



# Webinar: An Update on EU Plant Protection Regulatory Processes

The EU General Food Law

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# Your presenters



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Commercial Director



Dr Mike Carroll  
Principal Plant Protection Consultant

# About us

**tsg**

Regulatory and science-based services for the chemical, biotechnology and related industries

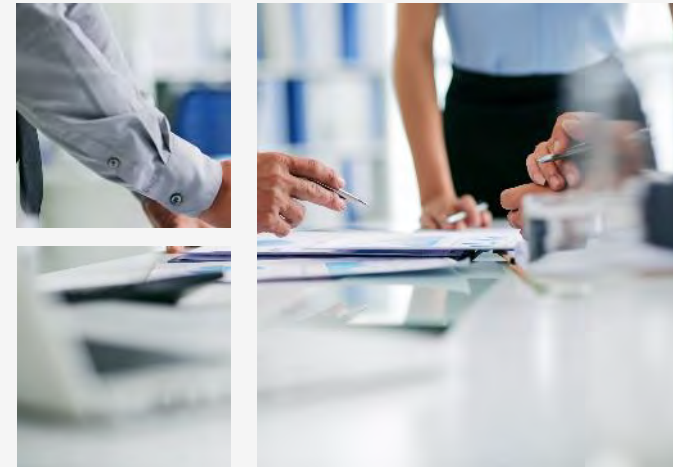
Experts in:

- Toxicology
- Chemistry
- Biology & microbiology
- Entomology
- Agronomy
- Environmental studies
- Public health
- Public policies

To excel in the provision of scientific, regulatory and registration services to the chemical and related industries

12 European & US offices serving a global market

Established in 1990  
100+ staff globally



Scientific and regulatory support





Core values:

