

The Risk Assessment process – the voice of the scientist

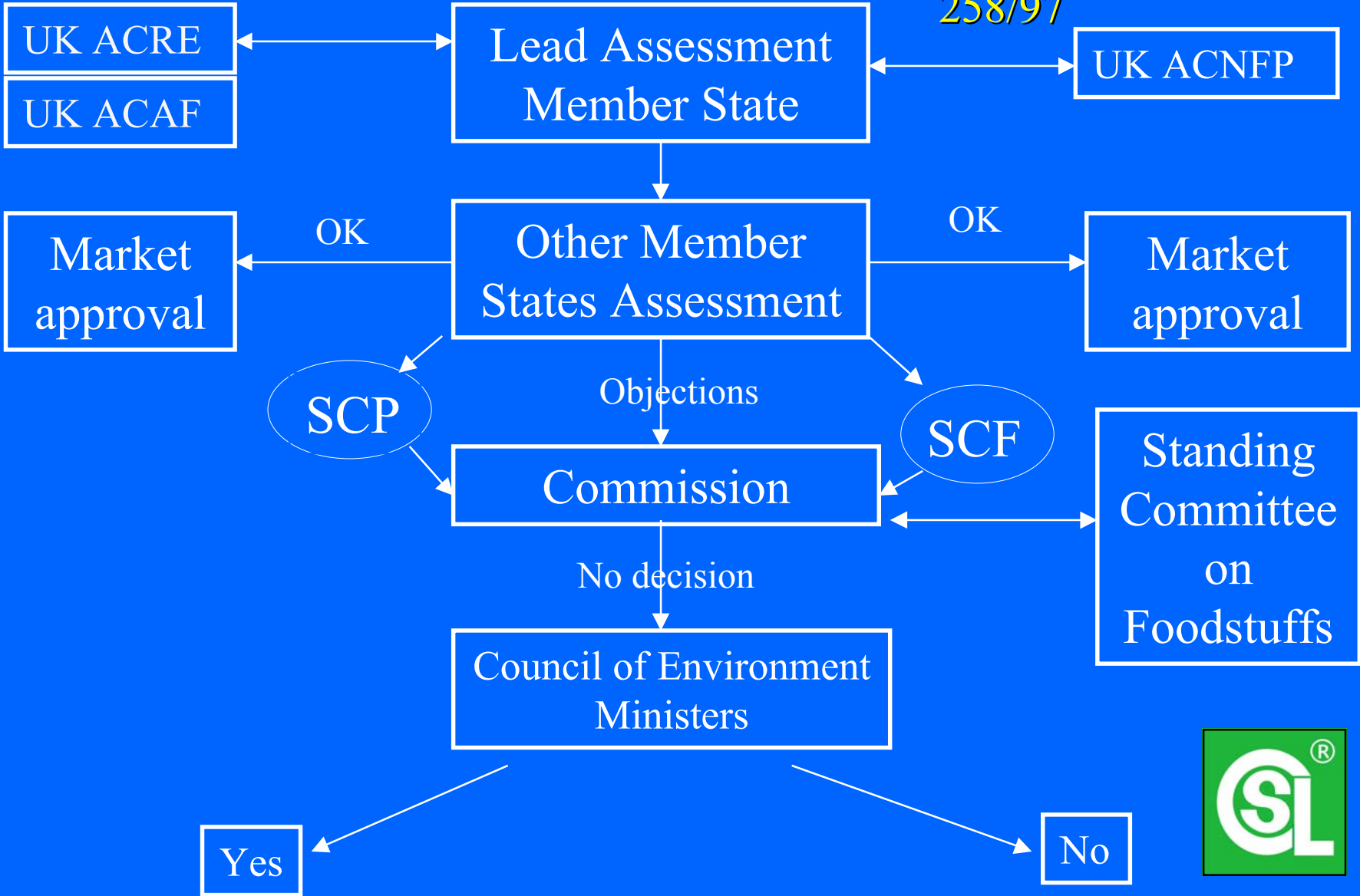
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Releases to the environment 2001/18/EC

