

CZ – Central Institute for Supervising and Testing in Agriculture

Section of agricultural inputs

 Department of plant protection products

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Instructions for official recognition of testing organisations

For conduction of experiments or tests for research and development purposes

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**Introduction**

Experiments and tests for research and development purposes including **the release into the environment of unauthorized plant protection product or unauthorized use of a plant protection product** may be conducted if the Member State in whose territory the experiment or test is to be carried out has assessed the available data and granted a permit for trial purposes. (Article 54, paragraph, Regulation of The European Parliament and Council (EU) No. 1107/2009)

An application for permission of experiments or test is not needed if the member state has granted the person concerned the right to undertake certain experiments and test and has determined the conditions under which the experiments and tests have to be undertaken. (Article 54, paragraph 4 Regulation of The European Parliament and Council (EU) No. 1107/2009)

Act No.326/2004 Coll., § 45

The decision on eligibility to conduct experiments and tests (GEP Certificate) issued by Central Institute for Supervising and Testing in Agriculture (Institute) is based on an application of a natural person or legal person that is competent to conduct experiments and test in accordance with requirements of the Good experimental practice. (Paragraph 1)

The GEP Certificate is granted for period of five years and may be renewed. (Paragraph 4)

Act No.245/2011 Coll. amending Act č.326/2004 Coll.

Transitional provisions

2. The decision on eligibility to carry out of experiments and tests issued before the last amendment of Act. No. 326/2004 Coll. has entered into force ceases to be valid by expiration of 5 years from the date of effective of that amendment of the Act.

The application for the renewal of the GEP Certificate shall be submitted at least 90 days before the expiration of decision validity (par. 5).

Central Institute for Supervising and Testing in Agriculture (Institute) is entitled to

1. Supervise the compliance of certified persons with the GEP requirements,
2. Prescribe and approve the guidelines for testing of products,
3. Require information and documentation related with GEP requirement
4. Require information on preparation and conducting of tests with products as well as documentation on testing of products and places where the tests are held.

(Paragraph 7)

Holder of the decision is obliged to notify to Institute at least 3 days before the first application of tested product or before the sowing seeds

1. name or the code of the product,
2. name or the code of the active substance,
3. crop,
4. pest or other use,
5. maximum dose within one treatment.

(Paragraph 11)

**Regulation No.32/2012 the products and further plant protection products, § 4, 2**

The documentation for proving of eligibility to carry out experiments and tests in accordance with the requirements of the GPE includes

1. Documentation about organisation structure and technical conditions that includes:
	1. Description of testing organisation and its activities in agriculture,
	2. Organisation of testing organisation including specification of responsibilities, within the management and within carrying out its expert activities**,**
	3. Internal system of training of employees in field of ensuring of the quality of work, working procedures and occupational safety,
	4. The description of buildings, premises and plots for experiments including premises for storage of product samples,
	5. The description of the manner of safety collecting and elimination of useless rest of products, packagings, the rest of application machinery and the water remaining after the cleaning of application machinery
	6. The description of handling/treatment with treated plants or plant products,
	7. Machinery, apparatus and other equipment for carrying out tests,
	8. The rules for archiving of the documentation,
	9. The rules of internal quality control system.
2. Standard operating procedure for all kind of activities related to conduct experiments,
3. Metrological order that sets up rules for manipulation, maintenance and calibration of used measuring instruments,
4. Record of maintenance and calibration of used apparatus and equipment,
5. Records of training, completed courses and trainings to carry out designated functions.

**For gaining The Decision on eligibility to carry out experiences is needed to:**

1. Submit the application for official recognition of eligibility to carry out experiments and tests (the form is available on the website of the Institute – forms to download “The application for official recognition of eligibility to carry out experiments according to § 45/2 Act. No. 326/2004 Coll., )
2. Work out documentation unnecessary for assessment of eligibility to carry out experiments (according the regulation No. 32/2012 Coll., paragraph 4/2).
3. Enable to conduct audit at the places that are related to the conduct of experiments

Detailed description of this situation including fees and terms is available on websites of the Institute – life situations “The official recognition to conduct experiments and tests for purpose of finding out products efficacy in the Czech Republic (Officially recognized exams)”.

