Foreword

To respond to the need for a sustainable and publicly available summary of the trainings delivered in the framework of the Better Training for Safer Food Initiative, we decided to launch a series of training booklets in selected technical fields. These booklets shall help the participants of our trainings to share the received information and knowledge with their colleagues back in their home countries. The booklets shall also help in the preparation of training for future participants, and at the same time they will give a brief introduction on the latest developments to interested readers in the discussed technical field.

I hope that this booklet will be a useful tool for its readers, and I would invite those interested in the respective European legal framework and its development to visit the relevant pages of the Europa website, indicated on the back cover of this booklet.

Salvatore Magazzù
Head of Consumers and Food Safety Unit, Executive Agency for Health and Consumers (EAHC)

How to use this booklet

The information presented gives some of the key learning outcomes of this training course and complements these with additional information. It is not intended to provide a complete picture of EU law and regulations in this area and should be read as the training provider’s interpretation of the issues affecting PPP evaluation and registration at the time of publication. Discussion points that arose in similar courses are highlighted with blue boxes marked with an exclamation mark.

Glossary

BTSF
The Better Training for Safer Food programme (BTSF) is a European Commission (EC) initiative that organises training in the areas of European food and feed law, plant and animal health and welfare regulations. [www.ec.europa.eu/food/training_strategy](http://www.ec.europa.eu/food/training_strategy) and [www.ec.europa.eu/eahc/food](http://www.ec.europa.eu/eahc/food)

CIRCA
Communication and Information Resource Centre Administrator is an extranet tool, developed by the EC. It enables a given community (committee, project group, etc), geographically spread across Europe, to maintain a private space on the internet where they can share information, documents and participate in discussions. [www.circa.europa.eu](http://www.circa.europa.eu)

EAHC
Based in Luxembourg, the Executive Agency for Health and Consumers (EAHC) implements the EU Health and Consumer Programmes and the BTSF initiative. Set up in 2005 as the Public Health Executive Agency, it was transformed into the EAHC in 2008. [www.ec.europa.eu/eahc](http://www.ec.europa.eu/eahc)

EFSA
The European Food Safety Authority (EFSA) is the keystone of European Union (EU) risk assessment regarding food and feed safety. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides independent scientific advice and clear communication on existing and emerging risks. [www.efsa.europa.eu](http://www.efsa.europa.eu)

RMS
Rapporteur Member State. The initial scientific and technical evaluation for the European Community is conducted by one of the Member States of the Community, the rapporteur.
# Contents

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glossary</td>
<td>2</td>
</tr>
<tr>
<td>Food Safety in the EU</td>
<td>4</td>
</tr>
<tr>
<td>Better Training for Safer Food</td>
<td>4</td>
</tr>
<tr>
<td>Why is PPP training important?</td>
<td>5</td>
</tr>
<tr>
<td>PPP regulation in the EU</td>
<td>6</td>
</tr>
<tr>
<td>Evaluation and registration of plant protection products</td>
<td>6</td>
</tr>
<tr>
<td>- Progress made in meeting re-registration requirements</td>
<td>7</td>
</tr>
<tr>
<td>- Workload Challenges for 2010 and beyond</td>
<td>9</td>
</tr>
<tr>
<td>- Work of the Post-Annex I Group</td>
<td>10</td>
</tr>
<tr>
<td>- Work-sharing at re-registration</td>
<td>11</td>
</tr>
<tr>
<td>- Improved communication between MS</td>
<td>15</td>
</tr>
<tr>
<td>- Confirmatory data</td>
<td>16</td>
</tr>
<tr>
<td>- New Regulation</td>
<td>17</td>
</tr>
</tbody>
</table>

Contact information
Food safety is a key issue for the European Union. Since the launch of the White Paper on food safety of 2000, a major overhaul of food safety laws has been undertaken based on a comprehensive food safety strategy. The central goal is to ensure a high level of protection of human health and consumers’ interests in relation to food.

