Overview of the European Regulatory System for Plant Protection Substances
Regulatory Framework

How are pesticides regulated and what is meant by product ‘registration’ within the EU?
Regulatory Framework

- **Regulatory approval** needs to be granted by a **competent authority** before a plant protection product can be marketed.
  - Provides the ‘licensure to sell’ the product
  - **Legal requirement** by Member State (MS) authorities within EU
  - Need to demonstrate that the pesticide works (**Efficacy**)
  - There must be no unacceptable risks to **human or animal health** and the environment

- **Registration** is the process by which a plant protection product is evaluated by the responsible local government body, against required scientific criteria, and approved as safe for use

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Evolving social/political trends

Public perception
- Focus has moved from benefits of pesticides to concern over their safety

Regulators
- More regulation
- More testing
- More stringent standards (higher hurdles)

Industry
- In-depth assessment of registrability
- Greater risk assessment capability
- More stewardship
- Compliance requirements

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Goal in Pesticide Regulation

Access to benefits of pesticide use

BALANCE

Provide society with protection from adverse effects

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Existing European Legislation

- The directive sets out clear criteria for considering the safety of active ingredients as well as the safety and effectiveness of the plant protection products in which the actives may be used.

**Active ingredient (AI):** is the substance in a plant protection product that is biologically active.

**Plant protection product (PPP):** The AI is usually formulated with other materials and this is the product sold (syn. formulation or formulated product).

1. A harmonised process for considering the safety of active substances at an EC level, and once safety of the active substance has been established,

2. Product authorisations to be considered at a national level using the established harmonised criteria.

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework


- Contains 6 Annexes:
  - **Annex I** – ‘positive’ list of active substances that are authorised for use in plant protection products.
  - **Annex II** – list of tests and studies required for an active substance to support Annex I inclusion.
  - **Annex III** – list of tests and studies required on a plant protection product active substance either/or
    - required for at least one representative product to support the active substance on Annex I
    - to support an application for product authorisation following inclusion of the active substance in Annex I.
  - **Annex IV & V** – Specific phrases and precautions, additional to general classification & labelling.
  - **Annex VI** – Sets out the ‘Uniform Principles’; harmonised criteria for evaluating products at national level (ensures authorisations issued in all MS are assessed to the same standards).

Source: J. Freeman, KNOELL Academy April 2011
The key points of Directive 91/414/EEC are that it provides:

1. A positive list of active substances (which forms ‘Annex I’ of the Directive) that have been shown to be without unacceptable risk to people or the environment
2. A mechanism for adding active substances to Annex I either as existing active substances (under the EC Commission Review Programme) or new active substances
3. A harmonised authorisation process for the marketing and use of plant protection products by Member States only after an active substance is included in Annex I

Source: J. Freeman, KNOELL Academy April 2011
Actors involved in the EC decision making process

- Company (Applicant)
- Member State (MS) authority(s)
- European Food Safety Authority (EFSA)
- Public Consultation

Can the active substance be included in the positive list of substances for use in Plant Protection Products in the EC?

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 1

Company (Applicant) → Complete dossier → Member State (MS) authority(s)

- Companies prepare an **Application (New AS)** or **Notification (Existing AS)** for the inclusion of an active substance in Annex I of Directive 91/414/EEC
- Application/Notification consists of **a complete dossier**, addressing fully the requirements of the Directive
- Dossiers can be submitted in paper or electronic formats (CADDY)
- Fees are charged by the MS authority to cover the evaluation and processing of the application

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 2

- To facilitate a harmonised authorisation process, 1 competent MS authority is assigned to take responsibility, on behalf of the Commission, for the evaluation of the application – known as the Rapporteur Member State (RMS)
- The RMS produces a Draft Assessment Report (DAR), which is their report on the evaluation of all submitted studies and risk assessments
- The DAR also contains recommendations on inclusion or non-inclusion of the active substance in Annex I of Directive 91/414/EEC
- The DAR is submitted to the European Food Safety Authority (EFSA) for independent scientific evaluation

Source: J. Freeman, KNOELL Academy April 2011
Procedures involved in the EC decision making process

Step 2  Evaluation of a dossier by a RMS

- For **New AS** the applicant can apply to a Member State of their choice to act as Rapporteur. For **Existing AS** the applicant is required to submit to a Member State that the Commission nominates as Rapporteur (via a published regulation, listing AS for review).
- RMS assesses whether the application complies with the Directive requirements (**completeness check**) and reports it’s findings to the Commission.
- **Standing Committee on the Food Chain and Animal Health (SCoFCAH)** considers the RMS report – opinion on completeness is given.
- Positive decisions are published by the Commission in the **Official Journal**.

Source: J. Freeman, KNOELL Academy April 2011
Procedures involved in the EC decision making process

Step 2 Evaluation of a dossier by a RMS

- Following the completeness check step, the dossier is evaluated by scientific experts within the RMS authority.
- RMS technical experts refer to a series of guidance documents established by the Commission to facilitate a harmonised evaluation and risk assessment process.
- The Draft Assessment Report (DAR) is generated by the RMS.
- The finalised DAR is submitted by the RMS to the Pesticide Risk Assessment Review Unit (PRAPeR) of EFSA.

