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Harmonised Risk Indicators under Directive 2009/128/EC

Advisory Committee Meeting

26 November 2018

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Legal base & Objective

- Article 15.1 of SUD Directive provides for the establishment of pesticide risk indicators at EU level

- The objective is "*to measure the progress achieved in the reduction of risks and adverse impacts from pesticide use for human health and the environment"* (Recital 20).

- Commission's response (December 2017) to the European Citizens' Initiative "Ban glyphosate" committed to establish HRIs by end 2018

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Phased development and scope of indicators

- Range of indicators to be developed over three phases (Hazard based, Implementation based, Impact based)

- Criteria for First phase development:

(a) Relatively simple to calculate

(b) Uses existing and reliable official data

(c) Meets the requirement in SUD to use data collected by ESTAT and "other relevant data" (Article 15.4)

(d) Historical data available to validate approach

(e) No additional burden on Member States

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Feedback from PAFF meeting Major/common themes

- Data linked to sales of Article 53 authorisations not available for approved actives and no legal basis to collect this data
- Query on legal basis for list of low-risk and CfS actives
- Statistical data handling queries
- Limited Low Risk availability

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Current timeline

- Feedback Mechanism
- Indicative vote SCPAFF Dec
- Vote January 2019
- PRAC 3 months
- Publication Q2 2019
- Transposition period

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Draft Directive 1

- Indicator 1
- Hazard based harmonised risk indicator
- Sales volumes x weighting
- Trends in groups/categories optional for MS

Harmonised Risk Indicator 1

Row	Groups						
	1		2		3		4
(i)	Low-risk active substances which are approved or deemed to be approved under Article 22 of Regulation (EC) No 1107/2009		Active substances approved or deemed to be approved under Regulation (EC) No 1107/2009 and not falling in other categories		Active substances approved or deemed to be approved under Article 24 of Regulation (EC) No 1107/2009, which are candidates for substitution		Active substances which are not approved under Regulation (EC) No 1107/2009
(ii)	Categories						
(iii)	A	B	C	D	E	F	G
(iv)	Micro-organisms	Chemical active substances	Micro-organisms	Chemical active substances	Which are not classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors	Which are classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors and where exposure of humans is negligible	
(v)	Hazard Weightings applicable to quantities of active substances placed on the market in products authorised under Article 28 of Regulation (EC) No 1107/2009						
(vi)	1		8		16		64

