11 November 2022

Pre-release

EU-SRS

Veterinary Vaccines EU-SRS User Guide

Guidance on the naming and building of veterinary vaccine substance records in EU-SRS

Disclaimer

This document is created as an addition to deliverable D2.8 EU-SRS Data Management Plan of Unicom Work Package 2: Implement IDMP – Substance Management in Europe, since the scope of Unicom is limited to Human Medicinal Products.

This guide will be a living document, used by the Substances Validation Group (SVG) for creation and maintenance of substances in EU-SRS.

The current version is a pre-release. Your feedback, if any, is welcomed by **8 December 2022.** Comments can be sent to Steven de Wit (e-mail: s.d.wit@cbg-meb.nl).

Your feedback will be considered when preparing the official release which will be submitted as Unicom deliverable to the European Commission in January 2023.

Document control

This document is subject to a regular review by the Substance Validation Group (SVG). It is a living document, and changes will be captured in the version history section.

Document ownership

This document is owned by the SVG.

Revision history

Version	Date	Changes made	Author(s)
N/A	11.11.2022	Pre-release	Maike Gömmel, Celine Lorteau, Annet Rozema

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List of abbreviations

Abbreviation	Complete Form
CV	Controlled Vocabulary
EMA	European Medicines Agency
EU-SRS	European Substance Registration System
ISO IDMP	ISO Identification of Medicinal Products
Ph. Eur.	European Pharmacopoeia
RMS	Referentials Management Services
PT	Preferred Term
SPC	Summary of Product Characteristics
SMS	Substance Management Services
SPOR	Substances, Products, Organisations & Referentials (EMA)
SSG	Specified Substance Group
SVG	Substance Validation Group

1 Introduction

The EU Network is currently implementing the ISO IDMP standards in a phased programme based on the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referential (collectively referred to as “SPOR”) master data. ISO IDMP compliant business services for the central management and supervision of data in each of the four SPOR areas will be established through an iterative and incremental delivery approach. Through the Substance Management Services (SMS) of the SPOR programme EMA will provide the EU network centralised substance data management services.
The European Substance Registration System (EU-SRS) will become the scientifically rigorous back-end for the Substance Management Services of SPOR. EU-SRS will be accessible to the EU regulatory network, enabling the unambiguous identification of substances used in medicinal products based on their scientific properties in accordance with ISO IDMP standard 11238 and ISO IDMP technical specification standard 19844. EU-SRS allows the unique identification of substances which will support various purposes including the enhancement of traceability of pharmacovigilance, non-clinical, clinical and quality findings with a high degree of precision to substances by their scientific identity.
The Substance Validation Group is responsible for building substance records in EU-SRS. In addition, the SVG defines guidance and best practices for substances management in EU-SRS (per substance type). Lastly, the SVG provides EMA with cleansing feedback on substance records in SMS; the EMA SMS team will process this feedback in SMS.

1.1 Purpose

The purpose of this document is to provide practical guidance regarding naming of vaccines for the various levels build in EU-SRS and correct building of records in EU-SRS.

1.2 Scope

Naming rules and registration of veterinary vaccine substances are in scope of this document. Veterinary chemicals are treated like human chemicals and are therefore not in the scope of this document. This document is to be used together with the overall EU-SRS Substance Maintenance Process, which describes in detail the workflow between EMA and SVG.

2 Defining a Veterinary Vaccine Substance

2.1 Definition

According to Regulation (EU) 2019/6 an immunological veterinary medicinal product means a veterinary medicinal product intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity. Veterinary vaccines are immunological products providing active immunity.

In EU-SRS they are built as 'Structurally Diverse' (substance type according to ISO IDMP), in which the antigens are described as individual substances and they can be of different substance type. For non-conventional vaccines (e.g., protein antigens made from recombinant techniques, DNA vaccines) a relationship is added to for example 'Protein' or 'Nucleic Acid' as alternative definition.

2.2 EU-SRS hierarchy

EU-SRS provides the opportunity to establish relationships between the records and therefore a hierarchy can be built. This hierarchy consists of three levels:

- **Species/Author level (highest level, mandatory)**
  e.g. Leptospira interrogans, (Stinson, 1907) Wenyon, 1926 emend. Faine and Stallman, 1982, Whole
- **Serovar/Serogroup/Serotype level (middle level, optional**)
  e.g.: Leptospira interrogans, Serogroup Icterohaemorrhagiae, Whole
  e.g. : Leptospira interrogans, Serogroup Canicola, Whole
- **Strain/Fraction level (lowest level, mandatory))**
  e.g.: Leptospira interrogans, Serogroup Icterohaemorrhagiae, Serovar Icterohaemorrhagiae, Strain 601895, Inactivated
  e.g.: Leptospira interrogans, Serogroup Icterohaemorrhagiae, Serovar Copenhageni, Strain Ic-02-001, Inactivated
  e.g.: Leptospira interrogans, Serogroup Icterohaemorrhagiae, Serovar Icterohaemorrhagiae, Strain Verdun, Inactivated

The records regarding one substance are interlinked in the built hierarchy. One record on the species/author level may have many records on the serovar and strain level below.

An example how the hierarchy looks like is provided in Figure 1.

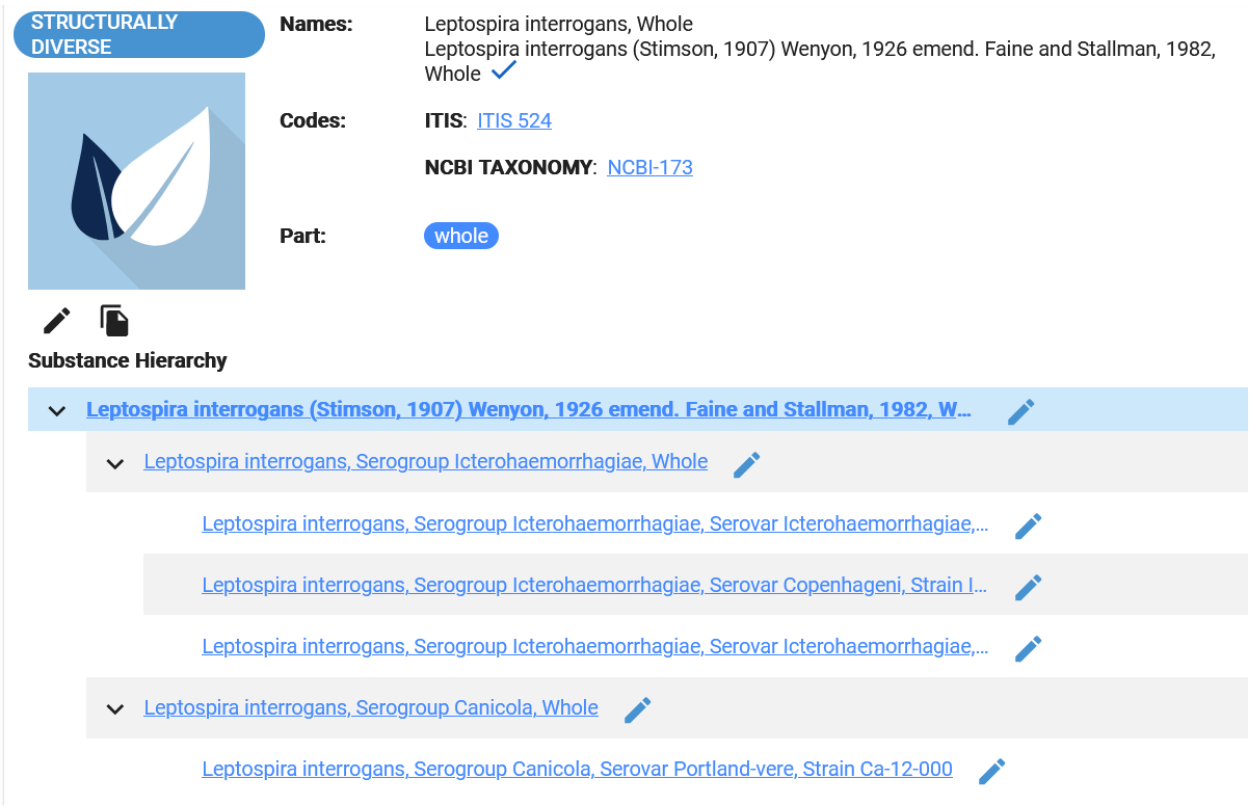

Figure 1. Example of a hierarchy that demonstrates the relationship between related veterinary vaccines substances. Example shown: Leptospira interrogans.

3 Naming of Veterinary Vaccines

This chapter provides details around naming of veterinary vaccines in EU-SRS and SMS.

Detailed instructions regarding the building of records in EU-SRS as well as detailed field definitions can be found in section 4 and the appendices (section **Fout! Verwijzingsbron niet gevonden.**).

3.1 Acceptable sources for naming of veterinary vaccines substances

Acceptable sources for naming are**:**

- NCBI (public, National Centre for Biotechnology Information) - https://www.ncbi.nlm.nih.gov/Taxonomy/Browser/wwwtax.cgi
- ICTV (public, International Committee on Taxonomy of Viruses) - https://talk.ictvonline.org/taxonomy/
- ITIS (public, Integrated Taxonomic Information System, https://www.itis.gov) – ITIS is no longer maintained, NCBI is the better source (if possible)
- LPSN - List of Prokaryotic names with Standing in Nomenclature (dsmz.de) - https://lpsn.dsmz.de
- SPC
- Official naming bodies if applicable, as listed in the General EU-SRS User Guide (e.g., INN)

3.2 Name types

The EU-SRS system will contain name type information according to ISO 11238, such as:

- Official Name: reflects the organization that assigns or recognizes the name associated with the substance. These names are typically non-proprietary names that are used in the labelling of pharmaceuticals. The domains and jurisdictions in which the official name is used are also captured, tracked and maintained within the terminology.
- Scientific Name: is based on the biological taxonomic nomenclature and reflects the current scientific knowledge based on acknowledged scientific/ taxonomic databases, which are however no official naming bodies (no jurisdiction applies) - applicable for naming species of organisms (including e.g., microorganisms, plants and viruses)
- Common Name: used if the name is neither an ‘Official Name’ nor a ‘Scientific Name’ or a ‘Code’.
- Code: Company Code/name for a substance provided in an early stage of development

3.3 Naming convention

Each unique substance receives an SMSID from SMS, and each SMSID has a Preferred Term, which is in case of veterinary vaccines substances the common name characterised as ‘Additional Listing Name’ in EU-SRS. The Preferred Term in EU-SRS is the name most accurately describing the substance at a given time and could change during the lifetime of a substance. The Preferred Term in EU-SRS is included as Alias in SMS (see Table 1). Other relevant names (besides the SMS-Preferred Term) can be included as aliases in EU-SRS.
The SMS-Preferred Term is used in several forms visible to industry. Going forward, it is planned that these forms (such as eAF) will also display the aliases.

3.3.1 Preferred term

Every record in EU-SRS (independently of the level) has a Preferred Term (PT), which is characterised as 'Display Name' in the system. Whenever possible the PT should be the 'Official Name' (name type) given by an official naming body but every other name type might also be suitable. For veterinary vaccines substances the 'Scientific Name' type will be mainly used. The PT will be marked in the system with a blue tick mark on the overview page of the record and is the name of the record. An example for PT fields to be filled in is shown in **Figure 2**.

Table 1. Business rules for the Preferred Term (PT)

Business Rules	Applicable to
The Substance scientific/ taxonomic name is designated as the Preferred Term (preferred name type: 'Official Name' or 'Scientific Name').	EU-SRS, all levels
The Preferred Term in SMS (Substance Common name) is designated as 'Common Name' and 'AL' (= Additional Listing Name) should be ticked.	EU-SRS, all levels
The Substance Common name shall always be accompanied by a Scientific/taxonomic name in the SMS and EU-SRS records.	SMS, EU-SRS

The substances included in SMS are mainly on Strain/Fraction level, so no hierarchy is included in SMS in contrast to EU-SRS. However, some Species level records and Serovar/ Serogroup/ Serotype level records can be found in SMS. They have been mainly created due to old products, where the substance was not well defined enough to build a strain level. These supposed Species and Serovar/ Serogroup/ Serotype level records from SMS need to be included on Strain/Fraction level in EU-SRS with the addition "Strain unknown" to build a correct hierarchy. Therefore, in the following tables also examples for SMS-PTs are given for Species/Author level and Serovar/ Serogroup/ Serotype level.

The Preferred Terms in SMS and EU-SRS are listed in the following table:

Table 2. Preferred Terms (PTs) in SMS and EU-SRS

Level	PT in SMS (if any)	PT in EU-SRS
Species/Author level	Common name	Scientific/taxonomic name
Serovar/Serogroup/Serotype level	Common name	Scientific/taxonomic name
Strain/Fraction level	Common name	Scientific/taxonomic name

As the PT is mostly different between SMS and EU-SRS on all levels it is necessary to include the PT of the other system as Alias in the records. This means that the PT in EU-SRS is included as Alias into SMS, and the PT in SMS is included as Alias into EU-SRS (please see section 3.3.2).

In **Table 3** an exemplary comparison of available PTs in SMS (common name) and corresponding PTs in EU-SRS (scientific/taxonomic name) is shown for all three levels.

