# Technical guidance: FOTS annual reporting



## 1) General points

- The annual report must be submitted before 1 March each year
- The reporting concerns animals that were used the previous year (e.g., within 1 March 2023 you should report on animals used in 2022). NOTE: If animals have been included in an experiment in the previous year, but still is included in an ongoing experiment it should not be reported (should be reported the year it is removed from the experiment)
- You need to report on all FOTS IDs that had valid approval the reporting year irrespective of whether you have used animals or not
- Mattilsynet (The Norwegian Food Safety Authority) has published a guide on important points to consider when reporting:

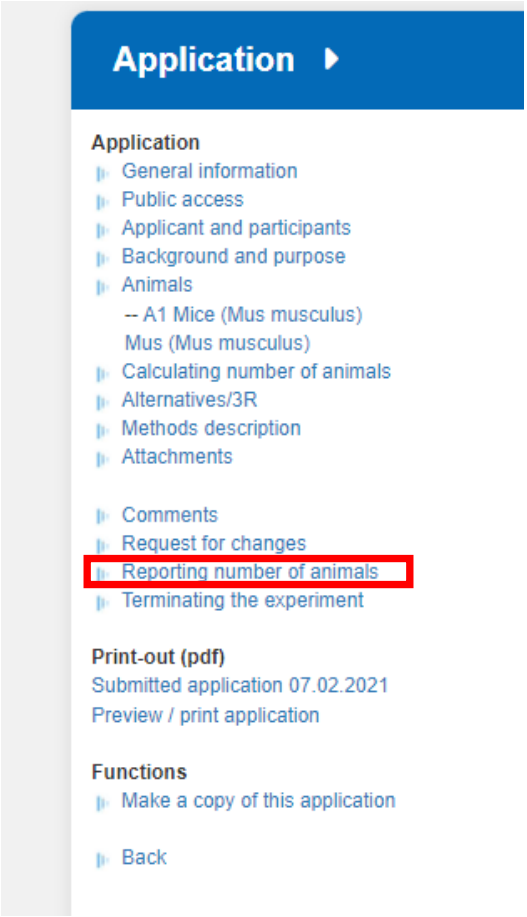
  Bruk av forsøksdyr: Veiledning om rapportering | Mattilsynet

  *As this information is only available in Norwegian, you find an English Translation of this information at the end of this document*

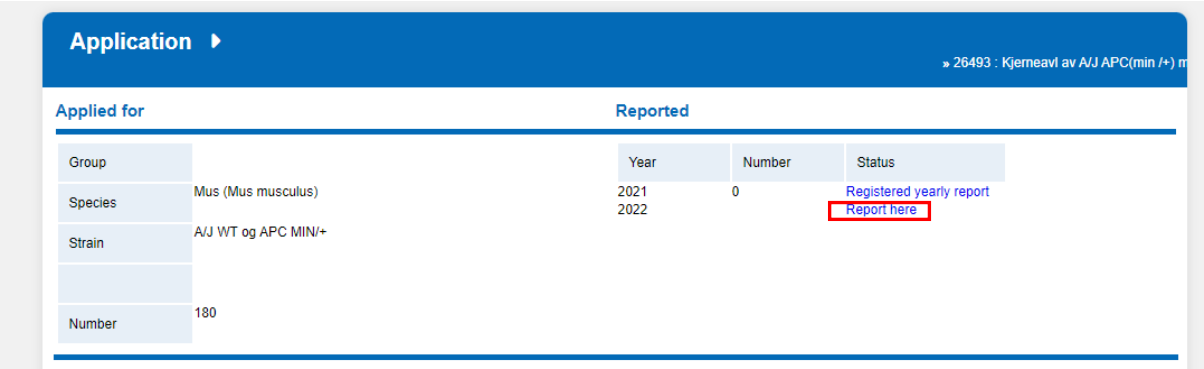
On the next pages you find a step-by-step technical guidance on how to report in FOTS.

