

Transfer of duties to the project management => Duty of documentation

User with dynamically changing GMO placement and disposal

status 03/2021

Please submit a signed copy of this form once to GHL ghl@wzw.tum.de
(The original remains with you)

Notice: The current GHL project leader (GHL-PL) of the genetic engineering facilities at the Greenhouse Laboratory Center (TUM-School of Life Sciences) obligates the responsible S1 project leader of an experimental group (PL-VA) and all employees participating in the experiment, who, within an experiment or a series of experiments, bring GMOs into the facility at different times or have them inactivated (dynamic GMO placement and disposal) for the facilities 234, 858, 1189 and 1287 according to § 2 of the Genetic Engineering Recording Ordinance (GenTAufzV) for proper documentation => (recording lists at the experimental unit).

1.-Details of the person in charge of the S1-project-manager (PL-VA) of the experimental group

Mr./ Mrs.	title	first name	last name
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

is obligated, effective today, for GMO experiments in the following genetic engineering facility(ies) of safety level (S1) at the Greenhouse Laboratory Center:

234 (GHL1) 858 (GHL2) 1189 (GHL3) 1287 (GHL5) all are possible

to carry out the proper documentation of all GMOs brought in by the experimental group or sorted out for disposal and to oblige the cooperating employees to do so as well. .

2.-Mandatory transfer

Notice: The tasks and responsibilities result from §14 GenTSV as well as from the respective valid operating manual of the genetic engineering facilities.

You hereby undertake, as of today's date, to comply with the recording obligation resulting from §14 GenTSV and § 2 of the Genetic Engineering Recording Ordinance (GenTAufzV) on your own responsibility (see points 4a and 4b). .

date	Consent / Signatur S1-project-manager-chair/WG	date	signature S1-project-manager-GHL Dr. Susanne Steger
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

3.-Handover

All important documents for trial registration, guidelines for GMO documentation and sample trials are available on the GHL homepage at any time (<https://www.ghl.wzw.tum.de/internal>). The important information for you is compiled under the registration form:

„GHL-registration_annex-9B-dynamic alternating GMO placement“

4.-Duties of the responsible project manager of the experimental group (S1-PL-Chair/WG)**a) Duties according to § 14 Genetic Engineering**

General: The project leader of the respective experimental group instructs all persons involved in the project to comply with the recording obligation according to § 2 of the Genetic Engineering Recording Ordinance (GenTAufzV) and to carry it out according to the GHL regulation. .

b) Transfer of operator duties: You are responsible for:

- 1) The submission of a signed, properly numbered and completed **GMO list** with all GMOs planned for the experiment, e.g. in the form of an Excel spreadsheet (sample [Appendix 4B](#)).
- 2) In case of list extension: subsequent submission of new GMO additions to the GHL-PL prior to introduction into the GHL rooms.
- 3) Briefing of all personnel involved in an experiment who independently introduce new GMOs into the GHL facility or release them for disposal.
- 4) Proper recording of all GMO inputs and outputs analogous to the GMO list submitted by you in the **GMO documentation list** (attach to the respective experimental unit). In addition to the respective **GMO list number**, the **number of inputs/outputs** is also noted, as well as the **date**, the **actor** in legible writing and his **signature**.

Please sign on page 1 and submit only these two pages to the GHL Project Manager (susanne.steger@wzw.tum.de). The remaining pages are for your information only. You can also find the forms on the GHL homepage (Internal).

If you have any questions, please do not hesitate to contact the project manager:

Tel.: +49.08161 71 5020

susanne.steger@wzw.tum.de

S1-Guideline for GHL-User

(status 2021)

Handling regulations with Genetically Modified Organisms (GMOs) at GHL

Note: The project management (PL) of the genetic engineering S1 facilities (234, 858, 1189 and 1287) at the Greenhouse Laboratory Center of the TUM School of Life Sciences obligates all experiment organizers - experiments **with** or **without** genetically modified plants (GMOs) - to follow the operating instructions at GHL. The operating instructions are based on guidelines of the valid TUM organizational order "Genetic Engineering in Contained Systems" (OrgV GenT-igS) on the basis of §14 Genetic Engineering Safety Ordinance (GenTSV).