Table 3. Comparison of SMS-PT and corresponding EU-SRS-PT

Name on Strain/Fraction level	PT in
Leptospira interrogans, serogroup Canicola, serovar canicola, strain 117, Inactivated	SMS
Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 117, Whole, Inactivated	EU-SRS
Foot-and-mouth disease virus, serotype A, strain Turkey 14/98, Inactivated	SMS
Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Whole, Inactivated	EU-SRS
Foot-and-mouth disease virus, Inactivated	SMS
Foot-and-mouth disease virus, Strain unknown, Whole, Inactivated	EU-SRS
Foot-and-mouth disease virus, serotype A, Inactivated	SMS
Foot-and-mouth disease virus, Serotype A, Strain unknown, Whole, Inactivated	EU-SRS
Eimeria necatrix, Live	SMS
Eimeria necatrix, Strain unknown, Whole	EU-SRS
Bordetelle bronchiseptica, Live	SMS
Bordetella bronchiseptica, Strain unknown, Whole	EU-SRS

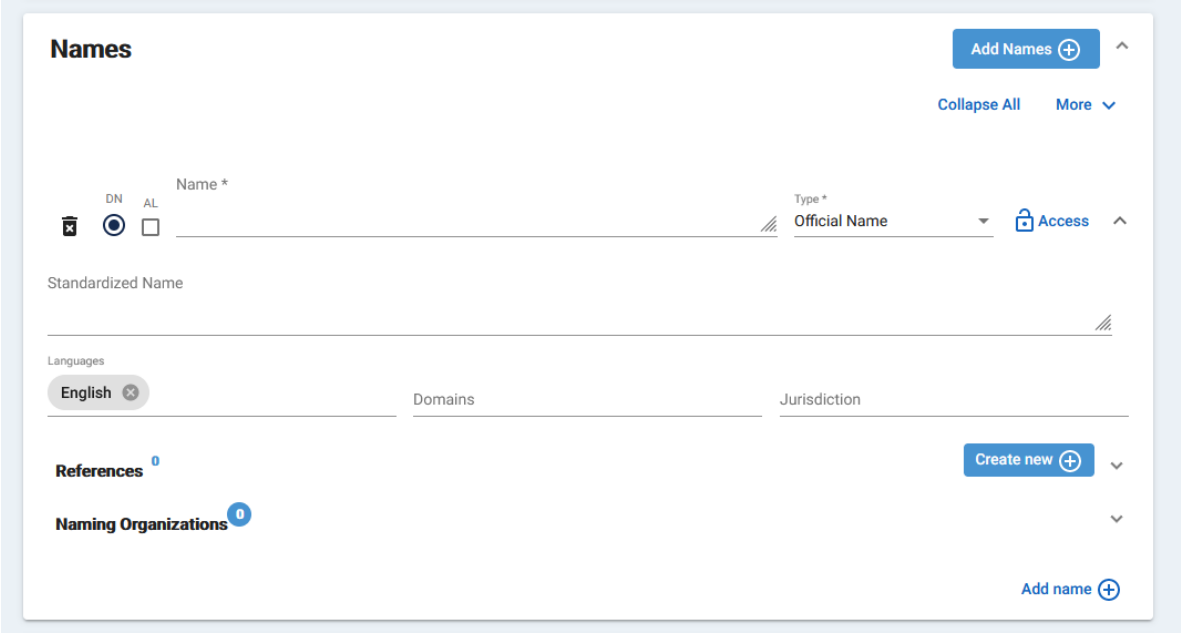

Figure 2. Example for PT fields to be filled in EU-SRS

Jurisdiction

In case of selecting 'Official Name' as name type an additional field 'Naming Organizations' is available, where the respective Naming Organization should be included.

A full list of acceptable naming organisations and jurisdiction is included in the General EU-SRS User Guide (which will be released at the end of December/beginning of January).

3.3.2 Aliases

Preferred Term in SMS (SMS-PT)

If there is a record in SMS, which might not be the case for Species/Author level and Serovar/ Serogroup/ Serotype level and is always the case on Strain/Fraction level, the PT will mostly be different between SMS and EU-SRS. Therefore, it is necessary to include the PT of the other system as alias in the records. This means that the PT in EU-SRS (display name) is included as alias into SMS, and the PT in SMS is included as alias into EU-SRS (see Table 4).

Therefore, at least on strain level, each record in EU-SRS should have at least one alias (= Additional Listing Name) besides the EU-SRS-PT (= Display Name). More aliases are always possible, if necessary (no tick box applied). Note that the first 4 name entries will be displayed in the overview page of the record.

Table 4. Names in SMS and their transfer in EU-SRS

SMS	EU-SRS
Common name = PT	Common name = Alias, choose name type 'Common Name' and tick box 'AL'
Scientific/taxonomic name = Alias	Scientific/taxonomic name = PT, choose applicable name type (e.g., 'Systematic Name') and tick box 'DN'
Other name (e.g. Acronym) = Alias	Other name (e.g., Acronym) = Alias, choose name type 'Common Name' (no box ticked!)

For the SMS-PT the tick box 'Additional Listing Name' is necessary to differentiate the SMS-PT from other 'Common Names'. It will be marked with a grey tick mark on the overview page of the record.

Example for an Additional Listing Name in EU-SRS (PT in SMS) is included in Figure 3.

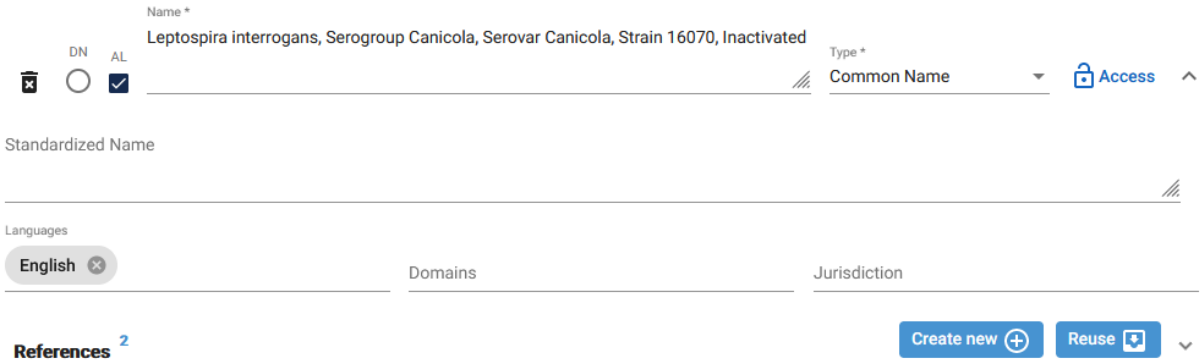

Figure 3. Example for AL in EU-SRS

This means, that every strain record has at least two names displayed: The EU-SRS-PT (Tick box 'DN', blue tick mark) and the SMS-PT (Name type 'Common Name', Tick box 'AL', grey tick mark).

If the PTs are identical, it is possible to tick 'DN' and 'AL' in the same name. This name would then have both tick marks on the overview page of the record (one blue and one grey).

Other aliases

Relevant names, being not the SMS-PT, can be included as additional names, mostly of the name type 'Common Name'. In these cases, the 'DN' box and the 'AL' are not ticked!

On the overview page of the records the first 4 names are visible in the following order: Preferred Term, Additional Listing Name and then the aliases.

All name entries are visible in the name section within the record.

Examples:
In general, an Alias can be defined as any other name.
A synonym is in most cases another name entry within the same Name type.

PT (= appropriate Name Type + DN) (= Scientific/taxonomic Name)

Alias (= Common Name) (= Additional Listing Name, if it is the SMS-PT)

Alias (= other Common Name) (can be a Ph. Eur. Definition, Literature, Acronym)

Alias (= Official Name) (can be sourced from an official naming body)

3.3.3 Reference information

All public records must have at least one public reference where the “PUBLIC_DOMAIN_RELEASE” tag is populated (otherwise the record cannot be public). The reference may be a publicly available database (please refer to the acceptable naming sources described above in section 3.1). In general, the SPC should contain this information.

Each name (independently of the access) must have a reference (also Alias, Acronym, Synonym...)! References can be newly created or reused (once added to a record) by selecting the tick box. Independently of the tag mentioned above names can be marked as public using the tick box “Public Domain”. This is specific for this name and has no influence on the accessibility of the whole record.

A list of relevant references for veterinary vaccines can be found in Appendix 5.3. A complete overview will be included in the General EU-SRS User Guide, (which will be released at the end of December/beginning of January).

3.4 Naming syntax

The naming syntax is described for the Veterinary domain use case.

The syntax will follow two types of rules:

- One applicable for a bacterium, fungus and parasite
- One applicable for a virus

Note that also if the active substance is a recombinant or purified protein (a ‘Fraction’), the syntax used conforms to the respective parent organism from which the protein originates.

Examples:

- Active substance: Leishmania infantum Excreted Secreted Proteins (ESP)
  -> Choose parasite syntax because the active substance is purified from Leishmania infantum.
- Active substance: Feline leukemia virus, Envelope P45 protein (E. coli MZ-1 is used as host strain to express the envelope Recombinant plasmid pB0TF70D expressing the FelV subgroup an envelope recombinant P45 protein.)
  -> Choose virus syntax because the active substance originates from Feline leukemia virus.
- Active substance: Pasteurella multocida, Serogroup D, Toxin, recombinant (Host = Escherichia coli, Strain AD494(Des)pLysS)
  -> Choose bacterium syntax because the active substance is a protein from Pasteurella multocida.

The capitalization of each syntax group

Microorganism: sentence case as per general taxonomic rules.

The words ‘Serogroup’, ‘Serovar’, ‘Serotype’ and ‘Strain’ as well as the name of the serogroup, serovar, serotype itself should start with upper case (if available).

‘Part' and 'Status’ should start with upper case (if available).

3.5 Conventional vaccines - Bacterium/fungus/parasite for the veterinary domain

3.5.1 Species/Author level

Preferred Term

As described in the naming convention the scientific/taxonomic name is used as Preferred Term at Species/Author level. In EU-SRS this implicates that the scientific/taxonomic name is the displayed name (Preferred Term, 'DN' ticked in the details).

The Species/Author level contains the scientific/taxonomic name with the organism 'Species' name. (The other taxonomic levels as 'Family', 'Genus', 'Serovar / Serogroup / Serotype' are named and described as fields in the EU-SRS database.)

For bacteria, fungi and parasites (but not for viruses), the Preferred Term for the species level also includes the original(s) publications ('Author(s)' and 'Year'). In exceptional cases the author can also be omitted for parasites.

The substance name at this level also includes the 'Part' ('Whole' when the complete organism is the source).

The **syntax** for the scientific/taxonomic name at Species/Author level is:

<Microorganism name>, <(Primary) secondary author>, <Year>, <Part>

Examples:

- Bordetella bronchiseptica, Ferry 1912) Moreno-Lopez, 1952, Whole
- Leptospira interrogans, (Stinson, 1907) Wenyon, 1926 emend. Faine and Stallman, 1982, Whole
- Clostridium perfringens, (Veillon and Zuber, 1898) Hauduroy et al., 1937, Whole
- Eimeria necatrix, (Tyzzer et al., 1932), Whole
- Trichophyton mentagrophytes, (C.P. Robin) R. Blanch., 1896, Whole

Aliases

Besides the Preferred Term aliases may be included in the record (optional). The common name of the microorganism, mentioned in the related substance(s) at the strain/fraction level (corresponding to SMS PT) can be recorded as an alias, as well as e.g., acronyms or synonyms. The name type is 'Common Name'.

The **syntax** for the common name at Species/Author level is:

<Microorganism name>

Example:

- Synonym for Bordetella bronchiseptica (Common name): Bacillus bronchisepticus

Example: Bordetella bronchiseptica

Reference NCBI:

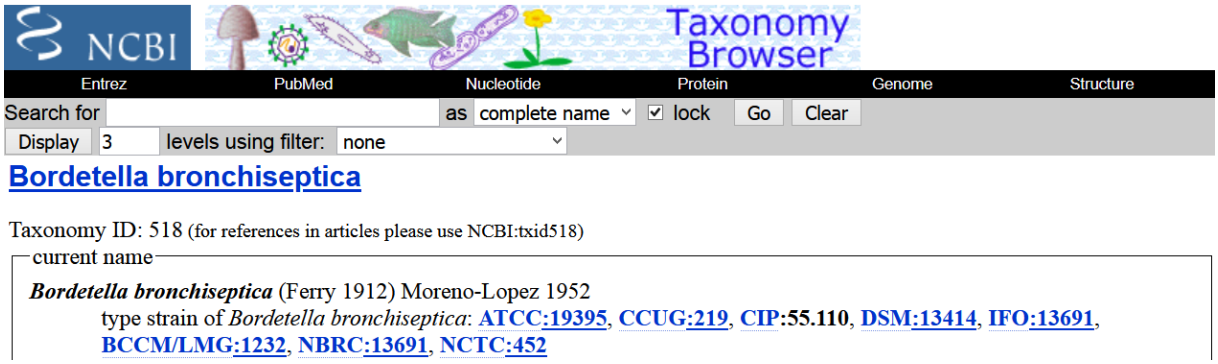

Figure 4. Result of entry 'Bordetella bronchiseptica' in the NCBI database

According to the rules mentioned above the following names can be used:

- Scientific taxonomic name: Bordetella bronchiseptica, (Ferry 1912) Moreno-Lopez, 1952, Whole (PT in EU-SRS, name type 'Scientific Name')
- Common name (Alias, optional): Bacillus bronchiseptica

Synonyms:
The NCBI 518 ID record also provides a few synonyms which can be included as aliases e.g.,

- Bacillus bronchisepticus
- Bacterium bronchisepticus
- Alcaligenes bronchisepticus
- Brucella bronchiseptica
- Haemophilus bronchisepticus

Note: adding additional aliases should be avoided, unless they provide additional information. Every name must have a reference. Multiple names can have the same reference.

