Pre-market chemical risk assessment is controlled entirely by industry

A chemical's manufacturer provides essentially all the data for most (pre-market) chemical risk assessments (RA); academics study a chemical only once it is marketed. For two randomly-chosen high production chemicals, *despite new European Union mandates to evaluate all data*, just 13% of the herbicide bentazon and 15% of the flame-retardant hexabromocyclododecane's published toxicity studies were found in their pre-market RA, and a systematic review on bentazon concludes it has greater hazards than indicated in its RA. *More important, for both, academia's toxicity studies were designated as lower quality than industry's*, despite showing hazards at lower doses.

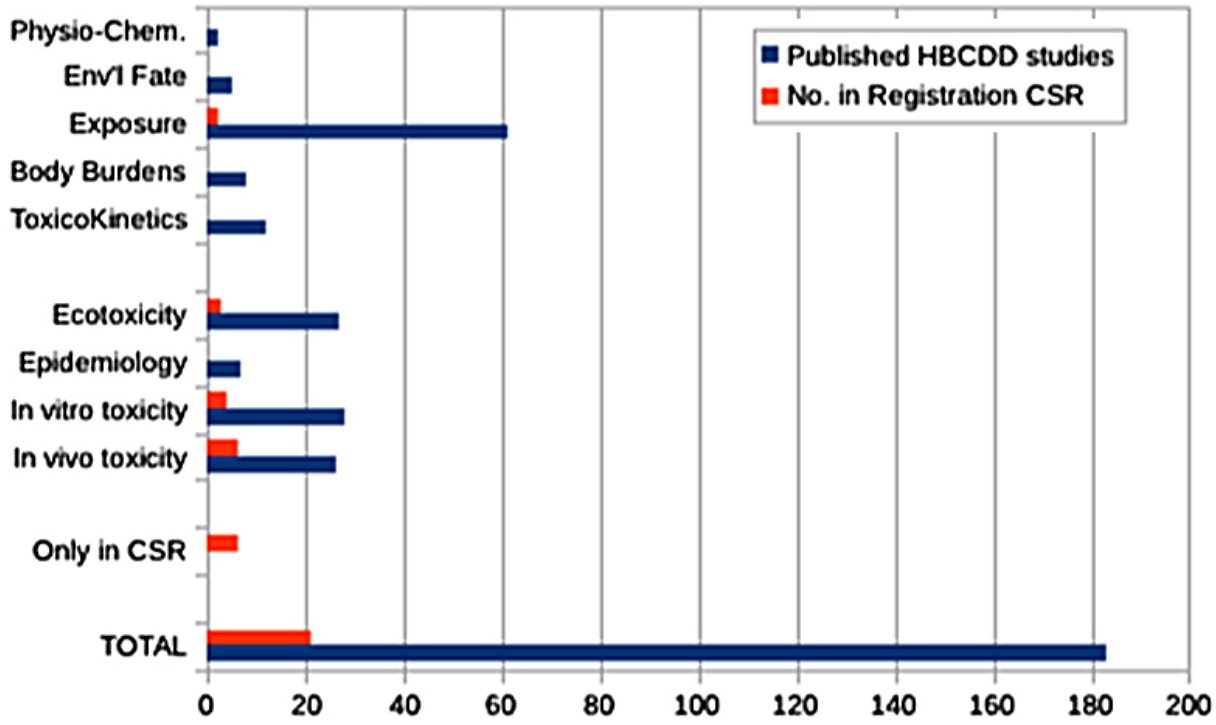

Fig. 1. Number of HBCDD studies found by REACh registrant's CSR vs published, by type. CSR, Chemical Safety Report; HBCDD, hexabromocyclododecane.

The accuracy of industry's test methods is analyzed and found to be replicable but insensitive, thus inaccurate. Their *chronic* exposure doses are derived from poisonous levels, so they do not even test our actual exposures; second, the animals are killed at the human age equivalent of ~62 years old, avoiding much chronic disease; third, they often resort to historic negative controls (an unscientific practice) when they do find toxicity, The synthetic pharmaceutical petrochemical

industry originated them, and by 1983 the Organization for Economic Cooperation & Development mandated these test guidelines (TG) methods be accepted for any new study for pre-market RA. In sum, no pre-market RA has ever used anything but an industry study to set the safe dose with. For existing studies, industry's "Klimisch" criterion is universally used to evaluate quality, but it only states that TG studies produce the best data.

However, no TG can answer the realistic exposure's effect hypotheses of academics; therefore, crucially in pre-market RA, tens of thousands of published experimental findings are ignored, which allows exposures to occur. I estimate over 6,000 low dose toxicity findings are published–common because we did not evolve in the presence of petrochemicals and because so much biochemistry in a cell requires low strength signals, which may be easily disrupted.

Klimisch data quality rank assigned by industry to the toxicity studies in REACh HBCDD Authorisation dossier

	K1 (Reliable)	K2 (Not as good)	K4 (Unreliable)	Unranked
Studies by industry	c. 30	11	4	c. 6
By academia	0	10	9	2*

* The 67 missing toxicity findings from academia of course were not ranked.

Fig. 2. REACh Registrant's ranking of HBCDD study reliability. HBCDD, hexabromocyclododecane.

Few appreciate all this (post market 'review' RA make some use of academia's toxicity findings but remain heavily influenced by TG data). Scientific and social debate on what are the most *accurate* elements test methods is urgently indicated. Borrowed from evidence based medicine (EBM), rigorous 'systematic review' of all information is the most objective answer.

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Publication

The inadequacies of pre-market chemical risk assessment's toxicity studies-the implications.
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