

TRUE NAMES, PRODUCT CODES, AND ESTABLISHMENT CODES

Overview

This chapter describes the conventions for assigning True Names for biological products and assigning Product Codes to the True Names. The Product Code system was initiated many years ago, based on the needs of the Veterinary Biologics Program at that time. The Program, and the variety of regulated products, has evolved since then, and numerous exceptions to the general conventions discussed in this chapter now exist. Implementing a new coding system would be burdensome to the biologics industry, so the CVB currently configures codes to the extent possible according to the established system.

Because the current system has many exceptions to the general business rules, firms should not attempt to code products themselves. Initial submissions should be designated as “unassigned.” Designating a submission as “unassigned” also serves as the flag to create essential records for the new product in CVB databases.

True Names

The True Name includes all of the antigenic fractions of the product for which there is a label claim. (Thus, the product may contain other “unclaimed” antigens.) The following conventions apply:

General

1. Each word of the True Name is capitalized (even species names). Italics are not used.
2. Antigens (“fractions”) are separated by hyphens.
3. The antigens are usually listed in alphabetical order. Occasionally, fractions are listed in “historic” order of licensing (e.g., Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3- Respiratory Syncytial Virus Vaccine).
4. Some antigens are listed taxonomically (especially “newer” disease agents, for example, Bovine Coronavirus), but many antigens are listed by the disease they cause (e.g., Bovine Rhinotracheitis, Canine Distemper, etc.).
5. Taxonomic modifiers to specify the host species are only used with the first antigen (e.g., Bovine Rhinotracheitis-Virus Diarrhea instead of Bovine Rhinotracheitis-Bovine Virus Diarrhea).
6. Modifiers of the product *form* may be used at the end of the list of antigens and are separated from the antigens by commas (e.g., Killed Virus, Avirulent Live Culture).
7. See the current Product Code Book for previously established True Names.

Viral products

1. Viral products are called vaccines, regardless of whether the virus is killed or live
2. The viability of the virus(es) in the product is noted at the end of the True Name (e.g., Killed Virus *or* Modified Live Virus *or* Modified Live & Killed Virus). For products

containing both live and killed viruses, there currently is no mechanism to determine by the True Name which are killed and which are live.

3. The viral serotype or subtype also may be noted as a modifier, added at the end of the “main part” of the True Name. Under the current system, however, the modifier(s) may not appear immediately after the fraction(s) it describes.

Examples:

- West Nile Virus Vaccine, Killed Virus
- Bovine Rota-Coronavirus Vaccine, Modified Live Virus
- Encephalomyelitis Vaccine, Eastern & Western, Killed Virus
- Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus
- Bursal Disease-Newcastle Disease-Bronchitis Vaccine, Standard & Variant, Mass & Ark Types, Killed Virus

Bacterial Products

1. Products containing whole, killed bacteria are called *bacterins*. Those containing live bacteria are called *vaccines*.
2. Products containing sterile, nontoxic, antigenic derivatives extracted from bacterial organisms or spent culture medium are called *bacterial extracts*.
3. Products containing inactivated toxins extracted from bacterial organisms are called *toxoids*.
4. If a toxin-producing bacterial species is included in the product, and the product contains a whole culture or a concentrate thereof, with the toxic growth products inactivated but still antigenic, then the product is called a *bacterin-toxoid*. (Note that the bacterin-toxoid designation only applies to those products for which there is a potency test for the toxoid fraction.). No distinction is made to identify which fraction in a multiple fraction bacterin-toxoid includes the toxoid (similar to the lack of distinction in multiple virus products as to which fraction is live or killed).
5. Fractions are listed by genus and species. If more than one organism of the same genus is included in the product, the genus name is listed only once, and the fractions are usually alphabetized by species (e.g., *Vibrio Anguillarum-Ordalii-Salmonicida* Bacterin).
6. If types are specified in the True Name (e.g., *Clostridium perfringens*), then the modifier is added after the name of the fraction (e.g., *Clostridium Perfringens* Types C&D Bacterin-Toxoid).
7. The viability of bacterins is not described with modifiers because a bacterin, by definition, is killed. The viability of live products is reflected in the use of “vaccine” and also may be reflected in modifiers such as “avirulent live culture.”