Summary - Species/Author level

Table 5: Naming summary of species/author level for bacteria/fungi/parasites

Name Type	Syntax / Examples
Scientific taxonomic name = appropriate Name type = Preferred Term = Display name *Obligate*	<Microorganism name>, <(Primary) secondary author>, <Year>, <Part> ► Bordetella bronchiseptica, (Ferry 1912) Moreno-Lopez, 1952, Whole ► Eimeria necatrix, (Tyzzer et al. 1932), Whole
Common name (= SMS-PT = Additional Listing Name) *Obligate if provided*	*<Microorganism name>* *Not applicable on Species/Author level.*
Alias other than SMS-PT (e.g., 'Common Name')	<Microorganism name> ► Bacillus bronchisepticus ► None in this case

Each name must have a reference. Multiple names can have the same reference.

3.5.2 Serovar/Serogroup/Serotype level

Preferred Term

The 'Serovar/ Serogroup/Serotype' level (if applicable) shall be placed in the EU-SRS database hierarchy below the 'Species/Author' level.

As described in the naming convention the microorganism scientific/taxonomic name is used as Preferred Term at Serovar/Serogroup/Serotype level (e.g. 'Leptospira interrogans, Serogroup Icterohaemorrhagiae, Whole'; 'Leptospira interrogans, Serogroup Canicola, Whole'). In EU-SRS this implicates that the scientific/taxonomic name is the displayed name (Preferred Term, 'DN' ticked in the details).

The organism's name is captured from an acceptable source (see section 3.1) and will consist of the microorganism's name and the serovar/ serogroup/ serotype name.

The **syntax** for the scientific/ taxonomic name at Serovar/Serogroup/Serotype level is:

<Microorganism name>, <Serovar/ Serogroup/ Serotype>, <Part>

Examples:

- Leptospira interrogans, Serogroup Icterohaemorrhagiae, Whole
- Leptospira interrogans, Serogroup Canicola, Whole
- Clostridium perfringens, type C, Whole

Aliases

Besides the Preferred Term aliases may be included in the record (optional). The common name of the microorganism, mentioned in the related substance(s) at the strain/fraction level (corresponding to SMS PT) can be recorded as an alias, as well as e.g., acronyms or synonyms. The name type is 'Common Name'.

The **syntax** for the substance common name at Serovar/Serogroup/Serotype level is:

<Microorganism name>, <Serovar/ Serogroup/ Serotype>

Summary – Serovar/Serogroup/Serotype level

Table 6. Naming summary of serovar/serogroup/serotype level for bacteria/fungi/parasites

Name Type	Syntax / Examples
Scientific/taxonomic name = appropriate Name type = Preferred Term = Display name *Obligate*	<Microorganism name>, <Serovar/ Serogroup/ Serotype>, <Part> ► Leptospira interrogans, Serogroup Canicola, Whole ► Clostridium perfringens, type C, Whole
'Common Name' (= SMS-PT = Additional Listing Name) *Obligate*	*<Microorganism name>, <Serovar/Serogroup/ Serotype>* *Not applicable on Serovar/Serogroup/Serotype level*
Alias other than SMS-PT (e.g., 'Common Name') *Optional*	<Microorganism name>, <Serovar/Serogroup/ Serotype> ► None in this cases

Each name must have a reference. Multiple names can have the same reference.

3.5.3 Strain/Fraction level

Preferred Term

The 'Strain/Fraction' level shall be placed in the EU-SRS database hierarchy below the 'Species/Author' level and below the 'Serovar/Serogroup/Serotype' level, if applicable.

As described in the naming convention the microorganism scientific/taxonomic name is used as Preferred Term at Strain/Fraction level (e.g.: Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Whole, Inactivated). In EU-SRS this implicates that the scientific/taxonomic name is used as the displayed name (Preferred Term, 'DN' ticked in the details).

The strain itself has its particulars in terms of attenuation, deletion, thermosensitivity, etc. These particulars should be included in EU-SRS.

For parasites, stages of development (e.g., sporulated oocysts) are indicated at this level.

The **syntax** for the scientific/taxonomic name at Strain/Fraction level is:

<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Developmental stage*>, <Antigen*>[a], <Part>[b], <Status>[c]

*if applicable

a) Note: The 'Antigen' is a 'fraction' of the strain / is produced by the strain and may include modification information – it should only be included in the name if it is the active substance

b) Note: The EU-SRS system has the field 'Part' which contains the CV-value 'Whole'

c) Note: Status will include modification e.g., Inactivation (note: the EU-SRS field 'Status = Source material state' has several CV-Values for 'Live')

Examples:

- Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Whole, Inactivated
- Clostridium perfringens, type C, Strain 578, Beta toxoid
- Eimeria necatrix, Strain 033, Sporulated oocysts, Whole

Aliases

Besides the Preferred Term the common name used as PT in SMS, should always be included as alias in the record as an Additional Listing Name ('AL' ticked), Name type 'Common Name'. The Common name is inclusive the status, e.g., live or inactivated.

Further aliases (e.g., synonym) can be included if necessary (e.g., as name type 'Common Name').

The **syntax** for the substance common name at Strain/Fraction level is:

<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Status>[b]

*if applicable

[a)] Note: The 'antigen' is a 'fraction' of the strain/ is produced by the strain and may include modification information – it should only be included in the name if it is the active substance

[b)] Note: Status will include modification e.g., Inactivation (note: the EU-SRS field 'Status = Source material state' has several CV-Values for 'Live')

Examples:

- Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Inactivated
- Leptospira interrogans, Serogroup Icterohaemorrhagiae, Serovar Copenhageni, Strain 820K, Live.
- Eimeria necatrix, strain 033, Live.

Example 1: Leptospira interrogans

Table 7: Example for naming in SMS and EU-SRS on strain/fraction level (Leptospira interrogans)

SMS	EU-SRS
► Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Inactivated (PT)	► Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Whole, Inactivated (PT) ► Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Inactivated (Alias, Additional Listing Name)

Example 2: Eimeria necatrix

Table 8: Example for naming in SMS and EU-SRS on strain/fraction level (Eimeria necatrix)

SMS	EU-SRS
► Eimeria necatrix, strain 033, Live (PT)	► Eimeria necatrix, strain 033, sporulated oocysts, Whole (PT) ► Eimeria necatrix, strain 033, Live (Alias, Additional Listing Name)

Summary Strain/Fraction level

Table 9. Naming summary of strain/fraction level for bacteria/fungi/parasites

Name Type	Syntax / Examples
Scientific/taxonomic name= applicable Name type = Preferred Term = Display Name *Obligate*	<Microorganism name>, <Serogroup*/ Serovar*/ Serotype*>, <Serovar*>, <Strain>, <Developmental stage>*, <Antigen*>[a], <Part>[b], <Status>[c] ► Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Whole, Inactivated ► Eimeria necatrix, Strain 033, Sporulated oocysts, Whole ► Mannheimia haemolytica, serotype A1, strain M4/1, Whole, Inactivated
'Common Name' (= SMS PT = Additional Listing Name) *Obligate*	<Microorganism name>, <Serogroup*/ Serovar*/ Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Status>[c] ► Leptospira interrogans, Serogroup Canicola, Serovar Canicola, Strain 601903, Inactivated ► Eimeria necatrix, Strain 033, Live

	► Mannheimia haemolytica, serotype A1, strain M4/1, Inactivated
Alias other than SMS-PT (e.g., 'Common Name') *Optional*	< Microorganism name>, <Serogroup*/ Serovar*/ Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Status>[b] ► None in this case ► None in this case ► Pasteurella haemolytica, serotype A1, strain M4/1, Inactivated

Each name must have a reference. Multiple names can have the same reference.

*if applicable

[a)] Note: The 'antigen' is a 'fraction' of the strain/ is produced by the strain and may include modification information – it should only be included in the name if it is the active substance

[b)] Note: The EU-SRS system has the field 'Part' which contains the CV-value 'Whole'

[c)] Note: Status will include modification e.g., Inactivation (note: the EU-SRS field 'Status = Source material state' has several CV-Values for 'Live')

3.6 Conventional vaccines - Virus for the veterinary domain

3.6.1 Species/Author level

Preferred Term

As described in the naming convention the scientific/taxonomic name is used as Preferred Term at Species/Author level. In EU-SRS this implicates that the scientific/taxonomic name is the displayed name (Preferred Term, 'DN' ticked in the details). In contrast to the bacterium/parasite syntax the author is not included in the name on this level, e.g., 'Gallid alphaherpesvirus 1, Whole'.

The Species/Author level contains the scientific/taxonomic name with the organism 'Species' name. (The other taxonomic levels as 'Family', 'Genus', 'Serovar / Serogroup / Serotype' are named and described as fields in the EU-SRS database.)

The substance name at this level also includes the 'Part' ('Whole' when the complete organism is the source).

The **syntax** for the scientific/taxonomic name at Species/Author level is:

<Microorganism name>, <Part>

Example:

- Gallid alphaherpesvirus 1, Whole

Aliases

Besides the Preferred Term aliases may be included in the record (not obligate). The Common name of the microorganism, mentioned in the related substance(s) at the strain/fraction level (corresponding to SMS PT) can be recorded as an alias, as well as e.g., acronyms or synonyms. The name type is 'Common Name'.

The **syntax** for the viral common name at Species/Author level is:

<Microorganism common name>

Examples:

Example 1: Gallid alphaherpesvirus 1

- Scientific/ taxonomic name (= PT): Gallid alphaherpesvirus 1, Whole (PT in EU-SRS, name type 'Scientific Name')
- Substance Alias (Acronym): GaHV-1 (name type 'Common Name')
- Substance Alias (Synonym): Infectious laryngotracheitis virus (name type 'Common Name')

Figure 5: Result of entry 'Gallid alphaherpesvirus 1' in the NCBI database

Example 2: Foot-and-mouth disease virus

- Scientific taxonomic name: Foot-and-mouth disease virus, Whole (PT in EU-SRS, name type 'Scientific Name') (NCBI: 12110)
- Substance Alias (Acronym): FMDV (name type 'Common Name')
- Substance Alias (Synonym): Foot and mouth disease virus (name type 'Common Name')

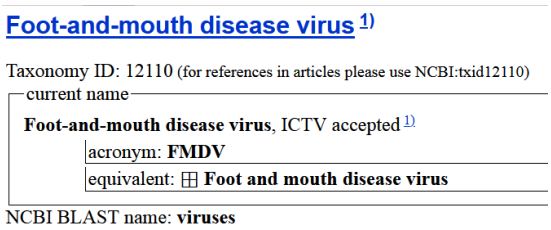

Figure 6. Result of entry 'Foot-and-mouth disease virus' in the NCBI database

Summary - Species/Author level

Table 10. Naming summary of species/author level for virus

Name Type	Syntax / Examples
Scientific taxonomic name = appropriate Name type = Preferred Term = Display Name *Obligate*	<Microorganism name>, <Part> ► Gallid alphaherpesvirus 1, Whole
'Common Name' (= SMS-PT = Additional Listing Name) *Obligate if provided*	*<Microorganism name>* *Not applicable on Species/Author level.*
Alias other than SMS-PT (e.g., 'Common Name') *Optional*	<Microorganism name> ► Avian infectious laryngotracheitis virus ► GaHV-1

Each name must have a reference. Multiple names can have the same reference.

3.6.2 Serovar/Serogroup/Serotype level

Preferred Term

The 'Serovar/ Serogroup/Serotype' level (if applicable) shall be placed in the EU-SRS database hierarchy below the 'Species/Author' level.

As described in the naming convention the microorganism scientific/taxonomic name is used as Preferred Term at Serovar/Serogroup/Serotype level (e.g., 'Foot-and-mouth disease virus, Serotype A, Whole'). In EU-SRS this implicates that the scientific/taxonomic name is the displayed name (Preferred Term, 'DN' ticked in the details).

The organism's name is captured from an acceptable source (see above section 3.1) and will consist of the microorganism's name and the serovar/ serogroup/ serotype name.

The **syntax** for the scientific/taxonomic name at Serovar/Serogroup/Serotype level is:

<Microorganism name>, <Serovar/ Serogroup/ Serotype>, <Part>

Example:

- Foot-and-mouth disease virus, Serotype A, Whole

Aliases

Besides the Preferred Term aliases may be included in the record (optional). The common name of the microorganism, mentioned in the related substance(s) at the strain/fraction level (corresponding to SMS PT) can be recorded as an alias, as well as e.g., acronyms or synonyms. The name type is 'Common Name'.

The **syntax** for the substance common name at Serovar/Serogroup/Serotype level is:

<Microorganism common name>, <Serovar*/ Serogroup*/ Serotype*>

*if applicable

Example:

- 'FMDV-A

Foot-and-mouth disease virus (FMDV) has seven distinct serotypes named O, A, C, SAT 1, SAT 2, SAT 3 and Asia 1 (https://en.wikipedia.org/wiki/Foot-and-mouth_disease).