The EU integrated approach to food safety aims to assure a high level of food safety, animal health, animal welfare and plant health within the EU through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. The implementation of this approach involves the development of legislative and other actions:

- To assure effective control systems and evaluate compliance with EU standards in food safety and quality, animal health, animal welfare, animal nutrition and plant health sectors within the EU and in third countries in relation to their exports to the EU
- To manage international relations with third countries and international organisations concerning food safety, animal health, animal welfare, animal nutrition and plant health
- To manage relations with the European Food Safety Authority (EFSA) and ensure science-based risk management

One way to assist in strengthening capacity in the area of food safety is through the European Union’s recent initiative Better Training for Safer Food. Launched in 2005, it provides training to both European and third country officials responsible for checking that EU rules related to food, feed, animal health and welfare and plant health are properly applied.

The EU integrated and global approach towards food safety requires an effective and efficient management of official controls systems by competent authorities, calling for a high level of controlling staff competence to ensure that official controls are efficient, objective and adequate. A European dimension to training supports this approach by raising staff’s capacity to perform high standards of control activities, promoting a harmonised, uniform level. Training is also important to exchange and spread best control practices across Europe while ensuring greater coherence, thus guaranteeing food businesses equal treatment wherever controls are carried out.

It is essential that all involved in importing live animals, feed, food or plants are familiar with EU import requirements. The involvement of participants from third countries in training leads to better understanding of EU food laws and import procedures, therefore lowering the hurdle for third countries to place goods on the EU market. It also leads to better compliance with EU requirements, by reducing and simplifying import controls.
The main objective of the initiative Better Training for Safer Food may be summarised as follows:

- Ensuring and maintaining a high level of consumer protection and of animal health, animal welfare and plant health
- Promoting a harmonised approach to the operation of Community and national control systems
- Creating an equal playing field for all food businesses
- Enhancing trade of safe food
- Ensuring fair trade with non-EU countries and, in particular, developing countries

Why is PPP training important?

Human health and the environment is a major focus for EC policy on the authorisation of plant protection products (PPP). Starting in 1993, the EC began a Community-wide review process for all active ingredients used in PPP within the EU.


Once an active substance has been included in Annex I of Council Directive 91/414/EEC, Member States (MS) must ensure authorised plant protection products comply with harmonised European standards. In particular, MS must re-evaluate products in accordance with Annex VI to the Directive (the Uniform Principles) and on the basis of dossiers satisfying the data requirements of Annex II (active substance related data) and Annex III (product related data). This process is defined as re-regISTRATION (details p.7).

No PPP can be used unless it has first been scientifically established that:

- They have no harmful effects on consumers, farmers and local residents/passers-by
- They do not cause unacceptable effects on the environment and
- They are sufficiently effective against pests

The evaluation and registration training workshop ensures that national-level competent authority staff are up to date with the latest procedures. The workshop aims to:

- Strengthen harmonisation of activities, development of work-sharing and planning
- Address member states needs in relation to on-going re-registration activities
- Enable Member States to prepare for the requirements of future legislative developments concerning marketing of PPP

From 2003, the European Food Safety Authority (EFSA) has been dealing with risk assessment issues, while the EC is responsible for the risk management.

www.efsa.europa.eu
Council Directive 91/414/EEC lays down detailed data requirements to allow a comprehensive risk assessment to be performed as well as the approval and authorisation procedure for active substances and products containing these substances. www.ec.europa.eu/food/plant/protection/evaluation/legal_en.htm

Before marketing and use, the safety of each active substance has to be proven in terms of human health (including examining residues in the food chain), animal health and the environment. It is the industry’s responsibility to provide the data showing that a substance can be used safely.

