**How to get approvals of use of Plant Protection products for nursery cultures in EU.**

All approvals and registrations are based on the EU regulation 1107/2009. Most national registrations are also dependent on additional national rules, because the Regulation allows all MS to add national regulation and demand for documentation based on specific environmental arguments. Denmark has strict national rules for the protection of the ground water, and Sweden has strict rules on surface floating water. Other countries have their specific extra rules.

Active substances have to be approved of EU by a procedure according to Regulation 1107/2009. Approved substances are listed at the Annex 1 list.

Ordinary approvals. Chemical Products (1 or more active substances in a specific formulation) produced and marketed as a plant protection product must be approved under the Regulation 1107/2009.

Products produced and used for other purposes can also have an efficacy in regulating pests or diseases. These products can be approved as Basis Substances under the EU Regulation 1107/2009 Article 23.

Plant Protection Products can only be used in a MS if it is approved by the national agency in the MS.

Documentation is to be delivered by the company who wants to have the license for the marketing.

An approval (registration) is given for the use against specific pests and diseases in named cultures or culture groups. Definitions on cultures or culture groups are not well defined, and the same names are not always used in applications in the different MS.

Typically you see manufactures only makes applications for cultures and pests of economic importance in agriculture. An ordinary approval of a Plant Protection Product is made by the manufacturer or a company who has the license to marketing. They only send in applications for use in cultures and against pest and diseases with a potential market. Their reason for this is partly because the documentations are expensive, and partly because they are afraid of damage in high value cultures with a possible compensation reclaim.

An approved plant protection product can be given a Minor Use Approval (EMAS) for other cultures and uses. This is also approved for a MS by the National Agency. If the manufacturer will not invest in documentation for the safe use in specific minor cultures in the different MS, the EU regulation 1107/2009 makes it possible for others to apply for EMAS in a MS if the product is market in the MS.

An Application will often need specific national documentation added to the documentation used in EMAS in a different MS. If there are alternative products approved for protection against the pests or diseases an EMA is not given. Argumentation has to be documented. It might be emphasising the need for a resistance management or if other pests and diseases are possible to regulate than mentioned in the given registration.

Economic obstacles.

You need an organisation to finance the application work.

It can be expensive to pay for the needed trials to get the documentation at an acknowledged research institute (GEP).

The costs of the application differ from MS to MS. You need a professional to make the application, and you need to pay a fee to the National Agency for the application.

EMUDA – EU Commodity Expert Group. A way to have help in national approvals is to get documentation used in other MS to be used in an EMAS. This can be done by the exchange of documentation within the EU Commodity Expert Group.

The documentation data (dossier) is based on data from the manufacturer and additional research on environmental issues. The nursery industry in each MS must finance the research and the application work. In Denmark by GAU (fond). In UK by AHDB.

The EU Minor Use Foundation in Paris is financed by the EU Commission. 1 person is employed to work as a coordinator for the different Commodity Expert Groups – also the Commodity Expert Group for ornamentals (which also contain fruit and forest nursery plants).

**Standard procedure for approvals work:**

Approval of active substances:

* Positiv list (Annex I)
  + EU RMS (Rapporteur Member State)
* New criteria
* ”Normal” active substance (conventional plant protection products)
* Low risk active substance (microbiology and also allowed for organic growing)
* Basic substance ( products used for other purposes than PPP)

More regulations now and in the future:

* Safeners og synergists
  + Separate regulation (December 2014, 5 years of adaptation)
* Co-formulants
  + Negative list (Annex III) (from June 2016)
* Adjuvants
  + Waiting for new approval criteria
  + Separate regulation (from ??)

Normal approval:

* Try to get the Chemical Companies to put the highest possible number of minor crops and pests on the label. Someone have to do the lobbying.
* The Companies sometimes forget to put a crop or a pest on the label
* So, help the Companies not to forget

Minor use:

* No demand for efficacy data in Denmark
* No demand for selectivity data in Denmark
* Residue data is still required, no changes
* Minor use approvals can come on the label

**Applications for minor use – protected ornamentals ( =in a Greenhouse) a Danish example:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **Active substance** | **Field of Use** | **Pest** | **Status** |
| Acrobat New | Dimethomorph + mancozeb | Fungicide | Phytophtora | Approved |
| BA-6 | 6-benzyladenin | PGR |  | Approved |
| Aliette WG 80 | Fosetyl-Al | Bactericide | Erwinia and Pseudomonas | Refused |
| Previcur Energy | Propamocarb + fosethyl-Al | Fungicide | Pythium | Approved |

