



Failing to apply the
**precautionary
principle
in pesticide
authorisation:**

*the costly consequences
for whom?*

Angeliki Lysimachou, PhD
Environmental Toxicologist and Science Policy Officer
ENSSER PP Conference
Centre for Interdisciplinary Research, Bielefeld
October 14-15th 2019



EUR-Lex
Access to European Union law

Precautionary principle



- Treaty on the Functioning of the European Union- Article 191
- Reg 1107/2009 (Pesticide Regulation)
 - Art. 1(4). *“The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment.”*
 - Art. 13(2). Risk management decision must comply with the conditions of the precautionary principle as laid down in General Food Law (Reg 178/2002)



EUR-Lex
Access to European Union law

Precautionary principle



- Reg. 178/2002 (General Food Law) Art. 7 on PP.

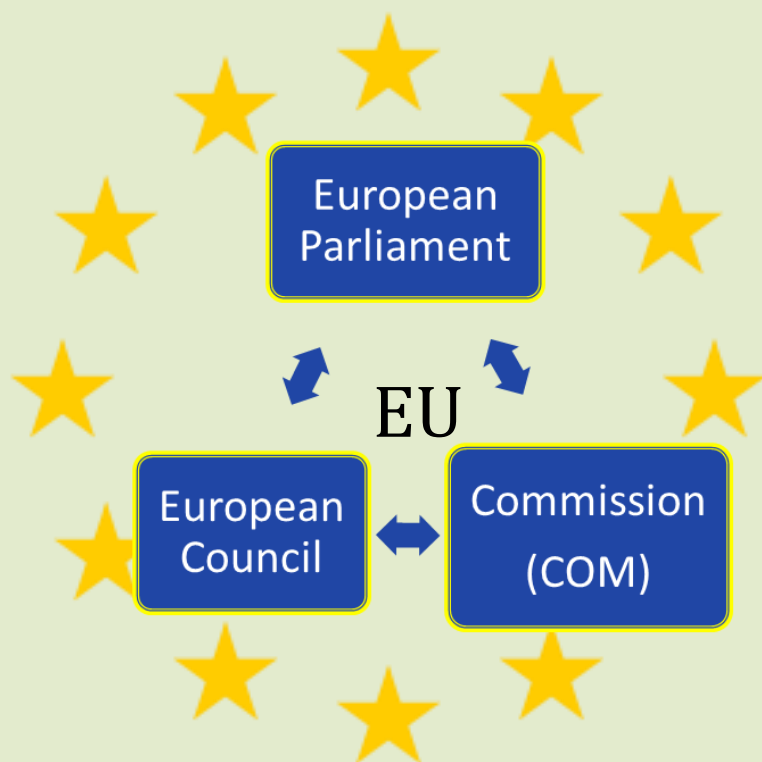
1. “In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.”

Risk managers: European Commission and Member States

Legal requirements - pesticides



Plant Protection Product Regulation (PPPR) 1107/2009:



- High level of protection for ALL
 - Humans, animals, environment
- Protect the vulnerable
 - Pregnant women, children, babies
- Apply the precautionary principle
- Consider active substances, products and residues (food & environment)
- Consider mixture effects (cocktails)

Mutagens, Carcinogens, Toxic
to Reproduction, Endocrine
Disruptors, PBTs



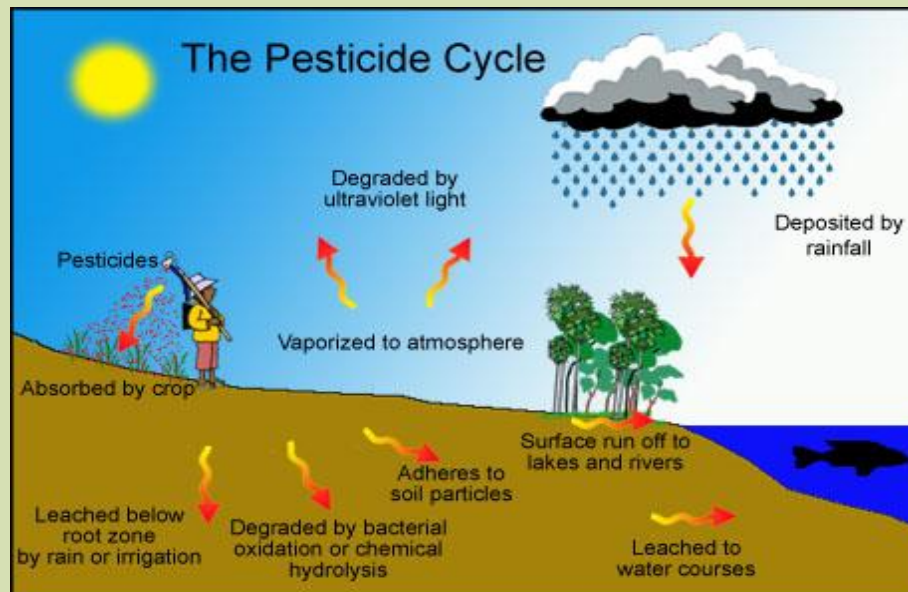
Hazards



Failing to implement PP

Legal paradox: pesticide products are designed to be toxic to living organisms and are applied on open spaces

