

New generation GM animals – practical and regulatory implications

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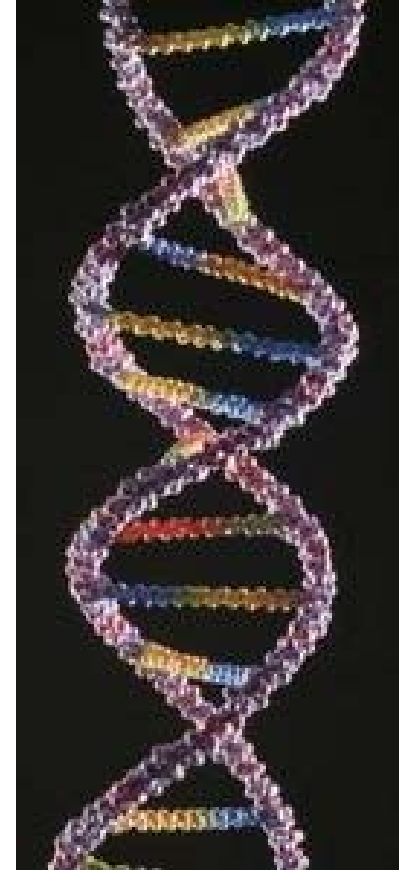


New generation GM animals

- **Background**
- **Advancements in GM technologies**
- **Applications – where are they in the pipeline?**
- **Existing regulatory frameworks**
- **Observations and insights**

Background

- Since the emergence of the first GM animals in the 1980s, science has evolved, from conventional injection techniques to far more refined methods.
- Regulatory frameworks have had to adapt to the challenges presented by the new technologies.
- Focuses on regulation in the EU, US, India, China, Argentina, Brazil and Australia.



Advancements in GM technologies

Limitations; low efficiency and targeting issues

Ability to more easily and precisely modify animals with less effort and cost required

Nuclear injection

SCNT

RNAi

Lentiviral vectors

Homing Endonucleases

ZFN

TAL effector nucleases

1980

Present day

Applications

GM animal applications

Disease resistance	BSE, mastitis, visna virus, avian influenza, parasitic resistance, modeling human disease
Pharmaceutical /medical/ industrial	Production of pharmaceutical proteins, production of polyclonal antibodies, animal organs for transplantation, bulletproof vests and anti-ballistic missile systems
Productivity	Enhanced growth rates and milk production
Environmental	Decreased phosphorous in manure, nutritional value, fat content, protein content

- **Transformative applications** – production of pharmaceutical proteins (bioreactors) and disease resistance
- **Significant challenges** for applications that enhance productivity
- **Only pharmaceutical applications** have been approved for commercialisation

Existing regulatory frameworks

- **US** – *focuses heavily on risks and risk of technology transfer towards the developing world.*
- **EU** – *risk-based approach, EFSA developing risk assessment approach (food/feed safety, environment, AHW)*
- **China** – *work is being undertaken to improve Chinese regulation so that the system is prepared to deal with the outcomes of their extensive research program.*
- **Australia** – *Gene Technology Act (2001) establishes national framework for GMOs, being applied in Asia.*

