

claire robinson **view from the top**

Time to bring risk assessment into the real world

A baffling schism appears to exist between what independent scientists say about the health effects of chemicals and other risky products and what industry and regulators say. Typically, the scientists point to data showing problems, while industry cites other studies showing safety. Why is there this difference?

One answer is that regulatory risk assessments of chemicals, genetically modified foods and other risky substances are primarily based on studies commissioned by the very companies that stand to profit from approval of the product.

The problem with this system is bias. Scientific reviews comparing industry-sponsored or affiliated datasets with independent datasets on the same substance show that industry studies are more likely to reach a favourable conclusion. The most notorious example is in the tobacco industry, which successfully delayed regulation for decades by creating doubt about the ill effects of smoking. But the same situation affects many products in everyday use, including the food-packaging chemical bisphenol A, mobile phones, pharmaceuticals, medical products and genetically modified foods.

At the same time, regulatory bodies such as the European Food Safety Authority reject large numbers of independent studies showing harm from these products. Controversial cases include bisphenol A, where EFSA rejected hundreds of independent studies showing harm from low doses in favour of just two industry-funded studies showing safety. It's a similar story with the sweetener aspartame. Independent studies carried out at the Ramazzini Institute in Italy suggest it can cause cancer at low doses close to the present acceptable daily intake for humans. But EFSA dismissed the data and reaffirmed aspartame's safety.

These cases are not unusual. Public interest groups point to a long and growing list of chemicals condemned by independent data yet blessed by regulatory approval: octylphenol, triclosan and brominated flame retardants, all used in consumer products, as well as the pesticides glyphosate—the main ingredient of the herbicide Roundup—and neonicotinoids, suspected of being implicated in bee colony collapse.

Regulators often reject independent studies because they are not performed according to the norms for industry tests carried out for regulatory purposes—Good Laboratory Practice rules and standardised protocols set

out by the OECD. But GLP is not a hallmark of reliable science. It is a set of rules for how experiments are to be carried out and recorded. GLP was implemented in the 1970s to combat widespread industry fraud in testing for regulatory purposes. At odds with its original purpose, GLP is now used by industry and regulators as a shield to defend products against the inconvenient findings of independent science.

As for standardised OECD tests, they are being criticised by independent scientists for using outdated and insensitive methods. At a recent conference debate at the European Parliament, Fiorella Belpoggi, director of the Cesare Maltoni Cancer Research Centre at the Ramazzini Institute, explained why OECD tests miss the vast majority of cancers triggered by chemical agents. In OECD tests, the experimental rodents are killed at two years old—the equivalent of only 60 to 65 human years. So the majority of cancers, which show up after this age, are not seen. OECD tests also fail to expose animals while they are developing in the uterus and during infancy, despite evidence that exposure in these vulnerable periods results in many more cancers.

To overcome these limitations, Ramazzini researchers use a human-equivalent model that mirrors how humans are exposed to carcinogens. In a study on aspartame, the animals were allowed to live out their natural lifespan. Yet EFSA rejected the study partly because many old rodents had lung infections, which it saw as a confusing factor—even though this reflects the reality of human old age, when lung infections are common.

At Earth Open Source, we believe it's time to bring risk assessment into the real world through rigorous science. First, industry must not be allowed to test its own products. It should pay for testing through a fund administered by government, which would commission independent laboratories to conduct studies. Commercial labs will provide what regulators demand. So, if regulators reward scientific rigour, the labs will provide that.

Second, risk assessments must be based on the totality of data. Not conforming with GLP or OECD protocols must not be used to exclude data. And finally, standardised tests must be redesigned to reflect human reality and up-to-date science.

A fundamental reform of risk assessment is the only way to restore public confidence in the regulatory system.

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'It was hardly a robust year for science funding—the increase didn't even keep up with inflation.'