**General information on applications for authorisation of plant protection products acc. to Art 33, with reference to Art. 34
Regulation (EC) No. 1107/2009**

In the light of a common European approach taken by Regulation (EC) No 1107/2009 the following harmonisations are beeing implemented regarding applications according to Art. 33 in connection with Art. 34 (exemption from the submission of studies acc. to Art. 34 (1)) of Regulation (EC) No 1107/2009. The adaptions to the application procedure in Austria are based on the harmonised rules in the light of recital 9 and 25 as well as Article 1 of Regulation (EC) No 1107/2009. Furhtermore, the application of the rules set out in the Regulation in the light of currently valid Guidance Documents for applications of authorisation of plant protection products, require a uniform approach throughout the European Union.

**From April 2023 applications** acc. to **Art. 33 in connection with Art. 34 can only be processed if the documents required for the application acc. to Art. 33 are submitted entirely. This includes the submission of a complete dossier, with the exepmtion of the documents referred to acc. Art. 34 (1).**

The application acc. to Art. 33 with reference to Art. 34 is processed according to a zonal procedure:

In order to accommodate your application within the zonal application framework, and to ensure a quick as well as efficient process in the light of the framework set out by Regulation (EC) No 1107/2009, you are required to request an application slot. **For zonal applications with Austria as zonal Rapporteur Member State (zRMS) please contact**: [ppp@baes.gv.at](ppp%40baes.gv.at)

The expiry dates of product authorised in Austria acc. to Art. 33 will be set following the framework layed down by Art. 32. Therefore the approval of the active substance or at least one of the active substances contained in the relevant product, must not expire within a year from the date of application.

**Applicants who submit an application acc to Art. 33 with reference to Art. 34 must therefore provide:**

* cover letter (signed) in paper form **by regular mail**: short description (including the trade name and authorisation number of the reference product) including a list of attachments

[reference to more than one authorised plant protection product within the same application is not possible.]

* GAP-tables in German and English electronically and in paper form
* application form
* declaration that no unacceptable co-formulants are used in the formulation
* a complete and a summary dossier for each point of the data requirements of the plant protection product **(electronic submission)**
* dRR (word-format): Part A (risk management; national), Part B (data evaluation and risk assessment; core and national addenda), Part C (confidential information; core)
* in the submitted dRR: **a list of studies** (including studies covered by a data access agreement (LoA), or data out of protection, as well as own studies to justify the data requirements). The list should contain a justification as to why the data are considered unprotected acc. to Art. 34 (1).

[concerned member states will need to consider data access and whether the reference product is authorised on national level]

In addition, the following documents may be required, where relevant:

* Letter of access (LoA) in the original, adressed to the Federal Office for Food Safety.
* Comparative assessment if the active substance is a candidate for substitution. [for authorisations based on Art. 34, no exemptions acc. to Art. 50(3) can be granted]
* conclusion of the Member State assessing equivalence of the technical active substance/s included in the plant protection product
* a copy of the application for a maximum residue level as referred to in Art. 7 of Regulation (EC) No 396/2005 or a justification for not supplying such information

Additional general information:

Assessment of formulation comparison acc. to Art 34 (2) c (check for comparability of your formulation with the formulation of the reference product) is conducted as part of the assessment procedure after an application has been made. Where it is concluded that the product is not comparable, a submission of appropriate tests and study reports in acc. with Art. 33(3) is required.

Uses applied for shall be either identical or in a reduced number compared to the reference product. Once the product has been authorised, an applicantion for an extension of use acc. to Regulation (EC) No 1107/2009 can be submitted.

For information regarding the Austrian reference product, please visit the official Austrian Plant Protection Product Register: <https://psmregister.baes.gv.at/psmregister/faces/main>. [There must not be a pending renewal procedure for the intended reference product.]

The dRR must be a standalone document (a single reference to evaluations of other products is not allowed, the complete evaluation or a robust summary of the related product must be taken up in the dRR. When referring to previous assessments (e.g. another product RR) there is no need to duplicate that assessment for the new product submission. Instead full reference should be made to the earlier product assessment and a brief summary provided. The end points derived, should be used in the risk assessment for the new product. It is further important to demonstrate through robust summaries that those assessments were conducted to appropriate standards (i.e. that Art 36 (1) is complied with and that the relevant Guidance Documents were respected at the time of application); and that they apply to the new product application.

(Technical guidance documents on the presentation and evaluation of plant protection product dossiers in the format of a (draft) Registration Report (SANCO/6895/2009 rev 2.2, from 26 January 2018)

The dRR should include a full assessment of all sections of the risk assessment including efficacy following the guidance applicable at the time of application; only information relevant for the uses applied for in the zone of application should be included. Furthermore, the exemptions set forth in the Art. 34 do not allow an exemption from requirements set forth by Art. 36.1 for the product. (Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010 rev 11, from 25 January 2021)

Following the procedural steps set out above, please send the application by regular mail to:

Bundesamt für Ernährungssicherheit

Spargelfeldstraße 191

A-1220 Wien

Further information:

Application fee: <https://www.baes.gv.at/en/official-announcements>