Examples:

- *Haemophilus Paragallinarum* Bacterin
- *Leptospira Canicola-Icterohaemorrhagiae* Bacterin
- *Escherichia Coli-Salmonella Cholerasuis-Typhimurium* Bacterin
- *Streptococcus Equi* Bacterial Extract
- *Escherichia Coli* Bacterin-Toxoid
- *Pasteurella Multocida* Vaccine, Avirulent Live Culture

Products containing Bacteria and Viruses (Vaccines with Bacterins/Toxoids)

1. If the product contains viral and bacterial/toxoid fractions, viral components are grouped separately from the bacterial components.
2. Each group is sorted (separately) into the “normal” order for a viral vaccine and for a bacterin.
3. Viral components are listed before bacterial components in the combined name.
4. Commas are inserted before and after viral modifiers in the middle of the True Name.

Products containing miscellaneous organisms

1. Products containing Mycoplasma are named according to the conventions for bacterial products.
2. Products containing fungi, protozoa, rickettsiae, or chlamydiae (or just about anything else) are named according to the conventions for viral products.

Platform Products

1. The True Name should identify the product as being a Platform. Add “Platform” at the end of the True Name. See the following examples:
 - a. Porcine Circovirus Vaccine, Type 2, Killed Baculovirus Vector Platform
 - b. Porcine Epidemic Diarrhea Vaccine, RNA Platform
 - c. Swine Influenza Vaccine, DNA Platform
2. New Product Codes are not issued for each new variant, as per VSM 800.213. When new gene of interest (GOI) sequences are approved, they are added to the Outline of Production.
3. For each new variant, the swap-out should be comparable; i.e. the same segment of the GOI.
4. Each GOI variant will be given a running “sequence version” number, which will be included in the Outline of Production table of approved sequences for that Code.
5. For monovalent products, the product labeling should state “[fraction 2] Sequence Version x” directly under the True Name. For products containing 2 or more variants of the same GOI, “[fraction] Sequence Versions x and y.” For products containing 2 or more different GOIs, “[fraction 1] Sequence Version x, [fraction 2] Sequence Version y.”

Recombinant organisms

Note: This category of products historically has been subject to the most variability in naming. Do not necessarily rely on previously assigned True Names for guidance.

1. The True Name is based on the entities for which there is a biological claim.
2. If an antigen(s) is expressed in a recombinant system, then extracted/purified from the vector, the product is a *subunit vaccine*.

Example: Master Seed is a baculovirus that expresses recombinant FIV env protein. FIV env protein is extracted for inclusion in the vaccine. True name = Feline Immunodeficiency Virus Vaccine, Subunit
3. If a gene(s) is deleted or inserted into an organism to produce a recombinant seed, current policy is to name the recombinant product the same as a conventional product.

Example: Master Seed is an *aroA* deletion mutant of *Salmonella typhimurium*. The True Name of the modified live product is Salmonella Typhimurium Vaccine, Avirulent Live

Culture.

4. If a foreign gene is inserted into an expression vector and a) the final product contains both the vector and the expressed foreign protein, and b) there is a label claim for the vector as well as the insert protein, then the True Name includes the identity of the vector. The inserted genes are reflected in the True Name, and the identity of the vector appears as a modifier.

Example: Master Seed is a Marek's Disease virus serotype 3 (formerly known as Turkey Herpesvirus) with a gene insert that expresses a protein from Marek's Disease virus serotype 1.

- If the product has been proven efficacious as an aid in the prevention of Marek's Disease due to serotypes 1 and 3, then the True Name is Marek's Disease Vaccine, Serotypes 1 and 3, Live Marek's Disease Vector.

5. If the criteria for #4 above apply *except* that efficacy against disease caused by the vector has *not* been established, the identity of the vector is not currently included in main part of the True Name.

Examples: Master Seed is a Marek's Disease virus serotype 3 (formerly known as Turkey Herpesvirus) with a gene insert that expresses a protein from Newcastle Disease Virus.

- If the product has been proven efficacious as an aid in the prevention Newcastle Disease but not Marek's Disease, then the True Name is Newcastle Disease Vaccine, Live Marek's Disease Vector.
- If the product has been proven efficacious as an aid in the prevention of Newcastle Disease and Marek's Disease due to serotype 3, then the True Name is Marek's Disease- Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector.

6. The term "vector" is used when the organism that receives the foreign genes is replication competent without the gene inserts. If the recipient organism has had essential genes deleted and the foreign inserts are necessary to restore replication competence, then the term "chimera" is used. The CodeMaster will make the final determination regarding the appropriate True Name associated with products designated as Chimera.

Antibody Products

See Antibody Products chapter for naming conventions.