Table 11. Example for naming in SMS and EU-SRS on Serovar/Serogroup/Serotype level (Foot-and-mouth disease virus)

SMS	EU-SRS
▶ No record	▶ Foot-and-mouth disease virus, Serotype A, Whole (PT) ▶ FMDV-A ▶ Aphtovirus A
▶ No record	▶ Foot-and-mouth disease virus, Serotype Asia 1, Whole (PT) ▶ FMDV-Asia 1 ▶ Foot-and-mouth disease virus Asia 1
▶ No record	▶ Foot-and-mouth disease virus, Serotype O, Whole (PT) ▶ FMDV-O ▶ Aphtovirus O
▶ No record	▶ Foot-and-mouth disease virus, Serotype SAT 2, Whole (PT) ▶ FMDV-SAT 2 ▶ Aphtovirus SAT2

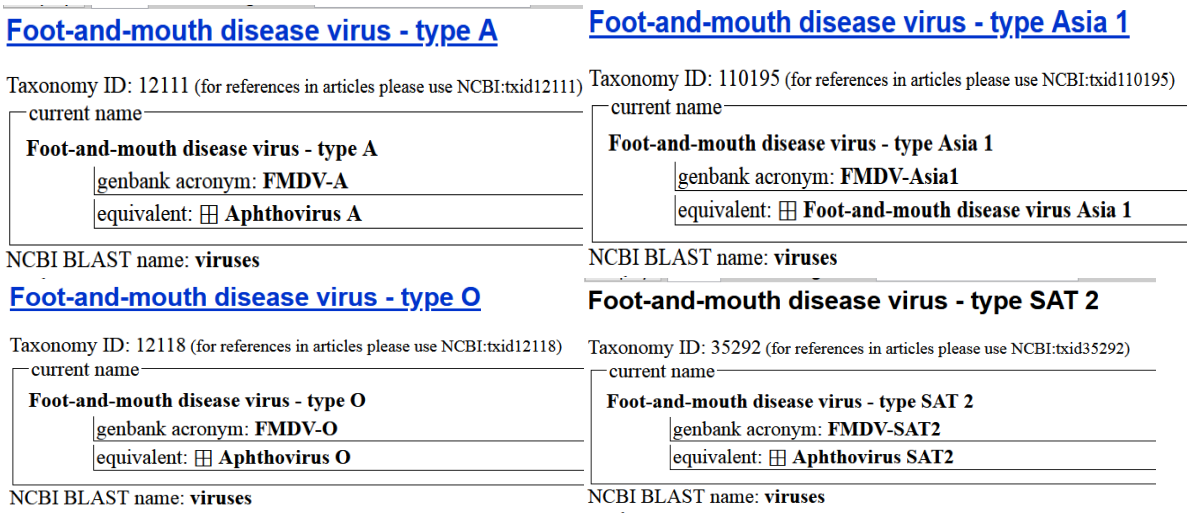

Figure 7. Result of entry 'Foot-and-mouth disease virus, Serotype' in the NCBI database

Summary – Serovar/ Serogroup/Serotype level

Table 12. Naming summary of serovar/serogroup/serotype level for virus

Name Type	Syntax / Examples
Scientific/taxonomic name = appropriate Name type = Preferred Term = Display Name *Obligate*	<Microorganism name>, <Serovar/Serogroup/Serotype>, <Part> ► 'Foot-and-mouth disease virus, Serotype A, Whole
'Common Name' (= SMS-PT = Additional Listing Name) *Obligate*	*<Microorganism name>, <Serovar/Serogroup/ Serotype>* *Not applicable on Serovar/Serogroup/Serotype level*
Alias other than SMS-PT (e.g., 'Common Name') *Optional*	<Microorganism name>, <Serovar/Serogroup/Serotype> ► FMDV-A ► Aphtovirus A

Each name must have a reference. Multiple names can have the same reference.

3.6.3 Strain/Fraction level

Preferred Term

The 'Strain/Fraction' level shall be placed in the EU-SRS database hierarchy below the 'Species/Author' level and below the 'Serovar/Serogroup/Serotype' level, if applicable.

As described in the naming convention the microorganism scientific/taxonomic name (provided by SMS) is used as Preferred Term at Strain/Fraction level (e.g.: Avian infectious laryngotracheitis virus, Strain CHP50, Whole). In EU-SRS this implicates that the scientific/taxonomic name is the displayed name (Preferred Term, 'DN' ticked in the details).

The strain itself has its particulars in terms of attenuation, deletion, thermosensitivity, etc. These particulars should be included in EU-SRS.

The **syntax** for the scientific/taxonomic name at Strain/Fraction level is:

<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Part>[b], <Status>[c]

*if applicable

a) Note: The 'Antigen' is a 'fraction' of the strain / is produced by the strain and may include modification information – it should only be included in the name if it is the active substance

b) Note: The EU-SRS system has the field 'Part' which contains the CV-value 'Whole'

c) Note: Status will include modification e.g., Inactivation (note: the EU-SRS field 'Status = Source material state' has several CV-Values for 'Live')

Examples:

- Gallid alphaherpesvirus 1, Strain CHP50, Whole, Inactivated
- Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Whole, Inactivated
- Classical swine fever virus, glycoprotein E2

Aliases

Besides the Preferred Term the common name used as PT in SMS should always be included as alias in the record as an Additional Listing Name ('AL' ticked, Name type 'Common Name'). The Common name is inclusive the status, e.g., live or inactivated.

Further aliases (e.g., synonym) can be included if necessary (e.g., as name type 'Common Name').

The **syntax** for the substance common name at Strain/Fraction level is:

<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Status>[b]

*if applicable

[a)] Note: The 'antigen' is a 'fraction' of the strain/ is produced by the strain and may include modification information – it should only be included in the name if it is the active substance

[b)] Note: Status will include modification e.g., Inactivation (note: the EU-SRS field 'Status = Source material state' has several CV-Values for 'Live')

Examples:

- Avian infectious laryngotracheitis virus, strain CHP50, Live (PT SMS, Common name in EU-SRS = Additional listing Name)
- Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Inactivated (PT SMS, Common name in EU-SRS = Additional listing Name)
- GaHV-1, strain CHP50, Live. (Alias)
- FMDV, serotype A, strain Turkey 14/98, Inactivated (Alias)
- Classical swine fever virus, glycoprotein E2

Example 1: Gallid alphaherpesvirus 1

Table 13. Example for naming in SMS and EU-SRS on strain/fraction level (Gallid alphaherpesvirus 1)

SMS	EU-SRS
▶ Avian infectious laryngotracheitis virus, strain CHP50, Live (PT) ▶ GaHV-1, strain CHP50, Live (Acronym/ Alias)	▶ Gallid alphaherpesvirus 1, Strain CHP50, Whole (PT) ▶ Avian infectious laryngotracheitis virus, Strain CHP50, Live (Alias, Additional Listing Name) ▶ GaHV-1, Strain CHP50, Live (Acronym/ Alias)

Example 2: Carnivore protoparvovirus 1

Table 14. Example for naming in SMS and EU-SRS on strain/fraction level (Carnivore protoparvovirus 1)

SMS	EU-SRS
▶ Feline panleucopenia virus, strain PLI IV, Live (PT) ▶ Carnivore protoparvovirus 1, strain PLI IV, Live (Alias) ▶ FPLV, strain PLI IV, Live (Acronym/ Alias)	▶ Carnivore protoparvovirus 1, Strain PLI IV, Whole (PT) ▶ Feline panleucopenia virus, Strain PLI IV, Live (Alias, Additional Listing Name) ▶ FPLV, Strain PLI IV, Live (Acronym/ Alias)

Example 3: Foot-and-mouth disease virus

Table 15. Example for naming in SMS and EU-SRS on strain/fraction level (Foot-and-mouth disease virus)

SMS	EU-SRS
▶ Foot-and-mouth disease virus, serotype A, strain Turkey 14/98, Inactivated (PT) ▶ FMDV, serotype A, strain Turkey 14/98, Inactivated (Alias)	▶ Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Whole, Inactivated (PT) ▶ Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Inactivated (Alias, Additional Listing Name) ▶ FMDV, Serotype A, Strain Turkey 14/98, Inactivated (Alias)
▶ Foot-and-mouth disease virus, serotype Asia 1, strain Shamir, Inactivated (PT) ▶ FMDV, serotype Asia 1, strain Shamir, Inactivated (Alias)	▶ Foot-and-mouth disease virus, Serotype Asia 1, Strain Shamir, Whole, Inactivated (PT) ▶ Foot-and-mouth disease virus, Serotype Asia 1, Strain Shamir, Inactivated (Alias, Additional Listing Name) ▶ FMDV, Serotype Asia 1, Strain Shamir, Inactivated (Alias)
▶ Foot-and-mouth disease virus, serotype O, strain Taiwan 3/97, Inactivated (PT) ▶ FMDV, serotype O, strain Taiwan 3/97, Inactivated (Alias)	▶ Foot-and-mouth disease virus, Serotype O, Strain Taiwan 3/97, Whole, Inactivated (PT) ▶ Foot-and-mouth disease virus, Serotype O, Strain Taiwan 3/97, Inactivated (Alias, Additional Listing Name) ▶ FMDV, Serotype O, Strain Taiwan 3/97, Inactivated (Alias)
▶ Foot-and-mouth disease virus, serotype SAT2, strain Saudi Arabia, Inactivated (PT) ▶ FMDV, Serotype SAT2, strain Saudi Arabia, Inactivated (Alias)	▶ Foot-and-mouth disease virus, Serotype SAT2, Strain Saudi Arabia, Whole, Inactivated (PT) ▶ Foot-and-mouth disease virus, Serotype SAT2, Strain Saudi Arabia, Inactivated (Alias, Additional Listing Name) ▶ FMDV, Serotype SAT2, Strain Saudi Arabia, Inactivated (Alias)

Summary Strain/Fraction level

Table 16. Naming summary of strain/fraction level for virus

Name Type	Syntax / Examples
Scientific/taxonomic name= appropriate Name type = Preferred Term = Display Name *Obligate*	<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Part>[b], <Status>[c] ► Gallid alphaherpesvirus 1, Strain CHP50, Whole ► Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Whole, Inactivated ► Classical swine fever virus, glycoprotein E2
'Common Name' (= SMS-PT = Additional Listing Name) *Obligate*	<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Status>[c] ► Avian infectious laryngotracheitis virus, Strain CHP50, Live ► Foot-and-mouth disease virus, Serotype A, Strain Turkey 14/98, Inactivated ► Classical swine fever virus, glycoprotein E2
Alias other than SMS-PT (e.g., 'Common Name') *Optional*	<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Antigen*>[a], <Status>[b] ► GaHV-1, strain CHP50, Live ► FMDV, Serotype A, Strain Turkey 14/98, Inactivated ► CSFV, glycoprotein E2

Each name must have a reference. Multiple names can have the same reference.

*if applicable

[a)] The 'antigen' is a 'fraction' of the strain/ is produced by the strain and may include modification information – it should only be included in the name if it is the active substance

[b)] The EU-SRS system has the field 'Part' which contains the CV-value 'Whole'

[c)] Status will include modification e.g., Inactivation (note: the EU-SRS field 'Status = Source material state' has several CV-Values for 'Live')

3.7 Non-conventional vaccines – special information on strain level

For non-conventional vaccines the building of the Strain/Fraction level is different from conventional vaccines and the syntax differs dependently on the kind of vaccine, as described in the following chapters.

If there are genetic modifications, they should be described between the strain and the status.

With regard to rules set in connection with UPD, <modification> is not a field foreseen. Any genetic modification is strain specific and therefore when indicating the strain, there is no need to specify details which are particulars of this strain. However, the field 'modification' is foreseen in EU-SRS and this information can be described in EU-SRS.

In the veterinary domain the following use cases are applicable so far:

- Vaccines using deletion mutants (e.g., Poulvac E. coli, Vepured, Hiprabovis IBR Marker Live)
- Vector vaccines (e.g., Innovax ILT, Purevax Rabies, Proteq West Nile, Nobivac Myxo RHD, Suvaxyn Circo+MH RTU)
- DNA vaccines (e.g., Clynav)

Other types of vaccines may be under development, e.g., RNA vaccines.

Non-conventional vaccines would in principle be built as structurally diverse, with a relationship to for example a nucleic acid as alternative definition.

3.7.1 Vaccines using deletion mutants

Syntax of Preferred Term in SMS (common name):

<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Modification*>[a], <Status>[b]

*if applicable

[a)] Note: The strain may include modification information

[b)] Note: Status will include modification e.g., Inactivation

Syntax of Preferred Term in EU-SRS (scientific/taxonomic name):

<Microorganism name>, <Serogroup*/Serovar*/Serotype*>, <Serovar*>, <Strain>, <Modification*>[a], <Part>, <Status>[b]

*if applicable

[a)] Note: The strain may include modification information

[b)] Note: Status will include modification e.g., Inactivation

Example 1: Bacterium (strain)

Table 17. Example for naming in SMS and EU-SRS for bacterial vaccines using deletion mutants (*E. coli*)

SMS	EU-SRS
► Escherichia coli, type O78, Strain EC34195, Live (PT) ► Escherichia coli, type O78, Strain EC34195, AroA gene deleted, Live (Alias)	► Escherichia coli, Type O78, Strain EC34195, AroA gene deleted, Whole (PT) ► Escherichia coli, Type O78, Strain EC34195, Live (Alias, Additional Listing Name)

Example 2: Bacterium (strain/fraction)

- PT in SMS: Escherichia coli, Shiga toxin detoxified Stx2e, recombinant.
- PT in EU-SRS: Escherichia coli, Genetically modified recombinant Stx2e antigen.

