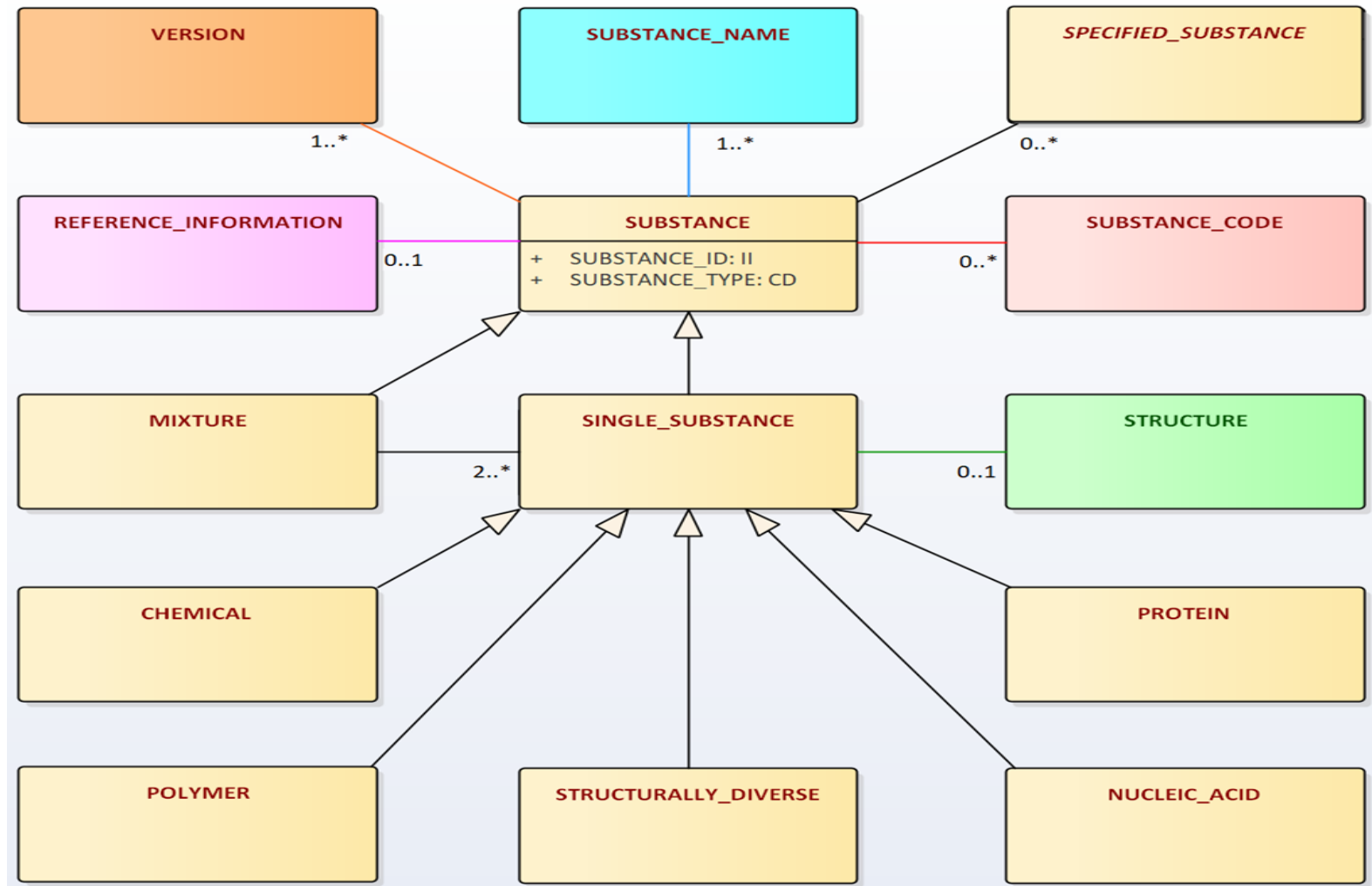


# ISO 11238 Standard and Implementation Guide

Larry Callahan , FDA; Herman Diederik, CBG/EMA ; Archana Newatia, FDA;  
Tyler Peryea , NCATS/NIH; Noel Southall, NCATS/NIH; Frank Switzer, FDA;  
Panagiotis Telonis, EMA

