Plant breeding has the potential to save more than 1 million children each year.

THE EVOLUTIONARY STORY OF FOUR VITAL CROPS

- Without plant breeding, we would have little to eat and what we did have, wouldn’t be very tasty or nutritious.
- Most of the crops familiar to us today didn’t even exist in the wild!
- Humankind has been breeding plants for 10,000 years to improve yield, quality and taste and plant breeders today continue to improve crops with modern tools like biotechnology.
- Maize, wheat, rice, potato
Maize

- Maize (corn) originated from teosinte – a grass that was only two or three inches long with 12 hard kernels.
- After a few thousand years of selective breeding we now have modern maize which is 10 times bigger, has 500+ soft kernels and tastes delicious!
- Maize is now one of the most important crops on the planet.

**Investment & Innovation**

- More than 50 million identified Single Nucleotide Polymorphisms (SNPs) – ie point mutations – catalogued from 103 lines (Soybean 5 million so far)
- Same protein (300-400 aa) from 2 corn lines will differ on average by 3-4 aa due to SNPs
- 85% of the genome sequence of the reference inbred (B73) is identified as transposable elements – jumping genes
- Yellow maize is the result of A 382-bp Ins2 into phytoene synthase promoter region
  - Prevents the carotenoid pathway shutdown in the seed
  - Ie activation of a tissue dormant pathway

The Future of Crop Improvement with Genome Editing Technology

- The rate of crop improvement must increase to meet the demands of a growing population. Although conventional breeding has delivered today’s high-yielding crops, genome editing technologies e.g. CRISPR/Cas9, Cpf1; Gene Silencing, Gene Drives etc now offer a faster and more precise approach to generate novel crop varieties. If genomics can provide high-quality crop genome assemblies and functional annotation as starting material, genome editing has the potential to accelerate crop improvement and broaden the range of traits generated in novel varieties.
Alternative CRISPR system could improve genome editing

- In a paper published in Cell on 25 September, a team led by synthetic biologist Feng Zhang of the Broad Institute in Cambridge, Massachusetts, reports the discovery of a protein called Cpf1 that may overcome one of CRISPR/Cas9’s few limitations; although the system works well for disabling genes, it is often difficult to truly edit them by replacing one DNA sequence with another.

The Future of Crop Improvement with Genome Editing Technology

- The unclear regulatory status of genome edited crops in most countries and the lack of distinction between non-transgenic genome edited and transgenic modified crops remain important hurdles for the deployment of genome editing in crop improvement. As the functions of more crop genes are revealed and regulatory frameworks are adapted to new technologies, genome editing can provide a powerful new tool to shape the future of agriculture and support global food security.

What Is A 'Gene Drive' - The Hottest New Thing In Science?

- By inserting the CRISPR technology into the organisms, which can edit genes, gene drives cut and paste the desired gene into each generation of offspring, bypassing the normal patterns of inheritance. When a gene drive is used, the inheritance pattern on the right hand side of the figure is predicted. In only a few generations, the trait will be present in almost every member of the population. Why? Because the gene drive overrides the alleles that were inherited. It takes whatever was inherited and edits it to insert the gene that is being inserted. So, even if the fly inherited a yellow gene - a red one is cut and pasted in, making the fly red.

Bringing a crop protection product to market

- [https://youtu.be/ao1HsAk7j.s](https://youtu.be/ao1HsAk7j.s)

INVESTMENTS IN PLANT SCIENCE
Food Quality & Nutrition
Investing in agriculture is two to four times more effective at reducing hunger and poverty than any other sector. However getting these innovative new traits from the lab to their fields requires a tremendous level of investment

- Imagine spending $50 every minute for 11 years! See what the plant science industry invests to create new pest management tools for farmers
Costs for New GM and NPBT Crops

• To bring a new crop protection product to market, it takes roughly $286 million USD and 11 years of research and development
• FSANZ spends about A$1M in a budget of about A$18M on risk assessment of GM and NPBTs – EL2, 2X EL1, peer review by Section Head, GM, CEO, FSANZ Board – tempered by cost recovery but this adds costs to industry.