Example 3: Virus

Table 18. Example for naming in SMS and EU-SRS for viral vaccines using deletion mutants (IBRV)

SMS	EU-SRS
► Infectious bovine rhinotracheitis virus[1], strain CEDDEL, gE- tk- double-gene deleted, Live (PT) ► Bovine alphaherpes virus type 1[2], strain CEDDEL glycoprotein E deleted, thymidine kinase deleted, Live (Alias)	► Bovine alphaherpes virus type 1, Strain CEDDEL glycoprotein E deleted, thymidine kinase deleted, Whole (PT) ► Infectious bovine rhinotracheitis virus, strain CEDDEL, gE- tk-double-gene deleted, Live (Alias, Additional Listing Name)

Note[1]: Common Name

Note[2]: Taxonomic name

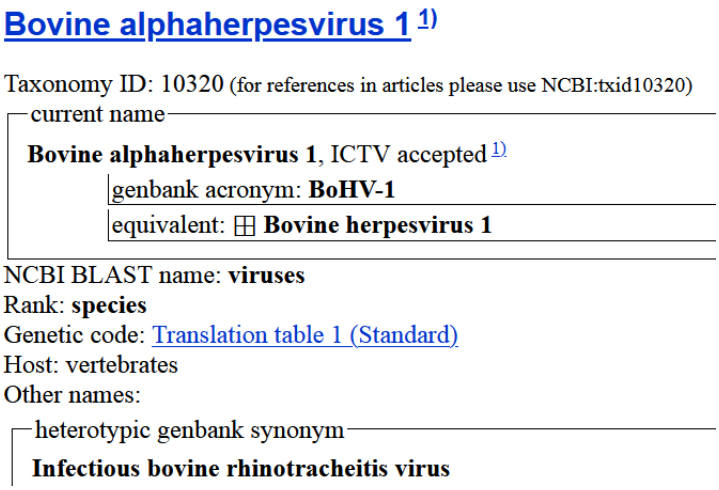

Figure 8. Result of entry 'Bovine alphaherpesvirus 1' in the NCBI database

3.7.2 Viral vector vaccines

Syntax of Preferred Term in SMS (common name):

<Vector>, <Strain*>, <Inserted microorganism>, <Status>

*if applicable

Syntax of Preferred Term in EU-SRS (scientific/taxonomic name):

<Vector>, <Strain*>, <Inserted microorganism>, <Antigen>, <Part>, <Status>

*if applicable

Example 1:

Table 19. Example for naming in SMS and EU-SRS for viral vector vaccines (HVT expr. ILT)

SMS	EU-SRS
▶ Turkey herpesvirus 1[1], Strain HVT/ILT-138, Expressing avian infectious laryngotracheitis[2], Live (PT) ▶ Meleagrid herpesvirus 1[3], strain HVT/ILT-138, expressing Gallid alphaherpesvirus 1[4] gD and gI, Live (Alias) ▶ HVT 1, strain HVT/ILT-138, expressing avian infectious laryngotracheitis, Live (Alias)	▶ Meleagrid herpesvirus 1[3], Strain HVT/ILT-138, Expressing Gallid alphaherpesvirus 1[4] gD and gI, Whole (PT) ▶ Turkey herpesvirus 1[1], Strain HVT/ILT-138, Expressing avian infectious laryngotracheitis[2], Live (Alias, Additional Listing Name) ▶ HVT 1, strain HVT/ILT-138, Expressing avian infectious laryngotracheitis, Live (Alias)

Note[1,2] Common name

Note[3,4] Taxonomic name

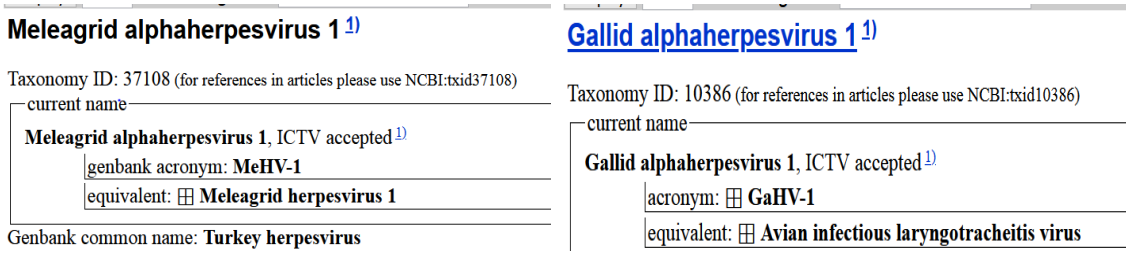

Figure 9. Result of entry 'Meleagrid alphaherpesvirus' and 'Gallid alphaherpesvirus' in the NCBI database

Example 2:

Table 20. Example for naming in SMS and EU-SRS for viral vector vaccines (Canarypox expr. Rabies)

SMS	EU-SRS
▶ Canarypox virus expressing Rabies virus, Live (PT) ▶ Canarypox virus (vCP65)[1] expressing Rabies virus glycoprotein G, Live (Alias)	▶ Canarypox virus (vCP65)[1], Expressing Rabies virus glycoprotein G, Whole (PT) ▶ Canarypox virus expressing Rabies virus, Live (Alias, Additional Listing Name)

Note[1]: All the recombinant canarypox virus are identified by a number (e.g., vCP65)

Example 3:

Table 21. Example for naming in SMS and EU-SRS for viral vector vaccines (Canarypox expr. WNV)

SMS	EU-SRS
► Canarypox virus expressing West Nile virus, Live (PT) ► Canarypox virus (vCP2017) expressing West Nile virus preM/E genes, Live (Alias)	► Canarypox virus (vCP2017), Expressing West Nile virus preM/E genes, Whole (PT) ► Canarypox virus expressing West Nile virus, Live (Alias, Additional Listing Name)

Example 4:

Table 22. Example for naming in SMS and EU-SRS for viral vector vaccines (Myxoma expr. RHDV)

SMS	EU-SRS
► Myxoma virus, strain 009, expressing Rabbit haemorrhagic disease virus, Live (PT) ► Myxoma virus vector, Strain 009, MGF and M11L genes deleted, expressing Rabbit haemorrhagic disease virus capsid protein gene VP60, Live (Alias) ► Myxoma virus, Strain 009, expressing RHDV, Live (Alias)	► Myxoma virus vector, Strain 009, MGF and M11L genes deleted, Expressing Rabbit haemorrhagic disease virus capsid protein gene VP60, Whole (PT) ► Myxoma virus, Strain 009, Expressing Rabbit haemorrhagic disease virus, Live (Alias, Additional Listing Name) ► Myxoma virus, Strain 009, Expressing RHDV, Live (Alias)

Example 5:

PT in SMS: Porcine circovirus type 1, expressing the Porcine circovirus type 2 ORF2 protein

PT in EU-SRS: Chimeric Porcine circovirus type 1, expressing the Porcine circovirus type 2 ORF2 protein, Inactivated

3.7.3 DNA vaccines

DNA vaccines are not very common in the veterinary domain. Currently there is one centrally authorised product ('Clynav') in the European Union intended for use in Atlantic salmon. The active ingredient is the DNA plasmid pUK-SPDV-poly2#1 coding for salmon pancreas disease virus proteins. The expressed proteins induce a protective immune response in vaccinated Atlantic salmon against salmonid alphavirus subtype 3 (SAV3).

If no DNA sequence is available, only a 'Structurally Diverse' record should be created and when it becomes available later a 'Nucleic acid 'Alternative definition' record can be attached.

Syntax of Preferred Term in SMS (common name):

<Parent strain [1] name>, <DNA used as active substance>

Note [1] Strain of the DNA used

Syntax of Preferred Term in EU-SRS (scientific/taxonomic name):

<DNA used as active substance including the encoded product>, <Part>

Example 6:

Species/Author level in EU-SRS: Salmon pancreas disease virus, Whole (NCBI 84589) (Structurally diverse record)

Serovar level in EU-SRS: Salmonid alphavirus subtype 3, Whole (NCBI: 1183064) (Structurally diverse record)

Strain level:

Table 23. Example for naming in SMS and EU-SRS for DNA vaccines (SPDV)

SMS	EU-SRS
► Salmon pancreas disease virus, DNA plasmid pUK-SPDV-poly2#1 encoding structural polyprotein (PT) ► DNA plasmid pUK-SPDV-poly2#1 coding for salmon pancreas disease virus proteins (Alias) ► pUK-SPDV-poly2#1 DNA plasmid supercoiled encoding Salmonid alphavirus, subtype 2, structural polyprotein (Alias) ► DNA plasmid pUK-SPDV-poly2#1 coding for salmon pancreas disease virus proteins (Alias)	► DNA plasmid pUK-SPDV-poly2#1 coding for salmon pancreas disease virus proteins (PT) ► Salmon pancreas disease virus, DNA plasmid pUK-SPDV-poly2#1 encoding structural polyprotein (Alias, Additional Listing Name) ► pUK-SPDV-poly2#1 DNA plasmid supercoiled encoding Salmonid alphavirus, subtype 2, structural polyprotein (Alias) ► DNA plasmid pUK-SPDV-poly2#1 coding for salmon pancreas disease virus proteins (Alias)

3.7.4 RNA vaccines

So far, no veterinary RNA vaccines are on the market (neither mRNA nor saRNA).

An **mRNA vaccine** is a type of vaccine that uses a copy of a molecule called messenger RNA (mRNA) to produce an immune response. The vaccine delivers molecules of antigen-encoding mRNA into immune cells, which use the designed mRNA as a blueprint to build foreign protein that would normally be produced by a pathogen (such as a virus) or by a cancer cell. (WIKIPEDIA)

If no RNA sequence is available, only a ‘Structurally Diverse’ record should be created and when it becomes available later a ‘Nucleic acid ‘Alternative definition’ record can be attached.

Generally, mRNA vaccines are delivered using a vector including Lipid nanoparticles and polymer and peptide vectors. These are considered excipients. Sometimes viral vectors are used in that case the recombinant viral vector model should be followed to record the substance.

4 Building Veterinary Vaccine Records

This chapter describes step-by-step how a veterinary vaccine is built in EU-SRS. It describes the high-level process steps to be taken, and the detailed steps in EU-SRS itself. The veterinary record building process is divided in the following high-level steps:

1. Select microorganism
2. Build and adjust records in EU-SRS
3. Track microorganism ready for review
4. Review microorganism in EU-SRS

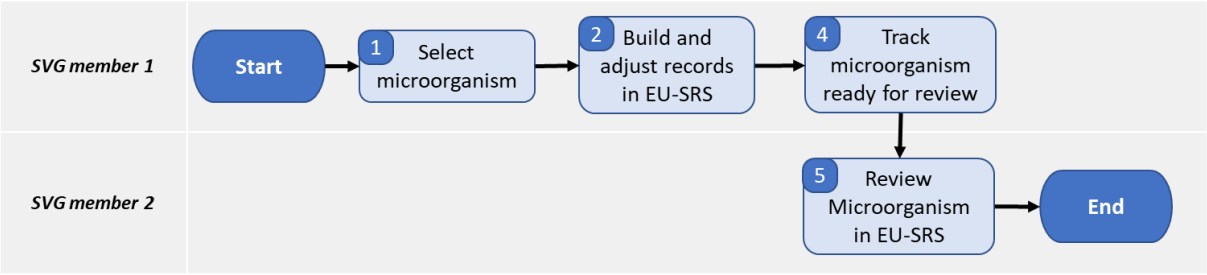

Figure 10. High level veterinary record building process

4.1 Veterinary data load

Records are loaded as concepts into EU-SRS from SMS. These records contain a very limited number of data elements in populated fields. The records available in SMS with the status CURRENT are loaded into EU-SRS. This means that all microorganisms included in a currently registered product in the EU should be findable in the EU-SRS database as a concept and ready for finalizing with the rest of needed elements to be filled. Field guidance is provided in tabular format in Appendix 5.1 (Concepts, Species/Author level, Serovar/Serogroup/Serotype/Strain level). An overview is provided in Appendix 5.2. This includes assistance to understand what values are allowed in a specific field.

Note: not all species/author levels and serovar levels are in SMS - they need to be created completely new in EU-SRS.

4.2 Veterinary record building process

No confidential dossier data should be included for veterinary vaccines substances. The starting point for building new veterinary vaccines is the SPC, which is public; all information that is needed is expected to be available in the SPC for new veterinary vaccines. In some cases, it might be necessary to provide so called ‘confidential information’ in the name to make the differences between records. When that is the case that name entry can be made ‘Protected’ as well as the reference can be ‘Protected’ without the ‘Public Domain’ tick.

When SVG members start working with the veterinary records, a few activities need to be performed. All loaded records need the following checks by SVG members:

1. Verify availability of Species/Author Level and create Species/Author level where needed
2. Build a hierarchy between Species/Author levels, Serovar/Serogroup/Serotype levels and Strain/Fraction levels
3. Change the Substance Type from Concept to the Structurally diverse Substance Type
4. Add data to the records where available and necessary to uniquely identify the record. If necessary, substantiate the data with public references.

4.2.1 Step 1: Select microorganism

It is crucial to build hierarchy in EU-SRS, for which a Species/Author level is needed as the highest level. SVG members are asked to work on a full Microorganism, with all substances belonging to that level and creating any substance that was not part of the data load. A substance review should also be performed per full microorganism. To select a new microorganism, a list in Teams was published.

On this list in Teams, SVG members should always indicate which microorganism they work on to avoid double work.