Source: J. Freeman, KNOELL Academy April 2011
The finalised DAR is considered by all Member States
A detailed scientific assessment of the evaluation and risk assessments is undertaken by EFSA and other MS technical experts
EFSA may also refer issues to its independent Panel on Plant Protection Products and their Residues (PPR)
EFSA presents its conclusions on the risk assessment to the Commission in a report known as the **EFSA Conclusion**

Source: J. Freeman, KNOELL Academy April 2011
Procedures involved in the EC decision making process

**Step 3**

**European Food Safety Authority (EFSA)**

- When the DAR is received by the Pesticide Risk Assessment Review Unit (PRAPeR) of EFSA, it is distributed to all MS and applicants as part of the commenting process.
- Comments are invited by all parties in a standardised format.
- EFSA experts also provide their own comments at this stage.
- PRAPeR make the DAR available for **public consultation** (excluding confidential parts).
- EFSA collates a **Reporting Table** of comments, grouped in **columns** relating to the sections of the DAR and sends to the RMS, who then provides their comments.

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 3

European Food Safety Authority (EFSA)

Evaluation of DAR by EFSA (and other MS)

- The completed table is sent by the RMS back to EFSA, whose experts assess the responses and create a final column indicating their proposals for further action.

- The EFSA table will identify:
  - Whether the comment has been addressed
  - Whether it remains a concern, requiring further consideration (i.e. an open point)
  - Whether it needs to be addressed by further data or information (i.e. a data gap)

- An ‘Evaluation Table’ may be created, listing all the open points and data gaps identified in the commenting period.

- The Evaluation Table is considered with the DAR, including any addenda.

Source: J. Freeman, KNOELL Academy April 2011
Procedures involved in the EC decision making process

Step 3

European Food Safety Authority (EFSA)

Evaluation of DAR by EFSA (and other MS)

- **Expert meetings** are organised by the PRAPeR unit of EFSA
- **Applicants** have opportunity to place comments in the EFSA Evaluation Table ahead of the meetings
- The **RMS** can also comment on the applicants feedback
- Various active substances are usually considered in a ‘**Round**’ of expert meetings, covering the 5 key technical areas (PhysChem, Mammalian Toxicology, Residues, E-fate and Ecotoxicology)
- Experts attend from the MS and EFSA
- Meeting conclusions are recorded in an **Expert Meeting Report** and the Evaluation Table is updated

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 3

Evaluation of DAR by EFSA (and other MS)

- **RMS** is consulted on the outcome of the expert discussions and the Evaluation Table is finalised.
- **EFSA** draft their conclusions document, which is then circulated to the MS.
- MS feedback is then taken into account when EFSA finalise their conclusion document.

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 3

- EFSA produce a final version of their conclusion
- **The EFSA conclusion** presents a comprehensive summary of the risk assessment
- The conclusion:
  - Lists specific conclusions
  - Provides reference values and endpoints
  - Identifies conditions to be considered in relation to risk, including critical areas of concern
- Final EFSA conclusion is sent to EU COM and applicant (+ on website)

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 4

European Commission

Risk Management & Decision Making Process

- EFSA conclusion is considered by EU COM & MS
- COM produces a proposal for inclusion or non-inclusion depending on risk assessment and possible risk management options
- The COM proposal is subject to MS voting, followed by adoption and publication

Source: J. Freeman, KNOELL Academy April 2011
Regulatory Framework

Procedures involved in the EC decision making process

Step 4

European Commission

Risk Management & Decision Making Process

- After the EFSA conclusion is received by the EU COM, it may consult with MS at the **Standing Committee on the Food Chain and Animal Health** (SCoFCAH)
- SCoFCAH considers wider **regulatory & legislative aspects** to help the COM develop its regulatory decision
- The COM also seeks comments on the EFSA conclusion from the notifier/applicant

Source: J. Freeman, KNOELL Academy April 2011
Procedures involved in the EC decision making process

Step 4

European Commission

Risk Management & Decision Making Process

- The timelines for this final part of the process are set out in the legislation for existing AS (but are also similar for new AS)
- Within 6 months of receiving the EFSA conclusion, the COM has to submit a review report to SCoFCAH
- The review report is sent with either/or:
  - A draft directive to include the active substance in Annex I
  - A draft decision for the withdrawal of authorisations of products containing the active substance

Source: J. Freeman, KNOELL Academy April 2011
What happens after a decision on inclusion?

- Member States (MS) must ensure that authorised plant protection products **comply with harmonised EU standards**
- **Products** must be re-evaluated in accordance with Annex VI of Directive 91/414/EEC (**the Uniform Principles**)
- Dossiers must satisfy the data requirements of **Annex II** (AS related data) and **Annex III** (product related data)
- The process is termed **re-registration**
- Triggers the requirement to **establish EU MRLs**
What happens after a non-inclusion decision?

- The published decision will set out the timescales that MS must apply for withdrawal of products containing the active substance.
- Non-inclusion triggers the re-consideration of existing MRLs.
- ‘Re-submissions’ applications can be made for existing AS. As set out in Commission Regulation (EC) No. 33/2008.
- Re-submission directive makes provision for a ‘regular’ or ‘accelerated’ process depending on the review stage of the non-included compound and the period of time elapsed since the non-inclusion decision entered into force.

Source: J. Freeman, KNOELL Academy April 2011