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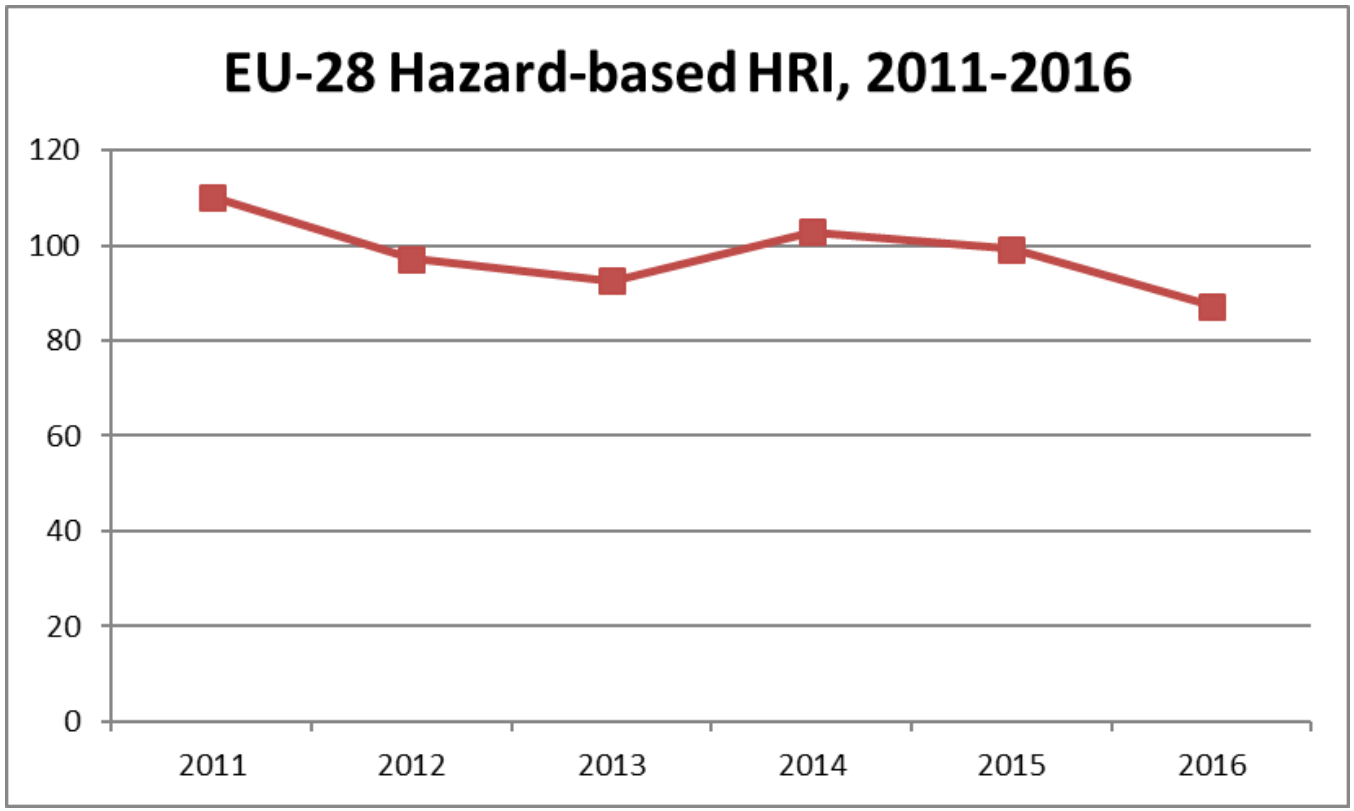
HRI EU-28



