

PESTICIDES FORMULATIONS ASSESSMENT: PROPOSITIONS FOR A REAL IMPLEMENTATION OF 1107/2009

Workshop on the assessment of pesticides – May 23rd, 2023



Secrets Toxiques asks for an alignment of
assessment criteria for representative
formulations on the assessment criteria for active
substances

Two-years long experimental tests with a whole-
mixture approach

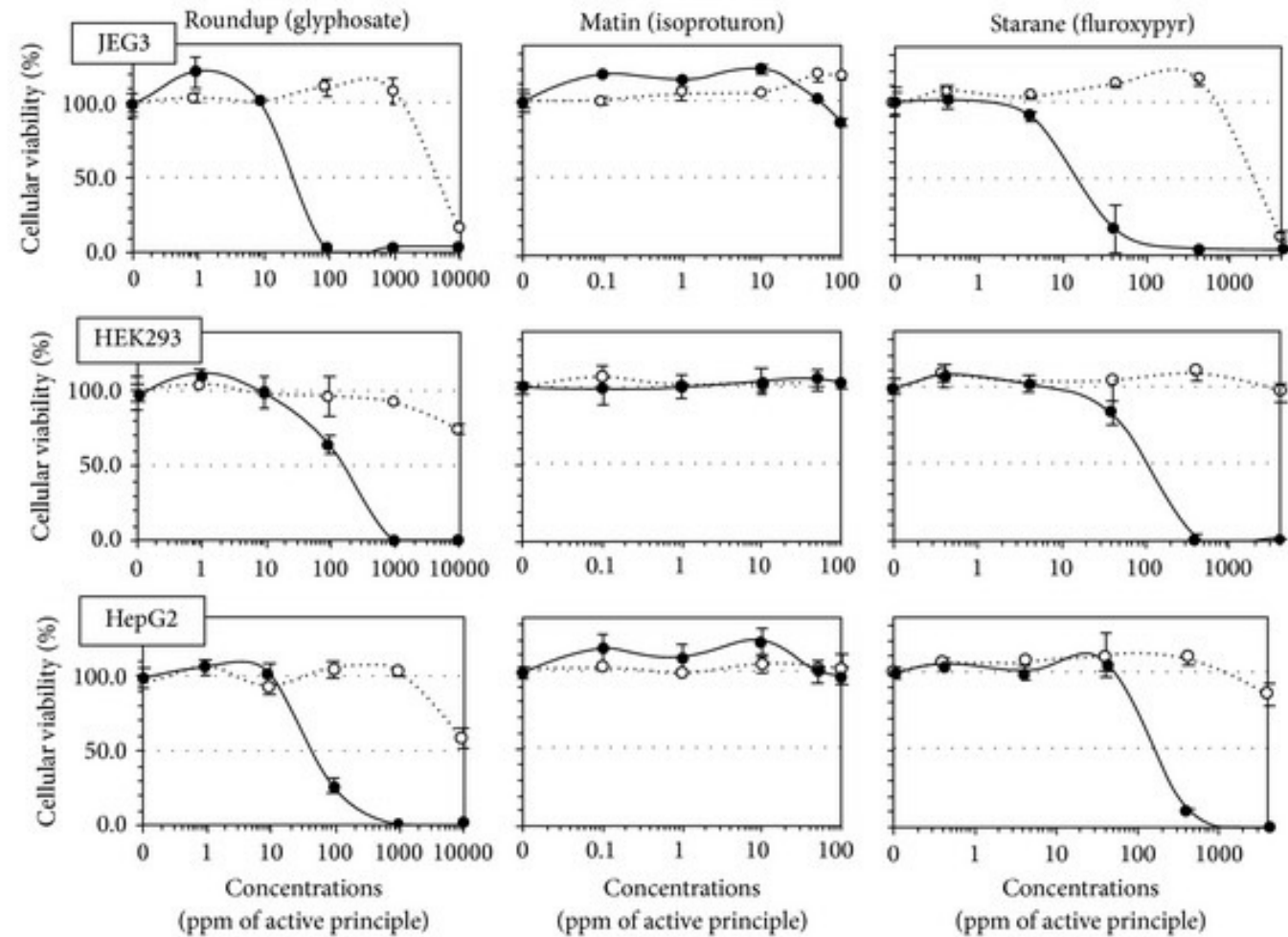
Only realistic way to meet the objectives of
1107/2009

The legal and scientific importance of assessing formulations

Major Pesticides Are More Toxic to Human Cells Than Their Declared Active Principles

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Studies on pesticides formulations (examples)

- Adam, A., Marzuki, A., Abdul Rahman, H., & Abdul Aziz, M. (1997). The oral and intratracheal toxicities of ROUNDUP and its components to rats. *Veterinary and Human Toxicology*, 39(3), 147-151.
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- Mesnage, R., Defarge, N., Spiroux de Vendômois, J., & Séralini, G.-E. (2014). Major Pesticides Are More Toxic to Human Cells Than Their Declared Active Principles. *BioMed Research International*, 2014, 1-8. <https://doi.org/10.1155/2014/179691>
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Reg. 1107/2009 clearly demands the proof of product's innocuity in normal conditions of use
(Art. 4.3 and 29)

CJEU in Blaise decision (point 116)

CNDASPE November 7th 2022: Risk assessment performed by ANSES does not meet the requirements of EU regulation

Farmers poisoned by co-formulants (Paul François)

Professional diseases resulting from chronic
pesticides exposure

What is done today and why it is insufficient

What is done today

CLP regulation

Adverse outcome pathway

No method for synergistic effects

What is done today

Component based-approach...but lack of methods
and important data gaps for long-term toxicity of
individual components

Solution pushed forward so far

Fill the data gaps: bringing up Sisyphus rock

Undeclared components in commercialised products

- Defarge, N., De Vendômois, J. S., & Seralini, G. E. (2018). Toxicity of formulants and heavy metals in glyphosate-based herbicides and other pesticides. *Toxicology reports*, 5, 156-163.
- Seralini, G. E., & Jungers, G. (2020). Toxic compounds in herbicides without glyphosate. *Food and Chemical Toxicology*, 146, 111770.
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EFSA's guidelines recommend a whole-mixture approach

- Uncertainty about the precise composition of commercialised products => « poorly defined mixture »
- « *The whole mixture approach is particularly relevant for mixtures whose composition is partially known or difficult to characterize* »

Ref. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals

<https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5634>

What we ask for

Perform on representative formulations, taken as a whole mixture, the long-term toxicity tests detailed in section 5.4, 5.5, 5.6 of Part A of Annex of Regulation 283/2013 setting data requirements for active substances

Equivalent tests for ecotoxicity (sections 8.1.2.2, 8.2.2, 8.2.5)

Double importance: MS tend to take EFSA's value of reference to assess the products they authorize

Animal testing issues

- Ex-post control is not a solution
- Replace AS tests by RF tests, since AS is never used alone in reality
- Reduce the amount of authorized products