Novel foods and novel food ingredients EC No 258/97



Changes to the regulatory framework introduced by 2001/18/EC

90/220/EEC	2001/18/EC
Suggests <i>guidelines</i> for risk assessment procedures by competent authorities	Includes <i>procedures</i> for risk assessment
Requirement for monitoring of releases depends on risk assessment	Mandatory requirement for risk assessment
When granted, consents are for an unlimited time period	Consents are restricted for 10 years, after which a further application must be made
Consultation of Scientific Committees is <i>optional</i>	Consultation of Scientific Committees is <i>mandatory</i>
Public consultation <i>optional</i>	Public consultation <i>mandatory</i> , and a requirement for public registration of releases
	Introduction of ethical considerations
	A requirement for the Commission to report on the socio-economic advantages and disadvantages of GMOs which have been authorised for placing on the market
	New traceability requirements

EC Scientific Committee on Plants

Mandate: 1997 - 2000 : 2000 - 2003

Scientific and technical questions relating to plants intended for human or animal consumption, production or processing of non-food products as regards characteristics liable to affect human or animal health or in the environment, including the use of pesticides.

◆ **plant protection products
(91/414/EEC)**

◆ **genetically modified
organisms
(90/220/EEC, 2001/18/EC)**

SCP achievements to January 2003

Total 113 opinions adopted

32 GMO opinions - 7 crops: maize, oilseed rape, sugarbeet, potato, tomato, cotton, chicory

19 specific GM dossiers

3 GM micro-organisms

5 guidance documents

8 'Article 16' opinions

**Common Joint SCP/SCF/SCAN GM Working
Group**



European Food Safety Authority

Scientific Committee + 8 scientific panels

- ◆ Food additives, flavourings, processing aids and materials in contact with food
- ◆ Additives and products or substances in animal feed
- ◆ Plant health, plant-protection products and their residues
- ◆ **Genetically modified organisms**
- ◆ Dietetic produces, nutrition and allergies
- ◆ Biological hazards
- ◆ Contaminants in the food chain
- ◆ Animal health and welfare



Guidance document for the risk assessment of GM plants and derived food and feed

Risk assessment consists of sequential steps to identify characteristics which may cause adverse effects, evaluate their potential consequence, assess the likelihood of occurrence and estimate the risk posed by each identified characteristic of the GMO



Risk assessment of GM plants and products should take account of

- ◆ **The characteristics of the donor and recipient organisms**
- ◆ **The genes inserted and expressed**
- ◆ **The potential consequences of genetic modification**
- ◆ **The potential environmental impact following deliberate release**
- ◆ **The potential toxicity and allergenicity of gene products and metabolites**
- ◆ **The compositional, nutritional, safety and agronomic characteristics**
- ◆ **The influence of food processing on the properties of the food or feed**
- ◆ **The potential for changes in dietary intake**
- ◆ **The potential for long-term nutritional impact**



Risk assessment strategy

- ◆ **Start with comparative analysis which further structures the safety assessment procedure**
- ◆ **Appropriate non-GM comparator**
- ◆ **Intended effects – targeted/original objective of transformation**
- ◆ **Unintended effects – consistent differences from non-GM control lines**



Clean vector technologies

- ◆ **Only DNA essential to modification of trait is transferred to the plant**
- ◆ **Choice of marker gene (e.g. antibiotic markers)**
- ◆ **Reduce environmental exposure and potential risks from transgenes and products**
- ◆ **Avoid/minimise superfluous transgenes/sequences**
- ◆ **Avoid/minimise superfluous expression of transgene**
- ◆ **Avoid/minimise dispersal of transgenes in the environment**



Guidance document – safety assessment 1

- ◆ **Molecular characterisation**
- ◆ **Comparative analysis**
 - ◆ Comparator choice
 - ◆ Field trials
 - ◆ Compositional analysis
- ◆ **Environmental assessment**
 - ◆ Impact/gene flow to wild plants
 - ◆ Impact/gene flow to non-GM crops
 - ◆ Impact on organisms and ecological processes



Guidance document – safety assessment 2

- ◆ **Food/feed safety assessment**
- ◆ **Toxicology**
 - ◆ Novel proteins
 - ◆ Novel metabolites
 - ◆ Impact on natural food constituents
 - ◆ Whole GM food/feed
- ◆ **Allergenicity**
- ◆ **Wholesomeness – nutritional assessment**
- ◆ **Animal products**



Issues

- ◆ **Post-marketing monitoring**
- ◆ **Co-existence of GM and non-GM crops**
- ◆ **Adventitious presence of GM in non-GM**