The Bad........

• Non-scientific media dominates the media. From alarmist pseudo-documentaries like Food Inc. and GMO OMG, to the scientifically painful inept fiction Consumed, media in this space are designed to shock and scare, knowingly at the expense of scientifically precise information.
• Deep presence of non-scientific websites, books and films that abandon science to perpetuate a popular and profitable myth. Fear is their main vehicle. For anti-corporate reasons or simply to promote high-priced, lifestyle-based food products, there are many that create hyperbole and disparaging imagery around the science of genetic engineering. Many opposed to the technology are only experts at producing media targeted to tarnish the favorable applications of these helpful technologies.

The Bad......

• Viewpoint: Greenpeace, environmental activists spread misinformation on honeybees and pesticides
• Herbicide-tainted Ben & Jerry’s ice cream? NY Times falls for anti-science group’s dubious attack on glyphosate
• Punch line: The story of glyphosate, a relatively benign herbicide, being found in Ben and Jerry’s ice cream is bad science, bad journalism, and says a lot about what passes for news at the New York Times.
Jane Goodall: Famed chimp researcher embraces questionable science on GMOs, gene drives

Jane Goodall is a primatologist, ethologist, and anthropologist, and founder of an eponymous institute that advocates for environmental conservation and animal welfare. Goodall has stirred controversy because of her vocal opposition to crop biotechnology, and more recently, CRISPR gene editing, and her promotion of what many scientists say is quack science.

Goodall published the book "Seeds of Hope: Wisdom and Wonder from the World of Plants" and dedicated a chapter to GMOs, writing: "The most recent monstrous crime against plants – at least in my view – is the tinkering with their DNA." Goodall noted that the book’s chapter on GMOs "is perhaps the most controversial of this book and one I feel the most passionate about."

It Gets Badder........

- Goodall wrote the foreword for lawyer Steven Druker’s controversial 2015 anti-GMO book “Altered Genes, Twisted Truth: How the Venture to Genetically Engineer Our Food Has Subverted Science, Corrupted Government, and Systematically Deceived the Public”.
- She called it “one of the most important books of the last 50 years”, and joined him on a promotional tour. Goodall described Druker as a hero worthy of a Nobel prize.

Ideological hypocrisy? Environmentalists once supported land-based aquaculture—until it included genetically modified fish

• There is a certain irony in the fact that Food and Water Watch has advocated, in the recent past, for some of the things this new GMO fish is designed to do. Namely, it would be grown in land-based facilities designed to prevent it from escaping into the wild. And even if it did escape, these fish are bred to be sterile, offering another safeguard against them creating problems for native fish. In other words, the AquAdvantage fish would never be in position to plague those northern European salmon-fishing spots now dealing with pink salmon — considered an invasive species in the U.K., where the Atlantic salmon is native.

And the Downright Ugly........

The now-discredited Gilles-Éric Séralini study on GM corn and rats in Mother Earth News. He framed the study as the “longest-running GMO study” (at two years) — which was not accurate. Later that year, Australian researcher and anti-GMO advocate Judy Carman released a study on pigs, this one clocking in at 154 days, and claimed that the longer-term study found differences in inflammation among pigs fed GM feed. The actual data from these, and other, studies, does not actually support the claims of harm made by the authors. But that hasn’t stopped activists from demanding animal feeding studies of increasingly longer durations, even up to 30 years.
The Good..........

- 20-year GMO report card: Biotech shrinks ag’s ecological impact, increased farm income $167 billion

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<th>ENJOY THIS</th>
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<td>BRING THIS HOME</td>
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With GMO insect-resistant sugarcane approval, Brazilian farmers poised to reap benefits of biotech pipeline

- In June, Brazil became the second country, after Indonesia, to approve the commercial cultivation of genetically engineered insect-resistant sugarcane designed to naturally ward off the potentially devastating sugarcane borer. The borer causes an estimated $1.5 billion in losses to Brazilian farmers each year.