**Minor use approvals in 2012-2013 in Denmark– nurseries (outdoor use):**

* Mancozeb-products: Botrytis, Peronospora etc.
* Shirlan (fluazinam): Peronospora, Phytophtora
* Kumulus S (sulphur): Fungicide/insecticide
* Proline (prothioconazol): Fusarium
* Flexity (metrafenon): Mildew
* Teppeki (flonicamid): Aphides
* Steward (indoxacarb): Lepidoptera, pollen beetle
* Movento SC 100 (spirotetramat): Coccoidea, cecidomyiidae
* Biscaya OD 240 (thiacloprid): Aphides, weevil (Curculionidae), Lepidoptera, pollen beetle
* Callisto (Mesotrion): Herbicide
* MCPA-products: Herbicides
* Matrigon 72 SG (clopyralid): Herbicide
* Command CS (clomazon): Herbicide
* DFF (diflufenican): Herbicide
* Cerone (ethephon): PGR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **Active substance** | **Field of Use** | **Pest** | **Status** |
| Revus | Mandipropamid | Fungicide | Phytophtora | Approved |
| Primus | Florasulam | Herbicide | Marchantia latifolia | Approved |
| Aliette WG 80 | Fosetyl-Al | Bactericide | Erwinia and Pseudomonas | Refused |
| Goltix | Metamitron | Herbicide |  | Applied |
| Previcur Energy | Propamocarb + fosethyl-Al | Fungicide | Pythium | Approved |

EU is divided in different zones.

The most important for ornamentals are the 3 geographic zones and greenhouse zone. There is also a “zone” for seed treatments.

**Mutual recognition:**

Can be applied when the authorisation was granted by

* a Member State which belongs to the same zone
* a Member State which belongs to a different zone

a Member State for use in greenhouses, seed treatment etc.

**Exemptions - emergency situations in plant protection (dispensation):**

* Only possible when there are no other options
* It can be given for a period not exceeding 120 days

Examples in Denmark: Basamid for soil disinfection and Captan against Neonectria marcrocarpa in Abies sp.

**Approvals in a specific zone:**

* Zone evaluation
  + Zone Rapporteur Member State (ZRMS)
  + Co-operation in the zone
* Evaluations time (ZRMS)
  + One Year (+ 6 Month)
  + Other countries in the zone
  + 120 Days for national evaluation in the zone

**Challenges in the northern zone:**

* Real effort by the authorities in the zone to establish common directives with a few national demands
* As far as possible approvals should be based on dossiers, which are prepared for the other zones
* The value of the sale in the Nordic zone is < 4% of the total sale in EU
* The value of the sale in Hungary is the same as in the whole Nordic zone

**Challenges in Denmark:**

*Specific Danish demands concerning:*

* + Groundwater
    - No leaching of active substances and metabolites (even harmless) is accepted.
  + Persistence in soil
    - The half-life of the active substance and relevant metabolites must not exceed 180 days.
  + Minor use applications
    - If there is an existing normal authorisation and no minor use authorisations for the applicate purpose, the Danish EPA will reject the application unless we can verify that the product can solve a specific problem like resistance management etc.

*New Danish pesticide strategy legislation*

* + The Danish EPA has made an environmental and health impact index.
  + The impact on environmental and health had to be reduced with 40% at the end of 2016
  + New taxes on pesticides. Highest taxes on the most harmful active substances.

*Spray drift of pesticides*

* + Until now the Danish EPA has refuse to extend approvals (changing spraying distance to water etc.) if growers and farmers use methods like:
    - low-drift nozzles
    - tunnel sprayer
    - etc.

**There is a need to work together in the Nordic zone:**

1. Share the workload (like the authorities)
2. Plan the mutual recognition, minor use etc.
3. Share data
4. Follow the work in the EU groups
5. Meet the producers of plant protection products
6. Cooperation between the Nordic/Baltic applicant working group

**How can ENA support the approval work in the member countries?**

1. Organize a list of approved (registered) products containing all registered products in the different countries. This will have to be updated every year! At least.
2. Every country can make a ‘wishing list’ of products they don’t have - but would like to use. Also for seed treatment.
3. Every country must identify the conditions for making national applications, and identify the offices (professionals) which can make the application work. And also a GEP Research Institute that can deliver the needed data.
4. Every country must identify the organisation which will finance expenses for paying the fee for national applications and research and application work.
5. EU Commodity Expert Group can support the representative of the different national offices making the application work by exchange of data used in other countries.
6. Needed GEP research for approvals of new products for all or a group of members of ENA could be financed and conducted in collaboration and organized by ENA

***BENT LEONHARD***