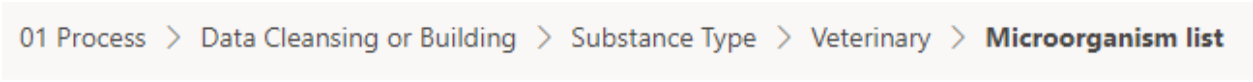

Figure 11. Location of Microorganism list in Teams

All relevant information, which should be included in EU-SRS (e.g., Preferred Term, aliases, species/author level, codes etc.) can be found in the final cleansed excel files in Teams.

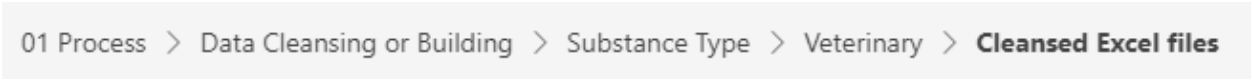

Figure 12. Location of Cleansed Veterinary Excel files in Teams

4.2.2 Step 2: Build and adjust records in EU-SRS

Once an SVG member has selected a microorganism and opened the respective Cleansed Veterinary Excel file to have the detailed information needed, records can be build (species/author levels) or adjusted in EU-SRS.

In EU-SRS the respective substances can be found by going to “Browse Substances”.

On the left side of the screen it is possible to sort using the classifications of a substance.

To find veterinary vaccines the following should be ticked:

- RMS domain: Veterinary use
- RMS category: Structurally Diverse – Vaccine
- Substance Type: Concept (if only the newly imported records from SMS should be shown)

Applying these filters will yield records that have not been adjusted yet. Additionally, SVG members can search on a specific name (Preferred Terms as well as aliases) by using the search functionality.

Substances built in EU-SRS are entered in a hierarchical manner describing a ‘Species/Author’, ‘Serovar/Serogroup/Serotype’ and ‘Strain/Fraction’ level for the live or inactivated organism (taxonomic species). The records regarding one substance are interlinked in the built hierarchy. One record on the species level may have many records on the serovar and strain level below. In addition, a ‘Fraction’ of the organism can be described in combination with the ‘Strain’ level. The fraction description – Antigen – may comprise strain and modification information.

Any existing record can be opened and edited by clicking on the pencil ("Edit Substance"). During this step, SVG members ensure that for each microorganism:

- A species/author level is present
- All records have a Substance Type 'Structurally Diverse' and are no longer a Concept (adding a Substance Type makes a Concept to a full-value record in the system)
- Records are linked to other records where a hierarchical link is present by means of a Relationship
- Records contain data as agreed and listed in Appendix 5.1

Steps in EU-SRS

The steps taken in EU-SRS are the same for all levels, except for differences in fields populated and the specific values. The table below summarizes the steps to be taken to finalize a record. Note that details on field level are listed in Appendix 5.1.

Table 24. High level steps to register a veterinary vaccine at species/author level

SMS	Step Name	Step Action
Step 1	Search Substance	Is the Substance and the Species/Author Level present in EU-SRS? ***Yes***: finalize the record according to the steps below ***No***: create the record manually from the start
Step 2	Verify information	Search to find the necessary information as described in section 4.2.2 to finalize the record.
Step 3	Adjust Substance Type	Is the actual information sufficient to create a complete substance record (e.g., Substance Type, references, hierarchy)? ***Yes***: Click *Edit Substance*, fill fields according Appendix 5.1.1 and adjust the substance type. ***No***: Do not change the Substance Type and leave the record as a Concept. Once information becomes available in the future, the record will be finalized.
Step 4	Finalize Record(s)	For each record belonging to the microorganism, fill in the applicable fields where possible according to Appendices 5.1.1 - 5.1.3 as applicable. Ensure that both the display name as EU-SRS PT Display Name ('DN') and the SMS PT as Additional Listing Name ('AL') are present.

Step 5	Ensure Hierarchy	Link the records to each other where necessary, so that the hierarchy looks as follows (if available):
		• Species/Author level
		  ○ Serovar/Serogroup/Serotype Level
		  ▪ Strain / Fraction Level

Step 6	Save Record	Submit the Record – errors should be reviewed, resolved (red error) or ignored if acceptable (orange error)

Acceptable source information

In order to change a substance from a concept into a full substance in EU-SRS with the belonging *Substance Type*, additional source information is needed. The same is relevant for records, which need to be created from the scratch, as they are not present in SMS and will therefore not be imported as concepts (mainly Species/Author level records). This information should be provided in the cleansed Excel files (4.2.1). For veterinary substances, it is agreed upon that only information provided in the SPC is relevant, and no dossier information should be used (however, this might be necessary for older substances). In case SVG members cannot find sufficient information for a specific substance, it is to be kept as a *Concept* and the Substance Type will not be adjusted. These records will be finalized at a later stage.

Acceptable public sources are defined in section 3.1.

4.2.3 Step 3: Track microorganism ready for review

Once a full microorganism is finished, mark this in Teams. This allows other SVG members to perform a peer-review per microorganism. The list of records ready for peer-review is available in Teams:

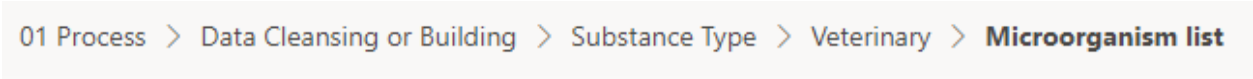

Figure 13. Location of Microorganism list with status

4.2.4 Step 4: Review microorganism in EU-SRS

A peer-review of a built record in EU-SRS is done per full microorganism. What record is fully built and ready for a review, can be found in the list available in Teams, as described under section 4.2.1. During a review, records are checked on all aspects described in section 4.2.1. Building a new daughter to an existing parent has to undergo full review.

5 Appendix

5.1 EU-SRS Field Guide

This section lists all EU-SRS fields and provides an explanation what rules apply to each field and when a certain field is used.

5.1.1 EU-SRS field guidance for editing a Concept

EU-SRS field name	Field details
Overview	
Preferred Term	*Automatically filled in from name section.*
Record Level Access	If no box is ticked the record is public. If it should be non public choose 'PROTECTED'. 'PROTECTD' means that the record cannot be exported.
Deprecated	*Relevant for a Deprecated Record.*
Substance tags	*Not applicable.*
Names	
Name *(Display Name/Preferred Term in EU-SRS, could be alias in SMS)*	Each record needs a Preferred Term, which is the displayed name in EU-SRS. It is the Scientific/ taxonomic name, which is in 'English-Latin' and includes the Part. The Status is included with the value 'Inactivated' if applicable since 'Whole' is implicit the live organism. Necessary details: Choose a name type, Language always 'English', tick 'DN' (=Display Name)', choose a naming organisation if 'Official Name' type was chosen, check if a public reference is given. Detailed information on the single fields can be found below. The Preferred Term in EU-SRS (Scientific/taxonomic name) should be the alias in SMS.
Name *(Additional name in EU-SRS, could be PT or Additional Listing Name in SMS)*	Additional names (e.g., name type 'Common Name') can be included in the record. At least one reference is needed per name. The Preferred Term in SMS (Common name) needs to be included as an Additional Listing Name in EU-SRS on strain/fraction level. Necessary details: choose a language, tick 'AL', Additional names (e.g., name type 'Common name') can be included in the record. For example, the Acronym and a shorter or a name which describes e.g., more the gene. Necessary details: choose a language (tick no box!)
Type	Each name type can be chosen, as appropriate. If it is possible to choose between more than one name type, the following priorisation should be used: Official Name, Scientific Name, any other name type. The Official Name is any name used by an Official Naming Body (e.g., INN). Please see sections 3.2 and 3.3.1. For veterinary vaccines we currently have no relevant Official Naming Bodies, so mostly 'Scientific Name' is used for the PT. PT = appropriate name type (e.g., 'Official Name', 'Scientific Name'), Alias = PT in SMS = 'Common Name', Other Alias = 'Common Name' or other name type
Access	If the information in the record is confidential, *Access* can be set to 'PROTECTED', but the name should have a public and a confidential reference.

EU-SRS field name	Field details
DN	DN = Display Name; Tick box to indicate what name should be the *Display Name* in EU-SRS (= Preferred Term in EU-SRS). Mandatory for the EU-SRS-PT.
AL	AL = Additional Listing Name; Field is mandatory for the SMS-PT (not to be ticked for other aliases).
Standardized Name	*Not applicable.*
Languages	Always *English*.
Domains	*Not applicable.*
Jurisdiction	Field is optional when an 'Official Name' type is selected. Please see section 3.3.1.
References	At least one public reference is needed per name. 'EMA List' is mostly given as standard reference during data load. References can be newly created or reused. More details about the single reference fields can be found in the next appendices tables in section "References".
Naming Organizations	Field is only displayed if 'Official Name' Type is chosen. If displayed it is conditional.
In principle it is not necessary to look at the fields mentioned below in the Concept. All these fields are also there in the finally chosen Substance Type after the reload of the site and therefore described in detail in table 'EU-SRS field guidance for editing a Structurally Diverse'. Note: In the Code section the SMSID could be provided as well as the UNII, if applicable.	
Codes	
Relationships	
Notes	
Properties	
References	
Change Reason	

Concept upgrade:

To upgrade a record from 'Concept' to e.g., 'Structurally Diverse'

1. Go to the field 'Advanced Features' in the headline
2. Click in the scroll down menu on 'Change Substance Class'
3. Choose the applicable substance class in the field 'New Class'.
4. Click on 'Validate and Submit'

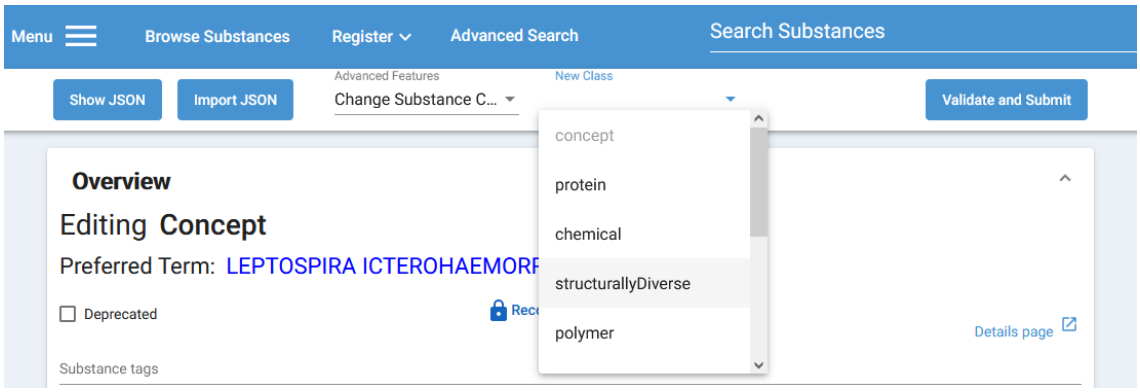

Figure 21. Concept upgrade in EU-SRS

5.1.2 EU-SRS field guidance for editing a Structurally Diverse Species/Author level

Before a record is built on Serovar/Serogroup/Serotype or Strain/Fraction level, it should be checked if the respective species/author level is available, which is crucial to build the hierarchy in EU-SRS. Most species/author level records should be imported from SMS as a concept and then need to be completed. If not, it is also possible to start from the beginning and to create a completely new record by clicking on 'Register Substance'.

EU-SRS field guidance for editing a Structurally Diverse Author level	
EU-SRS field name	**Field details**
Overview	
Preferred Term	*Automatically filled in from name section. When a record is created from scratch the name should be provided in the name section.* ***Decide if the name complies to the PT rules applicable for registration in EU-SRS.***
Definition Type	Always Primary.
Definition Level	Always Complete.
Deprecated	*Relevant for a Deprecated Record.*
Record Level Access	If no box is ticked the record is public. If it should be non public choose 'PROTECTED'. 'PROTECTD' means that the record cannot be exported.
Substance tags	*Not applicable.*
Definitional References	Field linked to Reference section.
Names	
Name *(Display Name/Preferred Term in EU-SRS)*	Each record needs a Preferred Term, which is the displayed name in EU-SRS. It is the Scientific/ taxonomic name, which is in 'English-Latin' and includes the Part. 'Whole' is implicit the live organism. Necessary details: Choose a name type, Language always 'English', tick 'DN' (=Display Name)', choose a naming organization if 'Official Name' type was chosen,

	check if a public reference is given. Detailed information on the single fields can be found below.
Name *(Additional name in EU-SRS, could be PT in SMS)*	*In general, not applicable (no corresponding SMS records).*
Name *(Additional name in EU-SRS)*	*May be added, but the Display Name is sufficient. Additional names (e.g., name type 'Common name') can be included in the record. For example, the Acronym or a common Synonym. At least one reference is needed per name. Necessary details: choose a language (tick no box!).*
Type	Each name type can be chosen, as appropriate. If it is possible to choose between more than one name type, the following priorisation should be used: Official Name, Scientific Name, any other name type. The Official Name is any name used by an Official Naming Body (e.g., INN). Please see sections 3.2 and 3.3.1. For veterinary vaccines we currently have no relevant Official Naming Bodies, so mostly 'Scientific Name' is used for the PT. PT = appropriate name type (e.g., 'Official Name', 'Scientific Name'), Alias = PT in SMS = 'Common Name', Other Alias = 'Common Name' or other name type
Access	If the information in the record is confidential, *Access* can be set to 'PROTECTED', but the name should have a public and a confidential reference.
DN	DN = Display Name: Tick box to indicate what name should be the *Display Name* in EU-SRS (= Preferred Term in EU-SRS). Mandatory for the EU-SRS-PT.
AL	*AL = Additional Listing Name: Field is mandatory for the SMS-PT (not to be ticked for other aliases).*
Standardized Name	*Not applicable.*
Languages	Always *English*.
Domains	*Not applicable.*
Jurisdiction	Field is optional when an 'Official Name' type is selected. Please see section 3.3.1.
References	At least one public reference is needed per name. For the Author Level NCB, ICTV or ITIS are preferred references. In contrast, e.g., SPC is not relevant on this level (no direct relation to a product). References can be newly created or reused. For detailed information see section 'References' below.
Naming Organization	Field is only displayed if 'Official Name' type is chosen. If displayed it is conditional.
Source Material	
Source Material Class	Choose one, e.g., 'Organism'.
Source Material Type	Field is conditional. Choose one (in most cases Bacterium, Virus or Parasite).
Source Material State	Displayed if 'Organism' is chosen. Choose Live.
Whole, Part/ Fraction, Full Fields	Default is 'Whole'. 'Part/Fraction' not applicable on species/author level. If 'Full Fields' is chosen, all possible fields are shown, which is not applicable.
Organism Details – many fields only displayed if 'Organism' is chosen	