# 11238 Substances



## Substances 11238 Version 2

- Proteins
  - Amino acid sequence, type of glycosylation, modifications and **source material**
  - Source material is now captured to allow plasma and milk derived proteins to be distinguished
  - Not yet implemented in G-SRS
- No other major changes at the substance level.
- G-SRS can capture alternative definitions
  - Peptides can be described as both chemicals and proteins
  - Short polymers as mixtures of chemicals
  - Chemicals can be captured as multiple tautomers

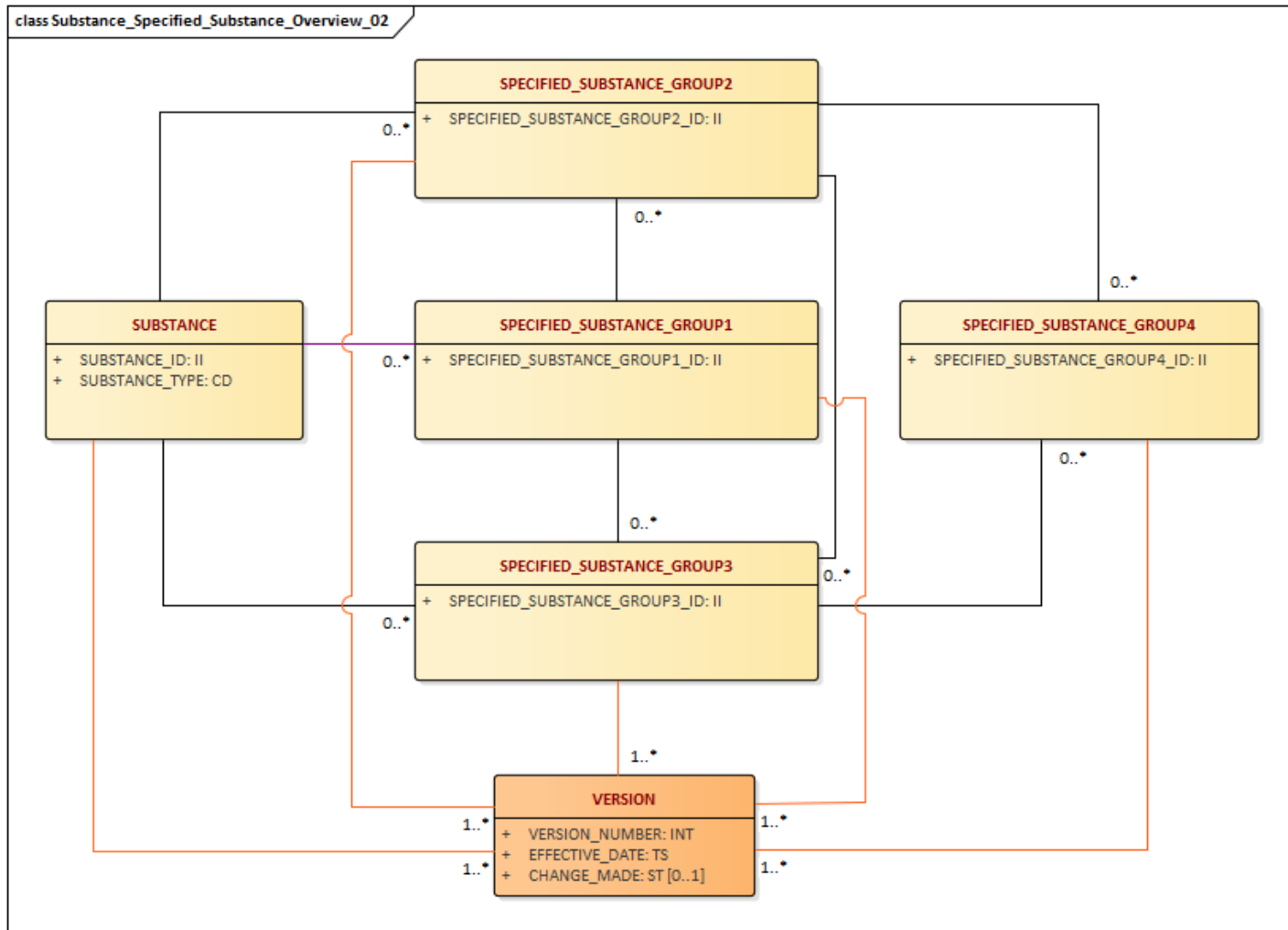
# Specified Substance

To be implemented with the G-SRS Application

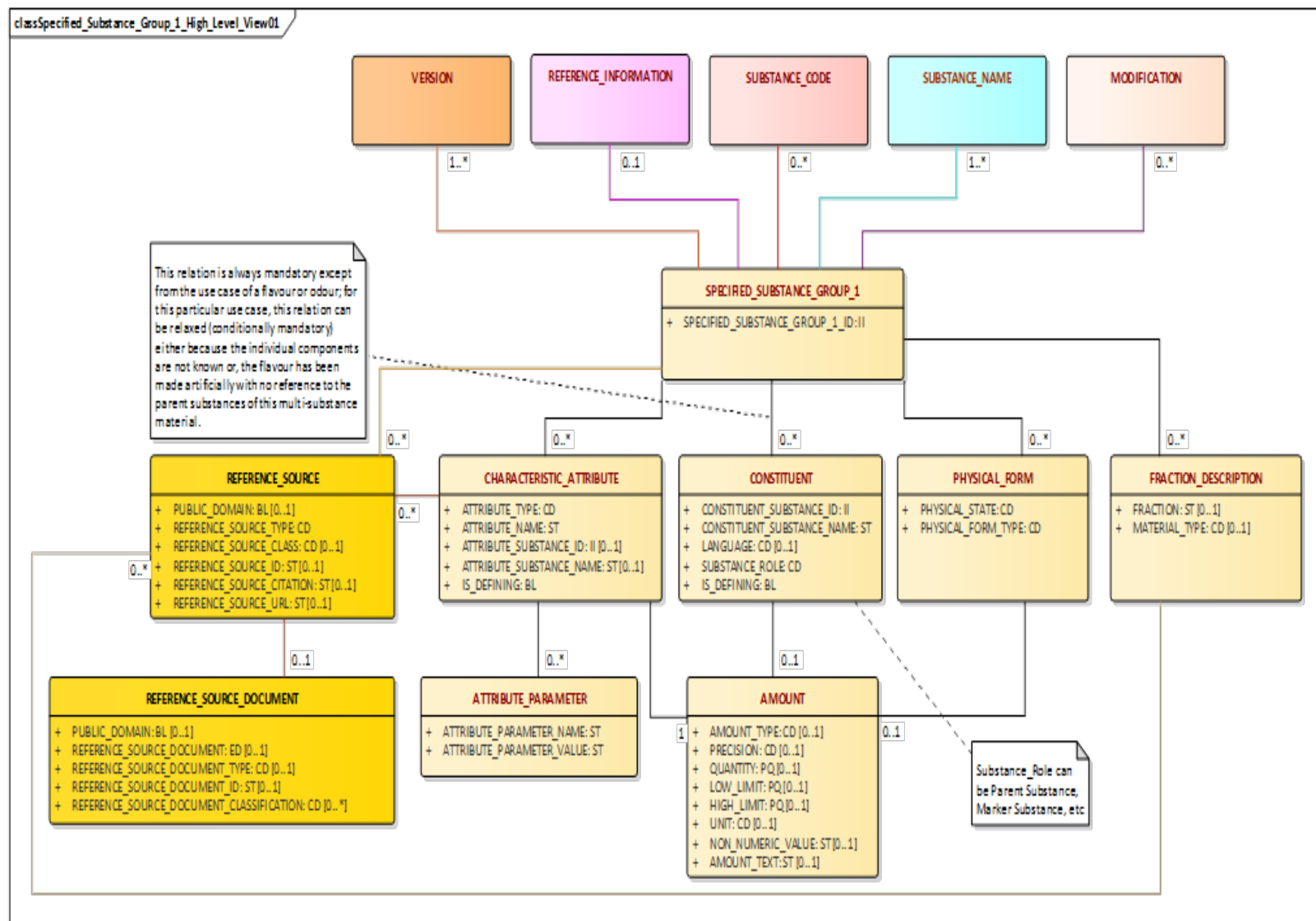
An explicit grouping of elements and concepts put forward in ISO IDMP