- They adversely affect non-target organisms in the environment and may lead to population effects
- The possibility of harmful effects to humans and animals is very high



Environ Sci Pollut Res (2015) 22:19632–19647
DOI 10.1007/s11356-015-5148-5

RESEARCH ARTICLE

Pesticide authorization

Sebastian Stehle¹ · Ralf Schulz¹

Organic chemicals ecosystems on the

Egina Malaj^a
Werner Brack

Occupatio Increases

Fortes, Cristina P
Bakos, Lucio PhD

Journal of Occupational and
doi: 10.1097/JOM.000000000

Agricultural farmland bird populations

P. F. Donald, R. E. Green and M. F. Heath
Proc. R. Soc. Lond. B 2001 **268**, 25–29

ELSEVIER

The effects of insecticides on butterflies — A review[☆]

Nora Braak^a, Rebecca Neve^a, Andrew K. Jones^a, Melanie Gibbs^b, Casper J. Breuker^{a,*}



ELSEVIER

Toxicology Letters

Volume 315, 15 October 2019, Pages 55–63



Environmental exposure to pesticides

ENDOCRINE
SOCIETY

JCEM

THE JOURNAL
OF CLINICAL
ENDOCRINOLOGY
& METABOLISM

J Clin Endocrinol Metab. 2015 Apr; 100(4): 1256–1266.
Published online 2015 Mar 5. doi: [10.1210/jc.2014-4323](https://doi.org/10.1210/jc.2014-4323)

Neurobehavioral Deficits, Diseases, and Associated Costs of Exposure to Endocrine-Disrupting Chemicals in the European Union

[Martine Bellanger](#), [Barbara Demeneix](#), [Philippe Grandjean](#), [R. Thomas Zoeller](#), and [Leonardo Trasande](#)

PMCID: PMC4399309
PMID: [25742515](https://pubmed.ncbi.nlm.nih.gov/25742515/)

