

Excerpt from MWG Discussion Document 4-20-09 Classification of Definition of synthetic Substance.

Synthetic – A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.” (7CFR 206.2)

A chemical change is intended to mean an event in which one substance becomes one or more different substances. A chemical change may result from specific types of chemical reactions such as:

- (1) Addition or combination reactions;
- (2) Decomposition reactions;
- (3) Displacement reactions; and
- (4) Protein configuration changes; and
- (5) Polymerization

The occurrence of these types of reactions does not necessarily result in a chemical change, however, because it is possible for the atomic composition or configuration of a substance to change without a change in the identity of the substance. This is particularly true for large, complex biomolecules or for substances that are mixtures of various chemical species. Therefore, the occurrence of a chemical change is identified based on the identity and empirical properties of the starting and resulting substances.

In cases where there starting and/or resulting chemicals or chemical mixtures have not previously been assigned recognized identities (e.g. CAS numbers) or where the occurrence of a chemical change is uncertain for other reasons, NOSB and NOP may consider additional factors such as:

1. Changes in the technical or functional properties (e.g. nutritional value, flavor, efficacy for an intended use) of the chemical involved;
2. Whether the chemicals involved are found in natural sources
3. Whether naturally occurring biological processes are involved;
4. The role of synthetic substances, if any; and
5. The extent to which chemical reactions of the types listed above are involved.