

How to prepare a supplementary application = amendment (SC)

Authors: UZH AWOs

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A. When is a SC needed?¹

When any or several of the 11 situations mentioned below apply; requests for several changes can be combined in the same SC.

1. Need for methodological changes that have equal/more burden on the animals than originally approved

2. Additional (groups of) animals needed to answer the same questions as already stated in the original license

Of important note: please be aware that, according to VETA's criteria for return of SCs:

- you cannot ask for significantly higher² animal numbers or more animals in a SC than in original application: in such cases, an application for renewal or a new application has to be submitted.
- if the SC is too extensive³ (e.g. new or significantly changed research questions), an application for renewal or a new application has to be submitted.

¹ the following requests can be sent via e-mail by the VETA, cc to the Animal Welfare Officers (AWOs): requests for **refinements** or when replacing group(s) of animals with other groups of animals which are not constrained, i.e., do not have a harmful phenotype (including Forms D if applicable). It is recommended to contact the AWOs before sending such requests to the VETA.

For **refinements**, please also consider these important points: is the refinement expected to cause changes, can you make comparisons before/after? Does it make sense to change? Can the research question still be answered?

² The VETA takes case-by-case decisions regarding what is considered to be "significantly higher" animal numbers, this cannot be defined in %. VETA's assessment whether the newly requested animal numbers are "significantly higher" depends on the research questions aimed to be answered and/or hypotheses to be tested.

³ According to art. 141 of the Animal Welfare Ordinance (TSchV), the experiments or series of experiments (from a valid license to perform animal experiments) are carried out to provide answers to **a certain number of precise questions or aimed at a very specific goal**.

3. To redistribute the animals e.g. between groups or between experimental series

4. To add a new animal category (technically mandatory to have all the categories needed to fulfill the report AC)

5. Replacements of (groups of) animals when the newly requested animals are mutants or genetically modified (GMOs) with a harmful phenotype (severity degree 1-3)

6. Update of health monitoring schemes/score sheets

7. Update of anaesthesia and/or analgesia

8. Change of location of experiment or change of light cycle

8.1. It should be **clearly indicated in section 10 of Form A** and **in the comments to be conveyed to the VETA** by the AWOI (the latter in the last pop-up comment field in animex-ch):

8.1.1. **what is the new/additional location (room or animal facility)⁴.**

8.1.2. where (room numbers) will the animals in experiment be housed at the new location.

8.1.3. where (room numbers) will the experimental procedures be conducted at the new location.

⁴If no animals in experiment will be moved between animal facilities (i.e., the entire experiment occurs at a single animal facility), please indicate this in section 10 of Form A for the respective location.

8.2. Changes between locations need explanations and details regarding the transfer of **animals** if these are **already in experiment** when the transfer takes place:

8.2.1. how is this done in practice and by whom (sections 23, 25 of Form A)

8.2.2. describe acclimatization to the new location (section 24 of Form A)

8.2.3. describe effects on the animals because of transportation (sections 33, 40 of Form A), stress-mitigating measures (section 35 of Form A)

8.3. In case of changes of type of light cycle for rodents:

8.3.1. acclimatization to the new cycle to be considered and described (section 24 of Form A)

8.3.2. changes of SOPs etc. if drugs are given in the drinking water depending on the phase of the light cycle (considering the water intake depending on the active/inactive phase of the cycle): to be addressed in section 23, 25; if applicable, also in section 26 of Form A

8.4. If **additional canton(s) are added (intercantonal experiment)**, please also indicate this in section 3 of Form A and in the comments to be conveyed to the VETA by the AWOI (the latter: in the last pop-up comment field in animex-ch)

9. Requirements post VETA inspections of animal experiments

10. Special conditions of the VETA on the license/decision = Form AB (e.g.: if you received a special condition to submit a SC for minor adjustments of score sheets according to last answer to the questions received for your application and to have the SC approved before experiments can start)

11. Exchange of deputy study director with study director or vice-versa (“workaround” in animex-ch); this also allows to update the entire personnel of the license, if applicable

11.1. Personnel changes (addition/removal of persons) can be done in all SCs at the same time with other changes requested.

11.2. Always mention in the comments field, upon submission of the SC to AWOI, the names of the persons added and/or removed and make sure they have adequate and updated education and training records approved by VETA.

B. Common considerations when preparing SCs

1. When writing the SC, you must take into account [VETA’s criteria for return for SCs](#) and [VETA’s and FSVO’s requirements for writing applications for licenses to perform animal experiments](#)

2. All SCs **must be reviewed by the Animal Welfare Officers**: only they can submit the SCs to canton via animex-ch.

3. **All sections of Form A that are affected by changes must be filled out.**

Indicate **clearly**, in the relevant sections of Form A, the changes you are applying for (do **not** copy-paste all the original text from the respective section of the approved license if you just want to make a minor change).

4. **Of important note, the following is a VETA criterium for return of SCs**: under section 20 of Form A, the reference to the previous knowledge gain/results is not explained in a comprehensible manner.

4.1. For A1-A5, section 20 of Form A should provide information about the **background of the changes**. Please also indicate the current status of experiments (which ones have started, which one have been completed, which ones are in progress, which ones should be modified), why changes are needed (reasons, explanations based on own research conducted so far, what happened that triggered the request to make changes, recent publications etc.), which type of changes are needed.

4.2. For A7: if **analgesia and/or anaesthesia** need to be changed because of issues encountered, then section 20 of Form A needs to be filled out as well, including this information. If the SC concerns a refinement of analgesia, then section 20 does not need to be filled out, as this is not a research question; this change needs to be addressed in section 26 of Form A.

5. **All obsolete attachments⁵** must be deleted from the “Documents” section of the SC in animex-ch and replaced with latest versions relevant to the experiments to be carried out. The new date and new version number must be indicated on all updated attachments: in the electronic title of the files and on the documents themselves (i.e., visible and clearly identifiable when hard copies are printed).

⁵ Where applicable, attachments uploaded under “Remarks” of the license upon VETA’s request (e.g. requests for refinements approved via e-mail by the VETA) can now be uploaded under “Documents”, replacing the obsolete versions of the attachments.

6. **Updates of GMO documents (Form D, Form M)**: to be done only if changes are needed e.g. monitoring of constraint finalized since last approval and/or if the conditions from points A.4. or A.5. above are met [if (an) additional GMO line(s) is/are added to the license via the SC].

7. It is **highly recommended** to upload under “Documents” of the SC, in animex-ch, a document that **summarizes** the changes. The document must be correctly labelled with a title and date. This helps VETA to see the extent of the SC and, if it is short/simple, potentially prioritize its review.

8. The changes can be implemented as soon as the SCs are approved by the VETA, despite the message displayed by animex-ch (please see the license/decisions for confirmation).

9. In case of intercantonal applications, it must be indicated who does which manipulation in which canton (under section 11). Moreover, it must be stated in comments which cantons are concerned by the SC.