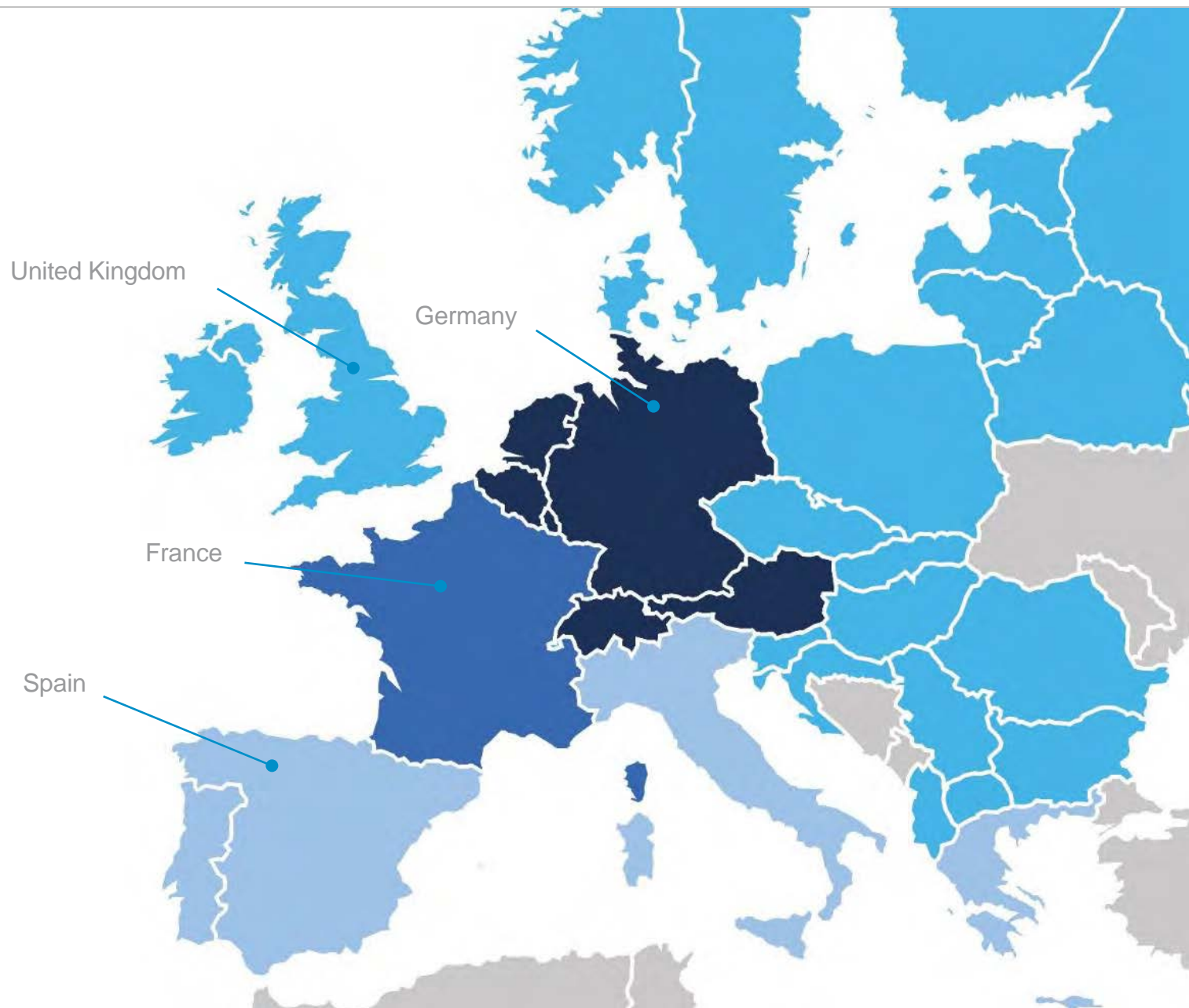
- Honest
- Reliable
- Professional

# European offices

- National approvals throughout the EU
- Liaison with regulatory authorities
- Scientific and regulatory support
- Regulatory and technical professionals in all offices
- Full pan-European dossier coverage

Countries coordinated from the following offices

- |   |   |
|---|---|
|  France  |  Spain |
|  Germany |  UK    |



# US and Canada offices

- Federal and state services
- Liaison with regulatory authorities
- Scientific and regulatory support

Sacramento, CA

Ottawa, ON

Washington, DC

■ TSG North American offices



# Agenda

EU Plant Protection  
Regulatory Introduction

EU General Food Law



# Agenda

**EU Plant Protection  
Regulatory Introduction**

EU General Food Law



Regulation is the craft of devising temporary remedies for recurring uncertainties – a series of expedients which are finally political judgements that may or may not be informed by science.





Regulation can be further defined as the amount of risk a politician is willing to accept with a given product or service and the amount of risk is inversely proportional to the level of regulation.

# Regulation: context

- The plant protection product industry is a highly regulated industry because politicians want to minimise risks
- However, this regulation can only apply to known risks
- The problem for policy makers is the unknown risk

# Social desirability bias rules government

“Government policies in any area do not triumph and endure because they work well. They triumph and endure because they sound good.”

*Caplan B (2007) The Myth of the Rational Voter, Princeton University Press*

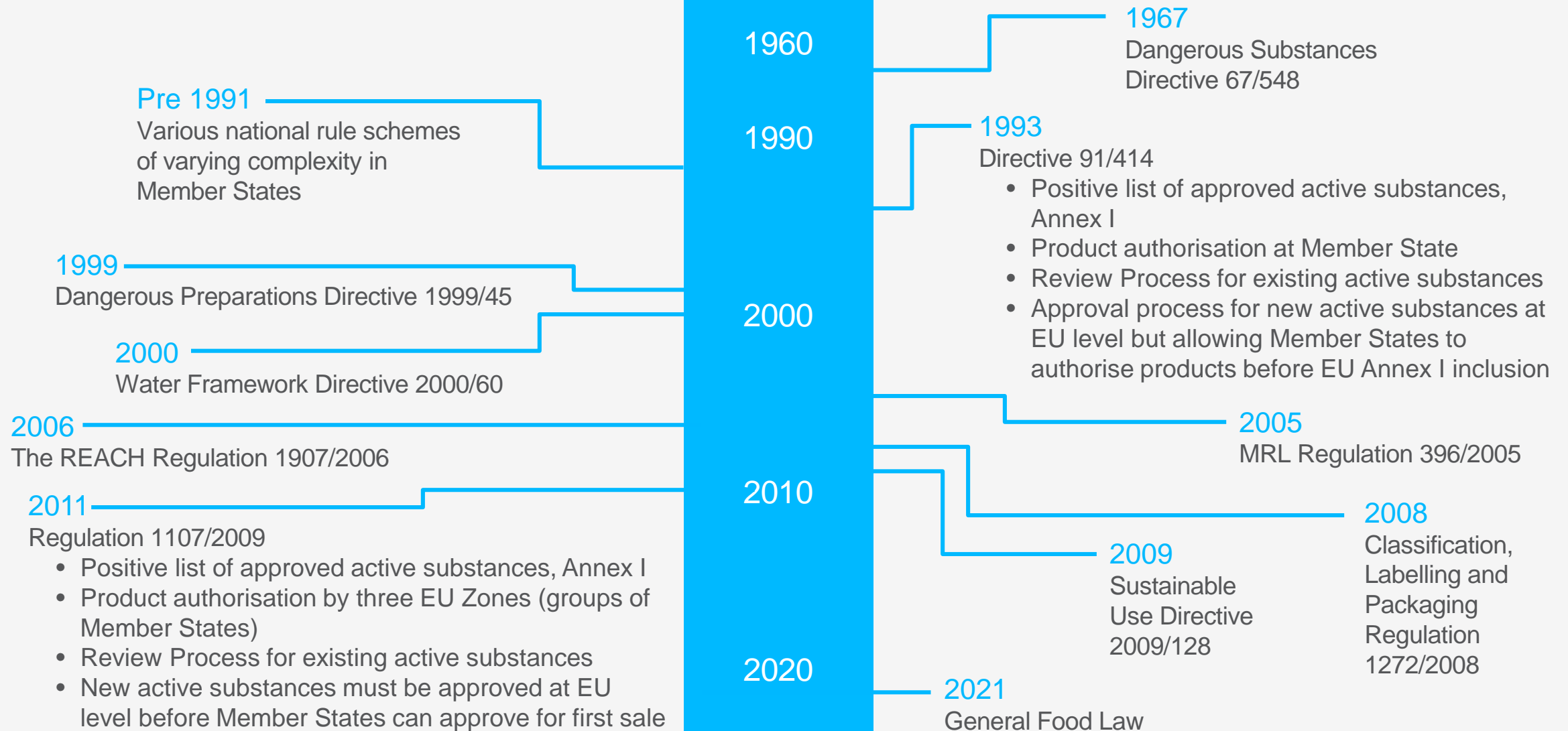
“The USA/EU\*\* has the strictest and most comprehensive regulatory process for plant protection products in the world to safeguard not only the food that US/EU citizens eat today but also our environment for future generations.”