Diagnostic Kits

1. The True Name includes the organism/disease entity(s) for which the kit is intended, followed by the words "test kit."
2. The True Name includes whether the kit detects antibodies or antigen in the unknown samples.

Examples:

- Canine Parvovirus Antigen Test Kit,
- Foot and Mouth Disease Virus Antibody Test Kit
- Equine Infectious Anemia Antibody Test Kit

For Further Manufacture Products

1. The phrase "For Further Manufacture" does not appear in the True Name. This condition of manufacture is listed as a restriction on the product license. It is also reflected in the Product Code.

2. If the FFM product is shipped in final form and composition (completed product), the True Name conventions described for final products apply.
3. If the FFM product is shipped in a preliminary form that is subject to further batching/assembly by the receiving manufacturer, then the main part of the True Name includes only the name of the antigenic fraction(s). The following modifiers are used to describe the type of product:
 - a. Avirulent live culture (for live bacteria)
 - b. Killed culture (for killed bacteria, fungi, mycoplasma, etc.)
 - c. Modified Live Virus
 - d. Killed Virus
 - e. Test Kit Component

Example:

- Bordetella Bronchiseptica, Avirulent Live Culture (shipped as culture fluids)
- Canine Parvovirus, Killed Virus (shipped as inactivated viral harvest)
- Mycoplasma Hyopneumoniae Killed Culture (shipped as 1000 liters of harvest material that will be diluted with 1 ml of saline and bottled by the final-use product licensee)
- Mycoplasma Hyopneumoniae Bacterin (shipped as completed product, to be bottled without modification by the final-use product licensee)
- Avian Influenza Antibody Test Kit Component (coated test plates shipped for final packaging with non-critical reagents by the final-use product licensee)

Allergenic Extracts

The main part of the True Name is Allergenic Extract. The type of allergen is listed as a modifier.

Example: Allergenic Extract, Mixed Grasses

If a company takes bulk extracts and compounds them into custom combinations for a particular animal based on a prescription from a veterinarian, then they are issued a product license with the following True Name: Allergenic Extract, Prescription Product.

Immunomodulators, Immunostimulants, etc.

These products are variable in nature and, consequently, it is difficult to establish standardized naming conventions. See the Codemaster for guidance.

Because even minor variations in formatting can affect how True Names sort in AIMS-LSRTIS, additional consistency rules have been implemented. See Appendix I.

Abbreviated True Names

The labeling and packaging rule implemented in 2016 provided the option of using an abbreviated true name on certain small labels. The abbreviated true name is printed on all product licenses from 2017 forward and by request for licenses issued prior to 2017. No abbreviation except the one appearing on the license may be used.

A list of published fraction abbreviations is maintained on the [CVB website](#), but a more

complete list is available internally on [SharePoint](#). Not all fractions are being assigned abbreviations, and not all are published, often because the products containing them are not (yet) published in the product code book.

When assigning a new abbreviation, make sure that it does not duplicate one already assigned.

- A virus is abbreviated with the abbreviation commonly recognized in the scientific literature, if one exists. The abbreviation should agree with the True Name regarding whether it is based on a taxonomic name or disease name. For example, IBRV is the abbreviation for bovine herpesvirus, instead of BHV, because the True Name is Bovine Rhinotracheitis Virus Vaccine. All virus abbreviations should end in “V”.
- Bacteria/rickettsiae are abbreviated according to genus and species. Typically, there are 1-2 letters for the genus (all entries for a given genus should be abbreviated similarly), followed by an intuitive abbreviation for the species. The total abbreviation length should not exceed 6 characters, if possible. (Some exceptions, by necessity, exist.)

Fractions are formatted into abbreviated true names according to the conventions described in Appendix II.

Product Codes

1. Product codes always take the format of XXXX.XX.
2. Many of the digits are associated with a particular meaning; care must be taken to assign the correct Product Code to a new product. *Beware:* Given the evolving nature of the Product Code system, there is an exception on the books for just about any rule.
3. Conventions:

First Digit

- 1=Vaccines (all live products, plus killed products made from virus seeds and other miscellaneous organisms)
- 2=Bacterins and Bacterial Extracts
- 3=Antibody Products (except antitoxin antibodies)
- 4=Vaccines + Bacterins/Bacterial Extracts/Toxoids
- 5=Diagnostic Products
- 6=Antitoxins
- 7=Bacterin-Toxoids
- 8=Toxoids
- 9=Miscellaneous (allergens, immunomodulators, cancer biologics, etc)

If the product is for further manufacture, it is coded as it would be for final-use product, except that letters are substituted for numbers (A=1, B=2, etc) in the first digit. The first digit should be based on the type of product that the FFM product is, not the type of final-use product into which it will be incorporated. (For example, an FFM antibody should be coded as a C-series product (corresponding to 3000-series for antibody products), even though it may be shipped to the final-use manufacturer for inclusion in a test kit (5000-series).)