- Group-1 Multiple substance materials (Coatings, Colorants, Flavorants); Physical Form; Extracts
- Group-2 Manufacturer and minimal manufacturing information
- Group-3 Grade of material (USP, EP, technical, standardized etc.)
- Group-4
  - Detailed manufacturing information,
  - Specifications

# Specified Substance



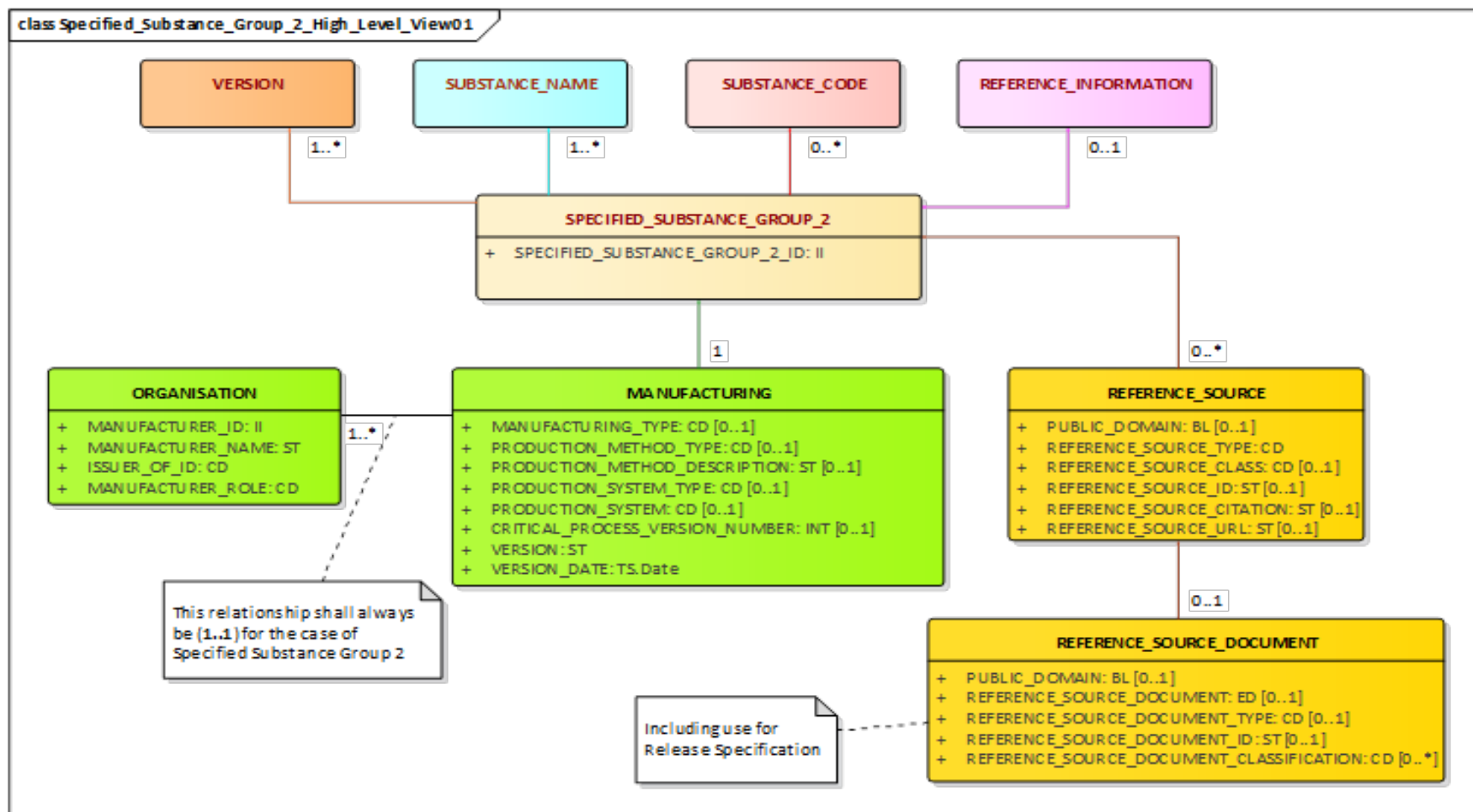