\*\*Fill in country of your choice



# EU pesticide regulatory history

## Selected key legislation



# The Regulatory Authorities

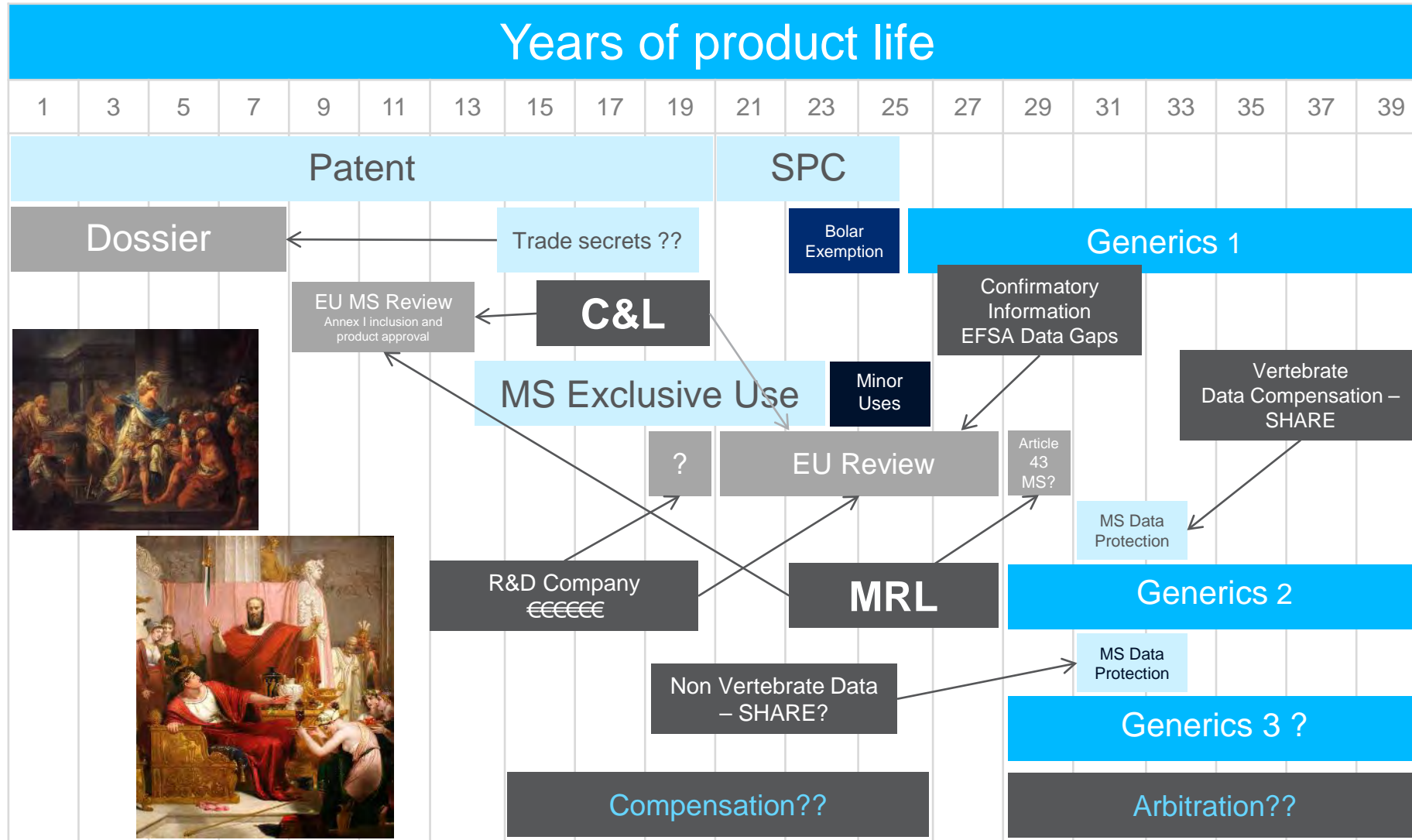
## 28 Individual Member State Authorities