**Officially recognised testing organisation** may conduct experiments and tests for purpose of finding out of products efficacy in range stated by the decision.

**GEP experiments** (before generally marked as registration) are experiments that are conducted according the principle of the Good experimental practise and shall be registered since they have been established. The experiments may be officially recognized for registration purposes.

These experiments may be conducted only on GEP stations and these stations are obliged to announce the experiments to the Institute.

**Non - GEP experiments** (before generally marked as experiments of orientation) are experiments that shall not be conducted in accordance with the principles of experimental practise and they may not be recognized for registration purposes with respect to evaluation of biological efficacy.

These experiments may be conducted:

* at GEP stations if they are conducted in range stated by the decision GEP. In this case the stations are obliged to announce only the experiments with unauthorized products or the unregistered using. The experiments with registered products that are corresponding with registration are not necessary to announce.
* in the case experiments are performed outside the GEP station plots, it is necessary to submit the application for permit to make an experiment or test according the article 54 Regulation of European Parliament and Council of Europe (EU) No. 1107/2009.

The internet application **Field experiments** **and GEP stations** has been used for the notification of GEP experiments since 2008, and all officially recognized testing organizations have the access to this internet application.

In case the testing organization cannot use the internet application it is obliged to notify to the Institute tests by another manner at least 3 days before carry out of the first application of the product.

**The inspection of GEP testing organizations**

The fields of inspection:

1. documentation of testing organization
2. knowledge of employees in the GEP field
3. equipment, store and the records on the storage
4. documentation on the experiments
5. inspection of experiments on the field

The protocol of the inspection is carried out during the inspection on-site. The representatives of the inspected testing organization are familiarized with the content of the protocol and the copy of the protocol is submitted or sent to the testing organization.

The part of the protocol is the list of findings, deficiencies or infringements and the deadline for its remedy.

The Institute suspends the GEP Decision in case the holder of the Decision violates the basic requirements of the Good experimental practice or the requirements stated in the GEP Decision.

When the holder of the GEP Decision remedies the deficiencies due to which the GEP Decision was suspended, the Institute cancels the suspension of the GEP Decision.

When deciding on the suspension of the GEP Decision the Institute takes into account seriousness of the violation of the GEP requirements, the duration of this situation, the consequences caused by this situation, also the fact whether there was a remedy.

This instruction shall serve as a guideline for completing of the documentation necessary for the decision-making on the eligibility to carry out experiments and tests in accordance with the GEP requirements.

Officially recognized persons must meet the following requirements:

1. To have at their disposal the sufficient scientific and technical **staff with necessary education, training, technical knowledge and experience** for carry out designated functions;
2. To have at their disposal all appropriate **equipment** required for the right conduction of intended experiments and measurements; this equipment must be properly maintained and calibrated before and after usage according the established program;
3. To have at their disposal appropriate **plots for experiments** and /or greenhouses, phytotronor stores; premises where the experiments are to be conducted, must not devalue or to have unfavorable influence on required accuracy during measurement.
4. To provide all corresponding staff with **the updated standard operating procedures and plans** for experiments;
5. Provide to appropriate authority on his demand detailed all detailed **information on experiments** before the beginning of the experiment including locations and data on tested plant protection products;
6. To ensure that **the quality of the work** is corresponding with its kind, range, volume and determined target;
7. **To keep records of all observations**, calculation and gained data, calibration records and final protocols from the experiment as long as, the product is authorized within the EU.

Other information could be found in the methods EPPO PP 1/181.