# Group 1 Specified Substance



# Group 1 Specified Substance

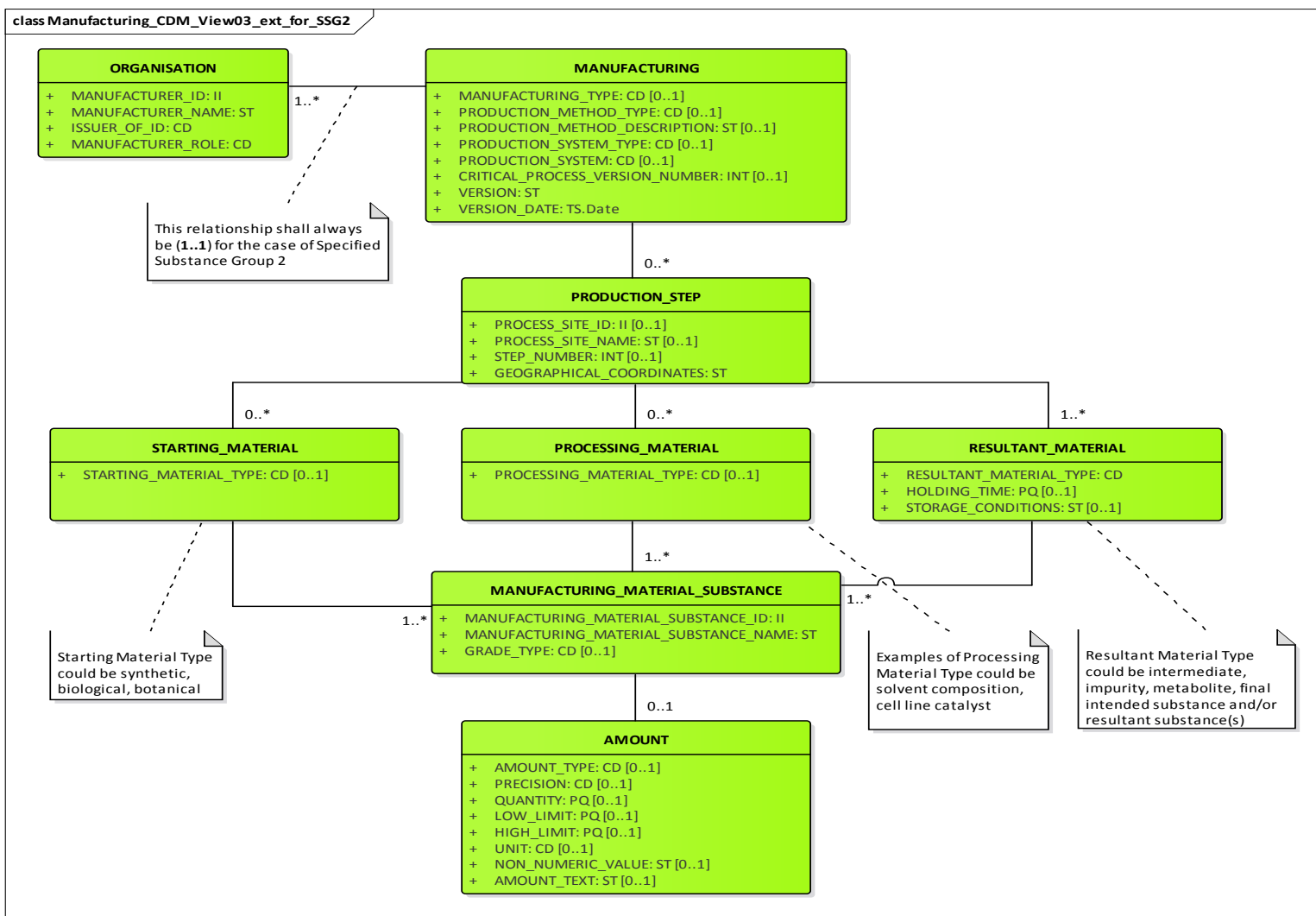
- Glycosylation details to be captured for proteins
  - Specific Glycans and Amounts
  - Site Occupancy for each site?
- Characteristic Attributes
  - Capture country of origin for plasma products
  - Pathogen testing or process attributes (log viral clearances)
- Distinguish Polymorphs
  - Reference to crystal structure

