

Plant-made Pharmaceutical Terms

Audit and monitoring system – Producers of plant-made pharmaceuticals are committed to working with regulatory authorities to ensure the safety of the manufacturing process. The industry will provide regulatory authorities with analytical methods and tools for monitoring the containment of plant-made pharmaceuticals and will fully cooperate with regulators in conducting reviews and audits of companies' containment procedures.

Containment – Containment includes procedures to prevent contamination of food or feed, direct exposure of humans during production, and environmental and non-target organism exposure until an acceptable level of exposure has been established.

Genetically modified foods – Genetically enhanced foods represent an area of significant importance in biotechnology. Scientific developments have made it possible to genetically alter food crops to improve quality or increase resistance to adverse environmental conditions or pests. Studies show that genetically engineered foods are absolutely safe for consumers and the environment.

Plant-made pharmaceuticals – The result of an innovative application of biotechnology, whereby plants are genetically modified to produce pharmaceutical substances for new therapeutics that can treat diseases and save lives.

New advances in biotechnology have made it possible to use plants not just as food crops, but also to produce pharmaceutical substances that can save lives. Plants can produce proteins that are essential building blocks for drugs that may treat and cure such widespread diseases as cancer, HIV, heart disease, diabetes, Alzheimer's and others.

Plant pharmaceuticals / Plant-made medicines – Used interchangeably with **plant-made pharmaceuticals**.

Production of plant-made pharmaceuticals – Plants are genetically enhanced to produce high-value proteins that are needed for the production of a wide range of therapeutics. These genetically transformed plants are grown in isolated fields to serve as biological factories for producing pharmaceutical proteins. After the plants are

harvested, they are processed to separate and purify the proteins, which are then sold to pharmaceutical companies to be used in the manufacturing of life-saving drugs.

Regulatory guidelines – Currently, the Food and Drug Administration (FDA) in the United States and Health Canada in Canada regulate the evaluation, production and distribution of pharmaceutical products. The U.S. Department of Agriculture (USDA) and the Canadian Food Inspection Agency (CFIA) regulate plant-made pharmaceuticals during development and field production. Manufacturers of plant-made pharmaceuticals are committed to working together with regulatory authorities to develop a transparent regulatory process that could be revised and updated, as appropriate, to reflect new data and information.

Risk assessment – Science-based risk-assessment studies will be conducted to determine the potential for and the impact of exposure to plant-made pharmaceuticals as part of establishing containment procedures.

Safe exposure level – Producers of plant-made pharmaceuticals are committed to working together with regulatory authorities to determine a safe level of exposure to plant-made pharmaceuticals. Containment procedures will be implemented to prevent contamination of food or feed, direct exposure of humans during production, and environmental and non-target organisms.

Standard operating procedures – Producers of plant-made pharmaceuticals adhere to strict, self-imposed guidelines and are building a protection system that strives to exceed existing government regulations. Standard operating procedures have been developed to cover every aspect of production and handling of plant-made pharmaceuticals to ensure that the manufacturing process is safe for humans and the environment.

The Biotechnology Industry Organization (BIO) represents more than 1,000 biotechnology companies, academic institutions, state biotechnology centers and related organizations in all 50 U.S. states and 33 other nations. BIO members are involved in the research and development of health-care, agricultural, industrial and environmental biotechnology products.