## 2) How to access the reporting form

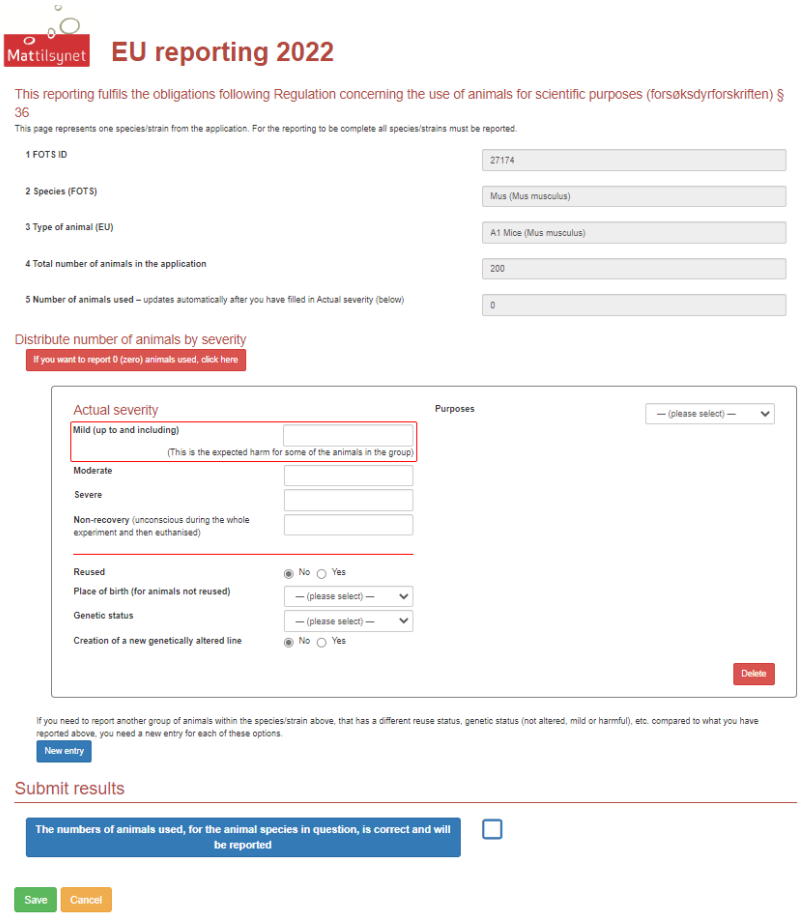
**On the individual FOTS id, choose "Reporting number of animals" in the left menu:**