# Specified Substance Group 2





# Specified Substance Group 2

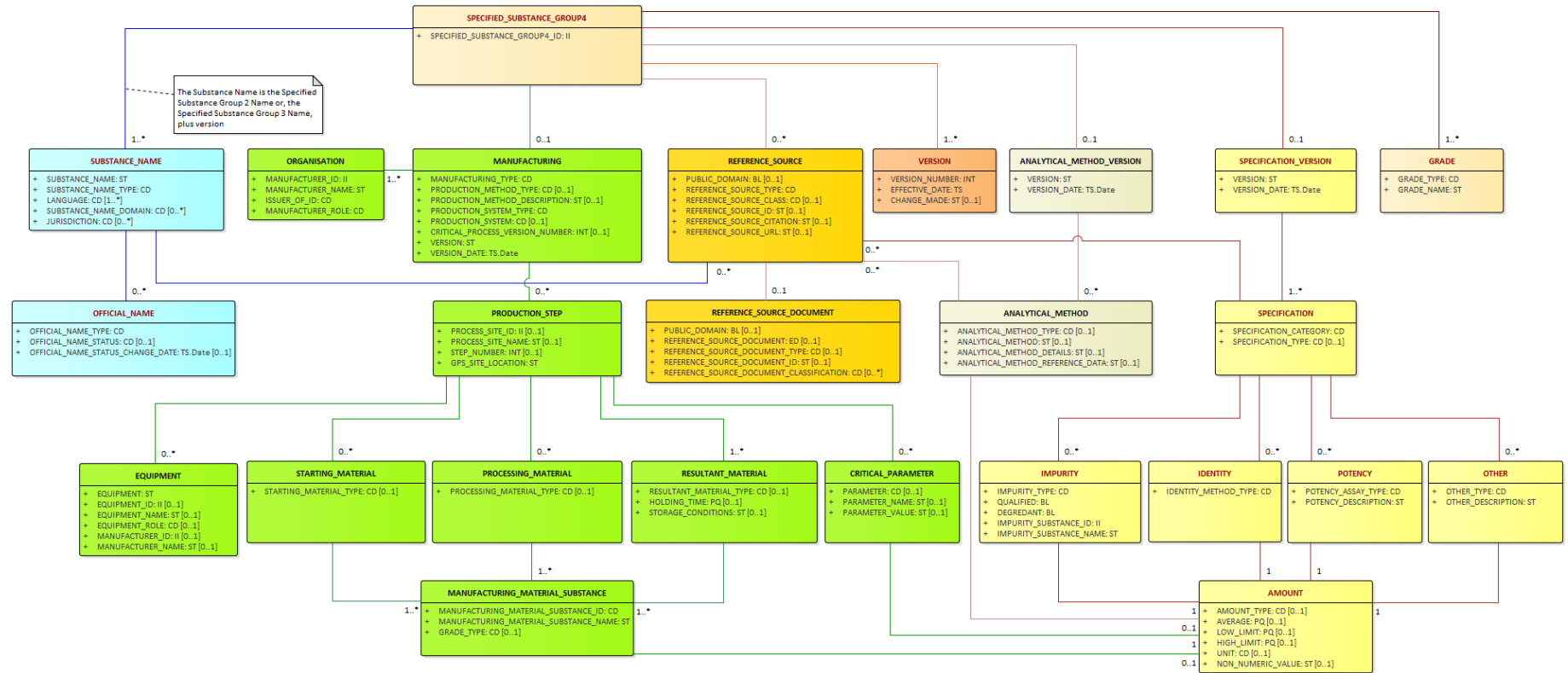


# Group 2 Specified Substance