Second and Third Digits

Historically these had significance for listing specific antigens in numerical, as well as alphabetical, order. Over time, the large number of products within a given group has sometimes required that we assign numbers far removed from the number originally assigned to that organism. In some instances, alphabetical sequences in the second and third digits have been used because all possible numerical sequences have been allocated. Whenever possible, however, we try to maintain the numerical sequence within the same group of organisms.

For monovalent parvovirus products, a “P” in the third digit indicates that the product is for pigs. Canine parvovirus products have an “M” in the third digit.

Fourth Digit

Indicates the viability of virus-containing products.

First priority:

8=Combination packages (license allowing co-packaging and combined use of >1 separately licensed component product): Both component products contain live fractions.

9=Combination packages: One component product is live, the other is killed.

If neither of these apply, then:

1=All viral fractions live

2=Frozen product (this naming convention is not currently being used)

3=“Frozen desiccated” product (not currently being used)

5=All viral fractions killed

6=Vaccine-Bacterin (4XXX.XX series) used as diluent in combination package (Note that some product lines evolve over time and the use of a given product as a diluent in a combination package may not be intended at the time the diluent component was licensed. Thus, not all diluents have 6 in the 4th position.)

7=Contains both killed and live virus components (in same vial)

Fifth Digit

In priority use/order, if more than one designation applies:

U=unlicensed (DEREA)

P=Platform conditional product

D=nucleic acid vaccine

R=contains recombinant seed(s)

B=ballistic product

I=implant product

C= licensed for use only in the State of California due to California Assembly Bill No. 1709 approved by the Governor September 23, 2010, and filed with the California Secretary of State on September 24, 2010

If none of the above apply, use the following to indicate the cells/substrate in vaccines:

0=primary cells
1=avian embryo (i.e., eggs, CAMs)
2=cell line
3=cell line and primary cells
4=avian embryo and primary cells
5=tissue origin (e.g., bursa-origin Bursal Disease Virus)
6=avian embryo and tissue origin
7=primary cells and tissue origin
8=cell line and tissue origin
9=avian embryo and primary cells and cell line
A=avian embryo and cell line
F=avian embryo and primary cells and tissue origin
E=primary cells and avian embryo and cell line and tissue origin

For diagnostic kits, use the following to indicate the type of test format:

0=agar gel immunodiffusion
1=complement fixation
2=enzyme-linked immunosorbent assay (ELISA)
4=immunohistochemistry
5=dot blot, solid phase substrate
7=Western blot
8=polymerase chain reaction

Sixth Digit

Ideally, this indicates the number of licenses with identical True Names for a firm. The first license is numbered “0” and subsequent licenses are numbered consecutively (if the next available digit is available for use). In some cases, especially with the Influenza Type A vaccines, consecutive digits may have been assigned to different subtypes, in which case, the next available digit that has the exact same True Name is used. The numbers are not reused when a license is terminated. Also, if a prelicense product is assigned a code but then never is licensed, the number should not be used for another product.

If a firm imports a product that is similar to a product they produce domestically (i.e., firm is a permittee as well as a licensee), do NOT assign the same Product Code to the domestically produced and imported versions. Instead, assign a different sixth digit. “Dual-status” firms such as these frequently mistakenly submit imported product serial information and other data under the licensee establishment number. This error is more easily caught if the code for the imported product is different.

Requesting a True Name and Product Code

The contact person (aka the Codemaster) keeps the master list of current and previously active codes and ensures consistency and continuity in code and True Name assignments.

Product Codes/True Names should not be requested until regulatory jurisdiction has been confirmed and there are no obvious obstacles to licensure (e.g., no concern over ingredient sources, foreign manufacturers have secured an acceptable U.S. permittee).

1. Fill out the Product Code Request Form and submit it to the Codemaster.

Provide the following information:

- a. What are the agents/antigens/fractions?
- b. What is the viability of each fraction?
- c. Is the product produced in media and/or some other substrate?
- d. Are any of the fractions derived from recombinant technology?
- e. Does the Establishment have any other product with the same True Name that is licensed (currently or previously) or has prelicense activity? (Use particular care in determining this, especially after mergers/buy-outs.)
- f. For bacterial products, is the product made of whole cells, extracts, toxoids, or a combination thereof?
- g. If the product is for further manufacture, will it be modified *in any way* by the licensee for the final use product?