On the registration form, you undertake to comply with the conditions set out in

- point-3.1 (experiments without GMOs)
- points 3.1 + 3.2 (experimentes with GMOs)

instructions for reading and complying with them. On the **registration form, you confirm by your signature** that you have understood all points and that you will instruct all employees involved in your project accordingly. The guidelines are also binding vis-à-vis HR6 and the Government of Upper Bavaria.

Guideline for S1 work at GHL (plants 234, 858, 1189 and 1287)

At GHL, work is carried out with genetically modified plants, so-called GMOs (**Genetically Modified Organisms**). Premises in which GMOs are to be used must be officially registered and approved by the control authorities (S1 facilities). In these facilities, precisely defined rules of conduct apply throughout Europe and Germany, which are laid down in the Genetic Engineering Act (GenTG) and various ordinances. One important instruction states that only instructed persons are allowed to be **alone** in an S1 plant.

The GHL project leader (PL) - Susanne Steger -, is responsible to HR6 (TUM University Department 6 - Health, Safety, Radiation Protection) as well as to the Government of Upper Bavaria to implement and ensure the regulations and laws in handling genetically modified organisms (GMOs).

This means that also experimenters, student assistants and technical assistants who do not work with S1 experiments need this short briefing and have to behave according to the guidelines. By signing that you have read and understood this document, you are considered to be an instructed person and are therefore obliged to comply with all S1 rules listed under point 3.

These rules are also posted in the form of operating instructions **in front of each individual S1 room** and are thus available at all times before entering the S1 rooms.

At GHL, work is carried out exclusively at safety level 1, which, according to §7 GenTG, "... according to the current state of science, is not expected to pose a risk to human health and the environment".

At GHIL, work is carried out exclusively at safety level 1, which, according to §7 GenTG, "... is not expected to pose a risk to human health or the environment based on the current state of scientific knowledge".

Duties of the responsible trial designer and all his employees

3.1 Experimental set-up: Experiments without GMOs

1. In general, please always pay attention to order and cleanliness in the experimental setups, as occasionally inspections by official authorities take place.
2. The person responsible for an experiment - referred to here as the experiment set-up person (VA) - instructs all persons involved in the project to read this form and to comply with the GHIL regulation according to the operating instructions. Employees who have not been instructed may enter the facilities when accompanied by instructed persons. In this case, the instructed persons are responsible for ensuring that the operating instructions are read and observed on site.+
3. **Never label NON-GMO plants with an orange label** (at the GHIL, orange GMOs apply).
4. Do not take or eat plants or plant parts such as fruits and flowers from other experiments.
5. Please always follow the operating instructions on the houses
 - Eating, drinking, smoking, snuffing, putting on makeup, and storing food and beverages in the S1 area are **prohibited**
 - pets are **prohibited**
 - do not take or eat plant parts
 - Keep doors closed during work
 - **Lab coats** are mandatory in S1 rooms unless explicitly waived by GHIL sign. (if necessary, ask the GHIL staff for a visitor's coat)
6. No work utensils may be stored in the rooms. If space is needed for storage utensils, a box can be provided in the connector (please check with the gardening team)
7. To ensure pathogen-free conditions on crops
 - In case of pathogen infestation, please inform the staff immediately and coordinate control strategies with the foreman/staff (Which measure is possible for the particular trial question?)
 - No transport of infested plants within the GHIL without a closed transport container.
 - No unauthorized placing of new plants in existing stands without prior agreement with the staff.
8. Authorized persons have access to the plants outside the opening hours only with an appropriate card authorization (personnel card, student card can be activated (R. Hansel, S. Kolbinger).
9. Any accident or injury will be reported immediately to the GHIL Master Gardener. If necessary, a doctor must be consulted.
10. For reasons of work safety, experimenters must never be alone in the facilities
11. Electrical and mechanical equipment may only be used with a CE certificate and/or a valid TÜV inspection sticker.