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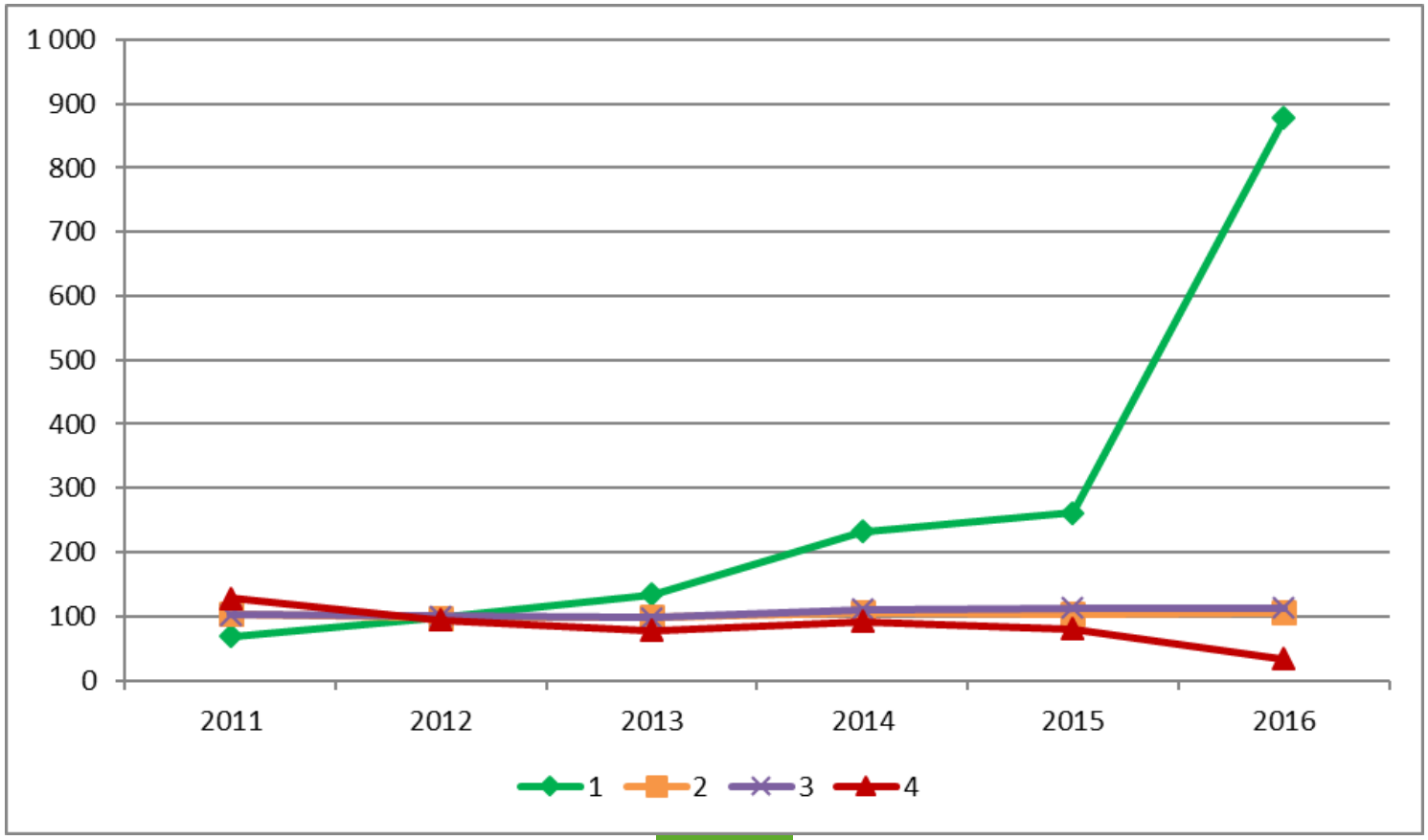
Sales trends Groups 1-4



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A revised draft Directive 2

- Indicator 2
- Strong political desire to measure trend in risk linked to Article 53
- No. of authorisations is the only harmonised data
- Harmonised risk indicator based on number of Article 53 authorisations
- Number of Art 53 authorisations x weighting

Harmonised Risk Indicator 2

Row	Groups						
	1		2		3		4
(i)	Low-risk active substances which are approved or deemed to be approved under Article 22 of Regulation (EC) No 1107/2009		Active substances approved or deemed to be approved under Regulation (EC) No 1107/2009 and not falling in other categories		Active substances approved or deemed to be approved under Article 24 of Regulation (EC) No 1107/2009, which are candidates for substitution		Active substances which are not approved under Regulation (EC) No 1107/2009
(ii)	Categories						
(iii)	A	B	C	D	E	F	G
(iv)	Micro-organisms	Chemical active substances	Micro-organisms	Chemical active substances	Which are not classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors	Which are classified as: Carcinogenic Category 1A or 1B and/or Toxic for Reproduction Category 1A or 1B and/or Endocrine disruptors and where exposure of humans is negligible	
(v)	Hazard Weightings applicable to the number of authorisations granted under Article 53 of Regulation (EC) No 1107/2009						
(vi)	1		8		16		64

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Further steps MS should take

- Calculate the HRI for the MS
- Identify trends
- Identify priority items
- Communicate the evaluation to the Commission and other MS
- Make this information public

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What will the Commission do with data?

- Calculate
- Publish annually
- Report to EP
- Engage with MS

- See policy going forward

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Suggestions for future indicators

- Implementation- certifications, advisors etc
- Number HA doses
- Soil and water residues etc
- Art 53 by volumes sold

- Others

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To conclude…..

- Indicators are a legal requirement
- Important to measure progress under SUD
- Commission response to ECI committed to a HRI
- Risk indicators need to be established under CAP
- Alternative is Commission established targets
- Risk linked to Article 53 is a priority and is captured by the new second indicator