If possible, forward a copy of the Outline of Production to the Codemaster for reference.

2. Forward the mail log submission (usually an Outline of Production) to the Codemaster in the electronic mail log. To do this from the active queue, select “initiate childflow.” Then select “Code Request” from the dropdown menu.

3. The contact person will assign the True Name and code, sign the form, and return it to the submitter. The childloop will be closed and the mail log will appear in the reviewer’s active queue again in the electronic mail log.

4. When to request a Product Code: For quality assurance and tracking purposes, a Product Code should be requested early in the licensing process for any product that has significant prelicense activity. This, however, is up to the reviewer’s judgment. It may not be prudent, for example, to assign a code to a product when a firm, especially a new establishment, makes casual inquiries into the licensing process without making any substantial data submissions.

5. When a Product Code and True Name have been assigned, the reviewer should notify the firm formally of the assigned True Name and Product Code.

Establishment C

Appendix I. Conventions for Formatting True Names

1. Strain/serotype designations before viability (live/killed) designations
Example: Bronchitis Vaccine; Standard & Variant, Killed Virus
NOT ~~Bronchitis vaccine; Killed Virus, Standard & Variant~~

2. If there is more than one viability for a certain kind of organism (e.g., virus), list the organism once.
Example: X Vaccine; Modified Live & Killed Virus
NOT ~~Modified Live Virus & Killed Virus~~

3. When listing multiple viabilities or multiple strains, the listed items are separated by an ampersand (not a comma) and there is a space before and after the ampersand.
Example: Encephalomyelitis Vaccine; Eastern & Western & Venezuelan, Modified Live
& Killed Virus

4. Use “modified live” instead of “live” when describing whole virus/organism. (Historically there was some splitting due to perceived degree of attenuation, but currently all are considered modified live.)

5. When describing vectors, indicate if it is live or killed
Example: Equine Influenza Vaccine, Live Canarypox Vector

6. Order for multiple types of an organism: 1) Modified Live (whole) 2) Killed (whole)
3) Live Vector 4) Killed Vector 5) Subunit
Example:Modified Live & Killed Virus, Live Canarypox Vector, Killed Vaccinia Vector
OR
...Modified Live & Killed Virus, Live & Killed Canarypox Vector

7. Order for different classes of organisms within a vaccine:
Always list virus first, then alphabetical by organism type:
Example: WXYZ Vaccine, Killed Virus, Killed Amoeba, Modified Live Chlamylidia, Killed Protozoa

Separate the description of each organism type by a comma. Use ampersands to list

multiple viabilities within one organism type.

Example for 6&7 combined: XYZ Vaccine; Modified Live & Killed Virus, Modified Live Chlamydia, Killed Rickettsia, Live Canarypox Vector

Appendix II. Formatting Rules for Abbreviated True Names

String fraction abbreviations, separated by hyphens, in the order listed in the true name. Use the examples below as guidelines for various true name formats.

Examples of Abbreviated True Names

Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus

- IBRV-BVDV Vaccine, MLV

Salmonella Choleraesuis-Typhimurium Bacterin

- Schol-Styph Bacterin

Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Killed Virus, Campylobacter Fetus-Haemophilus Somnus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin

- IBRV-BVDV-PI3V-BSRV Vaccine, KV, Cfet-Hsom-Lcan-Lgrip-Lhard-Lict-Lpom Bacterin

Encephalomyelitis-Rhinopneumonitis-Influenza-West Nile Virus Vaccine, Eastern & Western & Venezuelan, Killed Virus, Tetanus Toxoid

- EEEV-WEEV-VEEV-ERV-EIV-WNV Vaccine, KV, Ctet Toxoid

Porcine Circovirus Vaccine, Type 1 -Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin

- PCV1-PCV2 Chimera Vaccine, KV, MPhyo Bacterin

Fowl Laryngotracheitis-Marek's Disease Vaccine, Serotype 1 & 2 & 3, Live Virus, Live Marek's Disease Vector

- ILTV-MDV1-MDV2-MDV3 Vaccine, LV, LV MDV Vector

Feline Leukemia Virus Antigen-Feline Immunodeficiency Virus Antibody Test Kit

- FELV Antigen – FIV Antibody Test Kit