- DG SANTE (SANCO) represent the EU Commission
  - Risk management
- EFSA provide a scientific opinion on the reviews undertaken by the Member State authorities
- EFSA review for MRLs
- ECHA review for classification and labelling

Overall 32 individual decisions/opinions



# EU Registration Process Active/FM 1107/2009, MRL 396/2005, CLP 1272/2008





## Risk combines hazard and exposure

For harm to occur in practice – in other words, for there to be a risk – there must be BOTH the hazard AND the exposure to that hazard; without both these at the same time, there is no risk

Under the old directive 91/414 risk assessment was the guiding principle but under the regulation 1107/2009 in certain cases hazard will be used without reference to risk assessment

# Based on hazard

- EU policy can be summarised as follows:
  - For pesticides, it's not how much of the chemical you are exposed to that should worry you, but whether or not you are exposed at all
- Toxicologists are far more likely to emphasise dosage
  - Non-toxicologists tend to view chemicals as either safe or dangerous and they appear to equate even small exposures to toxic or carcinogenic chemicals with almost certain harm
  - Failure to recognise the importance of dosage leads to misguided and wasteful environmental regulations





“As the price of illusion goes up we become less fanatical and more objective.”

Caplan B (2007) *The Myth of the Rational Voter*, Princeton University Press

Are there enough trained people in the EU to do all the regulatory work proposed?

E.g. endocrine disruption, dietary risk and assessment of metabolites, co-formulants?



# Agenda

EU Plant Protection  
Regulatory Introduction

**EU General Food Law**



The EU General Food Law  
Voted by the  
European Parliament  
16 April 2019

Applies as law in the EU  
from early 2021

# Ensuring more transparency

Citizens will have automatic access to all studies and information submitted by industry in the risk assessment process.

Stakeholders and the general public will also be consulted on submitted studies.

*At the same time, the agreement will guarantee confidentiality, in duly justified circumstances, by setting out the type of information that may be considered significantly harmful for commercial interests and therefore cannot be disclosed.*

This information currently treated as trade secret is now to be a privilege and not a right.



# Trade secrets

Citizens will have automatic access to all studies and information submitted by industry including data previously considered trade secret.

This includes information such as manufacturing details, active ingredient technical specification and formulation recipe.

At the same time, the agreement will guarantee confidentiality, in duly justified circumstances, by setting out the type of information that may be considered significantly harmful for commercial interests and therefore cannot be disclosed.

The European Food Safety Authority (EFSA) will decide after a written application for confidentiality is made by the data holder – proof of commercial harm will be required to retain confidentiality.



# Increasing the independence of studies

- EFSA will be notified of all commissioned studies to guarantee that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies
- The Authority will also provide general advice to applicants, in particular SMEs, prior to the submission of the dossier
- Commission may ask the Authority to commission additional studies for verification purposes and may perform fact-finding missions to verify the compliance of laboratories/studies with standards





## Strengthening governance and scientific cooperation

- Member States, civil society and European Parliament will be involved in the governance of the Authority by being duly represented in its Management Board
- Member States will foster the Authority's scientific capacity and engage the best independent experts into its work

# Developing comprehensive risk communication

- A general plan for risk communication will be adopted and will ensure a coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties



The image shows the European Union flag, which is a blue field with twelve five-pointed gold stars arranged in a circle. The flag is waving on a silver flagpole against a blurred background of a building with windows.

# Conclusions

- The General Food Law represents a major change to the way the EU treats trade secrets and confidential business information in plant protection regulatory dossiers
- Information on active ingredient technical specifications, formulation recipes and manufacturing processes can no longer be assumed to be treated as trade secret
- This will have major implications for manufacturing compliance

Thank you for listening!

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