To prove the meeting of all requirements the testing organization shall draw up and maintain documentation including especially:

* The Quality Manual
* Metrological Order
* Standard Operating Procedures (SOP’s)

 The extent of other necessary documentation depends on the conception and range of above mentioned documentation and also depends on the size and structure of the testing organization. For example records of occupational training and experience shall be drawn up as an appendix of the Quality Manual, in the form of individual SOP or as an independent document.

Generally **the documentation must describe all situations and activities performed in relation with experimental activities in the testing organization.**

**The Quality manual**

= basic informative document on testing organisation shall include:

**General information on testing organisation**

* Name of the testing organisation, legal status
* Address
* Contact person, telephone, e-mail address
* Description of testing organisation
	+ Main activity (in the field of agriculture)

**Data on intended experiment activity**

* Existing and pretended focus of intended experiment activities
* Maximum pretended capacity of testing organisation in the field of tests and other experiments with products
* Share of experiments determined for gaining data for product registrations of total amount of experiments with products according the focus of experiments

**Organisation structure of the testing organisation**

* State of permanent employees and state of seasonal (temporary) employees
* Organisation structure of the testing organisation =organigram
* **“**Organigram**”** must include all employees, their subordination and substitutability. It could be part of the Quality manual or connected as an appendix. It could also be extended as individual document including signature and date. The document must be still valid /actual.
* Organizational and labour relation among seat of testing organization and experimental plots

**Data on employees and description of system of occupational training of employees**

* Qualification of employees, educational plan, incorporation into working system

Testing organisations must have extended summary of employees including description of their working incorporation and responsibilities. Data on working incorporation and responsibilities of employees must be sufficiently comprehensible. The summary shall be the part of the Quality manual or connected as an appendix. The document must be still valid.

In case new employees are accepted, the educational plans must be immediately composed with special emphasis on training and experience to carry out designated functions (see under, point 3).

* Internal educational system of employees

The required level of knowledge of employees that perform the experiments must be stated. The Quality manual must include the manner of registration of records on education and training and a person who is responsible for the registration of records.

The records must include these three parts:

1. Professional curriculum vitae including data on education and following practice in field (in the field of experiments)
2. The records on any kind of “formal” training = training that does not refer only to carry out designated functions (for example training for working with sprayer/sprinkler provided by producer) + copy of gained certificates
3. Data on training and experience to carry out designated functions (based on concrete carried out activities).
* Selection, training and incorporation of seasonal/temporary employees in working system

Records on occupational training and experience must be at the disposal even for seasonal employees (temporary worker, students and so on). In this case alternatively suffice above mentioned part 3 including training only for their working field (for example crop).

* The rules for remuneration of employees

**Records on occupational training and experience to carry out their designated functions**

Records on occupational training must include:

* + Appropriate list of tasks = activities that the employee shall do + link to the appropriate SOP (if it exists)
	+ Data on beginning of the training
	+ Data on gaining the required level of knowledge and abilities
	+ Signature of trainer

The requirements that the employee must meet to be able to carry out designated function individually, the workplace state these requirements regarding the kind of activity. The part of training can be for example training and verification of knowledge of appropriate SOP, practical training under supervision of experienced worker, attendance at the expert courses and so on.

More experienced workers could have in their records the link to gaining the required level based on previous level of knowledge (APC= intended level gained without training).

Records on training must be at the disposal during the inspections at the testing organization. If any part of the records is the part of personal employee file at the department of human resources, it is suitable to have a copy of these documents also at the appropriate experimental testing organization. The records must be still updated.

Specimen copy of the record on training and experience is stated in appendix No.1.

**Data on buildings, premises and plots for experiments at the testing organization**

The character of used plots and premises must not influence in the negative way the tests that are carried out. In case of plots for experiments can be used only such kind of plots that have at their disposal written data on “the crop sowed before the main crop” (předplodina), fertilization and plant protection products used at least two years backwards and there is a prerequisite for their required balance.