The evaluation process has 3 steps:

1. A Rapporteur Member State (RMS) transmits its preliminary conclusions on the substances to EFSA
2. A scientific risk assessment involving EFSA is carried out
3. Risk management steps are performed by the EC with the assistance of the Member States within the Standing Committee on the Food Chain and Animal Health (SCOFCAH)

If the evaluation shows that the substance has no harmful effects on human or animal health and any influence on the environment is within acceptable limits, the substance can be approved for registration. An EU list of approved active substances (Annex I to Directive 91/414/EEC) is established, and Member States may authorise only PPP containing active substances included in this list. www.ec.europa.eu/sanco_pesticides/public/index.cfm

A new legislative framework on pesticides was adopted by the European parliament and the Council in 2009. This legislative framework foresees tighter controls on the approval of PPP and establishes a mechanism for the substitution of more toxic pesticides by safer (including non-chemical) alternatives. A regulation (1107/2009) on placing plant protection products on the market, introducing stricter provisions (including criteria for approval of the active substances) and a directive (2009/128/EEC) on the sustainable use of pesticides (aiming to reduce the risk linked to their use and to ensure better training of users) has been adopted in 2009. www.ec.europa.eu/food/plant/protection/evaluation/new_reg_ppp_en.htm

Active ingredients used in PPP in the EU must not pose a threat to human health or the environment. In addition, they must not exceed Maximum Residue Levels (MRL). Harmonisation of evaluation and registration of PPP across the EU involves a process of re-registration. Active substances authorised for use in PPP are listed in Annex I of Directive 91/414 (www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31991L0414:EN:NOT). Member States must ensure that all such substances authorised for use on their territory comply with the conditions for inclusion. Re-registration relates to the evaluation, following the inclusion in Annex I of Directive 91/414/EEC, of PPP containing that active substance, which have to be examined in accordance with Annexes II, III and VI of the Directive.
Member States joining the EU in 2004 and 2007 have had to examine active substances, listed on Annex I of the directive prior to their accession and used in PPP available on their markets, in order to ensure compliance. Training is ongoing to support this process.

The workshop on evaluation and registration of PPP covers two main areas, firstly the phases defined as Step 1 and Step 2 of the re-registration process (with an examination of experiences to date and the necessary refinements) and secondly the new regulation (with emphasis on new provisions which will have to be implemented at MS level, such as zonal authorisations, mutual recognition and renewal and amendment of authorisations).

The workshop is set up like this because the EU evaluation process is based upon a two-tier registration system with active substances being assessed at Community level and products subsequently being registered by Member States.

The two key steps are defined as follows:

**Step 1**
This involves a check that the conditions and restrictions of the Annex I of the Inclusion Directive (91/414/EEC) are met. These include the technical specifications equivalence of the active substance and demonstrable access to a complete Annex II dossier.

**Step 2**
This involves the submission of a dossier satisfying, in the light of current scientific and technical knowledge, the requirements set out in Annex III for the PPP itself. In addition, there should be an assessment of the product in accordance with Annex VI of the Directive, the Uniform Principles.

**Progress made in meeting re-registration requirements – an overview**

Registration of PPP follows the 91/414/EEC Directive – a set of legislations which are gradually being put into practice. A number of key features are emerging. For example, the Directive does include a provision for mutual recognition of regulatory decisions whereby a second Member State does not need to request any supporting data in order to register a product already registered in another Member State. This only applies if agronomic, climatic and environmental factors are similar and the active ingredient has been included on the positive list.

Individual pesticides will continue to be regulated until all existing EC active ingredients are reviewed and placed on Annex I (positive list). PPP registration will apply to new active ingredients coming onto the market and existing EC reviewed active ingredients that obtain Annex I listing. Withdrawal of some PPP products, a reduction in registration of new products and tighter controls on permitted MRLs are all affecting the way pesticides are used. An understanding of these changes and their outcomes is gradually emerging.
Planning for re-registration allows a proper organisation of resources, and encourages an understanding of the flexibility in the re-registration system which allows time to inform the industry. Planning for re-registration takes into account the following issues:

**Considerations in planning for re-registration**

- How many products left to re-register list, with an easy-to-use format
- Check all non-inclusions. Are necessary authorisations revoked, including active products?
- Voluntary withdrawn actives – allow to continue until deadline (may need to include in plan following re-submission and inclusion)
- Group products via actives
- Mixed active products
- If you missed Step 1 and Step 2 deadlines – priority
- If you missed Step 1 deadlines but not Step 2 – take regulatory action for Step 1?
- Post inclusion letters for everything else where aligned with EU?
- Do you need to extend current authorisations?
- Prioritise relative to new product applications?