The Good Fighting Back.........Food Evolution Documentary....It’s Not All Bad News

- But this trend is changing with a new series of scientific documentaries. The first film is Food Evolution, directed by Scott Hamilton Kennedy. The documentary examines the issues by taking a close-and-personal look at several global agricultural situations, the personalities involved, the successes, and most painfully, the damaging consequences of our failure to deploy useful technology that can help those in need. Food Evolution conveys a scientific story with imagery, humanity and compassion that scientists never could alone. The film is narrated by Dr. Neil deGrasse Tyson, adding his gravitas to this important topic.

WANTED: BAD BUG THUGS

Every year insects around the world destroy millions of tons of crops meant for human consumption. Here are some of the biggest culprits that can be controlled by genetic modification of crops:
Canada approves 3 Simplot GMO potatoes that resist blight, reduce fungicide use by half

- Three types of potatoes genetically engineered by an Idaho company to resist the pathogen that caused the Irish potato famine are safe for the environment and safe to eat, Canadian officials said.
- The approval by Health Canada and the Canadian Food Inspection Agency means the J.R. Simplot Co. potatoes can be imported, planted and sold in Canada.
- The three varieties of potato — the Russet Burbank, Ranger Russet and Atlantic — were approved by U.S. regulatory agencies in February.

How Bangladesh emerged as world innovator in pest-resistant, nutritionally fortified GM crops

- The country began adopting hybrid seeds in the mid-1990s, and in 2013 became the first nation to commercialize insect resistant Bt brinjal (eggplant). Currently, there are about 6,000 farmers cultivating four varieties of the crop. Adoption has resulted in an 80%-90% reduction in insecticide use by the farmers who plant the crop.

Genetically-modified crops included in Queensland climate change plans

Environment Minister Steven Miles

- “For long term crops, there may even be options for using genetically-modified plants that are better able to withstand high temperatures.”
- Dr Miles said some crops may grow better in different areas due to climate change, but scientists would need to work on new hybrids and species that could tolerate different levels of heat and rainfall.
- The agriculture plan warns of increased heat stress in workers and animals, a drier climate with more intense rainfall leading to higher reliance on irrigation, an increase in cyclones and bushfires.

Nigeria poised to become Africa’s GMO superpower, overcoming NGO scare campaigns

- The Nigerian Academy of Science (NAS) declared this week that genetically-modified foods are safe for consumption. The NAS, citing overwhelming evidence from developed countries and thousands of studies, said the country was ready for the products and that they were safe for production and beneficial to the nation.
- Nigeria is now poised to join Egypt, Burkina Faso, South Africa and Sudan as the only nations in Africa to cultivate genetically engineered crops. Although no GE crops are presently being grown commercially, the government has sanctioned several trials, which if successful could result in the greenlighting of insect-resistant Bt cotton, cowpea (a legume) and corn; disease resistant and Vitamin A cassava; and nitrogen and water efficient rice.
First genetically engineered salmon sold in Canada

- The genetically engineered AquaBounty salmon shown here is about twice the size of its wild kin, although both are roughly the same age.
- US firm AquaBounty Technologies says that its transgenic fish has hit the market after a 25-year wait.

Food Safety

- Food is not inherently safe
- Presumption of safety
- Food considered safe on the basis of human experience:
  - no history of adverse effects
  - adequate knowledge in community to address any hazards
- No presumption of safety for foods with no history of safe use by humans e.g. GM foods; Foods produced from NPBTs
- A formal assessment process is applied to determine safety:
  - pre-market assessment

GM Food Safety Principles - Old Paradigm
The process for assessing the safety of GM foods is based on concepts and principles developed by international organisations such as the World Health Organization (WHO), the Food and Agriculture Organization (FAO) of the United Nations, the Organisation for Economic Co-operation and Development (OECD) and the Codex Alimentarius Commission:
- be based on the best current scientific knowledge
- be carried out on a case-by-case basis (because the safety concerns depend on the type of food and the nature of the genetic modification)
- fully consider the safety of each new component in a GM food (that is, any new DNA and protein) separately
- consider both the intended effects of the genetic modification (for example, the presence of a new protein) and the unintended effects (for example, changes to the levels of toxins or allergens)
- Approach does not rely on animal toxicity studies of whole food