All agro-technical interventions in the course of experiment must correspond with the good agricultural practice regarding their character and deadline (unless the guideline EPPO or the applicant provide otherwise).

**Rules for using plots and premises of other owners**

At the experiments carried out at other owner´s plot sometimes based on the agreement the owner of the plot carries out some of the interventions (sowing, fertilization, harvest and so on). Mostly afterwards during the season there are not at the disposal the data on agro-technique that was carried out, the data of sowing, carried out fertilization and so on. The owner of the plot notify about these data at the end of the season. This process is acceptable, provided that it must be specified in written form in advance.

General rules for such cases must be written in the Quality Manual or in SOP (standard operating procedure). Especially it is needed to specify who is responsible for concluding written agreement with the owner of the plot and what this agreement includes to ensure the disposal of all needed data for drawing up of final report from the experiment, alternatively how to ensure not to carry out unwanted interventions at the plot. It is suitable to state the specimen/example of this agreement as an appendix of the appropriate SOP.

**Data on apparatus and equipment**

Organization must have at the disposal suitable equipment and apparatus needed for activities that are related with experiments (sowing or planting, measuring, application of the product, harvest and so on), they must refer to character of carried out experiments (for example application frame refers to width of plots, small-plots-machinery are used for sowing and harvest, laboratory “mořička” for small parts of seeds etc.)

The testing organization must have drawn up the list of used machinery and apparatus. Brief list shall be the part of the Quality manual. Detailed data on individual machinery and apparatus including working procedures, than individual SOP must be stated; Metrological Ordery must include the requirements and data on calibrations.

The basic requirement for application machinery is sufficient application evenness and in case of sprayers the steady pressure at least for 2 minutes (without other pressure).As a priority are recommended types with clearing out residual-free against pressured air. Some kind of power sprayers can be also used, especially for spatial crops.

Application at permanent crops:

* For registration experiments at permanent crops must be used only “rosiče” (sprayers)
* It is not allowed to use for example sprayers with the arm perpendicularly to the ground
* Sprayer with head/extension can be used for care about permanent crops (for example one windshield nozzle), but only within the use of whirling windshield nozzle, increasing of application pressure and best until the time of complete foliage. Afterwards it is needed to use “rosič” due to sufficient penetration of application liquid into the foliage.

**Verification, calibration and inspection of the nozzle**

It is recommended each 2 years.

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**Verification, calibration and inspection of scales**

For scales used in regime GEP to weigh out of plant protection products into the experiments is valid:

1. It is not necessary to use scales stated in the list MPO (with accuracy 0.0001 g)
2. calibration is needed in minimum once per three years
3. if the testing organization lets the scales verified, it replaces this required calibration provided that the certificate on verification is valid for only two years
4. function of automatic calibration can substitute records on inter-calibration inspections if the process is described in SOP

Verification -> Certification on verification of the stated measuring instrument

* Scales according to the list MPO (regulation No. 345/2002, Coll.)
* Two years (the validity is marked in the certification or on the label)
* It is recommended to ensure the service before the verification, during the validity of the certification the service cannot be done

Calibration -> The calibration list

* Frequency is not stated by the law – GEP = 3 years (the validity accurately 3 years from the data of calibration), regarding the necessity even more often
* Calibration service is recommended

Inter-calibration inspections – according to SOP

Note: automatic calibration before each weighing

**Rules for staining**

In case the testing organization has in the decision the field of experiments “the staining of seed” then the testing organization must ensure the testing of the quality of staining. The test of staining is required at minimum once in five years and the record on the test that was carried out is used as a receipt for application for issuing or extension of the decision for this field of examinations.

For experiments with the stains must be always drawn up:

* The plan of study
* SOP for staining machinery, carry out of application and SOP for conducting of records on staining
* Protocol on staining
* The procedure of ensuring the internal inspection of the quality

These rules are valid especially for staining of seed for contractor out of experiments directly carried out at the testing organization.