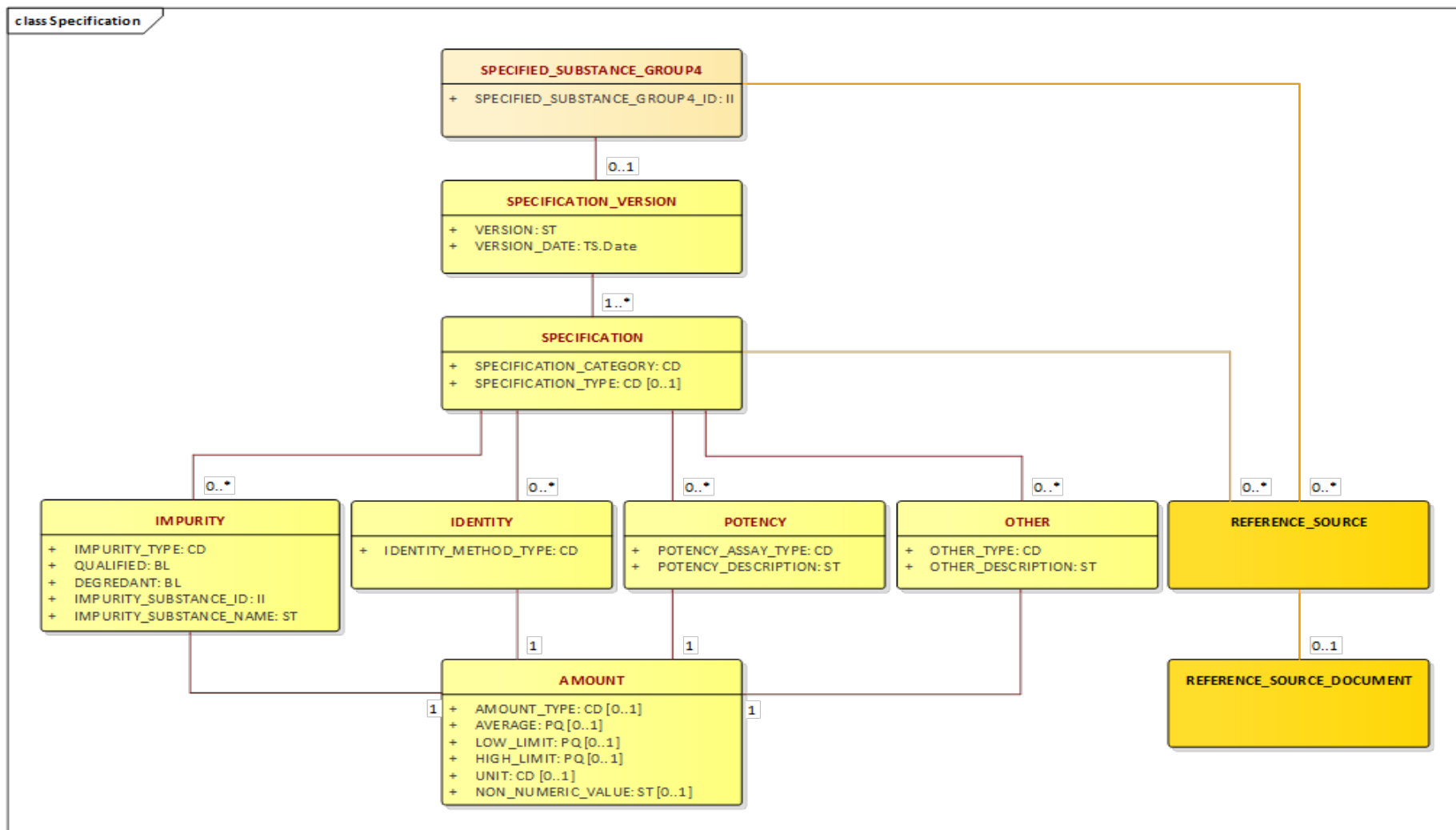
- Extended Manufacturing Model for Herbal and Allergenic Extracts
- Site of Manufacturing to be Captured?

