Assessment methodology and procedure for applications for minor uses under 1107/2009 in the Netherlands

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Basic policy principle

- Netherlands agriculture: strong in high-value specialised crops
- Sustainable, effective and safe plant protection package
- Shared responsibility by
  - Government
  - Plant protection industry
  - Farmers/growers
- Ctgb strategy 2011-2015 Focus on authorisation of PPPs for minor uses
Netherlands Program on minor uses

- Legal options:
  - Authorisation procedure for PPPs for minor uses
  - Simplified assessment methodology/procedure

- Instruments:
  - Fund Minor uses / Foundation: “Trustee”
  - Helpdesk Minor uses/ Helpdesk Ctgb

- Expert centre on Speciality crops
- International Cooperation
PPP authorisation for minor uses: Simplified assessment methodology/procedure

- Article 51 of Regulation 1107: assessment methodology for minor uses defined at the Member State level.
- Authorisations for minor uses: on a public list (website).
- The basic principle is that zonal assessments will be made where possible.
- The definition of a 'minor use' differs between the Member States. The Netherlands has developed its own decision tree.
- The Netherlands has adapted the assessment process and the assessment methodology.
I Request for authorisation of a new plant protection product (zonal)

• New zonal authorisation (new plant protection product)
• The GAP contains all intended uses, including the minor uses.
• As a result, the minor uses will be assessed zonally.

• Efficacy
  - Where possible: assess efficacy. This will allow the assessment to also be used later on in Member States where it applies to a major use.
  - Other Member States that always want the efficacy to be assessed can consider this to be a national-specific matter.
II Application to extend an authorisation with a minor use for multiple countries in the zone

- Extension for minor uses in multiple countries: a zonal assessment.
- Assessment with the assessment framework prevailing at the time.
  > Basic dossier should probably be updated.
- Turnaround time: maximum of 1 year + maximum of 6 months stop the clock).

Important discussion points:
- is it possible to realise a faster turnaround time
- is it possible to make an assessment with reference to the assessment framework of the primary authorisation
- is it possible to grant an authorisation without conducting a risk assessment if the intended use falls within the risk envelope, and, if relevant, the residue aspect (MRL) is satisfactory (see also III).
III Application to extend an authorisation with a minor use, only in the Netherlands (not zonally)

- Extention with a minor use in only one country: non-zonally.
- For this non-zonal route, the Netherlands has developed a new process.
- Accelerated ‘risk envelope approach’ procedure: maximum of ca. 16 weeks).
- In cases where one or more aspects must be assessed, an assessment will be conducted. If the dossier is complete and no supplementary data must be provided by the applicant, then a decision can be made on the application within probably a maximum of ca. 28 weeks.
- The above-mentioned assessment will use the assessment framework that applied when the plant protection product was authorised.
Only when new developments/insights strictly indicate the use of the actual assessment framework for one or more aspects, this will be applied.

During renewal of the authorisation all uses will be assessed according the actual assessment framework.

After authorisation, the extension is of course also reported on a list with minor uses (website). In addition, the authorisation could be actively reported in the zones. If this authorisation is compatible with their national requirements for minor uses, other countries can then adopt the authorisation as it stands or with a supplement, such as an efficacy assessment.

The aim is to make this procedure even more efficient (shorter turnaround time) after acquiring some experience.
III continued

- Unclear aspects in this course of action:
  - does Europe accept the use in the Netherlands of the assessment framework of the primary authorisation;
  - does Europe accept that no option for review will be offered because application is done in one country;
  - mutual recognition can be difficult for some Member States due to different basic assumptions/requirements than those in the Netherlands.

Describing 3 scenarios:

- Evaluation Manual on Minor Uses (English) :
  describes the decision methodology to determine a minor use, the assessment methodology and the procedures.
  Begin 2012
Simplified assessment methodology/procedure: future

The Netherlands: strives towards a pioneering role in Europe. The aim: harmonise assessment framework and turnaround time so that ultimately, if desired, all extensions of authorisations with minor uses can be handled zonally.

The Netherlands strives to harmonise accelerated procedures, including using the assessment framework from the primary authorisation and granting authorisations without risk assessment where this is possible.

A point of attention here is that in all situations going to the zonal level should not slow the process.
Fund Minor uses /Trustee

- **Aim**: financial support for obtaining approval
  - Registration costs, acquisition of data (e.g. residue trials and when necessary efficacy trials)
- **Awarding twice a year**
- **Financed**:
  - 50% Government; 50% growers associations
  - €600,000 per year available (maximum)
- **Application by stakeholders**
  (industry or growers association)
Fund Minor uses /Trustee

• Liability: industry or Trustee

  Trustee = Trust for solving liability issues
  – Trustee is initiated by Dutch Farmers Union (LTO Nederland), Trade (Agrodis) and Industry (Nefyto)
  – Trustee applies for a ‘third party’ of an authorization for an extension of use,
  – Trustee covers a liability problem which a holder of an authorization does not support
Helpdesk Minor uses (nVWA)
Helpdesk Authorisations (Ctgb)

• Helpdesk Minor Uses (nVWA, former Netherlands Plant protection service)
  – Signalling problems
  – Advice about the most efficient way to get approval for minor uses
  – Seek for structural solutions
  – Bringing together national and international stake holders
  – Website

• Helpdesk Authorisations (Ctgb, minor uses)
  – The Board decides on applications for authorizations
  – Helpdesk advises (potential) applicants on general and minor use issues (application procedure, dossier requirements etc.)
  – Since july 2011 special focus on minor uses, special request form
  – Website: www.ctgb.nl
Expert Centre on Speciality crops

• **Aim**
  - Dutch expertise on speciality crops bundled and promoted at international level
  - The Netherlands attractive for international companies, for research and advice, and for application of product authorisations

• **Who are participating in the Expert Centre?**
  - Agriculture (LTO Nederland, Plantum)
  - Industry (Nefyto)
  - Ministry of EL&I (Economy, Agriculture and Innovation)
  - Wageningen University and Research centre
  - Ctgb
Expert Centre on Speciality crops

• How does the Expert Centre work?
  – more insight into the various procedures via the digital portal of the Expert Centre.
  – easier to identify experts on specific sub-areas.
  – a better coherence of the “behind the screen” procedures
  – a faster and easier coordination between research, advice, financing and authorisations so that innovations that are based on Dutch expertise are (more) rapidly reaching the market.

• Website
International Cooperation

• On EU level, Netherlands wants to stimulate:
  – Prevent double work
  – Work sharing
  – European Fund for Minor Uses.

• Technical working groups

• Presentation Johan Roman,
  Minor Use Co-ordinator EU North
Thank you for your attention!