In case the experiments with stains that the testing organization conducts, the requirements for staining can be the part of classical plan of study (as requirements for application). It is not needed to draw up the individual plan of study only for staining. SOP, the protocol of staining and the procedure for ensuring the internal inspection of quality must be always drawn up.

**Brief data on security of needed documentation (methods, literature,…) and data on archiving**

The manner of ensuring of guidelines must be described and other corresponding literature for testing organizations including responsible persons and ensuring availability for workers.

The testing organization must have at the disposal the valid versions of guidelines EPPO issued for conducted experiments. The guidelines EPPO must be always used preferentially compared to other guidelines, unless the contractor determines otherwise (the guidelines EPPO provides the minimal requirements that must have been carried out).

The principles of work with guidelines EPPO and record of deviations:

* Without written agreement with the contracting authority it is obliged to use the last valid version of the guideline EPPO
* For using older version of the guideline EPPO or some national guideline, the written approval of the contractor is needed
* The use of other guideline than the last valid version of the guideline EPPO is needed to state the deviation already in the plan of study and also in the final report
* If the deviation from the guideline EPPO occurs during the experiment it is needed to record the deviation in the primary data, state in the final report and give a reason
* The deviation from the plan of study or SOP ( if it is not the deviation from the EPPO guidelines) is needed to state in the primary data (they need not to be stated in the final report)
* The guideline of EPPO must be kept in all details, also including for example to observe the influence on the other harmful factors and other non-target organisms, the influence on the applicability etc.

**Archiving**

It is sufficient to state general rules for archiving in the Quality manual, details shall be described in SOP. Archiving documentation includes:

* Primary data related to the experiments (including results of evaluation, data on experimental locality and plots, conditions of environment, application and other activities), plan of study (+records on any kind of adjustment and deviation) and related report from the experiment
* Records on conducted calibrations of the machinery and inter-calibration inspections
* Records on store of chemicals
* Original version of all SOP (valid and canceled versions)
* Original versions of the Quality Manual and the Metrological Ordery (valid and canceled versions)

This documentation need not be archived at the same place, but its storage must be known and stated.

In the Quality Manual and SOP the persons responsible for archiving and its content must be stated namely. Different employees can be responsible for different parts of archiving documentations (for example data on experiments, records on calibration, electronically archived data).

**Data on securing of system of internal supervising of quality**

The testing organization must establish and describe such kind of system to ensure that:

* Employees know all updated standards operating procedures
* The mistake is found out fast enough by the testing organization (not during the external inspection)
* Arisen mistake is removed immediately
* Testing organization takes measures immediately to ensure not to repeat the mistake again

Basic principles:

* Tasks and responsibilities of all employees (even seasonal workers) must be exactly specified in written form
* Activities during the experiments must be standardized, described in details and provably updated in SOP and in the Quality Manual
* The rules stated in SOP and in the Quality Manual must answer these questions:
	+ Where is the risk of possible mistakes?
	+ What is the possibility to avoid these mistakes?
	+ How to check whether these mistakes were made?
* all workers must be provably trained to carry out designated functions
* the referring documentation must be available to all workers (Quality manual, SOP, guidelines, plan of study and others that are connected with stated documentations)
* the documents that are in process of approving (Quality manual, SOP, Metrological order, plan of study, report from the experiment) must be inspected its rightness by the approver
* the system of evidence of deviation form approved documents and guidelines must be set
* evidence on the inspection of rightness of data transcription must exist
* the choice of apparatus must be exactly described, also the concrete activities which can be carried out by the apparatus, the system of its calibration must be also set
* the conditions on right store and manipulation with products that ensure its usage

Described standard must clearly state:

* What is necessary to inspect
	+ Activities
	+ Records, outputs
* Who does the inspection
* When/how often the inspection is
* What kind of records on inspections are kept

**The description of system of cooperation with customers and handling of complaints**

It is necessary to describe the system of cooperation with customers, especially to state who is authorized to deal with the customers. The manner of receipt and handover of the order must be described, including deadlines and manner of handling of complaints.

