

## Listing Fractions in Facility Documents

This document was developed for CVB-IC Specialists as an aid in determining what to consider as a “fraction” in the facility documents.

**The following fractions may be included in the facility documents** if they are used to prepare licensed product, test product, or if they are used or stored in R&D laboratories (if R&D is not separate and apart):

- Bacterial, viral, fungal, parasitic, and prion agents, both live and killed. List all bacterial, fungal, and parasitic agents by genus and species. For viruses, list the full virus name (rather than general viral class; for example, Bovine Viral Diarrhea Type II versus Pestivirus). For prion agents, list the type; for example, Chronic Wasting Disease.
- Peptides, if a component of final product
- Expressed proteins, if a component of biological product
- Recombinant organisms – list by organism rather than listing each individual recombinant.
- Cells
- Toxins
- Hybridomas, if foreign derived and for in vivo animal use
- Antibodies to a specific antigen
- Antitoxin to a specific antigen
- Master platforms for production platform technology based products

**Do not include the following as fractions in the facility documents:**

- Hybridomas, if not foreign derived and not for in vivo animal use
- Antiserums-positive or negative (diagnostic test kits)
- Fractions in R&D, if R&D is considered separate and apart by CVB
- Individual fractions used in autogenous products. Instead, in rooms where autogenous products are prepared these agents may be referred to collectively simply as ‘various autogenous agents’.
- Commercial biological indicators used as an aid in determining autoclave function

**How to report fractions in the facility documents:**

- Do not use abbreviations for fractions. Abbreviations may be acceptable if the full name is spelled out on the first usage, for example *Leptospira canicola* and thereafter *L. canicola*.
- List fractions in each room description within the blueprint legend, or make reference to a ‘Listing of Fractions’ in an addendum to the blueprint legend.
- Do not refer to fractions as “approved” or “licensed.”