Re-registration plans should be communicated by contacting applicants to request submissions and informing all parts of the regulatory organisation so that they can organise resources accordingly. Successful re-registration processes for new EU countries have included the following:

**Case study of a re-registration process**

- Put legislation in place. Equivalent Annex I and non-inclusions
- Listed all products authorised in spreadsheet format
- Taken into account date of accession – aim to have alignment of all products with EU position by this date
- Prioritised non-inclusions
- Revoked most products containing non-included actives, unless really an ‘essential use’
- Annotated list with inclusion status, and Step 1 and Step 2 deadlines
- Most already missed – so combined Step 1 and 2 with ease
- Sorted list of existing products based on inclusion data
- Divided into ‘manageable’ groups

Re-registration groups can spread the date of submission for each group of inclusions to give six monthly gaps over a two year period. Existing Active Substance (EAS) and New Active Substance (NAS), inclusions (Step 1 and 2) have risen sharply in 2009 and are forecast to continue rising through to 2015.

Ongoing problems that have been identified include the general issues of high workload, lack of experience, resources and guidance. More specific problems include: lack of essential documentation, differences between MS approach to assessments and prioritisation of new and existing product applications.
Existing active substance decisions and review reports are available online at: http://ec.europa.eu/food/plant/protection/evaluation/exist_subs_rep_en.htm

The following guidance documents are available to facilitate Step 1 of the evaluation process:

<table>
<thead>
<tr>
<th>Re-registration procedure</th>
<th>Guidance Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1 Re-registration procedures</td>
<td>SANCO/10796/2003 – rev. 10.42 October 2009 – on the re-registration of plant protection produces following inclusion of an existing active substance in Annex I of council directive 91/414/EEC</td>
</tr>
</tbody>
</table>

Table 1. EU Guidance documents for re-registration procedures

The Post-Annex I issues working group is coordinating Step 1 assessments by allocation of RMS, ensuring equivalence of identity and harmonising decisions in Member States.

Looking forward, for Step 2 of the registration process, work sharing and a new *modus operandi* are currently under development. The so-called ‘risk envelopes’, to cover all potential uses of the substances, are being encouraged to move a less individual-based assessment to one involving mutual recognition.

Moreover, the new regulation establishes a zonal system with 3 zones across Europe – North, Central and South. Work sharing is based on a 12 month timetable with mutual recognition of authorisations issued to be granted in 120 days. The substitution principle will be used for comparative assessments of PPP.

**Workload Challenges for 2010 and beyond**

Many of the work streams focus on initiatives to help maintain sufficient availability of plant protection products and encourage close cooperation with other MS.

A number of work streams have been identified for consideration, summarised below, reflecting a high workload for the immediate future of at least 100 projects per year.
Work streams | Considerations
---|---
New Substances | At least 50 DARS are in the EFSA process, awaiting MS comments
‘Green’ track substances | 9 substances from third stage, 17 micro-organisms and 42 chemicals from stage 4
Resubmissions | Some in regular procedure, others in accelerated procedure. Total of more than 50
AiR project | 7 in for renewal evaluation
Confirmatory data | A number for submission in 2010

Table 2. Workload challenges for 2010 and beyond

Frequently asked questions (FAQ) to the evaluation of new substances for registration can be found at: www.ec.europa.eu/food/plant/protection/evaluation/new_subs_faq_en.htm#q3

The challenges of fulfilling such a large workload in the forthcoming years, highlights the need for information exchange, harmonisation and work sharing.