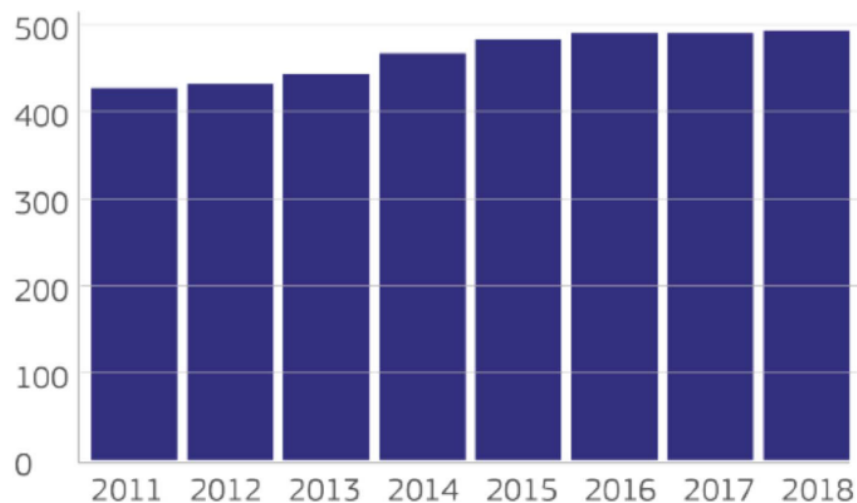


Increasing number of active substances



Availability of active substances

Total number of approved active substances per year

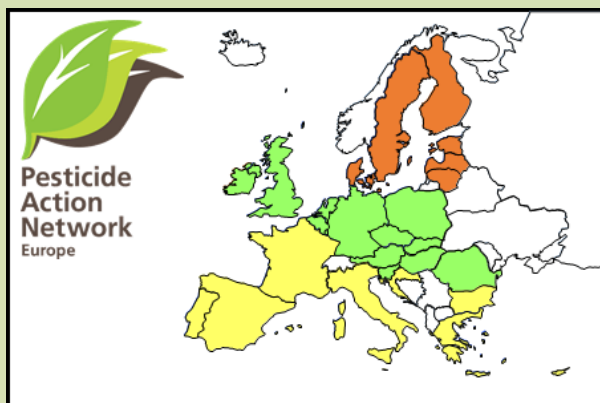


Health and
Food Safety

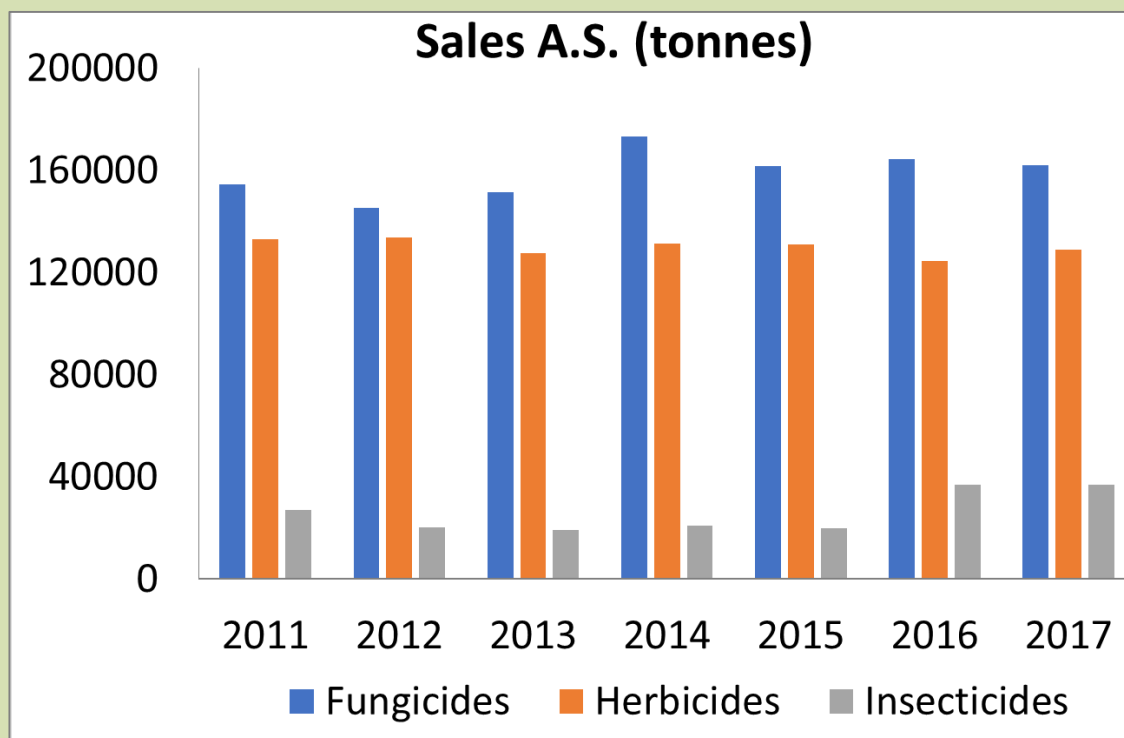
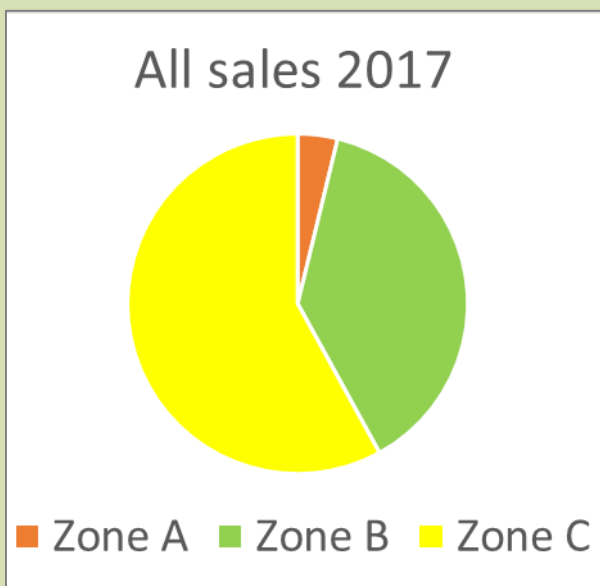
Pesticides – widespread use



