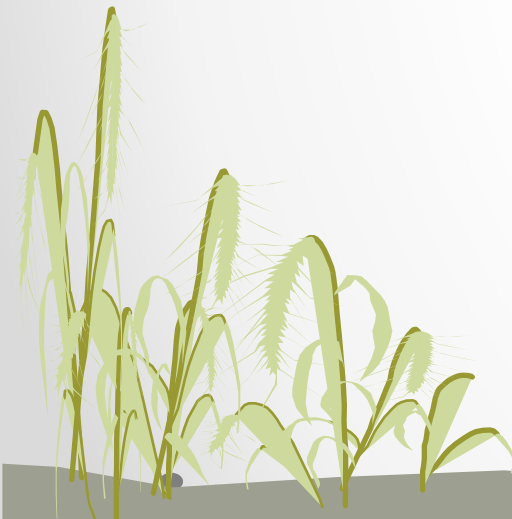


Fostering Innovation in Agriculture Through Enabling regulation

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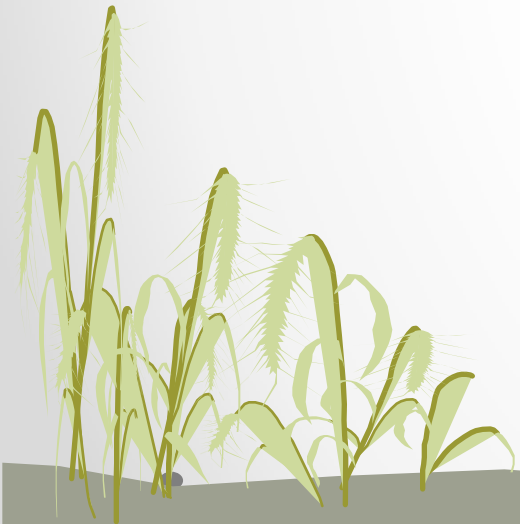
Fostering Innovation in Agriculture

- Report commissioned by the Agricultural Biotechnology Council (abc)
 - Compare regulatory systems around the world
 - Summarise the key features
 - Provide recommendations for enabling regulatory oversight
- Report was prepared by
 - **Monica Garcia-Alonso (EstelConsult Ltd)**
 - **Karen Holt (Holt Regulatory Solutions Ltd)**



Timing

- Climate change, food security, sustainable agriculture are more important than ever
- Innovation remains critical to address these challenges
- The UK has a unique opportunity to adopt regulatory policies that enable this innovation



FOCUS

- Risk assessment
- Canada
- Argentina
- Australia/New Zealand
- EU
- UK
- Interviews, literature reviews, personal experience



Risk assessment Requirements

- Linked to Policy objectives and protection goals
- Conducted by experienced trained risk assessors
- Science-based: Data collection linked to clear hypotheses testing
- Fit-for-purpose: answer relevant questions not endless data gathering
- Proportional: amount of data dependent on the product and the potential risk



Features of a non functioning system

- No transparent policy on innovation from the decision makers
- Lack of policy protection goals
- Highly politicised and complex voting procedure does not follow the text of the regulation
- Escalating data requests based on scientific preference rather than clear risk assessment principles
- Zero flexibility on the guidelines
- Zero possibility to discuss data package prior to, or during submission



- **Import files which take 5-7 years to approve**
- **Cultivation files which have been in the system for over 20 years**
- **Innovation is stifled**

Key Features of a functioning system

- Follow a science and risk-based approach performing fit-for-purpose risk assessments
- Foster the technical excellence of those performing the risk assessments that enables expert judgment built on experience
- Encourage consultative procedures
- Allow flexibility and proportionality
- Cooperate with other countries
- Actual text of the regulation (trait v process) does not appear to be the main consideration for a functioning GM approval system



- **Approvals in under 2 years**
- **Innovation supported**
- **Products are developed**

UK

- National listing; Food Safety Act and the Environmental protection act
- The first EU country to introduce a GM food under a voluntary system
- As part of the EU, UK voted based on the science
- Prior to the ECJ ruling, issued pragmatic opinions of gene edited products
- Innovation in the UK has been stifled because of poorly implemented EU regulation



What does this mean for the UK?

- Set clear policy and operational protection goals
- In the case of gene-edited products – apply the definition of the Cartagena Protocol to determine GM status
- Implement EU regulation according to the text of the legislation, but utilise Article 5 of Regulation (EU) No 503/13 to make data requirements flexible and proportional to the risk
- Invest in risk assessors and trust their judgement and experience
- Allow active product consultations throughout the process