Other frameworks

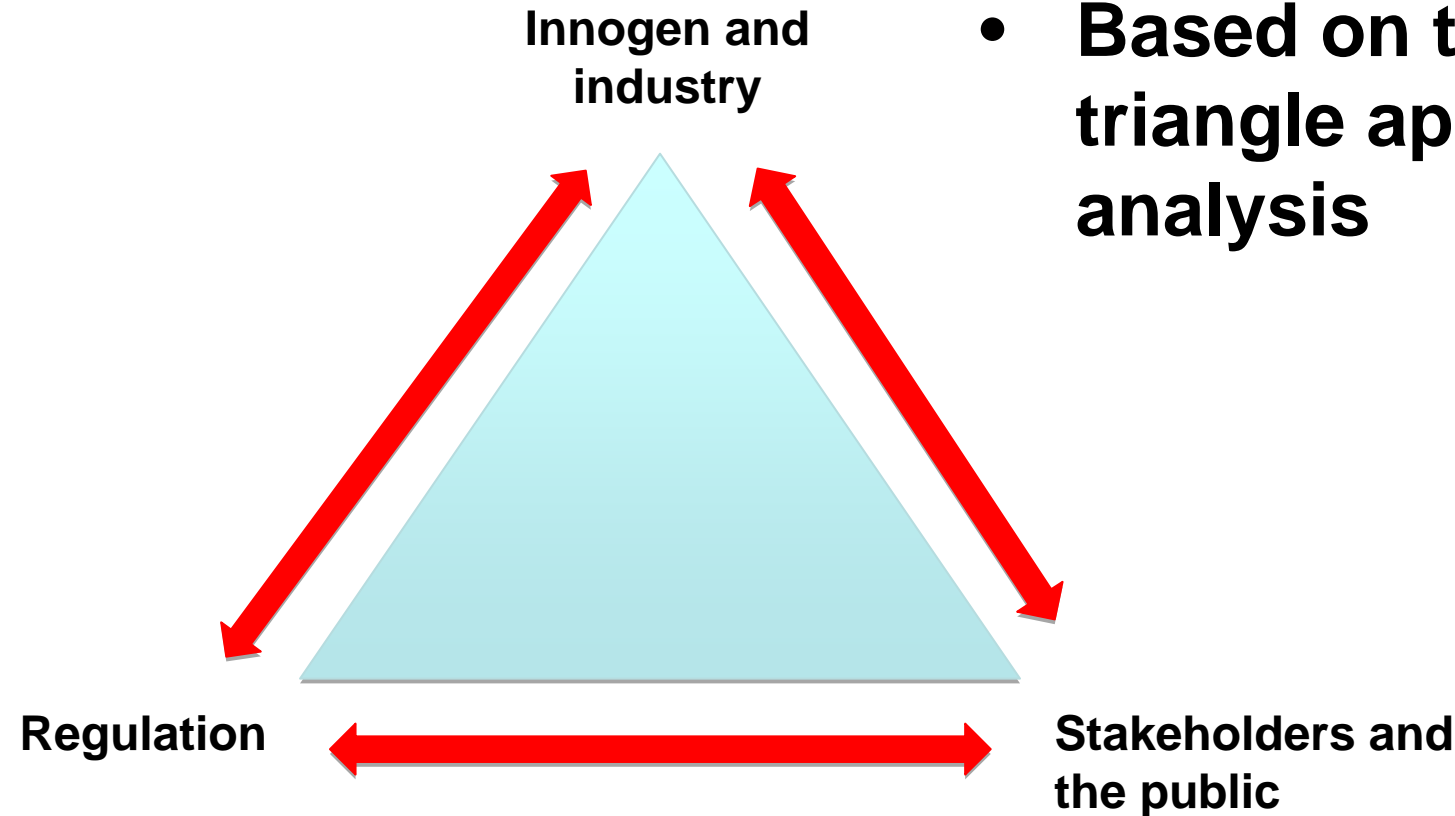
- **Argentina** - *based on the evaluation of the product on a case by case basis and not the process by which it was obtained.*
- **Brazil** - *a new Biosafety Law (2005) was produced in the hope of providing a smoother approval process.*
- **India** - *most active in risk communication through the use of media and formal risk communication measures.*

Observations

- ***Diverging pathways*** for GM animal applications dependent on their final use
- ***Ambivalence to GM technologies and their applications*** - no urgency or perceived need to use GM animals
- ***Lack of clear regulations*** - major limiting factor on GM animals reaching the market. The high amount of red tape is not encouraging companies to commercialise their products, stranded capital, lack of investment from venture capitalists

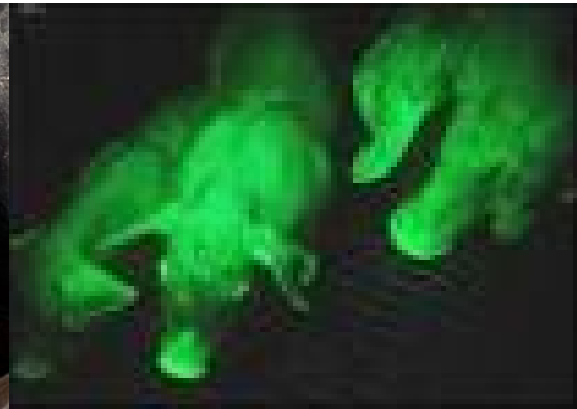
Smart regulation models

- **Based on the Innogen triangle approach to analysis**



Insights

- 1. *Relevance of GM applications*** – does a non-GM alternative exist?
- 2. *Regulatory frameworks*** - can they cope with the newer precise technologies?
- 3. *The role of science technology and innovation (STI) and system failures:***
 - lack of demand and venture capital, governance and changing policies and ineffective networks
- 3. *Technology transfer*** – is there a transfer from countries where scientific/technical capital is greatest?



Corrina Gibbs, Dr. Ann Bruce and Prof. David Castle