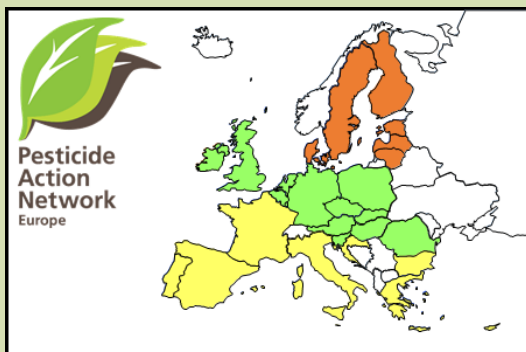
European Statistics on sales



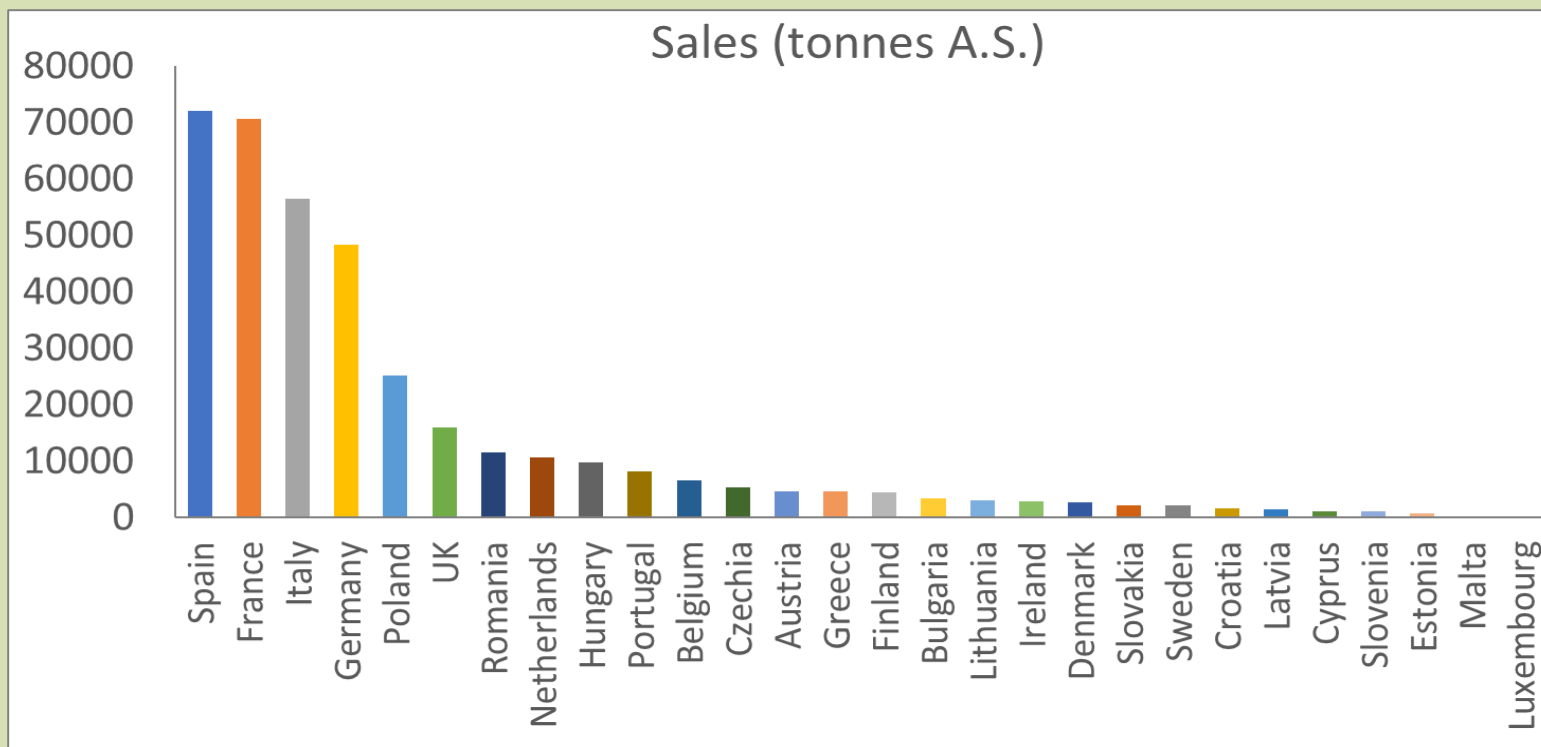
EU: Releasing
380,000 tonnes a.s./year



European Statistics

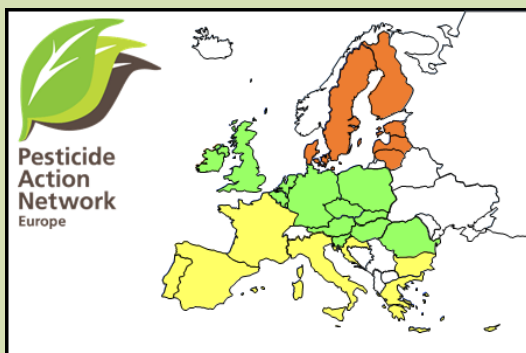


2016	EU land
Total EU agricultural area	40 %
Pesticide use	92 %

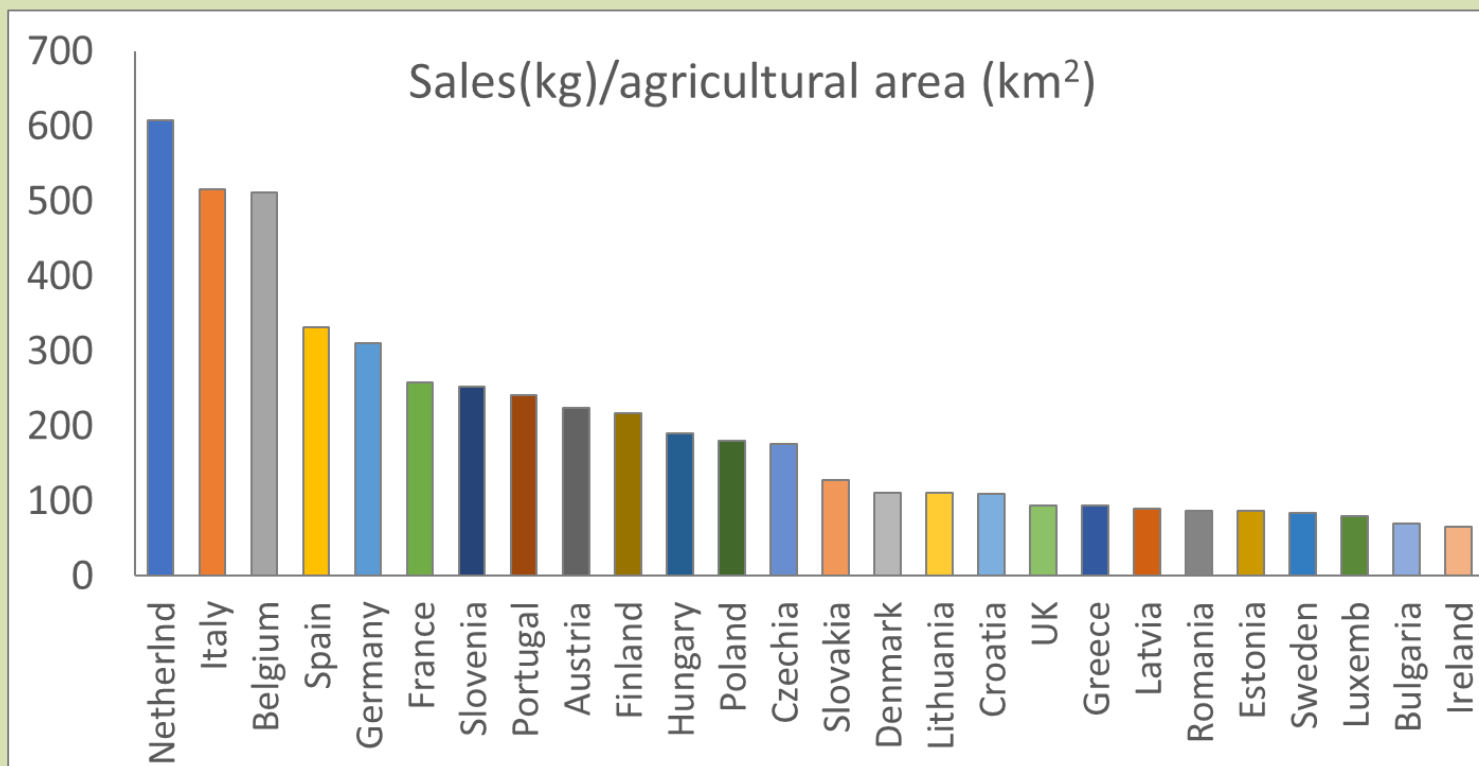


Eurostats, 2017

European Statistics



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Toxicity of authorised active substances

		type
Total A.S. approved	466	All
Carcinogens 2 (suspected)	23	HB(9), FU (10), IN (3), PG (1)