**Ensuring of sub-contracing relationships**

In case any part of efficacy experiments is ensured to the testing organization sub-contractingly and the testing organization does not have the GEP Certificate (for example if the contractor of the experiment demands the analysis of the quality indicators), the rules for this process must be drawn up in written form in the Quality manual and/or in SOP. The system must ensure that any kind of activity related to assessment of efficacy is carried out in compliance with requirements of GEP.

If the activity is carried out under the supervision abd according current SOP, it is sufficient to gain written statement from the sub-contractor that used machinery was properly calibrated/maintained and that records on this information exist. If the sub-contractor work is carried out without supervision, it must be required from the sub-contractor the data that the work was carried out according to written operating procedures by properly trained employees and with sufficiently maintained and calibrated machinery (for example the testing organization has its own Quality manual and Metrological order that covers the experimental field).

If the testing organization uses sub-contractors, it must be stated in the report from the experiment.

**Metrological ordery**

Metrological ordery shall include at minimum following chapters:

**List of legal provisions in the field of metrology**

**Ensuring of metrology for experiments**

* manner of security and calibration of machinery
* responsible person for ensuring metrology at the testing organization (= main “**metrologist**”)
* manner of conducting records on calibrations and maintenance that have been carried out. Records must be still updated and must be archived!

**List of measuring instruments and period of validity for verification of measuring instruments**

The list can be drawn up as individual list or together with other used machinery and apparatus (see a sample below). The exact indentification of the machinery/apparatus, the place of its permanent store, the possibility of using and requirements on maintenance/calibration shall be always stated. The part of summary can be also link to updated standards operating procedures (SOP or instruction manual), alternatively even the name of responsible person for using of machinery.

The sample:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of machinery / apparatus** | **identification** | **place of permanent store** | **Possibility of using**  | **Requirements on maintenance**  | **Link (SOP, instruction manual)** |
| weights OWA LABOR | 0001 | Room for weights (room No.4) | Weigh of product | calibration / validity 2 years  | SOP No. 5(instruction manual in drawer in room for weights) |
| Vermorel 2000 Electric | 058/1999 | hall (room No.25) | Application in experiments | Inspection before season | SOP No. 8 (exact instruction manual at metrologist) |
| Measuring cylinders/barrels  | Without label | Preparation room (room No.1) | Measuring of liquid products | none (calibration without restriction) | SOP No.6 |

Appendix (evidence lists of measuring instruments, verification lists of measuring instruments,...)

**Standard operating procedures (SOP)**

Standard operating procedures (together with using of plans of study) must include all information necessary for carrying out of appropriate kind of activity. All set of SOP must include all range of activities ensured by testing organization. Level of details included in SOP shall consider about level of education and training of employees regarding their using.

Management of testing organization is responsible for creation, comprehensibility and completeness of SOP and their availability for staff. The staff drawing up SOP must be clearly stated, including deadlines and manners of inspections. All SOP cease to be valid by the signature of responsible worker.

SOP is necessary to draw up for all **main range of activities** and each range of activities is possible to describe in one or more SOP, for example:

1. rules for inspections and actualization of documentation of testing organization
2. setting and conducting of experiments
3. plan of study (creation, conducting PS, archiving)
4. reception, store and manipulation with products including waste elimination
5. using, maintenance, cleaning, service and calibration of each apparatus or machinery
6. weight/ measuring of product, preparation of application liquidity including conducting of records
7. application of products
8. assessment of experiments – before application, efficacy, phytotoxicity (deadline, manner)
9. gaining, record and archiving of data
10. electronic records, drawing up and archiving
11. laboratory activities including sampling
12. harvest, activities after harvest

**Further information on creation of SOP and requirements for individual activities are stated in Appendix No. 2 – Standard operating procedures**