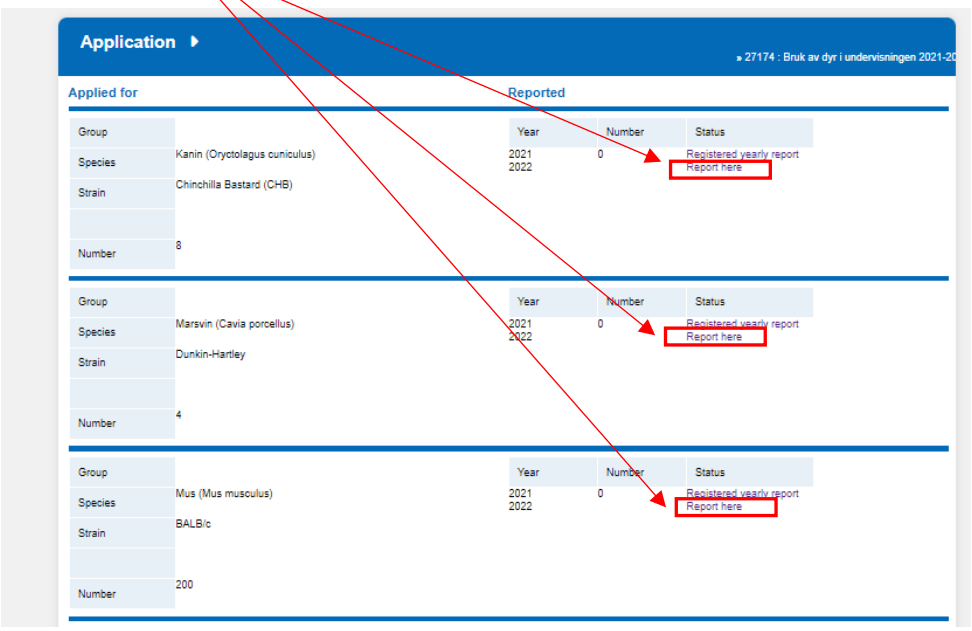

**In the page that opens, an overview of reporting status for current and previous years by species and strains is provided. In this example, the 2021 report has been submitted while the 2022 report is pending. Press "Report here" to enter the report form for 2022 (or year in question):**



**The report form opens:**



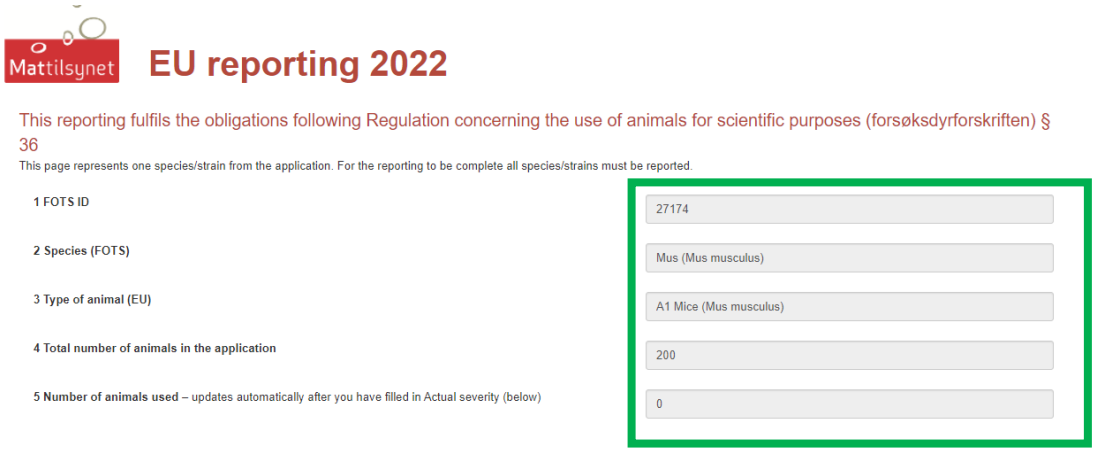

**NOTE: if several species or strains are included in the FOTS application you must register *one report form <u>for each</u> species/strain*:**



# 3) How to fill out the form

## a) Automatic generated information in the report form

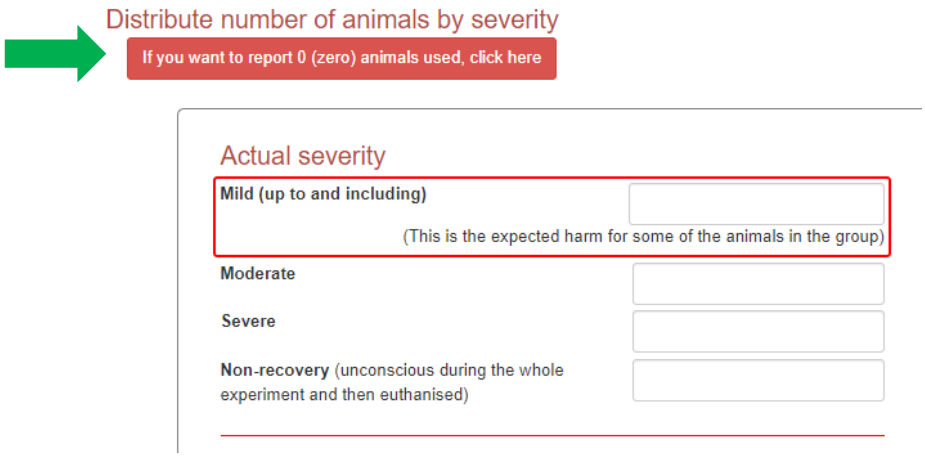
**Some information is already pre-filled in the form and/or will update automatically when you fill in the form, e.g., the fields marked with green triangle below:**




## b) Numbers of animals and actual severity

If zero (0) animals were used, press the red button marked with a green arrow in the figure below. You can then proceed to submit the form. Otherwise, you need to continue to fill out the form

Enter the number of animals used in the respective appropriate severity category. The severity reported should be the actual recorded severity. In the form, the prospective severity (e.g., the severity category chosen in the FOTS-application) is pre-marked with a red rectangle.



