

# “Innovation, Precaution and Benefit-cost Analysis – What Went Wrong with GMOs?”

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# About ITIF

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- Independent, nonpartisan research and education institute focusing on intersection of technological innovation and public policy, including:
  - Innovation and competitiveness
  - IT and data
  - Telecommunications
  - Trade and globalization
  - Life sciences, agricultural biotech, and energy
- Formulates and promotes policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress
- World's top think tank for science and technology policy, according to the University of Pennsylvania's authoritative *Global Go To Think Tank Index*

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# What is the purpose of regulation?

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- To prevent, manage, or mitigate *unreasonable* risk.
- $R = H \times E$
- Zero risk is *not* the objective.
- Absolute risk can rarely be calculated.
- Relative risk is easy to discern.

# What is a good regulation?

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- Applies measures proportional to risk (required by WTO/SPS)
- Calculates/makes decisions based on relative risk
- Costs imposed by regulation should be lower than resulting benefits (i.e., positive ROI)

# What are the relative risks of crops & foods improved through biotechnology?

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- **1986 - Coordinated Framework: No new legislation required.** <https://www.nap.edu/catalog/18907/introduction-of-recombinant-dna-engineered-organisms-into-the-environment-key>
- **NAS 1987 – no novel hazards; no unique hazards** <https://www.nap.edu/catalog/18907/introduction-of-recombinant-dna-engineered-organisms-into-the-environment-key>.
  - NAS – 11 studies/30 years all reaffirm 1987 findings.
  - Nicolia et al. 2013 An overview of the last 10 years of genetically engineered crop safety research <http://www.agrobio.org/bfiles/fckimg/Nicolia%202013.pdf>
  - A. L. Van Eenennaam and A. E. Young, Prevalence and impacts of genetically engineered feedstuffs on livestock populations [https://www.texasgrassfedbeef.com/sites/default/files/pdf/gmo\\_livestock\\_feeds\\_analysis\\_j\\_anim\\_sci-2014-van\\_eenennaam-4255-78.pdf](https://www.texasgrassfedbeef.com/sites/default/files/pdf/gmo_livestock_feeds_analysis_j_anim_sci-2014-van_eenennaam-4255-78.pdf)
  - Daniel Norero, 2017, More than 280 scientific and technical institutions support the safety of GM crops, <http://www.siquierotransgenicos.cl/2015/06/13/more-than-240-organizations-and-scientific-institutions-support-the-safety-of-gm-crops/>
  - EU: “The main conclusion to be drawn from the efforts of more than 130 research projects, covering a period of more than 25 years of research, and involving more than 500 independent research groups, is that biotechnology, and in particular GMOs, are not per se more risky than e.g. conventional plant breeding technologies...” [http://ec.europa.eu/research/biosociety/pdf/a\\_decade\\_of\\_eu-funded\\_gmo\\_research.pdf](http://ec.europa.eu/research/biosociety/pdf/a_decade_of_eu-funded_gmo_research.pdf)
  - Three decades, 30+ countries, 4 billion acres, hundreds of billions of meals eaten, not so much as a sniffle or headache attributable to “GM”.

# What “GMOs” are commercialized today?

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- Corn
- Cotton
- Soybeans
- Canola
- Squash
- Sugar Beet
- Alfalfa
- Papaya
- Potato
- Brinjal
- AquAdvantage Salmon
- Pharm cattle (Hematech)

# What was in the pipeline in 2000?

## Field Releases\* : Infrequent Crops and Microorganisms 1987 - 1999 (12/31/2000)

### Infrequent Crops : ( 5 or less issued)

<i>Allegheny Service Berry</i>	<i>Pea</i>
<i>American Chestnut</i>	<i>Pineapple</i>
<i>Belladonna</i>	<i>Plum</i>
<i>Chrysanthemum</i>	<i>Raspberry</i>
<i>Chicory</i>	<i>Spruce</i>
<i>Coffee</i>	<i>Sweetgum</i>
<i>Cranberry</i>	
<i>Eggplant</i>	<i>Sweet Potato</i>
<i>Geranium</i>	<i>Texas gourd</i>
<i>Gladiolus</i>	<i>Watermelon</i>
<i>Kentucky Bluegrass</i>	
<i>Oat</i>	
<i>Onion</i>	
<i>Papaya</i>	