3.2 Experimental set-up: Experimentals with GMOs

1. Work in the S1 rooms may only be carried out after consultation with the GHl project manager (PL-GHL) or BBS.
 - Therefore, for experiments with **fixed GMO placement and disposal**, a separate **Form-Z** (Record for a Genetic Engineering Work according to GenTAufzV) must be signed by the **responsible S1-PL of the research group** and handed over to the assigned master gardener before the start of the experiment for each GHl experiment number. The form will be archived by the GHl-PL, as required by law, and submitted to the relevant authorities as needed.
 - Experimental series or projects with **dynamic GMO stocking and disposal** must also be submitted in the form of a **numbered Excel list of all GMOs**. Subsequently, all GMO inputs and outputs must be independently documented by the VA on a **documentation list** attached to the experimental unit. For this purpose, a **declaration of commitment** is obtained from the responsible S1-PL of the working group. If new GMOs are added to the existing list, the additions must be forwarded to the GHl. These documents will also be properly archived by GHl-PL.
2. **Transgenic** plants are marked with an **orange** label (also possible as an additional label).
3. S1 plants may **only** be cultivated, stored, harvested, evaluated or otherwise processed in S1 rooms!
4. Transformation work may **NOT** be carried out in greenhouses, climate chambers or other cultivation units, even if these are designated as S1. A special S1 laboratory is available for these activities.
5. Transport of GMOs within the GHl is **exclusively** in the special S1 transport boxes! Also the shortest routes!
6. No reproducible plant tissue is allowed to leave the S1 facility!
 - Adhesive mats on the floor, nets in the ventilation, filter in the gully, S1-suction device
 - Lab coat obligation (autoclave) => prevent seed/pollen dispersal
 - ➔ Gown remains in GWH/PAR or is packed there to be taken away.
 - Cultivation of flowering GMO plants **only in inserted GWH**.
 - **Bagging** of flower/fruit stands if pollination partners of other work groups could be affected.
 - Avoid seed dispersal
 - ➔ Sowing and harvesting of plants is done at a work table in the respective S1 experimental unit. Substrate residues are sealed and labeled (GHl no.).
 - ➔ Clean the tables regularly (weekly) from seed (sweep, vacuum with S1 vacuum cleaner).
 - ➔ Place plants in such a way that no seed can fall to the ground (do not place directly on the edge).
 - ➔ Remove fallen seeds immediately
 - Separate S1 material into **compostable** and **residual waste** (labeled containers in GWH/VE)
 - ➔ **Yellow containers => compostable**
 - ➔ **White containers => residual waste** (also pots with seed adhesions e.g. Arabidopsis)
 - Wash and store S1 trays in the cabin house (if necessary, ask GHl staff for other premises).

- Disposal of S1 plants
 - Plant material and substrate must **always** be **inactivated** before disposal. (Autoclave => GHIL staff).
 - ➔ Seed- or fruit-forming **non S1 plants** of the same genus and species **with direct contact to S1 plants** and the probability of pollen transfer or widespread seed dispersal, must be treated as S1 plants with regard to disposal.
- Inactivation always takes place in consultation with GHIL personnel. Plant material and substrate are packaged together in an autoclave bag (in the case of large root balls, these are crushed beforehand so that the vegetation point is inactivated). However, the bags will remain in the respective experimental unit and will be collected by GHIL personnel for inactivation and disposal.
 - Compostable material (substrate and plant material)
=> fill bags loosely (fill 1/2 to 1/3 (weight!)).
 - Possibly use 2 bags on top of each other
 - **Note experiment number and location on the bag with permanent Marker!!!**
 - Chop up long, hard, rigid plant parts well so that nothing is pressed through.