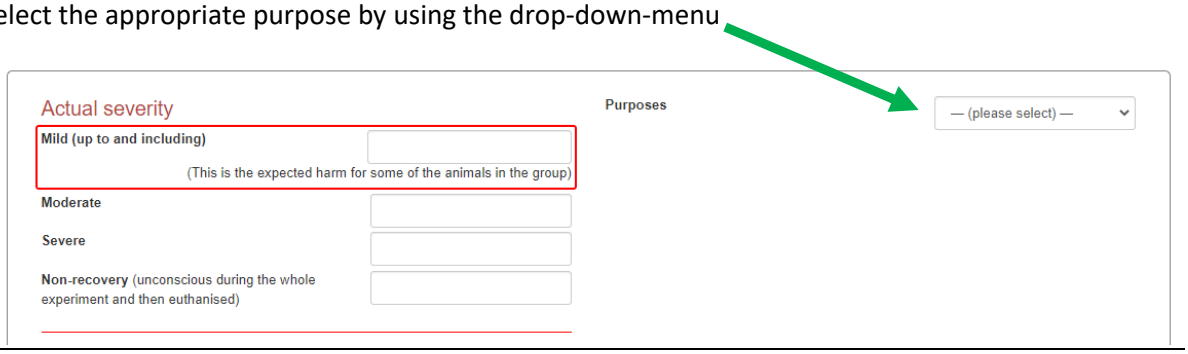

Please note that "Non-recovery" is only a relevant actual severity classification if that was the prospective severity classification of the FOTS id in question. If in doubt on how to report severity,

please the guidance from Mattilsynet (ENG) Bruk av forsøksdyr: Veiledning om rapportering | Mattilsynet (NOR) and/or contact PMSK.

## c) Purpose

### *I. FOTS-applications submitted before June 2022:*

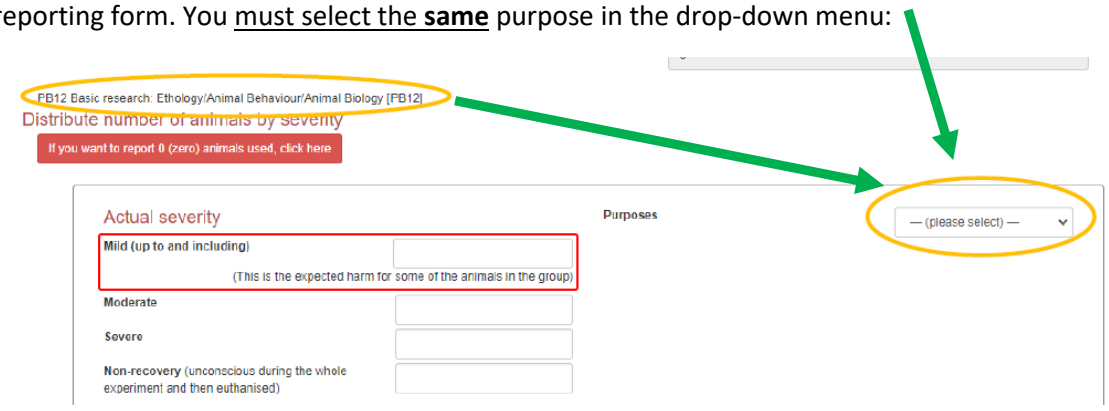
Select the appropriate purpose by using the drop-down-menu




**NB! Please see further guidance on selection of correct purpose in the** guidance from Mattilsynet (ENG) Bruk av forsøksdyr: Veiledning om rapportering | Mattilsynet (NOR)