Family	Field is mandatory.
Genus	Field is optional.
Species	This should come from NCBI, ICTV or ITIS.
Author	Mandatory on Species/Author level (except for a virus). Copy taxonomic database for name.
Infraspecific Type	*Not applicable.*
Infraspecific Name	*Not applicable.*
Developmental Stage	Field is optional. (Might be relevant for some vaccines.)
Hybrid Paternal Organism	*Not applicable. Only applicable for herbals etc.*
Hybrid Material Organism	*Not applicable. Only applicable for herbals etc.*
Agent Modifications	
Agent Substance	*Not applicable.*
Modification Process	*Not applicable.*
Modification Type	*Not applicable.*
Modification Role	*Not applicable.*
Amount	*Not applicable.*
Group	*Not applicable.*
Access	*Not applicable.*
Structural Modifications	
Molecular Fragment	*Not applicable.*
Modification Type	*Not applicable.*
Residue Modified	*Not applicable.*
Extent	*Not applicable.*
Location	*Not applicable.*
Group	*Not applicable.*
Access	*Not applicable.*
Amount	*Not applicable.*
Physical Modifications	

Modification Role	*Not applicable.*
Parameters	*Not applicable.*
Group	*Not applicable.*
Access	*Not applicable.*
Codes	
Code system	SMSID is always mandatory unless an SMSID is not (yet) available - then the SMS team will be asked for. Preferably other public sources are added when available, e.g., IT IS, NCBI Taxonomy (choose from CV list). Classification: Besides the codes from the source databases used, the classification of the substance is entered under code section, which is relevant for searching. To enter the 'category' or 'domain', RMS is selected from the drop-down list.
Code System Type	*This is a default value (automatically filled in and managed by Admin).*
Type	In nearly all cases default 'Primary' (code uniquely describes the substance). When the code is tied to a group/used for classification (Code system 'RMS') use 'Generic (Family)'. 'Superceeded' is set if the code is already deprecated.
Code	Alpha numeric value. Classification: Relevant is the code for the domain 'Veterinary use' and the category 'Structurally Diverse – Vaccine' Domain Veterinary use: 100000000013 Category Structurally Diverse-Vaccine: 200000005027 A complete overview of the possible Codes will be included in the General EU-SRS User Guide, (which will be released at the end of December/beginning of January.)
Access	Set to Public from the system after the import from SMS (standard = Public).
URL	This field is conditional: Mandatory for NCBI Taxonomy and ITIS, Optional for Wiki.
Code Text	*Should be filled automatically.* For Domain: RMS|Domain|Veterinary use For Category: RMS|Category|Structurally Diverse|Vaccine
Comments	*Not applicable.*
References	*Not applicable.*
Relationships	
Related Substance	*Not applicable*
Type *(purpose hierarchy)*	*Not applicable.*
Type *(purpose not hierarchy)*	*Not applicable.*
Access	*Not applicable.*

Mediator Substance	*Not applicable.*
Qualification	*Not applicable.*
Interaction Type	*Not applicable.*
Comments	*Not applicable.*
Amount	*Not applicable.*
References	*Not applicable.*
Notes	
Note	Field is optional and automatically populated by the system. Note: When the record is submitted, open the edit mode once again and delete all notes. Submit again and a lot of the first notes will be cleansed.
References	Field is optional. References can be newly created or reused.
Access	*Not applicable*
Properties	
Name	*Not applicable.*
Property Type	*Not applicable.*
Defining	*Not applicable*
Referenced Substance	*Not applicable.*
Parameters	*Not applicable.*
Amount	*Not applicable.*
References	*Not applicable.*
Access	*Not applicable.*
References	
Source Type	CV-List; Mandatory field Choose the applicable Source Type (e.g., NCBI taxonomy, ICTV, SPC) from the CV-List. Additional value not in CV is possible as temporary value (note: be careful with adding a new value, this needs to be communicated with the technical team).
Source text/Citation	Mandatory field and should represent the related value of the Source Type. Please see Appendix 5.3. A complete overview of the possible Source Types and respective Source text/Citation will be included in the General EU-SRS User Guide, (which will be released at the end of December/beginning of January).

Public Domain	Default is Public (Tick box), but it may be set 'Non-Public' in combination with a public reference.
Access	Default is 'Public'. Confidential = tick 'PROTECTED'.
URL	This field is optional but preferred to add when possible.
Source Id	Should have the Code of the Source Type.
Upload a Document	This field is optional.
Tags	If the access for the whole record should be public, it is required to have minimum one reference where this field is populated by 'Public domain release' tag (otherwise the record cannot be public). Please see Appendix 5.3.
Change Reason	
Change Reason	Add the reason of the change of the record that led to the creation of a new version. Use short notes (if something was added, edited or removed), e.g. Name, Code, RMS, Reference, Naming Organization.

5.1.3 EU-SRS field guidance for editing a Structurally Diverse – Serovar/Serogroup/Serotype and strain level

EU-SRS field guidance for editing a Structurally Diverse – Serovar/Serogroup/Serotype/Strain level	
EU-SRS field name	Field details
Overview	
Preferred Term	*Automatically filled in from name section when editing an existing record or when a record is created by copy. When a record is created from scratch the name should be provided in the name section.* ***Decide if the name complies to the PT rules applicable for registration in EU-SRS.***
Definition Type	Always Primary.
Definition Level	Always Complete.
Deprecated	*Relevant for a Deprecated Record.*
Record Level Access	If no box is ticked the record is public. The system sets the record by default on 'PROTECTED', so remove this tick to open the record and make it public. 'PROTECTD' means that the record cannot be exported.
Substance tags	*Not applicable.*
Definitional References	Field linked to Reference section.
Names	

Name *(Display Name/Preferred Term in EU-SRS, could be alias in SMS)*	Each record needs a Preferred Term mentioned in the Excel file, which is the displayed name in EU-SRS. It is the Scientific/ taxonomic name, which is in 'English-Latin' and includes the Part. The Status is included with the value 'Inactivated' if applicable since 'Whole' is implicit the live organism. Any other status is only applicable on Strain/Fraction level. Necessary details: Choose a name type, Language always 'English', tick 'DN' (=Display Name)', choose a naming organisation, check if a public reference is given. Detailed information on the single fields can be found below. The Preferred Term in EU-SRS (Scientific/taxonomic name) should be the alias in SMS on Strain/Fraction level (generally not applicable on Serovar/Serogroup/ Serotype level).
Name *(Additional Listing Name in EU-SRS and PT in SMS)*	The Preferred Term in SMS (Common name) needs to be included as an Additional Listing Name in EU-SRS (name type: 'Common name') on Stain/Fraction level (generally not applicable on Serovar/Serogroup/ Serotype level as there should be no corresponding SMS record). At least one reference is needed. Necessary details: choose a language, tick 'Additional Listing Name'.
Name *(Additional name in EU-SRS and SMS)*	Additional names (e.g., name type 'Common name') can be included in the record. For example, the Acronym and a shorter or a name which describes e.g., more the gene. At least one reference is needed per name. Necessary details: choose a language (tick no box!).
Type	Each name type can be chosen, as appropriate. If it is possible to choose between more than one name type, the following priorisation should be used: Official Name, Scientific Name, any other name type. The Official Name is any name used by an Official Naming Body (e.g., INN). Please see sections 3.2 and 3.3.1. For veterinary vaccines we currently have no relevant Official Naming Bodies, so mostly 'Scientific Name' is used for the PT. PT = appropriate name type (e.g., 'Official Name', 'Scientific Name'), Alias = PT in SMS = 'Common Name', Other Alias = 'Common Name' or other name type
Access	If the information in the record is confidential, *Access* can be set to 'PROTECTED', but the name should have an additional public next to a confidential reference.
DN	DN = Display Name: Tick box to indicate what name should be the *Display Name* in EU-SRS (= Preferred Term in EU-SRS). Mandatory for the EU-SRS-PT.
AL	AL = Additional Listing Name: Field is mandatory for the SMS-PT (not to be ticked for other aliases).
Standardized Name	*Not applicable.*
Languages	Always *English*.
Domains	*Not applicable.*
Jurisdiction	Field is optional when an 'Official Name' type is selected. Please see section 3.3.1.
References	At least one public reference is needed per name. E.g., 'EMA List' is mostly given as standard reference for centrally authorised products. SPC is also possible. The reference for the Species/Author level may be repeated at the serovar level (if no other public reference is available) and in some cases the serovar/ serotype has its own NCBI-taxonomy Identifier. This is a new reference entry. References can be newly created or reused. For detailed information see section 'References' below.

Naming Organization	Field is only displayed if 'Official Name' type is chosen. If displayed it is conditional.
Source Material	
Source Material Class	Choose one, e.g., 'Organism'.
Source Material Type	Field is conditional. Choose one (in most cases Bacterium, Virus or Parasite).
Source Material State	Displayed if 'Organism' is chosen. Choose one (in most cases Live, Live attenuated or Inactivated)
Whole, Part/ Fraction, Full Fields	Default is 'Whole'. When it is an antigen or fraction excreted by the strain, then choose 'Part/Fraction'. If 'Full Fields' is chosen, all possible fields are shown, which is not applicable.
Organism Details – many fields only displayed if 'Organism' is chosen	
Family	Field is mandatory.
Genus	Field is conditional.
Species	This should come from NCBI, ICTV or ITIS
Author	Not applicable.
Infraspecific Type	Field is conditional when available and important for the hierarchy (e.g., serovar/serogroup/serotype/strain).
Infraspecific Name	Field is conditional when the type is populated.
Developmental Stage	Field is optional. (Might be relevant for some vaccines.)
Hybrid Paternal Organism	*Not applicable. Only applicable for herbals etc.*
Hybrid Material Organism	*Not applicable. Only applicable for herbals etc.*
Parent Organism Details– only displayed if 'Part/Fraction' is chosen	
Source Material Parent	Field is conditional. It is necessary to delete the Organism details populated in the 'Whole' mode of the record because reference is made to this information in the selected 'Parent organism'.
Parts And Fractions – only displayed if 'Part/Fraction' was chosen	
Part	This field is optional for a certain type of vaccine, in most cases capsule or cell wall.
Part Location	*Not applicable.*
Fraction Name	This field is conditional for a certain type of vaccine (e.g., toxin).
Fraction Material Type	This field is conditional for a certain type of vaccine (e.g., protein).
Agent Modifications	
Agent Substance	Optional for certain type of vaccines, e.g., formaldehyde; Binary ethylenimine - BEI, ß-propiolactone (BPL).