**Work of the Post-Annex I Group**

There are 4 areas to be considered in the work of the Post-Annex I group: action following a vote, Step 1, Step 2 and confirmatory data. These are detailed in the table below.

<table>
<thead>
<tr>
<th>Issues</th>
<th>Action</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Action required following a vote</td>
<td>RMS – Annex inclusion document</td>
<td>Prepared immediately after decision, highlights all key documents and key issues, posted on CIRCA and available to all MS</td>
</tr>
<tr>
<td></td>
<td>All MS – Post-Annex I inclusion letter</td>
<td>Sent to all authorisation holders immediately after a decision on inclusion, details action required at Step 1 and 2, details action required re-confirmatory data in part B of Including Directive, spells out consequences of not meeting the deadline</td>
</tr>
<tr>
<td></td>
<td>If RMS cannot do Step 1, inform Commission (allocate DMS)</td>
<td></td>
</tr>
<tr>
<td>Step 1</td>
<td>Compliance checks</td>
<td>RMS to undertake assessment (2 months to complete), equivalence reports and data matching tables on CIRCA, update ‘Marten’s Table’; agree ‘tech spec’ considered for inclusion</td>
</tr>
</tbody>
</table>
Work-sharing at re-registration

The workload generated by re-registration procedures have highlighted the importance of sharing common objectives and work practices. The aims of work sharing in the Nordic, Central and Southern Zones are to:

- Achieve a common risk assessment for selected products
- Harmonise assessment criteria
- Avoid duplicate work
- Create expert groups for discussion of problematic areas
- One RMS and one co-RMS to do the work on behalf of others

Standardisation of the core assessment is a key factor, with use of the zonal risk envelope approach to minimise the uses assessed.

The core assessment, comprised of a full data evaluation and some risk analysis, can be used by other MS in that zone as a basis for their national assessments. Acceptance of that core assessment will aid preparation of national authorisations. Core registration reports may be adapted by MS and amended according to their (additional) national specific issues. Using the ‘risk envelope’ approach enables the core data evaluation and risk assessment in each zone to cover all uses required across that zone.
A new work-sharing programme focusing on re-registrations work is under development. Similarly, a guidance document on processes, assessment criteria, specific national requirements and risk mitigation options is under development.

The registration report has an EU standard evaluation format, prepared by the regulatory authority for products post-inclusion, new products or re-registration. In the new submission format. The company prepares the new submission format.

For the registration report, assessments coming under risk management (A) are a national issue, whereas risk assessments (B) and confidential information (C) are classified under the zonal identity.

**Table 4. Procedures to facilitate the zonal work-sharing process for PPP re-registration**

<table>
<thead>
<tr>
<th>Procedure 1</th>
<th>Procedure 2</th>
<th>Procedure 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant rationalises formulations and uses</td>
<td>Applicant submits to ZRMS and sends ‘holding’ letter to other affected MS in the zone</td>
<td>Other MS in zone (or in other zones) use this assessment</td>
</tr>
<tr>
<td>6 months before submission deadline applicant alerts zonal representatives</td>
<td>ZRMS assesses core dossier within one year</td>
<td>Can add national assessments not covered in core and assess within a year</td>
</tr>
<tr>
<td>Zone allocates one MS as ZRMS</td>
<td>ZRMS considers own national requirements and can issue authorisation</td>
<td>National authorisations all issued by final commission deadlines</td>
</tr>
<tr>
<td></td>
<td>ZRMS places assessment on CIRCA</td>
<td></td>
</tr>
</tbody>
</table>

**Work-sharing case studies have revealed the need for:**

- Rationalisation of formulations and GAPs (industry)
- Strong coordination
- Adherence to guidelines and agreed endpoints
- Transparency in the evaluation report
- Opportunities to comment on the assessment
The core B sections on risk can be classified as follows:

