



Are GMOs safe to eat?
Current inadequate safety requirements.

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How GM crops are made

Biolistics

Inserted randomly

Affect function of plant?

New substance produced?

Plants, animals, bacteria, fungi, viruses

Cauliflower mosaic virus

Antibiotic resistance

Most are genetically modified to be:

Resistant to a herbicide (e.g. glyphosate)

Make it's own pesticide(s)

Both

Multi-stacked

Safety testing gold standard. Clinical trial.

Animal testing

Phase I – toxicity in healthy volunteers

Phase II – therapeutic effect

Phase III – randomised controlled trial

Phase IV – monitor

Meta-analysis / Cochrane Collaboration

FSANZ safety tests

Food Standards Australia New Zealand - food regulator for ANZ Reviewed 12 FSANZ reports covering 28 GM crops

Determine:

- Information a regulator requires
- Safety assessments GM crop companies conduct and give to regulators
- How that compares to the gold standard

Four main things to test for

Allergies – done theoretically, not on animals or humans

Cancer – not done

Reproduction – not done

Toxicity – some testing

FSANZ requires:

Compositional comparison / substantial equivalence

Usually only amino acids

Sometimes anti-nutrients

Small sample sizes

Insufficient statistical information

No definition for substantial equivalence

Corn MON810 – 44% amino acids different

FSANZ does not require

Animal studies

Human studies

Any review of the raw data

Even less required for crops with "stacked" genes. In 2014, 76% of US corn planted was stacked with both Ht and Bt genes (USDA data)

Industry acute toxicity

Only animal testing done for 61%

Of protein expected to find

Oral gavage, observe 7-14 days

Assumes:

- Only new substance is GM'd one
- Plant-produced protein acts same as bacteria-produced
- Creates disease within 14 days

Industry animal feeding studies

The crop is fed to animals – RR soy not sprayed

Unusual human health models

Use farm animals not physiologically comparable to humans, eg chickens

Endpoints not relevant to human health, e.g. death, body weight, breast meat yield

Actually animal production studies

Industry animal feeding studies for toxicology

Long-term toxicology studies on animals relevant to human health are uncommon

Animals not fed for long enough for adverse effects to develop

Number of animals too low

Often only body weights and death rates

Organs rarely inspected internally

No blood biochemistry

Adverse findings not investigated further

Published

Carman J. Is GM Food Safe to Eat? In: Hindmarsh R, Lawrence G, editors. Recoding Nature Critical Perspectives on Genetic Engineering. Sydney: UNSW Press; 2004. p. 82-93

New techniques

Two main types

- **--** CRISPR-type
- → dsRNA

One main problem

Unintended effects?

dsRNA

Silence or activate genes
In plants – eg CSIRO - change type of starch in wheat and barley
In insects – dsRNA in plant \rightarrow insect \rightarrow silences gene \rightarrow insect dies
In insects – on skin
dsRNA in non-GM plants \rightarrow blood of people
Change gene expression in mice; human cells in tissue culture

dsRNA regulation

Three government regulators, three countries
Safety not considered at all or assumed to be safe
Plan for CSIRO wheat:

- No animal studies before being fed to people.
- Look for benefit only in people. Do not look for harm.

Heinemann JA, Agapito-Tenfen SZ, Carman JA (2013). A comparative evaluation of the regulation of GM crops or products containing dsRNA and suggested improvements to risk assessments. Environment International 55: 43-55.

What should happen?

- Bioinformatics ID any likely, unintended targets
- → ID all new intended and unintended dsRNA molecules
- Test on animal and human cells in tissue culture
- Long-term toxicology testing on animals
- Intended for people? Then test on people

Regulation

New techniques, rapidly changing, evolving
No regulation means no safety testing
No regulation means DIY gene editing allowed, not regulated

Labelling

No labelling means no choice

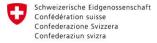
No labelling means "no" epidemiological studies

Thanks!

ANY QUESTIONS?

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