Modification Process	Optional for certain type of vaccines, e.g., inactivation.
Modification Type	Optional for certain type of vaccines, e.g., inactivation.
Modification Role	Optional for certain type of vaccines, e.g., crosslinking.
Amount	Optional for certain type of vaccines.
Group	Optional, if more than one modification is used. Numbering of the different steps can then be included here.
Access	Optional at strain level for certain types of vaccines (Yes or Not Protected information).
Structural Modifications	
Molecular Fragment	Optional at strain level for certain types of vaccines. The structure must be present in EU-SRS or should be pre-registered.
Modification Type	Optional at strain level for certain types of vaccines, in most cases proteins or polysaccharides. Drop-down list.
Residue modified	Optional at strain level for certain types of vaccines.
Extent	Optional at strain level for certain types of vaccines. Drop-down list.
Location	Optional at strain level for certain types of vaccines, in most cases partial or complete.
Group	Not applicable. (Is to be used if several modifications are done one after the other using a numbering.)
Access	Optional at strain level for certain types of vaccines (Yes or Not Protected information).
Amount	Optional at strain level for certain types of vaccines to define the proportions.
Physical Modifications	
Modification Role	Optional at strain level for certain types of vaccines. To be used in heat inactivated material.
Parameters	Optional at strain level for certain types of vaccines.
Group	Optional at strain level, if more than one modification is used. Numbering of the different steps can then be included here.
Access	Optional at strain level for certain types of vaccines (Yes or Not Protected information).
Codes	
Code system	SMSID is always mandatory unless a SMSID is not (yet) available – then the SMS team will be asked for. Preferably other public sources are added when available, e.g., NCBI Taxonomy, IT IS (choose from CV list). Classification: Besides the codes from the source databases used, the classification of the substance is entered under code section, which is relevant for searching. To enter the 'category' or 'domain', RMS is selected from the drop-down list.
Code System Type	*This is a default value (automatically filled in and managed by Admin).*

Type	In nearly all cases default 'Primary' (code uniquely describes the substance). When the code is tied to a group/used for classification (Code system 'RMS') use 'Generic (Family)'. 'Superceeded' is set if the code is already deprecated.
Code	Alpha numeric value. Classification: Relevant is the code for the domain 'Veterinary use' and the category 'Structurally Diverse – Vaccine' Domain Veterinary use: 100000000013 Category Structurally Diverse-Vaccine: 200000005027 A complete overview of the possible Codes will be included in the General EU-SRS User Guide, (which will be released at the end of December/beginning of January.)
Access	Set to Public from the system after the import from SMS (standard = Public).
URL	This field is conditional: Mandatory for NCBI Taxonomy and ITIS, Optional for Wiki.
Code Text	*Should be filled automatically.* For Domain: RMS|Domain|Veterinary use For Category: RMS|Category|Structurally Diverse|Vaccine
Comments	*Not applicable.*
References	*Not applicable.*
Relationships	
Related Substance	This level contains the relationship to another substance. It is used for the parent substance (hierarchy, to create connections between substances in EU-SRS): e.g., serovar level points to species level, strain level points to serovar level (if there is no serovar level the strain level points to species level directly). No relationship is used at species level (highest level). Hierarchy from Species->Serovar-Strain level is built for a Structurally diverse 'Whole' record by making use of the Relationship 'Parent Organism ->Infraspecific'. Each time for the next level the record is enriched. For a 'Fraction' record e.g., a toxin or toxoid a separate 'Parent/ Species/Author' record must be available and must be created in advance to be able to create the 'toxin' record. Adjustment of the taxonomical information in the 'toxin/ fraction' record must be taken into consideration in order to avoid duplicate definitional taxonomic information, e.g., it should be deleted. This section could also be used for creating a different type of relationship to the active moiety. This is managed by the selection 'Active moiety' by the system. It is used in cases that one described a mature protein which is related to the active form of that protein captured as a separate protein record e.g., tetanus vaccine.
Type *(purpose hierarchy)*	Any of the CV terms can be used. For building the hierarchy the value 'Parent Organism ->Infraspecific' should be used for vet. vaccines.
Access	Set to Public from the system after the import from SMS (standard = Public).
Mediator Substance	*Not applicable.*
Qualification - to be used as Properties	Optional for certain type of vaccines. Strength can be expressed as a property value 'Specification' in combination with the amount group
Interaction Type	CV list. May be used if applicable.

Comments	*Not applicable.*
Amount	Optional for certain type of vaccines. A specification of strength can be noted as a Non-numeric amount value (e.g., SPC value of rel. potency)
References	Each Related substance should have a reference. It is a Mandatory field. References can be newly created or reused.
Notes	
Note	Field is optional and automatically populated by the system. Note: When the record is submitted, open the edit mode once again and delete all notes. Submit again and a lot of the first notes will be cleansed.
References	Field is optional.
Access	*Not applicable.*
Properties	
Name	Optional for certain types of vaccines, e.g., to be used in stability registration or Inactivation conditions other than Physical modifications.
Property Type	Optional for certain types of vaccines.
Defining	Optional for certain types of vaccines, conditional for certain properties.
Referenced Substance	Optional for certain types of vaccines.
Parameters	Optional for certain types of vaccines.
Amount	Optional for certain types of vaccines.
References	Optional for certain types of vaccines. References can be newly created or reused.
Access	Optional for certain types of vaccines.
References	
Source Type	CV-List; Mandatory field Choose the applicable Source Type (e.g., NCBI taxonomy, ICTV, SPC) from the CV-List. Additional value not in CV is possible as temporary value (note: be careful with adding a new value, this needs to be communicated with the technical team).
Source text/Citation	Mandatory field and should represent the related value of the Source Type. Please see Appendix 5.3. A complete overview of the possible Source Types and respective Source text/Citation will be included in the General EU-SRS User Guide, (which will be released at the end of December/beginning of January.)
Public Domain	Default is Public (Tick box), but it may be set 'Non-Public' in combination with a public reference. Please see Appendix 5.3.
Access	Default is ‘Public’. Confidential = tick ‘PROTECTED’.

URL	This field is optional but preferred to add when possible.
Source Id	Should have the Code of the Source Type.
Upload a Document	This field is optional.
Tags	If the access for the whole record should be public, it is required to have minimum one reference where this field is populated by 'Public domain release' tag (otherwise the record cannot be public). Please see Appendix 5.3.
Change Reason	
Change Reason	Add the reason of the change of the record that led to the creation of a new version. Use short notes (if something was added, edited or removed), e.g. Name, Code, RMS, Reference, Naming Organization.

5.2 Veterinary vaccine data field overview EU-SRS

The table below summarizes all data fields captured in EU-SRS for each hierarchical level built in EU-SRS.

Summary of all EU-SRS data fields and their use at the different levels for veterinary vaccines (A = automatic load, X = mandatory, C = conditional[1], O = optional)

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Preferred Term	*Leptospira interrogans, (Stimson, 1907) Wenyon, 1926 emend. Faine and Stallman, 1982, Whole*	*Leptospira interrogans, Serogroup Canicola, Whole*	*Feline calicivirus, strain 255, Whole, Inactivated*	*Eimeria brunetti, strain 034, sporulated oocysts, Whole*	A	A	A
Definition Type	Primary	Primary	Primary	Primary	X	X	X
Definition Level	Complete	Complete	Complete	Complete	X	X	X
Deprecated							
Record Level Access	Public	Public	Public	Protected	X	X	X
Substance Tags							
Definitional References	Field linked to Reference section	Field linked to Reference section	Field linked to Reference section	Field linked to Reference section	X	X	X
Names							

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
1. Name *(Display Name/PT in EU-SRS, could be alias in SMS)*	Leptospira interrogans, (Stimson, 1907) Wenyon, 1926 emend. Faine and Stallman, 1982, Whole	Leptospira interrogans, Serogroup Canicola, Whole	Feline calicivirus, strain 255, Whole, Inactivated	Eimeria brunetti, strain 034, sporulated oocysts, Whole	X	X	X
2. Name *(Alias in EU-SRS and PT in SMS, Additional Listing Name)*			Feline calicivirus, strain 255, Inactivated	Eimeria brunetti, strain 034, Live			X
3. Name *(Alias in EU-SRS and SMS)*	*Not applicable*	*Not applicable*	FCV, strain 255, Whole, Inactivated FCV, strain 255, Inactivated	*Not applicable*	O	O	O
Type	1. Scientific Name (for the PT) 3. *Not applicable*	1. Scientific Name (for the PT) 3. *Not applicable*	1. Scientific Name (for the PT); 2. Common Name 3. Common Name	1. Scientific Name (for the PT); 2. Common Name 3. *Not applicable*	X	X	X
Access	Public	Public	Public	Public	X	X	X
DN (Display Name)	1. Yes (for the PT) 3. *Not applicable*	1. Yes (for the PT) 3. *Not applicable*	1. Yes (for the PT) 2. No 3. No	1. Yes (for the PT) 2. No 3. *Not applicable*	X	X	X
AL (Additional listing name)	1. No (for the PT)	1. No (for the PT)	1. No (for the PT) 2. Yes	1. No (for the PT) 2. Yes			X

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
	3. *Not applicable*	3. *Not applicable*	3. No	3. *Not applicable*			
Standardized Name							
Languages	English	English	English	English	X	X	X
Domains							
Jurisdiction	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*	O	O	O
References	*See section References*	*See section References*	*See section References*	*See section References*	X	X	X
Naming Organization	*Not applicable*	*Not applicable*	*Not applicable*	*Not applicable*	C	C	C
Source Material							
Source Material Class	Organism	Organism	Organism	Organism	X	X	X
Source Material Type	Bacterium	Bacterium	Virus	Parasite	X	X	X
Source Material State	Live	Live	Inactivated	Live	X	X	X
Whole, Part/ Fraction, Full Fields	Whole	Whole	Whole	Whole	X	X	X

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Parent Organism Details - only displayed if in section 'Source material record type' the entry 'Part/Fraction' is chosen							
Source Material Parent							C
Parts And Fractions - only displayed if in section 'Source material record type' the entry 'Part/Fraction' is chosen							
Part						O	O
Part Location							
Fraction Name			*e.g., Organism Name, Toxin if applicable*		C	C	C
Fraction Material Type			e*.g., Protein, if applicable*		C	C	C
Organism Details – many fields only displayed if in section 'Source Material Class' 'Organism' is chosen							
Family	Leptospiraceae	Leptospiraceae	Caliciviridae	Eimeriidae	X	X	X
Genus	Leptospira	Leptospira	Vesivirus	Eimeria	C	C	C
Species	Leptospira interrogans	Leptospira interrogans	Feline calicivirus	Eimeria brunetti	X	X	X
Author	(Stimson, 1907) Wenyon, 1926 emend. Faine and Stallman, 1982				X		
Infraspecific		Serogroup	Strain	Strain		O	O

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Type							
Infraspecific Name		Serogroup Canicola	Strain 255	Strain 034, sporulated oocysts		O	O
Developmental Stage	Mature	Mature		Sporulated Oocyst	O	O	O
Hybrid Paternal Organism							
Hybrid Material Organism							
Agent Modifications							
Agent Substance			e.g., Formaldehyde, β-Propiolactone, Binary ethylenimine				O
Modification Process			e.g., Inactivation				O
Modification Type			e.g., Inactivation				O
Modification Role			e.g., Crosslinking				O
Amount							O

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Group							O
Access							O
Structural Modifications							
Molecular Fragment							O
Modification Type							O
Residue modified							O
Extent							O
Location							O
Group							O
Access							O
Amount							O
Physical Modifications							
Modification Role			e.g., Heat inactivation				O

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Parameters			e.g., Temperature				O
Group							O
Access							O
Codes							
Code system	SMSID; IT IS	SMSID; NCBI Taxonomy	SMSID	NCBI Taxonomy	X	X	X
Code System Type					A	A	A
Type	Primary	Primary	Primary	Primary	X	X	X
Code	524	211880	300000018434	51314	X	X	X
Access	Public	Public	Public	Public	X	X	X
URL	https://www.itis.gov...	https://ncbi.nlm.nih.gov...	None for SMSID	https://ncbi.nlm.nih.gov...	C	C	C
Code Text							
Comments							
References							

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Relationships							
Related Substance		Leptospira interrogans, (Stimson, 1907) Wenyon, 1926 emend. Faine and Stallman, 1982, Whole = Parent of Leptospira interrogans, Serogroup Canicola, Whole	Feline calicivirus, Whole (= Parent of Feline calicivirus, strain 255, Whole, Inactivated)	Eimeria brunetti, Whole (= Parent of Eimeria brunetti, strain 034, sporulated oocysts) Note: the fraction/part will not include 'Whole'		X	X
Type *(purpose hierarchy)*		Parent organism -> Infraspecific	Parent organism -> Infraspecific	Parent organism -> Infraspecific Or Fraction/Part relationship		X	X
Access		Public	Public	Public		X	X
Qualification						O	O
Interaction Type						O	O
Comments							
Amount							
References						X	X
Notes							
Note					O	O	O

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
References					O	O	O
Access							
Properties							
Name						O	O
Property Type						O	O
Defining						O	O
Referenced Substance						O	O
Parameters						O	O
Amount						O	O
References						O	O
Access						O	O
References							
Source Type	NCBI Taxonomy	NCBI Taxonomy	ICTV	NCBI Taxonomy	X	X	X
Source text	NCBI Taxonomy	NCBI Taxonomy	ICTV	NCBI Taxonomy	X	X	X

EU-SRS field name	Example Species level	Example Serovar level	Example Strain level	Example Strain level	Author	Serovar	Strain
Public Domain	Yes	Yes	Yes	Yes	X	X	X
Access	Public	Public	Public	Public	X	X	X
URL	https://www.ncbi.nlm.nih.gov...	https://www.ncbi.nlm.nih.gov...	https://ictv.global/taxonomy/...	https://www.ncbi.nlm.nih.gov...	O	O	O
Source Id	173	211880		51314	O	O	O
Upload a Document					O	O	O
Tags	PUBLIC_DOMAIN_RELEASE	PUBLIC DOMAIN RELEASE	PUBLIC_DOMAIN_RELEASE		O	O	O
Change							
Change Reason					O	O	O

5.3 Relevant References for Veterinary vaccines

Source type	Citation	Comment	Public Domain	Tag
General reference (after go-live)				
EMA LIST	SMS	Reference for SMS Names, manual registration (just for public names)	Yes	PUBLIC_DOMAIN_RELEASE
EMA LIST	SVG	Reference for Public names without valid public source Manual registration	Yes	PUBLIC_DOMAIN_RELEASE
Specific reference				
European Procedure Number	Procedure number e.g., EMEA/V/C/00015	Definitional Reference	Yes	
ICTV	ICTV		Yes	optional PUBLIC_DOMAIN_RELEASE
ITIS	ITIS		Yes	
LSPN	LSPN		Yes	
NCBI Taxonomy	NCBI Taxonomy		Yes	
SPC	SPC		Yes	

A complete overview of the possible References will be included in the General EU-SRS User Guide, (which will be released at the end of December/beginning of January).