### Microorganisms: (issued )

*Clavibacter xyli*  
*Cephalosporium gramineum*  
*Cryphonectria parasitica*  
*Fusarium graminearum*  
*Pseudomonas putida*  
*Pseudomonas syringae*  
*Rhizobium efli*  
*Rhizobium fredii*  
*Rhizobium leguminosarum*  
*Rhizobium meliloti*  
*(TMV) Tobacco Mosaic Virus*  
*Xanthomonas campestris*

### Other organisms: (issued ) INVERTEBRATES:

- \* *Predatory Mites*
- \* *Predatory Nematodes*

\*Permits and  
Notifications

# Is the present approach working? (1/2)

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- **European Academies Science Advisory Council, 2015: The misuse of the precautionary principle has led to restrictive legislation and both a political and market mistrust of genetically modified organisms (GMOs). This has had a profound chilling effect on both public and private investment for European agricultural research.**
- **Evidence indicates that EU policy, practices and perspectives have sometimes constrained the use of crop genetic improvement technologies in African countries, creating difficulties for scientists, farmers and policy-makers.**
- **Evidence indicates that the slow and expensive EU GM regulatory framework has acted as an obstacle to agricultural innovation. The EU is falling behind international competitors in efficient land use for food production and other applications in the bioeconomy.**
- **The current EU regulatory framework adds to the time and cost of new crop development in Europe – on average four years and 7 million Euro in direct costs per variety.**
- **EASAC concludes that the potential benefits of crop genetic improvement technologies are very significant. [https://easac.eu/fileadmin/PDF\\_s/reports\\_statements/Easac\\_14\\_NBT.pdf](https://easac.eu/fileadmin/PDF_s/reports_statements/Easac_14_NBT.pdf).**

# Is the present approach working? (2/2)

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- **United Kingdom Advisory Committee on Releases to the Environment, 27 August 2013**  
**<https://www.gov.uk/government/publications/genetically-modified-organisms-the-case-for-new-regulations>**.
- **Our understanding of genomes does not support a process-based approach to regulation. The continuing adoption of this approach has led to, and will increasingly lead to, problems. This includes problems with consistency, i.e. regulating organisms produced by some techniques and not others irrespective of their capacity to cause environmental harm.**
- **Our conclusion, that the EU's regulatory approach is not fit for purpose for organisms generated by new techniques, also applies to transgenic organisms produced by 'traditional' GM technology. Whilst it is clear that these will be captured by the GMO legislation, the potential for inconsistency is inherent because they may be phenotypically identical to organisms that are not regulated.**

# How can we fix broken regulatory regimes?

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- Every regime on earth is broken, either by design or in implementation.
- The “Precautionary Principle” driving the EU approach (& emulators) is intellectually bankrupt and scientifically indefensible.
- “Process based” approaches are scientifically indefensible.
- It’s time to resurrect basic principles:
  - Regulations must be proportional to the hazards they aim to manage
  - Relative risk is the standard for comparison
  - Achieving zero risk is not the objective, but rather managing/mitigating *unreasonable* risk.
  - The opportunity costs of bureaucratically prolonged reliance on obsolete technologies must be factored in
  - Regulation must be informed by data and experience, not fear-based marketing driven by special interest mythmongering.
  - [http://www2.itif.org/2017-usda-aphis.pdf?\\_ga=2.252744265.1117129492.1552495030-1394096080.1536250378](http://www2.itif.org/2017-usda-aphis.pdf?_ga=2.252744265.1117129492.1552495030-1394096080.1536250378) & [http://www2.itif.org/2017-fda-comments.pdf?\\_ga=2.244446917.1117129492.1552495030-1394096080.1536250378](http://www2.itif.org/2017-fda-comments.pdf?_ga=2.244446917.1117129492.1552495030-1394096080.1536250378) & [http://www2.itif.org/2017-fda-ge-plants.pdf?\\_ga=2.244446917.1117129492.1552495030-1394096080.1536250378](http://www2.itif.org/2017-fda-ge-plants.pdf?_ga=2.244446917.1117129492.1552495030-1394096080.1536250378) & [http://www2.itif.org/2017-unshackle-agricultural-innovation.pdf?\\_ga=2.244446917.1117129492.1552495030-1394096080.1536250378](http://www2.itif.org/2017-unshackle-agricultural-innovation.pdf?_ga=2.244446917.1117129492.1552495030-1394096080.1536250378)



“Well, well—this should create a nice little wave of panic and hysteria.”

©1992 by Sidney Harris in *From Personal Ads to Cloning Labs*, W.H. Freeman

# Thank You!

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