<table>
<thead>
<tr>
<th>B core sections</th>
<th>Defined as</th>
</tr>
</thead>
</table>
| Identity – Physical or chemical properties and analysis | • Standard summary of identity and properties (tabulated)  
• Methods to include active substance in formulation and residues methods                                                                 |
| Mammalian toxicity (and exposure)                    | • Assessment of formulation toxicology, dermal absorption  
• Operator exposure  
• Bystander, worker and re-entry                                                                          |
| Metabolism and residues                              | • Summary of residues trials, and consumer risk assessment via EFSA Primo model  
• Metabolism date if not covered by DAR  
• Summary of maximum residue limits (MRLs)                                                                  |
| Environmental fate and behaviour                     | • Many SANCO guidance documents  
• Modelling (EU appropriate) and calculation of PECs rezonal risk envelope                                                              |
| Ecotoxicology                                         | • Many SANCO guidance documents  
• Assessment of studies and risk assessment                                                                     |
| Efficacy                                             | • Core assessments will be limited (resistance following crops, some efficacy trial work)  
• Most of work will be in the National section, reflecting nationally prepared draft label                          |

Table 5. Risk assessment core sections
Although the draft registration report format and work-sharing guidance documents are still being finalised, case study experiences do suggest that the key to efficiency is work-sharing. The applicant has a major role in the efficiency of work-sharing.

### Problems encountered may include:
- Complex existing active substances
- (Confidential) information exchange
- Specific national requirements
- National procedures/deadlines

### How do the documents relate to Annex III?
Documents A-J can all be incorporated into Part A, B and C, whereas documents L, M and N are all incorporated into Part B of the registration report. For document K, underlying data must still be submitted. Overall, the same information is presented in an evaluation format rather than an application one.

The new format will come with guidance on how to prepare submissions to ensure that there is the correct level of detail in each area and that there are the correct approaches to assessment, national and otherwise, in the core dossier.

Transparency is achieved by the MS confirming acceptability, or not, of the assessments, by indicating their opinion in the comment box.

### More work for evaluators?
The new system should mean no more typing out of lengthy assessments, no more time wasted formatting and more time to use expertise and regulatory skills.

### Hard for small business?
These will not have to use the draft Registration report. The optional approach is to supply a ‘standard’ Annex III dossier instead. The main benefit is to multinationals, overcoming the duplication of effort via the core dossier.

### How is core assessment defined?
The groups developing the draft registration report are using their years of experience and developing the content via a questionnaire completed by evaluators in each MS.
Ideas have been explored to handle some of the challenges, particularly those that come under differing national procedures:

- **No organisation of submission other than Step 2 deadline**
  Work-sharing guidance document allows for organisation via company alerts and zonal steering groups.

- **Different products/GAPs in different MS**
  Rationalisation by industry, and use of zonal risk envelope.

- **Differing approaches to assessment**
  Definition of core assessment and clarification of national assessment requirements via draft Registration Report development.

- **Differing approaches to procedures**
  Zonal work-sharing guidance document defines procedure that can be used by all MS.

- **Different approaches to risk mitigation**
  A particularly intractable problem but the new Registration Report recognises that risk management is a national issue (Part A).

**Improved communication between MS**

An important part of the new re-registration process and timetable demands is improving ways of communication between MS.

There are various ways of communicating including:

- **Zonal steering groups**
  These are formed by representatives of the CAs in each MS in the zone. They facilitate communication in work-sharing matters and organise allocation of work to MS in the zone. By coordinating work-sharing activities, they can seek to solve general issues related to work-sharing. Conference calls are made on a regular basis.

- **Contact points**
  It is proposed that each zone will have a single contact point for industry to submit applications they will make.
Confirmatory Data

Confirmatory data comes under Part B of the Inclusion Directive. As indicated in Table 3, confirmatory data guidelines initially suggested that all authorisation holders are informed of requirements in a Post-Annex I letter. Confirmatory data would only need to address the uses considered for Annex I, with Annex II data to be evaluated by RMS.