### *II. FOTS-applications submitted **after** June 2022*

The purpose was already selected when submitting the FOTS-application and is provided in the reporting form. You must select the **same** purpose in the drop-down menu:

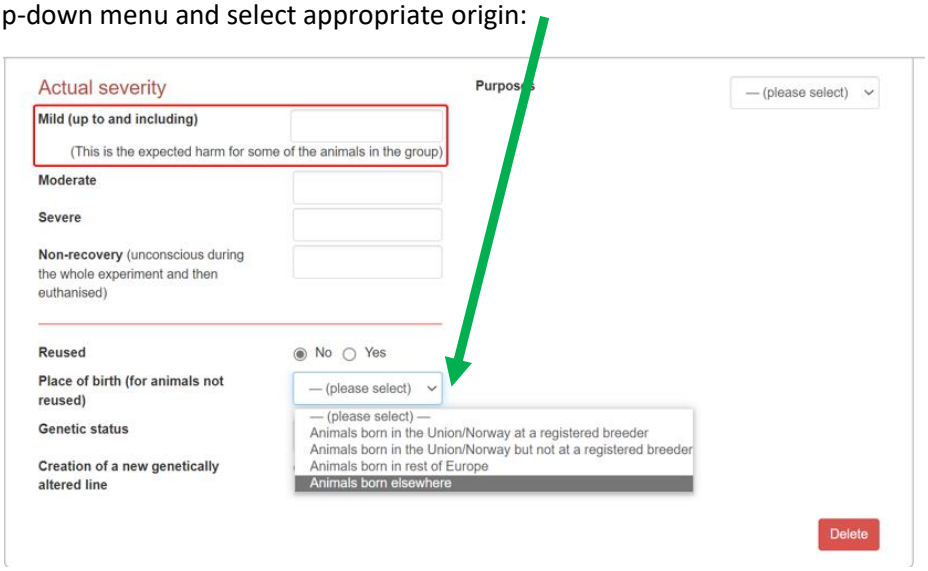



## d) Reused

Reuse means reusing animals from another approved FOTS id and requires special authorisation. Performing multiple procedures within the same FOTS ID is *not* reuse. Please see further information on reuse in the guidance from Mattilsynet (ENG) Bruk av forsøksdyr: Veiledning om rapportering | Mattilsynet (NOR)

## e) Origin (place of birth)

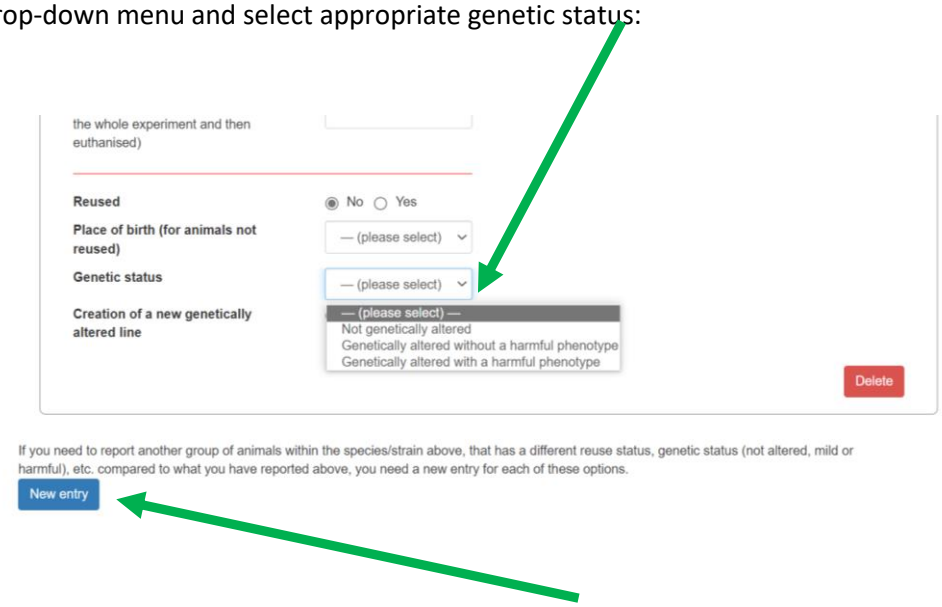
Use the drop-down menu and select appropriate origin:




Animals bred at your animal facility at OUS should be reported as "Animals born in the Union/Norway at a registered breeder". For other animals, including farm animals and wild animals, please see further information in the guidance from Mattilsynet (ENG) Bruk av forsøksdyr: Veiledning om rapportering | Mattilsynet (NOR)

## f) Genetic status

Use the drop-down menu and select appropriate genetic status:

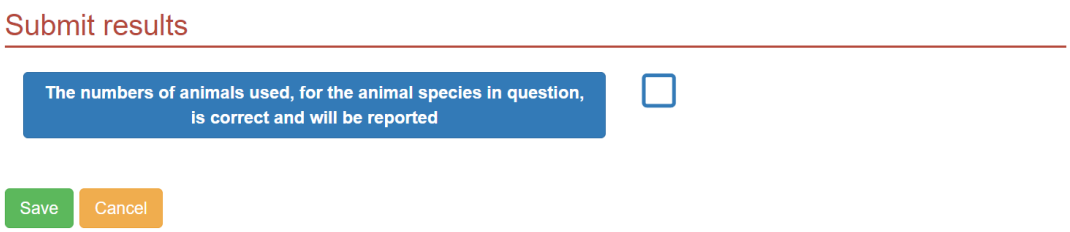



NOTE:

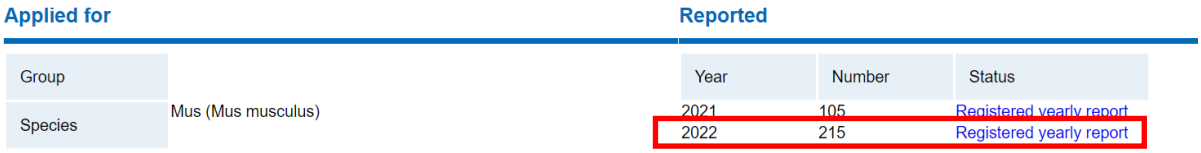
- If the FOTS ID involves the use of animals of different genetic status (altered/not altered; harmful/not harmful), you need a new entry in the form for animals with various status.
- Genetically altered animals (GAA) includes both GMO and natural mutants

### g) Submission of the report

The report is submitted when you confirm the correctness of the data AND save the page:




You are then returned to the main reporting page that confirms your reporting:




Confirmation of annual reporting will also appear on the front page of your FOTS id:


## 4) Guidance on reporting from Mattilsynet (English Translation)

The Norwegian text can be found here [Bruk av forsøksdyr: Veiledning om rapportering | Mattilsynet](), below you find an English translation of this information:

**The number of animals used in experiments must be reported annually along with purpose, where the animals were from, what degree of load they were exposed to, etc. Such reporting is used in statistics that are important for obtaining an accurate picture of the use of laboratory animals in Norway. Such statistics are requested by many and are useful in 3R work.**

Reporting is a requirement in Norwegian legislation and follows from the EU Directive on Animal Research. The different reporting categories are described here: EU reporting system Annex III, Parts A and B.

The Norwegian Food Safety Authority has experienced both inadequate reporting and incorrect reporting. Failure to report will result in daily penalties. Incorrect reporting may apply, among other things, to the purpose of the experiment and differentiation of the degree of harms/severity. To avoid incorrect reporting, please read this guide before reporting.

Please note that FOTS-applications submitted after June 2022 have rubrics for "the purpose of the experiment" and how many animals you expect in the different severity categories in the application form. What you indicated in the original FOTS-application will be the starting point for the reporting.

For assessment of severity, see the Norwegian Regulations on animal research, Appendix B Regulations relating to the use of animals in experiments - Lovdata (equal to Annex VIII in the EU Directive Consolidated TEXT: 32010L0063 — EN — 26.06.2019 (europa.eu)
For fish, see also Hawkins et al. (2011) Guidance on the severity of scientific procedures involving fish.

