighting factor = 1 according to HRI F2F1 SUR) the overall hazard weighting factor equals 1.7, 2.5 and 4.1. Group 2 chemical active substances (weighting factor = 8 according to HRI F2F1 SUR) have the range 3.3-11 (median value 4.8; n = 239). Group 3 chemical active substances (weighting factor = 16 according to HRI F2F1 SUR) have the range 6.8-13.3 (median value 7.8; n = 59).

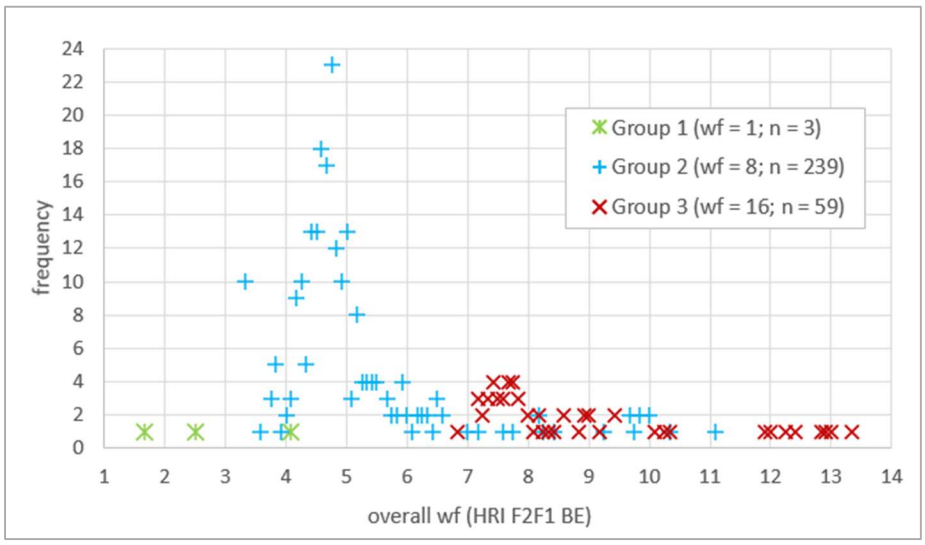

Figure 3: Frequency (number of substances) of the overall hazard weighting factor in HRI F2F1 BE. For substances in Group 1, 2 and 3 according to HRI F2F1 SUR.

The example dataset contains instances of chemical active substances with a single species group or aspect of environmental fate dominating the overall hazard weighting factor in HRI F2F1 BE (as described above for laminarin). The example dataset also contains instances of chemical active substances with a relatively high toxicity to one particular species group (e.g. bees, or aquatic) which is not reflected in the overall hazard weighting factor because the large hazard weighting factor corresponding with that relatively high toxicity is averaged out. In such cases the substance may not appear in the top5 contributions to the HRI F2F1 BE score. The behaviour of the HRI F2F1 BE and the outcome for the example dataset need to be further analysed.

The OECD recommended not to aggregate the risks to different species groups and to report the risk to each species group or protection goal separately (Pesticides Risk Indicators - OECD). In view of the flexibility of HRI F2F1 BE to incorporate aspects of ecotoxicity and environmental fate, it is recommended not only to report the HRI F2F1 BE score based on the overall hazard weighting factor,

but also to provide separate top5 chemical active substances for each species group and aspect of environmental fate considered.

The total HRI F2F1 BE score indicates towards 100 – 63 = 37% reduction in the hazards of the chemical active substances in 2018-2020. This is a further reduction compared to HRI F2F1 SUR. This is explained by the different values of the hazard weighting factors used in both indicators (Figure 3).