New proposals are now being suggested. Once COM and RMS are notified of the confirmatory data (Annex II, III and risk assessment), the DAR addendum to the EC is placed on CIRCA for comment (within one year of receipt). The DAR addendum focuses on the specific areas addressed by the confirmatory data, and compares against the issues considered by Annex I inclusion.

The RMS will include a statement that the assessment of the confirmatory data was acceptable (or highlight concerns to COM). Other MS have a short period to comment on the RMS assessment. If necessary, MS can ask for the underlying data from the notifying source, but in general they should refer to the RMS assessment. If RMS/MS raise concerns or differences of opinion, then COM determine whether there is a requirement for an EFSA peer review.

The RMS/COM decision is noted at the WGL and if critical end-points require amendment, the established procedures in the guidance document on Annex II data post-inclusion should be invoked.

Peer review
This will provide the opportunity for other MS to comment on the RMS assessment. The commenting table is similar to the one used in the EFSA peer review process for active substances. Strict deadlines must be adhered to.

Improving the availability of documents on CIRCA
Vital to enhanced communication between MS. CIRCA has various interest groups (IG) documents that are available, including plant protection products and their residues (non-confidential) and post Annex I data (confidential). Guidance documents are in preparation to deal with intra- and inter-zonal work-sharing.

Various problems have been highlighted with this approach:
• No requirement for all approval holders to submit data.
• Granting protection requires additional re-registration procedure to check access to newly protected data.
New Regulation

Council Directive 91/414/EEC aims to harmonise the registration of PPP across Europe. Registration of active substances is approved at community level resulting in the established positive list of active substances (Annex I). Products containing those actives substances are approved at MS level. The Directive sets up safety standards for products. Building on this directive, new regulations are set to come into force in 2011.

The purpose of the new regulation is to:

- Protect human and animal health and the environment
- Safeguard the competitiveness of agriculture
- Provide for a common market
- Speed up decision making

The major changes compared to 91/414/EEC are as follows:

- Division of EU into three zones
- Examination of authorisations by one MS on behalf of the other MS in a zone
- Deadlines in all steps
- Simplified data protection system

The scope of the new regulation is also different:

- Evaluation of synergists, co-formulants and adjuvants will be undertaken as well as for active substances

A work programme will be established for the gradual review of safeners and synergists on the market. Derogation will be for a period of 5 years. A co-formulant shall not be accepted if its residues or use have a harmful effect on human or animal health or the environment. COM may review co-formulants at any time. Co-formulants not accepted will be included in Annex III. Adjuvants shall not be placed on the market unless they have been authorised in a MS.

- Introduction of low risk substances, basic substances and candidates for substitution

An active substance shall not be considered of low risk where it is classified as: carcinogenic, mutagenic, toxic to reproduction, a sensitising chemical, immuno- or neuro-toxic, explosive, corrosive or it is persistent etc. A basic substance is an active substance which is principally not a substance of concern in terms of risk to human, animal or plant health or to the environment. Basic substances are not predominantly used for PPP purposes and are not placed on the market as such.

- Comparative assessment of plant protection products containing ‘candidates for substitution’
Various criteria define ‘candidates for substitution’ including classifying substances as carcinogen, or toxic for reproduction, category 1 or 2. Non-chemical control or prevention methods need to be available; candidates for substitution shall be approved for a period not exceeding 7 years.

**Authorisations of PPP**

In general, PPP are only authorised if active substance, safener and synergist have been approved and its co-formulant is not included in Annex III. PPP are authorised for a period not exceeding one year from the date of expiry of the active substance, safener and synergist.

