Non-Compliance with Art. 8(5) of PPPR EU 1107/2009: 'Evaluate the Published Literature'

Four pesticides re-authorized under the new Art. 8(5) are now critiqued 'cradle to grave'–from the drafting of the risk assessment (RAR) to EFSA's 'Peer Review Report' (PRR) & Conclusion. While EFSA or rapporteur member states (RMS) often show concern that the applicant (industry) initially fails to do (or submit the findings of) the required literature review (LR), the result *after EFSA's review* is the **same** as in the initial RAR: **never is the large majority of the published literature found; sometimes none**. Scientific methods (Hoffman et al. '17), indeed EFSA guidance, require that reviews search as widely as possible, and only exclude if obviously irrelevant, see. Even EFSA's guidance says this–it warns against dismissing as irrelevant studies not using industry's test methods.

Uniformly, industry is ignoring or not complying with that guidance or the law: 1) it *fails to define their exclusion criteria, often 2) openly admits **its** relevance criterion is that a study is not an industry one* (i.e. not a Guideline (OECD, USEPA, etc.) one. Nor 3) *are its relevance broadly defined* (e.g. they call for industry's Klimisch criteria); *and 4) assessment of relevance is horribly conflated with assessing* the *reliability* of data (e.g. in EFSA's 2011 Guidance on Art. 8(5)). *The* take-home **is that while deciding whose data is more *reliable* is debatable; a LR's initial relevance criteria must be very broad (only dismiss the obviously irrelevant).** Netherlands made this exact point commenting on the Fenhexamid RAR.

A key lesson of reading RARs & PRRs is that *all parties tend to exhaustively discuss any point* raised by any in the round-robin–so if more than current 20% of academia's studies got into the RARs, a lot more analysis of 'whose data is reliable?' finally occur! -T. Tweedale R.I.S.K. Consultancy

	Glyphosate	L-Cyhalothrin	Thiabendazole	Fenhexamide	esFenveralate
Number of published studies found by search strategy	**104**	**?**	**1,971**	**616**	**?**
Num. excluded *by screening title &/or abstract* for relevance (% excluded)	97 (93%)	?	1,878 (95%)	613 (99.5%)	? (? %)
Num. excluded by *full-text* evaluation of **relevance** to study question	2	?	65	3	?
Num. excluded by full-text evaluation of **reliability**	5	handful	28	-	22 + 4
Num. deemed to be reliable studies, to set a safe dose or any other decision in RAR	**0**	**0**	**0**	**0**	**0**

Notes:

L-cyhalothrin: industry never agreed to describe the LR they claimed to have made, EFSA only asked for immune & reprotox LR (why?).

esFenvarelate: industry appears not to have provided its search strategy. Numbers are for reprotox/endocrine + ecotox searches that were briefly described, other endpoints seem all to say "no relevant published studies found". TBD if all searches were read-across for 'Fenveralate' (esFenveralate is just one of the isomers, sold by concentrated it from Fenvar.).

Glyphosate: I came across this *updated* LR of the RAR's search for endocrine effects, recently requested by Eu. Parliament, EFSA, BfR, covering Jan. '14 – Oct. '16 only. Note the original RAR was *relatively* good at evaluation the published literature (still, only 52% of PubMed-found toxicity studies were even mentioned).

EsFenvarelate: No LR originally; RMS UK did one that found 29 possibly relevant ones; EFSA commanded Sumitomo to perform one (ED/reprotox only), it found to be relevant 22 published findings of possible ED, none dismissed without evaluation for a change. But the first of those (found by EFSA's PR, actually) was dismissed for no reason at all, and the second, at a dose 10x lower than the allegedly no effect level in the key study for the safe dose, was entirely ignored in EFSA's Conclusion (being found very late, that is only place it could have been discussed).