Traditional Codex Risk Assessment: Elements

1. Hazard identification
   Identification of the hazard associated with the chemical

2. Hazard characterisation
   Dose-response relationship

3. Dietary exposure
   Estimate of intake of chemical

4. Risk characterisation
   Probability of an adverse health effect

Acute toxicity
Allergy (type I)
Systemic toxicity
- sub-chronic
- chronic
Reproductive toxicology
Teratogenicity
Genotoxicity
Carcinogenicity
Traditional Risk Assessment

- Usually applied to a discrete chemical entity
  - e.g. new food additive
- Established studies used to identify and characterise hazard
  - e.g. animal toxicity studies, in vitro studies, metabolism, epidemiological studies
- Can derive “safe” levels of exposure (intake)
- Risk of adverse health effect and its impact determined

Whole Foods
- Traditional risk assessment not specifically designed to apply to whole foods
- Whole foods not like chemicals:
  - complex mixtures of compounds
  - not always fully characterised
  - difficulties with using traditional toxicity testing in animals

GM Food - Safety Assessment

- Modified approach used for GM foods (and any other whole foods)
- The safety of a GM food is assessed by comparison to its conventional counterpart having a history of safe use:
  - identification of new or altered hazards relative to the conventional counterpart
  - new or altered hazards subject to further assessment to determine any impact on food safety
Whole Food Toxicity Studies - why not?

- Potential for nutritional imbalances from overfeeding a single whole food
- Large multiples over anticipated human intake not achievable
- Sensitivity of animal studies to detect adverse effects from a constituent in the food may be limited
- If adverse effects are detected, may be difficult to relate these to an individual characteristic of the food

Animal Studies ..... A Huge Waste of Resources

- Animal studies are weak, lack power and have no hypothesis. If you study 500 parameters you’ll find something different between test and control groups. The longer you study, the more likely you will see differences between them. If you just look at a lot of data, and try to correlate with something, you’re more likely to make a false correlation than a true one. The few studies by anti-GMO activists cite significant differences but not actual harm.

- Currently, about 100 studies longer than 90 days have been conducted on GMO products in animals for risk assessment purposes. Only the infamous Séralini and Carman studies have raised serious safety issues. The bulk of the studies on GMOs — more than 2,000 — are 90 days or shorter, in line with accepted international guidelines. And many animal studies may not even be valuable, or even scientifically justifiable.

Data Sources

- A toxicity assessment does not necessarily require in vivo animal toxicity studies
- A toxicity assessment starts with a consideration of the potential for toxicity, e.g.
  - we know a lot about corn (maize)
  - Corn naturally has multiple transposons and single nucleotide polymorphisms
  - Genetic variation amongst corn varieties is greater than between humans and chimpanzees
  - A toxic corn has never been observed either naturally or in the multiple GM strains developed using multiple transgenes from multiple sources
  - There is no plausible mechanism for the de novo generation of toxicity in corn through insertion of a transgene
  - So, probability of producing a toxic GM corn, unrelated to the protein expressed by the transgene itself, solely through the method of insertion of a transgene, is zero
  - Therefore no requirement, or value, in toxicity studies on GM corn

What about studies purporting to show harm

- Even critical studies from anti GM activists groups tend to support GM safety when analysed honestly
  - Austrian study
    - The study itself was actually quite well conducted and extensively reported
    - Biased, selective and inept interpretation misrepresented the findings
    - When reviewed by experts the study revealed no evidence of reproductive toxicity
  - Seralini studies
    - The most positive statement that can be made is that these studies can always be used as bad examples!
  - Carman and Edwards – Pig studies fed on GM corn up to 60% of diet
### Peer-reviewed studies of GM feeds in livestock

<table>
<thead>
<tr>
<th>Study</th>
<th>Source</th>
<th>Study design</th>
<th>Test crop</th>
<th>Diet</th>
<th>Duration (days)</th>
<th>Results</th>
<th>References</th>
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**Predictable Outcomes**