Other contact persons:

S1-Project Manager:

Dr. Susanne Steger: Tel.: 08161 71-5020

susanne.steger@wzw.tum.de

Biological Safety Officer (BBS):

Dr. Stefan Engelhardt Tel.: 08161 71-5736

stefan1.engelhardt@-tum.de

RECORDING FOR A GENETIC WORK ACCORDING TO GENECHNICAL RECORDING REGULATION ¹

In the case of further work of stage 1, item 7 must be presented in detail on a special sheet. In the case of notified work (first work of stage 1 and further work of stages 2 to 4) or approved work, the documents must be kept as an essential part of the record in accordance with § 2 of the Genetic Engineering Record Ordinance (GenTAufzV).

1.-Name and address of the operators:

Technische Universität München, Arcisstr. 21, 80333 München

Gewächshauslaborzentrum, Dürnast 7-10, 85354 Freising, represented by Dr. H. Hausladen

(Managing director – representative of the operator: ILF)

2.-Location of the genetic engineering facility in which the genetic engineering work is carried out:

facillity 234 (GHL1), 858 (GHL2), 1189 (GHL3), 1287 (GHL5)

3.-PL:

Dr. Susanne Steger

(Name of S1-project-leader)

4.-BBS:

Dr. Stefan Engelhardt

(Name of biosafety officer)

5.-Time of approval of the genetic engineering facility and file number:

facillity 234 (GHL1): 55.1-8791-13.234 building: 4234

facillity 858 (GHL2): 55.1-8791-13.858 building: 4235

facillity 1189(GHL3): 55.1-8791-13.1189.413 building: 4232

facillity 1287(GHL5): 55.1GT-8791,GT_2-1287-1 building: 4105

6.-Subject of the work

Cultivation for various experimental purposes according to the questions of the respective working groups.

7.-working group

Experiment number

chair / working group

location of the experiment

is filled in by the GHL

is filled in by the GHL

8.-security level: **S1**

9.-Time of the start and completion of the genetic engineering work

GMO-list: no.: from/to

start of experiment

end of experiment

is filled in by the GHL

10.-Signature of S1-project-manager (chair / working group)

date

S1-PL-LS/AG name

signature S1-PL-LS/AG

date

Dr. Susanne Steger

GHL-PL name

signature GHL-S1-PL

¹ The records may not be made illegible by deletions or in any other way. No changes may be made that do not reveal whether they were made at the time of the original entry or at a later date. Veränderungen vorgenommen werden, die nicht erkennen lassen, ob sie bei der ursprünglichen Eintragung oder erst später vorgenommen worden sind.

Sample Examples (GMO-lists and GMO-documentation-lists)

GMO-list (f.e. excel-formate)

*G(enome) editing method: If used, please enter here e.g. CRISPR/Cas

GMO	donor		receiver			vector	nucleic acid	GMO		
no.	name	RG	name	RG	G-Editing*	name	name	name	RG	else
1										
2										
3										
4										
5										
...										

Example GMO-documentation lost (attach to the outside of the test unit) and must be carried out independently by the VA or instructed personnel!

Analogous to the template [ANNEX 4 GVO-documentation list](#)

date	GMO-no	number of plants	incomings	outgoings	name in block letters (Implementing person of the AG)	signature
01.01.2020	25	26	x		Frau Mustermann	
15.01.2020	40	30	x		Herr Versuchsansteller	
20.01.2020	1	15	x		Herr Versuchsansteller	
01.02.2020	25	15		x	Frau Mustermann	
15.02.2020	40	11		x	Frau Mustermann	
22.02.2020	2	30		x	Herr Versuchsansteller	
25.02.2020	1	40	x		Herr Versuchsansteller	
	...	15		x	Frau Mustermann	