Reproductive toxicity 1b	10	HB (3), FU (4), IN (1), RO (2)
Reproductive toxicity 2	20	HB (8), FU (9), IN (1)
Two PBT	49	HB (15), FU(23), IN (8), PG(2), RO (1)
Candidates for substitution	63	All
Endocrine disruption (ED)	27	-screening exercise- HB(10), FU (13), IN(3)
ED properties (potential)	104	-screening exercise-



Precautionary principle



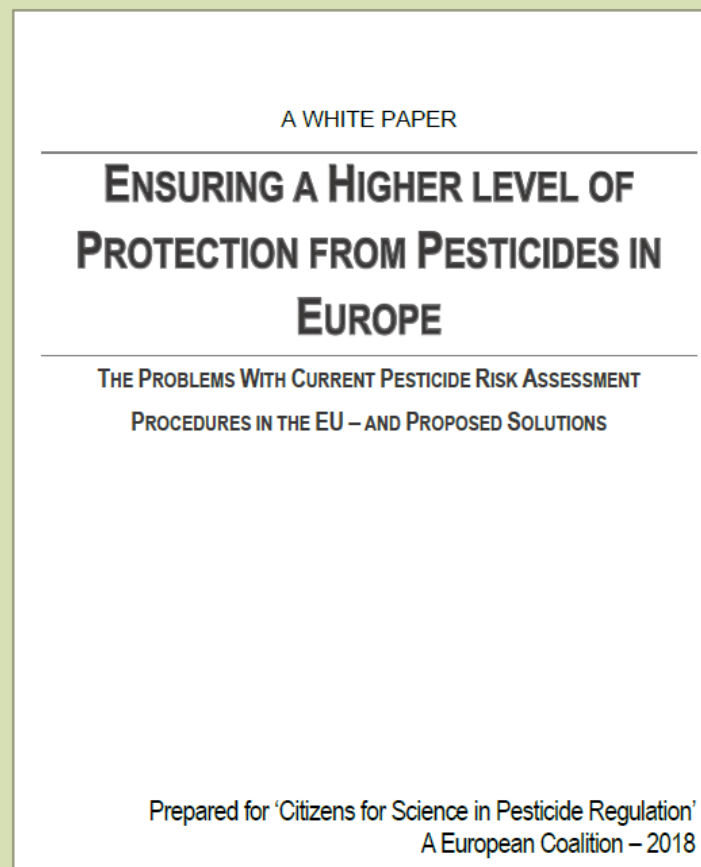
“Acting in accordance with the precautionary principle means taking action when you know there is a risk but you cannot assess precisely the level of risk.”