- Uniquely in the field of toxicology, risk analysis based on in vitro, in silico and process evaluation (principally agronomic & compositional analysis) is 100% concordant with WF studies in experimental animals
- Reflects both
  - Negligible potential for accidental generation of unknown, unexpected toxic substances through gene insertion; the “unknown unknowns” (GW Bush)
  - High LOD of bioassays for unknowns
- Rats are a poor substitute for a HPLC (GCMS etc)
Conclusions

- Classical toxicology has very little role in GM crop risk assessment.
- Whole food studies are unscientifically invalid, uninterpretable, unethical, and unnecessary.
- Key considerations are:
  - Known characteristics of the parent crop species
    - Chemical analysis for any natural toxins in the parent crop e.g.
      - Toxic alkaloids in species of the Solanaceae (potatoes, tomatoes etc)
      - Cyanogenic glycosides in cassava
    - Consideration of novel herbicide (or pesticide) residues from herbicide tolerance genes
      - Chemical analysis of residues
    - Evaluation of the crop development process
      - Proven agronomic characteristics consistent with the parent crop and transgene
- Toxicology studies may be useful:
  - On novel herbicide or pesticide metabolite(s) not previously characterised
  - Where a truly novel active protein is to be introduced for a specific purpose (e.g., the first use of BT toxin)

GM Food Safety

- GMO’s since 1996: Over 1000 scientific studies conducted
- 20+ years of use: 3 trillion meals and snacks consumed
- 9 billion animals feed GM feed every year in US – no effects on weight or reproductive performance
- 0 food safety or health issues

Food Derived Using All Plant Breeding Technologies - Safety Assessment

- Modified approach used for GM foods extended to NPBTs (and any other whole foods)
- The safety of a GM and NPBT-derived food is assessed by comparison to its conventional counterpart having a history of safe use:
  - Identification of new or altered hazards relative to the conventional counterpart
  - New or altered hazards subject to further assessment to determine any impact on food safety

THE COMPARATIVE APPROACH
Safety Assessment of GM Food – Current Paradigm

Key steps

- History of use – donor and host
- Description of genetic modification
- Molecular characterisation
- Characterisation of novel protein
- Assessment of potential toxicity
- Assessment of potential allergenicity
- Compositional analysis
- Nutrition/feeding studies in animals

Unintended Effects – Current Paradigm

- Can (???) arise from:
  - insertion of DNA into the genome
  - expression of the new trait
  - subsequent conventional breeding steps

EVIDENCE ??????? 20 year report card says NOT likely even though earliest insertions were untidy (“dirty”) compared to later GM foods and NPBTs even cleaner and more precise.

Does this tell us something?

Relevance of genome plasticity

- 2 principle sources of “risk” in plant breeding (both for conventional and new technologies)
  - The expression of an Inserted/introduced gene(s) – or modification of the expression of an endogenous gene
  - Random genetic variability arising from the process (whether natural, conventional, biotech, NBT),

- Variability in nature is the norm
  - Both phenotypic and genotypic variability in food crops is much greater than previously recognised
  - The potential risks arising from variability secondary to NPBT and recombinant DNA techniques is related to the magnitude of that variability in comparison to that occurring naturally or in conventional breeding

Formulation of the problem

- How variable is the phenotype without genome plasticity

- How common are gene insertions in nature
  - What are the sources of the inserted genes
  - What are the consequences of those insertion

- How common are point mutations in nature
  - What are the consequences

- Is there evidence for activation of dormant pathways from either
  - Tissue versus species specific dormancy

- Is there evidence for de novo generation of toxins from mutations or insertions
Why Concerns For Unintended Changes - We can now answer our original questions

- How variable is the phenotype without genome plasticity
  - Highly variability due to agronomic, climate and environment factors

- How common are gene insertions in nature
  - Found in every plant examined
  - Very common, both endogenous and exogenous genes
  - Have never resulted in de novo toxicity
  - May up regulate existing pathways
  - May activate pathways in a specific tissue when already present and active in the whole plant

- How common are point mutations in nature
  - Exceptionally common
  - Despite tens of millions of known SNPs in corn there has never been a toxic corn (or soy, or canola or tomato...)
  - Radiation mutation of plants under conventional breeding has never produced a de novo toxin

- Is there evidence for activation of dormant pathways
  - Tissue specific activation of pathways active in the plant but dormant in the tissue has been observed
  - Activation of pathways dormant in a genus has never been observed.