<table>
<thead>
<tr>
<th>Application</th>
<th>Examination</th>
<th>Provisional authorisations</th>
</tr>
</thead>
</table>
| • A list of intended uses in each zone
  • A proposal from the applicants to which MS will evaluate the application in the zone
  • A copy of any authorisation already granted
  • A copy of any conclusion of MS assessing equivalence | • A format of the assessment report shall be established
  • MS shall decide within 12 months
  • If additional information is needed, a 6 month extension can be granted | • Active substances not yet approved
  • PA for a period not exceeding 3 years
  • Maximum residue levels (MRLs) have been established in accordance with Reg. 396/2005 |

Table 6. Authorisation of PPP under the new regulation

**Approval of active substances**

In general, an assessment of an application may be performed by a number of MS together under the co-rapporteur system. The RMS may at any time consult EFSA. A completeness check is carried out within 45 days. The DAR is due within 12 months and should include a proposal to set maximum residue levels.

Time limits apply to the various stages of the approval process. For example, DARs are circulated for comments (time for commenting is 60 days) and EFSA provides their conclusions 120 days after the commenting round.

In terms of periods for approval, the first approval shall be for a period not exceeding ten years. For ‘candidates for substitution’, this is 7 years, for low risk substances 15 years and for basic substances an unlimited period of time.
Data Protection

Under the new regulation, data protection is:

- Vertebrate studies data sharing obligation
- Authorisation holder must claim protection and confirm it has not protected previously
- Applies to GLP/GEP studies only
- 10 years protection to active and product data from date of authorisation in MS
- 13 years for low risk PPP
- 2 ½ years renewal/review
- Minor use incentive – extended protection up to 2 years

Some general FAQ about the new regulation are answered below:

When will the new Regulation apply?
Date of application is 18 months from publication – 14 June 2011.

What will happen to Directive 91/414/EEC when the new regulation applies?
See Article 83 – it is repealed (but assessments will continue under the transitional measures).

Should MS prepare new national legislation to implement the legislation?
No, not for the main provisions, it is a regulation which is directly applicable.

What is the difference between approval and authorisation?
Approval is for active substances, authorisation for products/uses.

For how long will an authorisation be valid?
Authorisation may last for one year longer than approval expiry, but can be shorter – see Article 32.

Under what circumstances would MS be able to issue a provisional authorisation, prior to approval of a new active substance?
See Article 30 – provisional approval may only be given if there is no decision on approval within 30 months, if completeness checked, it is expected to comply with requirements and if MRL is in place.

Once an active substance approval has been renewed under the new Regulation, how long before industry must make a submission for renewal of product authorisation?
See Article 43 2 – only 3 months from the date of re-approval.

How long do MS have to assess that submission and issue a renewed authorisation?
See Article 43 5 – only 12 months from the date of re-approval – so only 9 months to evaluate and re-authorise.

Under what legislation would ongoing applications, at the time of publication of the new regulation, be assessed?
See the transitional arrangements – Article 80. The AIR renewals, NAS and re-submissions will all be assessed as under 91/414. Products, ongoing applications, and re-registration of products containing Annex I included actives would also be assessed under national law (includes 91/414).

Under what legislation will applications for re-registration be assessed (i.e. those products containing active substances that were included in Annex I of Directive 91/414/EEC)?
See answer above.
Further Information

Better Training for Safer Food
For information on training courses and to find the BTSF training booklets, please visit:
www.btsf.eu

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National Contact Points
BTSF National Contact Points (NCP) have been designated for EU Member States and certain other countries. NCPs are involved in coordination of the BTSF initiative on a national level. They provide country-specific information on training courses to contractors and propose participants.
www.ec.europa.eu/food/training_strategy/participants/ms_contact_points_en.htm

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Disclaimer

The content of this booklet reflects the information given on the training course: ‘Evaluation and Registration of Plant Protection Products’. The material presented is provided by the training course contractor. For the latest updates on the legislation, interested parties should consult the guidance documents at:
http://ec.europa.eu/food/plant/protection/index_en.htm

This booklet does not necessarily represent the view of the Commission Services.