Health Commissioner Vytenis Andriukaitis
Annual Conference of Safe Food Advocacy
Europe
Brussels 2017



Failing to implement PP

- Risk assessment – eliminating the evidence on adverse effects
- Active substance versus products
- Pesticide mixtures



<https://citizens4pesticidereform.eu/>



Risk assessment

- Data requirements are based predominately on industry-sponsored studies



- Confidential – *foreseen to change in 2021*
- Poor reporting of adverse effects
- Adverse effects dismissed for “unscientific reasons” (e.g. historical controls, secondary effects)



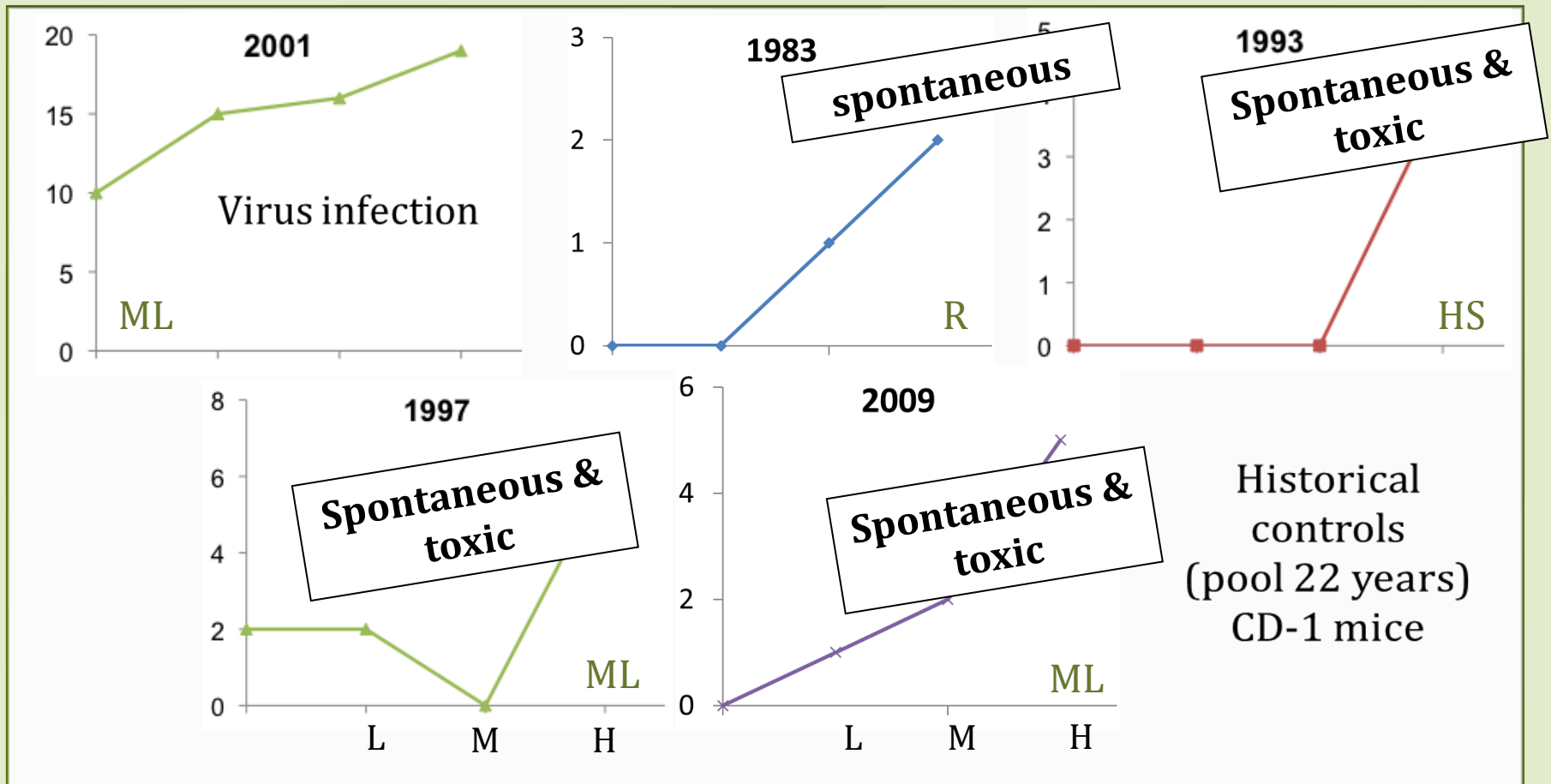
Dismissing adverse effects

- Carcinogenicity (glyphosate)