- Is there evidence for de novo generation of toxins from mutations or insertions
  - Not ever despite frequent, wide spread mutation and transposition of genes

Conclusions

- The plant genome is highly plastic
- Crops are naturally genetically unstable
- Variability seen in both phenotype and genotype is considerable and normal
- Wide spread gene insertions, deletions or SNPs in a non toxic crop have never produced a de novo toxin but may up regulate known toxins already present in a crop – as can stress related to pest pressure, climate, environment, agronomic practices
- From a purist scientific perspective, the need to regulate NPBTS and the extent of any regulation considered necessary should be weighed against the now substantial body of evidence of highly plastic plant genomes and the absence of consequent hazard beyond the up regulation of production of known toxins for that genus.

Maize

- More than 50 million identified Single Nucleotide Polymorphisms (SNPs) – ie point mutations – catalogued from 103 lines (Soybean 5 million so far)
  - Same protein (300-400 aa) from 2 corn lines will differ on average by 3-4 aa due to SNPs
  - 85% of the genome sequence of the reference inbred (B73) is identified as transposable elements – jumping genes
  - Yellow maize is the result of A 382-bp Ins2 into phytoene synthase promoter region
  - Prevents the carotenoid pathway shutdown in the seed
  - Ie activation of a tissue dormant pathway

Drawing on Experience

- Theoretical, tenuous, hazards postulated 20 years ago are discordant with 2 decades of data and experience
- The first principle of science is that if the theory does not match the data the theory is wrong, not the data
  - (Bartholomeaus Theory)
- So what does 20 years of data now tell us?
Compositional analysis

- Scientific basis for even this requirement is now highly questionable
- Hugely expensive with no evidence that it adds anything to public health and safety
- Clear evidence that considerable variation due to environment often exceeds genetic influence
- During GM commercialization backcrossing of elite hybrid with parent eliminates > 99.9% of hybrid genetics (repetitive selection for introduced trait)
- Requirements for GM crops but not “conventionally” bred crops, which have greater genetic alteration, is irrational, logically inconsistent, discriminatory (Bartholomeaus Theory)

Genetic engineering is changing radically — and regulations need to adjust

- Making things more complicated: Many new tools will increasingly make nonsense of our current regulatory distinctions between “genetically engineered” crops and “conventionally bred” crops. Some methods considered “conventional” under current rules can involve complex gene sequencing, or things like using radiation to induce mutations. It’s not clear that this is inherently “safer” than genetic engineering.
- So, as an alternative, the committee argues that regulations probably shouldn’t focus on specific plant-modification techniques. Instead, we should regulate crops based on the size and novelty of the changes being made — regardless of how it’s actually done. Here’s the key passage:

The best evidence suggests current GM crops are just as safe to eat as regular crops

- Emerging new plant breeding technologies have blurred the distinction between genetic engineering and conventional plant breeding to the point where regulatory systems based on process are technically difficult to defend.
- The USNAS committee recommends that new varieties — whether genetically engineered or conventionally bred — be subjected to safety testing if they have novel intended or unintended characteristics with potential hazards. It proposes a tiered approach to regulation that is based in part on new omics technologies that will be able to compare the molecular profiles of a new variety and a counterpart already in widespread use.
- The committee does caution that modifying the DNA of plants could conceivably introduce new allergens into our foods that are difficult to test for — though, again, we haven’t seen any broad upticks in allergies among people eating GM crops. (In any case, allergens are also a risk for traditional foods, particularly imported foods that are resistant to storage)
- That’s why the report ultimately concludes that “no differences have been found that implicate a higher risk to human health and safety from [current] GE foods than from their non-GE counterparts.”

