

(i) The intended use of which results or reasonably may be expected to result, directly or indirectly, in the substance becoming a component of food or otherwise affecting the characteristics of food, including any substance used to produce, manufacture, pack, process, prepare, treat, package, transport, or hold food, or any source of radiation that is intended for any of these uses; and

(ii) That is not recognized generally by qualified scientific experts as having been shown to be safe under the conditions of its intended use:

1. Through scientific procedures; or

2. Through either scientific procedures or experience based on common use, if the substance was used in a food before January 1, 1958.

(2) "Food additive" does not include a color additive.

(k) "Label" means a display of written, printed, or graphic matter on the container, other than the package liner, of a substance.

(l) "Labeling" means any label or other written or graphic material that:

(1) Is on a substance or its container or its wrapping; or

(2) Accompanies a substance.

(m) "Official compendium" means the most recent revision of the United States Pharmacopoeia and National Formulary, the official Homeopathic Pharmacopoeia of the United States, or any of their current supplements.

(n) (1) "Package" means any container or wrapping of a consumer commodity that is used for delivery or display to retail consumers.

(2) "Package" does not include any container or wrapping that is used only for:

(i) Transportation of a consumer commodity in bulk or quantity to a manufacturer, packer, processor, or wholesale or retail distributor; or

(ii) Shipment or delivery of a consumer commodity to a retail customer, if the container or wrapping bears no printed material that relates to a particular consumer commodity.

(o) "PERSON" INCLUDES:

(1) AN OPERATOR OF A FACILITY THAT IS OWNED BY A STATE OR LOCAL UNIT OF GOVERNMENT; OR

(2) A STATE OR LOCAL UNIT OF GOVERNMENT IF THE STATE OR LOCAL UNIT OF GOVERNMENT IS THE OPERATOR OF THE FACILITY.

[(o)] (P) "Secretary" means for the purposes of Subtitles 1, 2, 3, 4, 8, and 11 of this title, the Secretary of Health and Mental Hygiene or the Secretary's designee.