Table 7: Total HRI F2F1 BE score in three periods (Example dataset from MS Belgium with 322 active substances).

period	HRI score (-)	(%)
2011-2013	54370712	105%
2015-2017 (base)	51734800	100%
2018-2020	32457455	63%

Table 8 gives the Top5-chemical active substances contributing to HRI F2F1 SUR and to HRI F2F1 BE. These Top5-substances are almost the same for both indicators. The hazard weighting factor is given between brackets and the contribution to the indicator score is expressed in percentage. By definition, Group 4 chemical active substances have the same hazard weighting factor wf = 64 in both indicators (1,3-dicholoropropene, isoproturon, linuron). Group 3 chemical active substance metam (including metam-potassium and metam-sodium) is present in the HRI F2F1 SUR top5 only. This can be explained by the weighting factor for this substance: wf = 16 in HRI F2F1 SUR versus 8 in HRI F2F1 BE. For the Group 2 chemical active substances in Table 8 a similar difference between the weighting factor in both indicators can be seen; i.e. glyphosate (8 vs. 4.1), mancozeb (8 vs. 5), sulfur (8 vs. 4.7), prosulfocarb (8 vs. 5) and paraffin oil (8 vs. 4).

In view of these differences in weighting factor for the top5-substances shown in Table 1 and for the Group 1, 2, 3 substances shown in Figure 3, the behaviour and performance of these harmonized risk indicators need to be further investigated.

Table 8: TOP5-chemical active substance contribution (%) to the total score HRI F2F1 SUR and HRI F2F1 BE (wf = hazard weighing factor; Example dataset from MS Belgium with 322 active substances).

HRI F2F1 SUR						
nr.	Period 2011-2013	(%)	Period 2015-2017	(%)	Period 2018-2020	(%)
1	1,3-dichloropropene (wf 64)	11	1,3-dichloropropene (wf 64)	12	mancozeb (wf 8)	14
2	mancozeb (wf 8)	10	mancozeb (wf 8)	9	glyphosate (wf 8)	6
3	glyphosate (wf 8)	6	glyphosate (wf 8)	6	paraffin oil (wf 8)	4
4	isoproturon (wf 64)	6	metam# (wf 16)	5	sulfur (wf 8)	4
5	metam# (wf 16)	5	linuron (wf 64)	5	prosulfocarb (wf 8)	3
HRI F2F1 BE						
nr.	Period 2011-2013	(%)	Period 2015-2017	(%)	Period 2018-2020	(%)
1	1,3-dichloropropene (wf 64)	15	1,3-dichloropropene (wf 64)	17	mancozeb (wf 5)	15
2	isoproturon (wf 64)	9	mancozeb (wf 5)	8	glyphosate (wf 4.1)	6
3	mancozeb (wf 5)	8	linuron (wf 64)	7	sulfur (wf 4.7)	4
4	linuron (wf 64)	6	isoproturon (wf 64)	5	prosulfocarb (wf 5)	4
5	glyphosate (wf 4.1)	5	glyphosate (wf 4.1)	4	paraffin oil (wf 4)	3

including metam-potassium and metam-sodium

Group 2 contains 74% of the chemical active substances in the example dataset. The HRI F2F1 DK score can be calculated when the assignment of these Group 2 chemical active substances to the

new groups 2a and 2b becomes available. Table 9 shows the example substances with the hazard weighting factor according to HRI F2F1 DK and their contribution to the HRI F2F1 DK score in three periods.

Table 9: Example substances with the average quantity, the hazard weighting factor and their contribution to HRI F2F1 DK in three periods.

Group	1	2a	2b	3	4
Substance name	laminarin	ethofumesate	beta-cyfluthrin	aclonifen	asulam
CAS nr	9008-22-4	26225-79-6	1820573-27-0	74070-46-5	3337-71-1
Code EUROSTAT	F06_02_05	H99_02_01	I01_01_03	H99_08_01	H04_02_01
period	Quantity (kg)				
2011-2013	89	57994	1092	72001	10694
2015-2017	144	42598	904	81248	11693
2018-2020	92	43628	268	109639	15309
	Hazard weighting factor (-)				
	0.1	8	24	48	96
period	Contribution to HRI score				
2011-2013	9	463950	26204	3456048	1026624
2015-2017	14	340787	21699	3899880	1122496
2018-2020	9	349027	6423	5262688	1469664