Challenging the Current Paradigm

- Key Elements for All NPBTs including GM

  - Molecular characterisation.
    - Not needed for most risk assessments today — especially the “me too”. Only needed for first time new modification and then only after meeting testable hypotheses wrt likelihood of adverse effects.
    - Characterisation of the newly expressed substances (usually proteins).
      - Not needed for most risk assessments today — especially the “me too”. Only needed for first time new modification and then only after meeting testable hypotheses wrt likelihood of adverse effects such as potential toxicity and allergenicity (not likely).
  - Compositional analysis of the food.
    - Only needed to ensure modification has not increased known toxins. May be of value to ensure no nutritional risk e.g. increased or decreased specific essential nutrients that may present a health problem.
  - Nutritional impact (if appropriate).
    - Not needed except in exceptional circumstances where presents a safety risk. Should not be required purely for public health nutrition purposes such as comparisons regarding “healthiness” with similar foods produced using other methods (not food safety).
  - Useful for industry to undertake for proof of concept and marketing.

Type and location of commercially grown genetically engineered crops in 2015. In 2015, almost 180 million hectares of GE crops were planted globally. More than 70 million hectares were planted in the United States. (National Academies of Sciences. “Genetically Engineered Crops: Experiences and Prospects”)
New Challenges for Regulators

- E.g. Work using CRISPR on mushrooms where the process did not introduce any foreign DNA into the mushrooms. Developers wanted to know if the product would be considered a "regulated article" by the Animal and Plant Health Inspection Service, a division of the U.S. Department of Agriculture tasked with regulating GMOs.
- "APHIS does not consider CRISPR/Cas9-edited white button mushrooms as described to be regulated," they replied in 2015.
- The mushrooms were not the first genetically modified crop deemed exempt from current USDA regulations, but they were the first made using CRISPR.
- The heightened attention that CRISPR has brought to the gene editing field is forcing policymakers in the U.S. and abroad to update some of their thinking around what it means to genetically modify food.

Questions for the Future

- Is it time to rethink the necessity altogether for safety testing of GM food and other foods produced across all NPBTs?
- Well even though I believe they are not probably necessary at all........
- Or at least reduce regulatory food safety assessment requirements for GM foods based on 20 years of experience and, as a flow on effect, adopt a similar approach for food produced across all NPBTs that are likely to have no safety concerns based on testable hypotheses?
- Costs far outweigh the benefits! Is it just window dressing in our comfort zone to make us feel better about ourselves?
- Answer : Yes (my view)

Future Challenges – Can we afford to continue given the costs to society?

- The costs of safety testing for GM food alone— industry, government, consumers – is enormous
  - Industry research and data collection/trials, administration, training, resources – scientific, administrative and regulatory staff, laboratories etc etc – refer to previous slides on costs for regulation
  - Regulatory requirements and costs to governments (Federal, State/Territory, local council) – developing legal standards, recruiting and training staff to undertake assessments; labelling issues; enforcement issues, dispute settlements etc etc – difficult to estimate but to FSANZ alone probably conservatively A$1M/yr – in a budget of A$18M (subtracting cost recovery which adds to industry costs).
  - Costs to consumers eventually via taxes etc to support control systems
  - Multiply these across the globe
  - $ Billions - Trillions???? Imagine how these $$$$ could be better spent????

Conclusions : Safety Assessments Across All NPBTs

- We have vast experience of GM crops, GM food safety and accumulating knowledge on NPBTs
- Many regulatory assessment requirements are now unnecessary for crops such as corn, canola, cotton, rice based on 20 years of crop testing and consumption by the community with NO adverse effects
- The safety of all NPBTs should be treated the same as for GM food with same requirements depending on the crop
  - require no testing or reduced testing according to first and second points
- The safety of food derived from ALL NPBTs should be approached on a case-by-case basis in the same way as GM food safety, but testable hypotheses regarding the likelihood of adverse effects should be developed and regulatory requirements based on likely risk, not because the technology sounds scary! E.g. CRISPRs, ZFNs, gene silencing etc etc.
Food Risk Assessment

The Task...

Ensure Everything They Eat is Safe... for 90 years