# Specified Substance Group 4

class Specified\_Substance\_Group4\_CDM\_View01



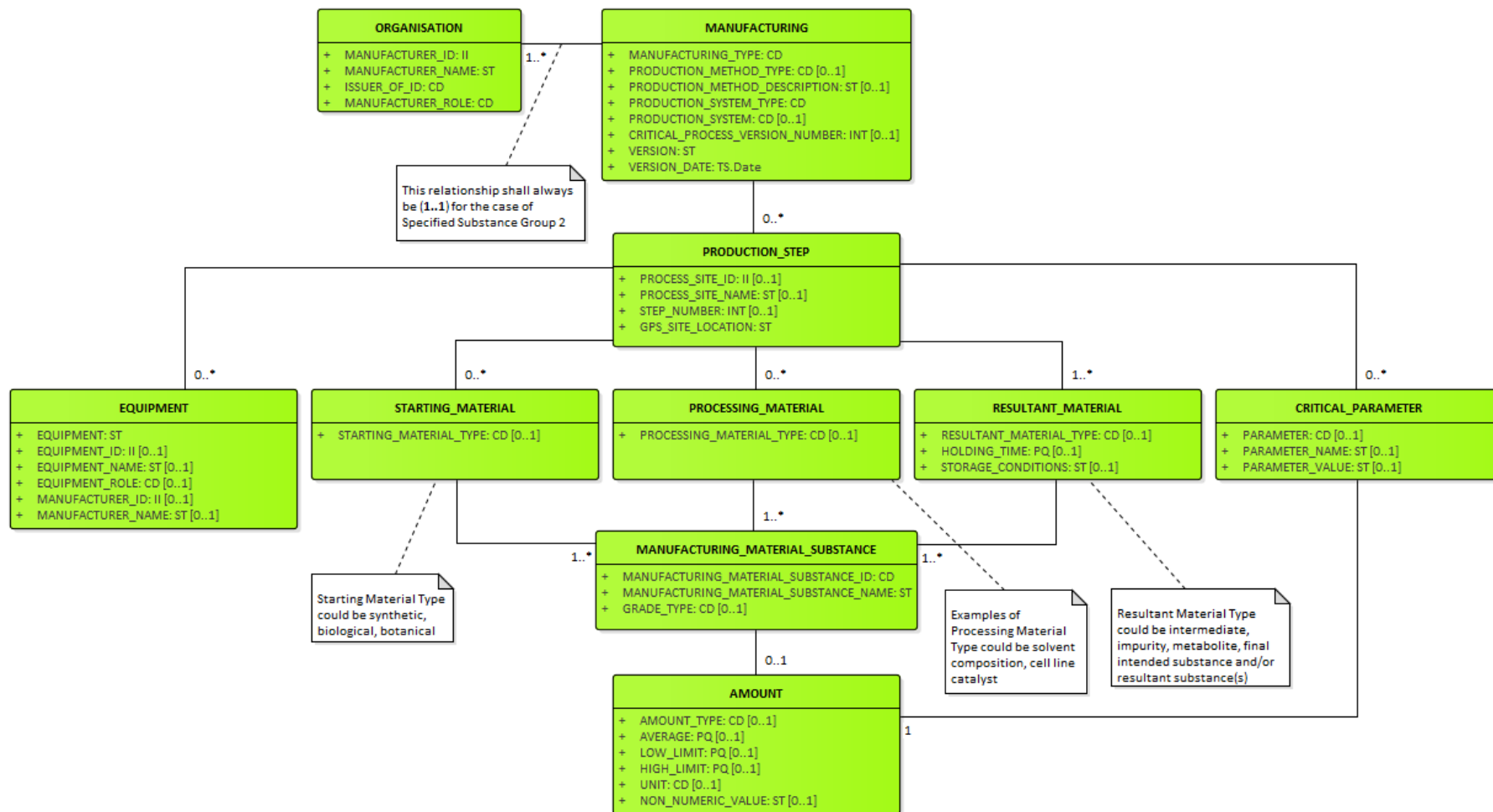
# Specification Model



# Manufacturing Model



class Manufacturing\_CDM\_View01



# Status of Standard

- Most of the 11238 changes in manufacturing and specification
- Do not specify messaging for substances
- Final Ballot in Liverpool for Version 3



# Acknowledgements



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