## Annual reporting

- Animals must be reported in the year they are "used", i.e. the year they are removed from the experiment.
  *Exception:* field experiments where animals cannot be removed from experiments. For example, if they are marked, released, and will remain marked for the rest of their lives. These must be reported in the year they are put into use.
- Each animal should only be reported once, except for reused animals. Remember that reuse of animals must be applied for and approved and concerns re-using an animal in *another* FOTS-application.

## Purpose of the experiment

For FOTS-applications submitted after June 2022, the purpose must be the same as in the original FOTS-application.

For FOTS-applications submitted before June 2022, the purpose must be selected when reporting. Choose the purpose and sub-purpose that best matches the main purpose of the experiment.

**The purpose "Basic research"**

The purpose "Basic research" should be used for studies of fundamental nature, such as studies of normal and abnormal structures, phenomena, or basic laws of nature.

The sub-purpose "Other" should only be used if there are no other adequate categories.

**The purpose "Translational and applied research"**
with various sub-purposes is to be used for applied and translational research (Section 10 b and c of the Laboratory Animal Regulations).

- Experiments with different feed and feed ingredients for fish or mammals must be reported as "Translational and applied research" and "Animal nutrition".
- Experiments with fish and mammals that are primarily concerned with welfare, e.g. testing of slaughter methods, must be reported as "Translational and applied research" and "Animal welfare".
- Trials with vaccines for fish that are under development must be specified as "Translational and applied research" and "Animal diseases and disorders".
- Trials necessary to test batch potency for fully developed vaccines (vaccines with marketing authorization) must be reported as "Regulatory use and routine production", with the subcategories "Regulatory use", "Quality control (incl. batch safety and potency testing)", "Batch potency testing", "Legislation for medicinal products for veterinary use and their residues" and "Legislation satisfying Union requirements" (in cases where there is a concurrence between the regulations of Norway and the EU).

The purposes **"environmental research" "Conservation of species" or "Protection of the environment for the sake of human or animal health or welfare**" may be appropriate for studies of loss of biodiversity, pollution and epidemiological surveys among wild animals.

# Reporting on animal origin ("Place of birth")

- Animals from ".... registered breeds" are animals born in or purchased from an approved Norwegian or European laboratory animal company (EU/EEA) that also has a permit for breeding ("breeder").
- Animals from ".... not at a registered breeder" is animals from animal husbandry, fish farms, wild animals, etc. in Norway or in an EU/EEA country.
- Report "Animals born in the rest of Europe" or "Animals born elsewhere" if wild or other animals are not born in the EU/EEA (incl. Norway).

# Severity category

When you apply in FOTS, you provide the expected (prospective) severity classification. This will be the starting point for reporting, but in the annual report you should report the *actual severity* level.

Make sure that the sum of the number of animals in these rubrics matches the total number of animals.

**"Non-recovery" (terminal)**

Only to be used where the entire experiment has taken place under general anesthesia and the animal has been euthanized while still under the same general anesthesia, without the animal having undergone any other procedures subject to application.

- Animals that have unexpectedly died under general anesthesia and which have not been subjected to procedures/stresses before anesthesia must be reported as «mild», not as «non-recovery».
- Animals that die because of infection in an infection trial must be reported as "severe", not as "non-recovery".
- Genetically modified animals with a harmful phenotype, and where all the experimental procedures has been carried out under general anesthesia (and the animal has not reawakened), must be reported *in accordance with the severity category of the harmful phenotype* (e.g., either mild, moderate, or severe), not as «non-recovery». This is because the effect of genetic modification is considered a regulated procedure.
- If animals have died from causes related to the experiment, the reported severity shall be "severe", unless a professional assessment has been made indicating that the load rate was less than "severe".
- If animals have died from causes *unrelated* to the experiment, the reported severity shall reflect the greatest burden on the animal in the experiment up to that point, provided that the supervision has been good.