

Consolidated version of

**The Swedish Board for Accreditation and Conformity
Assessment's (SWEDAC) Regulations and General Guidelines
(STAFS 2007:10) for the Accreditation of Bodies that Plan,
Carry out and Report Efficacy Evaluations according to GEP**

The translation includes the following amendment STAFS 2012:1

Scope

1 § These regulations apply to bodies that plan, carry out and report efficacy evaluations according to Good Efficacy Practice (GEP). These regulations apply to bodies that are accredited and bodies applying for accreditation by SWEDAC.

The regulations are a supplement to SWEDAC's Regulations (STAFS 2010:10) and General Guidelines for Accreditation. (*STAFS 2012:1*)

Requirements in standards and other documents

2 § An accredited body that carries out efficacy evaluations according to GEP shall fulfil the requirements in the following sections of SS-EN ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2005)*

1. management requirements
2. personnel,
3. test and calibration methods and method validation,
4. equipment,
5. measurement traceability
6. reporting of the results.

The accredited body shall also fulfil the requirements and carry out the tasks that are stated in The Swedish Chemicals Agency's Regulations (KIFS 2008:3) on Chemical Products and Biotechnical Organisms. (*STAFS 2012:1*)

3 § An accredited body shall have the competence to plan and carry out efficacy evaluations and to compile the results from these according to the procedures stated in the European and Mediterranean Plant Protection Organisation's (EPPO's) guidelines PP 1/181 - *Guideline for the efficacy evaluation of plant protection products*.

Use of the accreditation mark and other reference to accreditation

4 § When an accredited body reports results within the scope of its accreditation, the report shall be marked according to the regulations stated in 9 § SWEDAC's Regulations (STAFS 2010:10) and General Guidelines on Accreditation, followed by the text

REPORT

Issued by GEP Accredited Field Research Station

The accreditation mark and the text shall be placed on the front page of the report. (STAFS 2012:1)

Use of subcontractor

5 § An accredited body shall notify SWEDAC before each growing season if it intends to use the services of subcontractors which are not accredited and which they themselves intend to assess the competence of. SWEDAC shall be offered, in advance, the possibility to examine the body's assessment of the subcontractors before their services are used.

General guidelines to 5 §

SWEDAC's evaluation of the body's ability to assess subcontractors may consist of a documentation review or participation on site as an observer during the body's assessment of subcontractors.

Miscellaneous

6 § In individual cases and if special circumstances so require, SWEDAC may grant dispensation from these regulations.

STAFS 2007:10

These regulations come into force on 1 June 2007, on which date the Board's regulations (STAFS 2001:1) for the Accreditation of Bodies that carry out field research on the cultivation of plants shall cease to apply.

STAFS 2012:1

These regulations come into force on 2 May 2012.