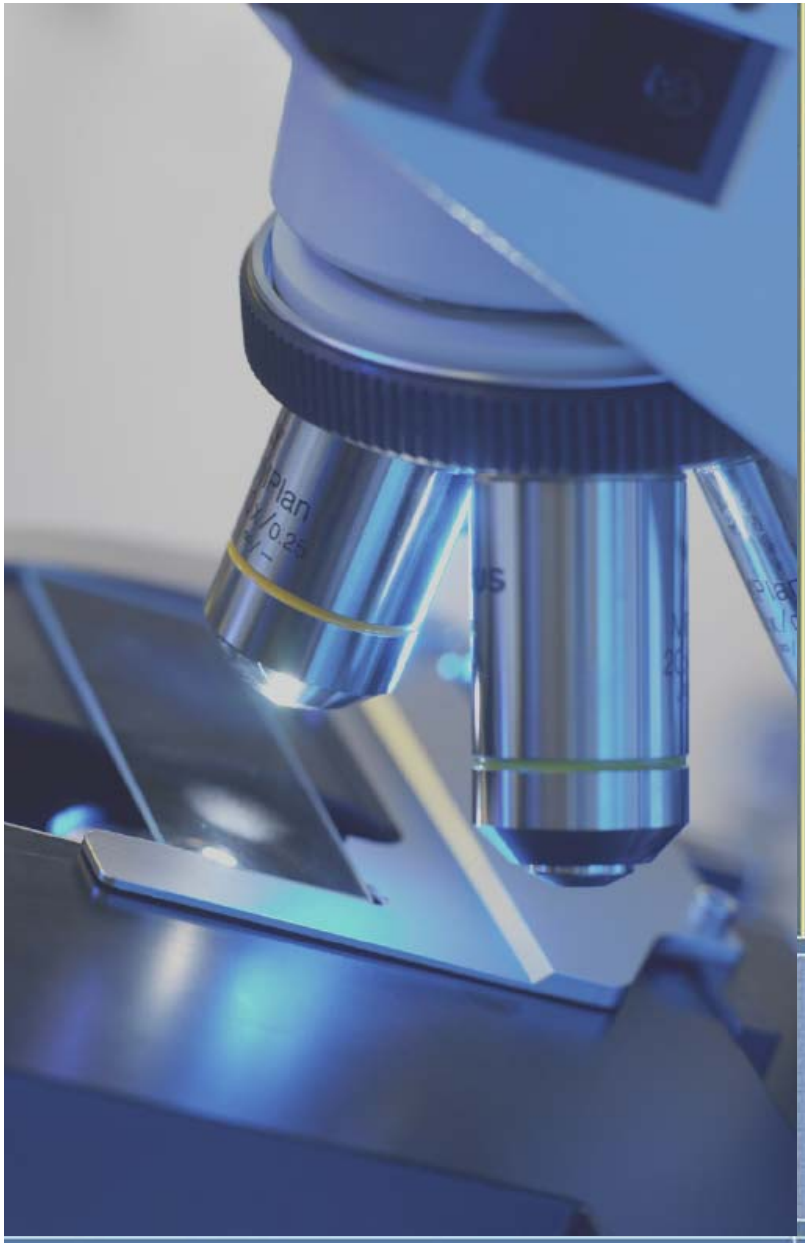

REACH Authorisation

Graham Lloyd

Regulatory/Technical

"REACH in Practice" Conference
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Steptoe & Johnson LLP & Regulatory Compliance Ltd

Authorisation

The objective:

Whilst allowing the EU market to function effectively - to reduce risks associated with the use of hazardous chemicals

By the introduction and implementation of control measures.

By encouraging the development of "safer" alternatives

Authorisation

High risk substances cannot be placed on the market unless:

They have been authorised.

They are exempt.

An authorisation decision is pending.

Identification of candidates

Agency to establish a candidate list of authorised substances

Competent authorities can identify substances that meet the criteria.

A member state can propose substances and prepare Annex XIV dossiers it believes should be included.

Information to be published.

Refer to the Member State Committee.

Full discussion on Annex before inclusion on the list.

Substances to be included

To include category 1 or 2:

Carcinogens, mutagens and reproduction toxins.
Persistent, Bioaccumulative, Toxic (PBT's)
Very Persistent, very Bioaccumulative (vPvB).
Endocrine disrupters.

Where there is scientific evidence a substance could be a high risk.

Annex XIV will contain a list of authorised substances.

Inclusion in Annex XIV

A decision to include a substance in the Annex XIV list will specify the following:

- **Substance identity**
- **Toxic properties on which the decision is based**
- **Transition arrangements**
- **Date from when use is prohibited**
- **Date for receipt of applications for authorisation**
- **Review periods**

Inclusion in Annex XIV

Some use categories can be exempt if risk is adequately controlled by existing legislation.

Agency to consult with the Member States Committee

Priority given to vPvB, substances with wide dispersive use and/or high volumes

Information to be made publicly available

Further action to restrict to be considered

Application for an authorisation

Sent to the Agency.

By a Manufacturer, Importer and/or Downstream User.

Can be sent in;

- **By one or more persons**
- **For several substances e.g. a group of substances**
- **To cover several uses**

Authorisation

To include:

- **Identity of the substance**
- **Contact details**
- **Specify uses for which the authorisation is sought**
- **A CSR**
- **An analysis of the alternatives (substitution)**
- **Research and development programmes**
- **Substitution plans**
- **A fee**

Application for an authorisation

May also include:

- **Any socio-economic analysis that has been performed.**

- **Justification for not considering risk from emissions where permits are granted or discharges are covered by other EU legislation**

Authorisation procedure

Agency to acknowledge receipt of the application.

Committees to check the application is complete.

Socio-economic and Risk Assessment

Committees to prepare draft opinions within 10 months.

If not complete the committees to request additional information within set time frames.

Socio-economic Committee

Will look at:

Any risk posed by the substance.

The implications of a refusal.

Analysis of any alternatives including risks of use.

Any substitution plans that are submitted.

Will review third party submissions.

Authorisation decisions

Full discussion to take place between the Committees, Agency, and applicants.

Information and decisions to be made available on Agency web site & in the EU Journal.

- **Summaries of the decisions**
- **Reasons for the decision**
- **Authorisation number**

Granting an authorisation

This is the role of the Commission.

Authorisation can be granted provided adequate control measures described are in place.

Information is included in the CSR & MSDS.

Where CMR thresholds cannot be established.

Granting authorisations

Further considerations

To show socio-economic benefits outweigh the risk to health and environment

Companies are required to find alternatives which must exhibit a lower overall risk and be technically and economically feasible

Refer to the Socio-Economic and Risk Assessment Committees.

Subsequent applications

When granted others can refer to parts of the application provided they have permission to do so.

Applicant to update the information in the original application.

Acknowledged by the Agency.

Use of authorised substances

Downstream Users can use a substance for which an upstream actor has received an authorisation.

Must follow the conditions of use.

Do not apply to substances in scientific research, Biocides, Plant Protection products, cosmetics & food contact materials

Obligations authorisation holders

As soon as available must include the authorisation number on the label.

DSU to notify the Agency within 3 months of first supply of the authorised substance

The Agency will keep a register of uses.

Information made available to CA

Thank you