Dismissing adverse effects

- Carcinogenicity (glyphosate)
 - Adult animals
 - Tumours in 5 mice studies – statistically significant following revision





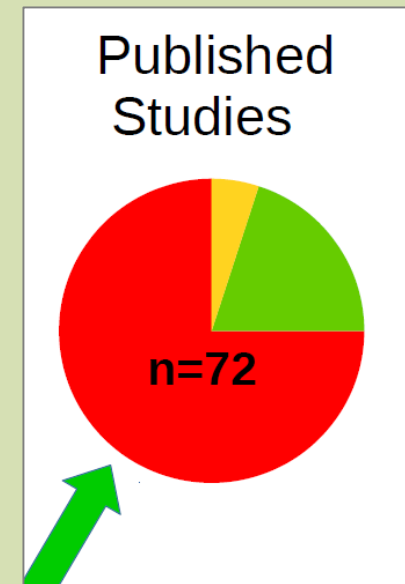
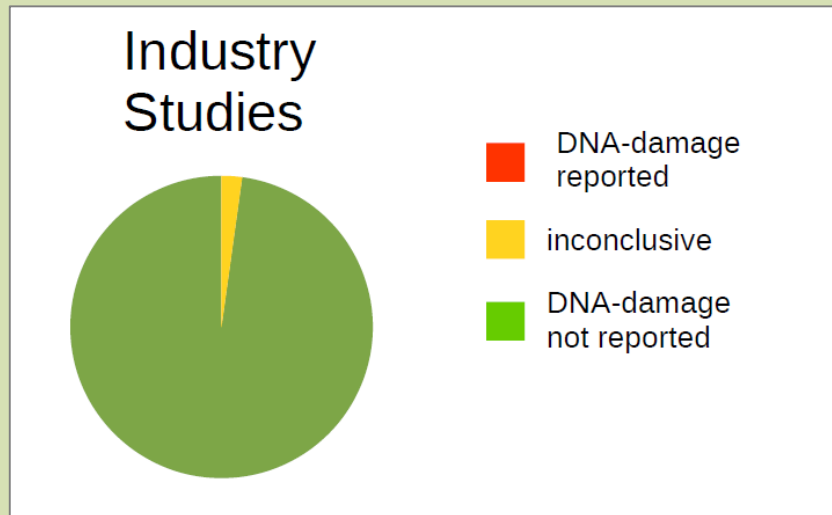
Risk assessment

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However, according to 1107/2009 Art. 8(5):

“Scientific peer-reviewed open literature, as determined by the Authority, on the active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier shall be added by the applicant to the dossier.”

Published Vs industry studies



Example: Studies on the genotoxicity of glyphosate

Source: Helmut Burtscher-Schaden, European Parliament hearing, PEST Committee 2018



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- Poor reporting of adverse effects
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- Confidential
- Academic studies dismissed as non reliable (Klimisch score, non GLP, non OECD)



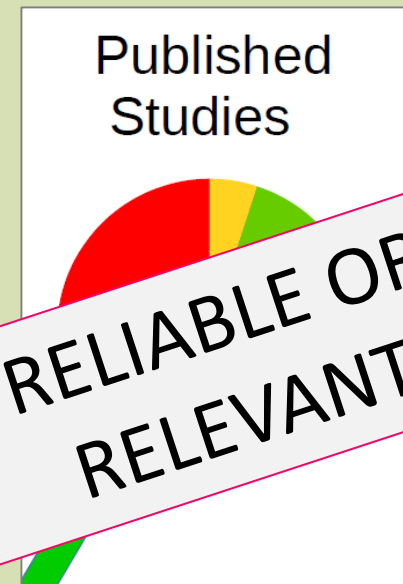
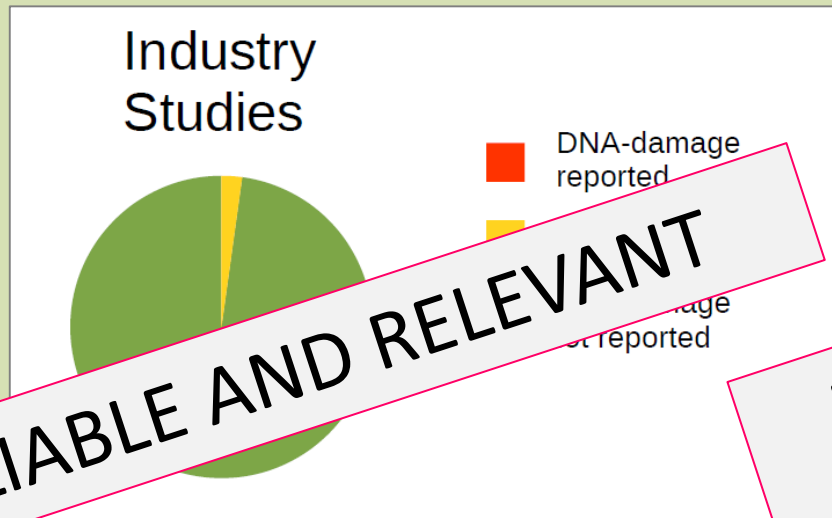
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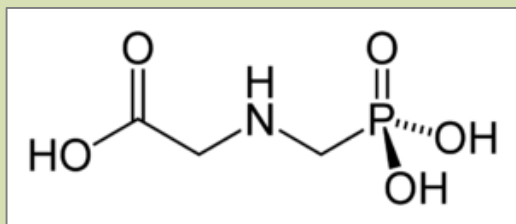
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Active Substance Vs Product

