Independent safety reviews will foster trust in GM technology

July 23 2014, by Jack Heinemann

To rebuild public trust in GM products, safety claims must be confirmed by independent research. Credit: IRRI Photos/Flickr, CC BY

The topic of releasing genetically modified (GM) products into food and the environment is highly polarised. But are we making any progress with it?

The debate is now so vicious and impatient that to have any engagement

is taken as permission by others to tell you that you are "pro" or "anti" everything that has to do with these products, even extending to accusations of your support for the science behind them.

But a 2013 report Where there is smoke, is there fire? Responding to the results of alarming studies on the safety of GMOs, by the Dutch Commission on Genetic Modification (COGEM), is an interesting divergence from the routine.

COGEM, a statutory advisory body of scientists created to provide advice to government on GM, makes nine major recommendations on how to better support the work of, and trust in, GMO safety regulators.

I am sceptical about some of the recommendations, and about singling out certain papers by name as "alarming", while apparently neglecting that others might one day turn out to be wrongly overconfident about safety. Those caveats aside, three of its recommendations could be helpful for (re)building trust in regulation of biotechnology products.

Three key recommendations

I evaluate what I believe to be three important recommendations as a single "package" because only taken together could they hope to restore or improve public trust and reduce polarisation.

1. carry out random repeat studies or supervised inspections of GMO safety studies by companies
2. ensure in-house knowledge and competences in specific areas of science and science communication within the ministries
3. promote scientific research into the safety of GMOs by making it more attractive for researchers to carry out counter-studies and repeat studies (for example through the provision of funding and access to research materials)

There are two ways that the capacity for repeating or overseeing industry studies could be developed. One way is in the regulatory agency itself, the other in the scientific community.

Regardless of the strategy chosen, the cost should be borne by the party that expects to make the profit and without creating any sense of entitlement for meeting those costs.

The capacity for independently repeating GMO safety studies is rare or extinct in most countries. As COGEM correctly states in its report:

It was a political decision to make the person or organisation wanting to place a product, such as a GMO, on the market legally responsible for demonstrating that it is safe. This has proved to be contentious, because the company or organisation given this responsibility also has an interest in the product being found safe.

The regulator, such as Food Standards Australia New Zealand (FSANZ) or New Zealand's Environmental Protection Authority (EPA), does not demonstrate the safety of the products it regulates. It endorses (or rejects) the claims of safety made by those developing the products. That makes the recommendation to carry out random repeat studies for GM products a significant departure from what happens now.

If the regulator were to carry out such studies as part of the risk assessment, it would mean that "in-house knowledge and competences" were not just based on ability to evaluate scientific studies, but extended to the design, conduct and defence of experiments capable of challenging or critically confirming the safety studies now solely supplied by those seeking regulatory approval.

Building the capacity for risk assessment

In complying with the recommendations, governments might choose instead to outsource the science to public sector laboratories. That way any study – whether it was evidence of safety or of harm – could be put to the test.

In doing so, they would contribute to the third COGEM recommendation which is to build capacity in the wider scientific community to conduct such studies.

If this were the strategy chosen, then the testing laboratories could neither benefit from the product under test nor from finding a harm. They also need to be protected from legal challenges by developers.

Those who would be conducting these experiments must have the reasonable expectation of a productive career regardless of what they may find. This is more problematic than it might seem.

Many funding bodies have mixed the objectives of science and innovation through intellectual property licensing. Even where non-commercial public-minded science is funded, it is at levels that a research scientist cannot count on to continuously support his or her work.

The COGEM recommendation exposes a systemic erosion of public capacity to independently challenge or affirm commercial science.

To enact the third recommendation is potentially revolutionary in that it requires substantive rethinking of how we support the non-entrepreneurial but creative, spirited, dedicated, ambitious and accomplished scientist and the institution in which they work.

Different standards of evidence review

Different standards of evidence gathering are applied to scientific and regulatory work. These are acknowledged by COGEM, but not explicitly evaluated. That is an important omission for a report seeking to find ways forward in regulation of controversial technological products.

The common high standard of peer-review in research is blind (or anonymous) peer review. The characteristics of a blind system are that the authors must convince an impartial editor that they have fully and properly addressed criticisms made by expert peers who are free to be frank because their identity is protected.

The standard practice used by regulators on their own decisions is to place themselves in the position of editor, choosing who will review their findings and whether, or how, to respond to any criticisms.

The standard practice used to approve new technological products is different still, as COGEM's report explains:

Applications for marketing authorisation of GM crops also contain unpublished and non-peer-reviewed information, which suggests that different criteria apply to different stakeholders […] the studies submitted in support of permit applications also undergo a type of review in the form of appraisals by the competent authorities and advisory bodies.

The regulator does act as a sort of referee of applications because it can ask for more information or call for new experiments within the limits of the regulator's governing legislation.

Nevertheless, this and other similar review systems in common use are less stringent types of review than most research journals use. This is because the reviewer is not anonymous (and therefore not fully protected) and the materials needed to replicate the developer's

experiments are not automatically available to those wanting to verify their findings. Where such materials are made available, it is by ad hoc and limited arrangements based on where you live or where you work.

Standards of decision-making

An irony in the way these different peer-review systems are applied is that the less potential impact a decision is likely to have on the general public the greater the stringency of review.

Scientific papers published in journals have no legal standing. They cannot compel someone to do, sell or use something. In contrast, regulatory decisions determine what products and potential harms and benefits people will experience from products.

In its report, COGEM states that:

In the natural sciences a single publication is usually insufficient to convince other scientists of the validity of a claim.

Yet unpublished work from developers are used to make regulatory decisions that affect what we put in our bodies.

COGEM also observes that it "is not possible to determine immediately whether the results [of an 'alarming study'] are valid or not, and so the value of the results will have to be investigated".

Likewise, it is not possible to determine immediately whether the results of a "reassuring study" are valid or not without further investigation and replication. This double standard is routine for regulators.

Recommendations needed to address underlying

issues of distrust

Adopting these three COGEM recommendations, and implementing them fastidiously, would significantly build the trust relationship between society, government and private enterprise.

The COGEM recommendations might be criticised for being heavy-handed and bureaucratic. Implementation may select for ever more clever ways to subvert the system. Alternatively, implementation may cause a transition toward a developer-regulator interface that delivers the desired trust.

COGEM's standing may help governments to rethink how they are regulating new products. They will have to resist considerable pressure from those who would prefer both reduced regulation on new technologies and less accountability. I believe that good regulation can pay for itself in public safety, sector confidence and public trust.

Nothing less ambitious than enthusiastic and uncompromised implementation of these key recommendations is likely to advance both trust in new technologies and ensure the creation of good technologies. If the COGEM strategy worked for GM, which invokes such passion in so many, then it would likely work for many kinds of new technologies and products.

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