- Products are not assessed as thoroughly for chronic toxicity as active substances
- Human/mammalian chronic toxicity of products is extrapolated from the RA of active substances



EU assessment



Assessment by
Member State



Active Substance Vs Product

European Court of Justice ruling (Case C-616/17):

- Are the general rules governing the approval of glyphosate unlawful?
- On active substance:
 - The identification of the active substances is not sufficient
- On products:
 - the effects caused by the interaction between a given active substance and, inter alia, the other constituents of the product must be considered
- Current testing of plant protection products are not suffice to exclude long-term carcinogenicity and toxicity

On cumulative and synergistic effects



Legal requirements

1107/2009, Art. 4 (2a & 3b):

Pesticide products (3b) and their residues (2a) “*shall have no **harmful effect on human health**, including that of vulnerable groups, or animal health... ..**taking into account known cumulative and synergistic effects** where the scientific methods accepted by the Authority to assess such effects are available; or on groundwater*”

396/2005, Art. 14. Decisions on applications concerning MRLs:

Account shall be taken of (2b) “*the possible presence of pesticide residues arising from sources other than current plant protection uses of active substances, and **their known cumulative and synergistic effects**, when the methods to assess such effects are available;*



On cumulative and synergistic effects



Effects of pesticide mixtures are not assessed

EPA Public Access

Author manuscript

Toxicol Sci. Author manuscript; available in PMC 2019 August 02.

About author manuscripts

Submit a manuscript

Published in final edited form as:

Toxicol Sci. 2018 July 01; 164(1): 166–178. doi:10.1093/toxsci/kfy069.

Mixed “anti-androgenic” chemicals at low individual doses produce reproductive tract malformations in the male rat

Justin M. Conley*, Christy S. Lambricht*, Nicki Evans*, Mary Cardon*, Johnathan Furr*†, Vickie S. Wilson*, L. Earl Gray Jr.*‡

Food and Chemical Toxicology

journal homepage: www.elsevier.com/locate/foodchemtox

Six months exposure to a real life mixture of 13 chemicals' below individual NOAELs induced non monotonic sex-dependent biochemical and redox status changes in rats

Anca Oana Docea^{a,1}, Eliza Gofita^{a,1}, Marina Goumenou^{b,1,1}, Daniela Calina^{c,1}, Otilia Rogoveanu^d, Marius Varut^e, Cristian Olaru^f, Efthalia Kerasioti^g, Polyxeni Fountoucidou^g, Ioannis Taitzoglou^h, Ovidiu Zlatianⁱ, Valerii N. Rakitskii^j, Antonio F. Hernandez^k, Dimitrios Kouretas^g, Aristidis Tsatsakis^{b,*}

in utero exposure to 18 chemicals < LOAEL caused cumulative effects on male reproductive development

Exposure of rats to mixture of 13 chemicals <NOAELs caused hepatotoxicity



Pesticide residues in food (2015)

Fruit or Vegetable	With residues	With multiple residues	Max residues/sample
Apples	67%	46%	<u>17</u>
Lettuce	58%	36%	<u>13</u>
Peaches	75%	53%	<u>15</u>
Strawberries	76%	63%	<u>15</u>
EU (Average)	47.2%		

European Food Safety Authority (2015)



On cumulative and synergistic effects



EFSA pilot study on chronic effects on thyroid:

- Based on probabilities and assumptions, uses industry studies
- Applies the precautionary principle to conclude there is no risk
- Concludes “*Consumer risk from dietary cumulative exposure is below the threshold that triggers regulatory action for all the population groups covered*”

Temporary solution: Apply an additional safety factor of 10



Windows of opportunity

- New Commission – European Green Deal- zero pollution ambition
- European Parliament Pest Committee 2019 report
- Pesticide and MRL Regulations REFIT (review) results – overdue
- Implementation of Sustainable Use of Pesticides Directive 2009/128/EC
 - pesticide use data (volumes and impacts)
 - set measurable pesticide use reduction targets
 - give priority to non-chemical alternatives
 - protect and restore biodiversity



Thank you!

Lets work together towards a healthier future

