Status of International Regulations for Ultraviolet Treatment of Foods

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Abstract
Ultraviolet (UV) treatment is a new technology that is used as an alternative to thermal processing to produce microbiologically safe foods with better quality, extended shelf-life and often with enhanced health benefits. Before food manufacturers can use any new UV process and product can be sold, the thorough regulatory assessments and evaluations of their safety have to be conducted. This article provides an analysis of major international approaches for the regulation of UV light for treatment of foods, feed and ingredients. The essence of food additive and novel foods regulations is discussed. The approved UV applications in the US, Canada and European Union (EU) for juice and milk products, mushrooms and yeasts are described and analysed.

In the last two decades, UV technology started quickly emerging in food production and processing. UV treatment is used to produce not only microbiologically safe foods but also products with better quality and, more often, with enhanced health benefits. The principal commercialization hurdles related to investment costs, full control of variables associated with the process operation and lack of regulatory approvals and guidelines have been delaying a wider and faster implementation of UV technology at the industrial scale.

In food industry, before any new or novel process can be used and product can be sold, the thorough assessments and evaluations of process and product safety have to be conducted by regulatory agencies. Potential microbiological, toxicological or nutritional concerns that can result from new processing or preparation techniques must be assessed. This article will briefly review existing international regulations that approved processes, processed foods, beverages and ingredients produced using UV continuous light. The differences in safety evaluation of UV treated foods by government agencies around the globe, such as food additive in the US and novel foods regulations in Canada and the EU, will be presented.

US FDA: food additive approach

According to CFR 21 part 179 (US FDA 2001), the US FDA considers UV light as radiation along with ionizing radiation, radiofrequency radiation, pulsed light and carbon dioxide laser and a source of radiation used to treat food is defined as a food additive (1). The additive is not literally added to

food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes and its use can affect the characteristics of the food. In assessing the safety of foods treated with all forms of radiation, the agency considers microbial efficacy, changes in chemical composition of the food that may be induced by the proposed treatment, including any potential changes in nutrient levels.

Juice products

In 2000, the US FDA amended the food additive regulations to provide for the safe use of UV radiation at 253.7 nm to reduce human pathogens and other microorganisms in juice products. It was determined that the amount of UV irradiation necessary for human pathogen reduction would depend on the type of juice, the initial microbial load and the design of the irradiation system (e.g., flow rate, number of lamps and time exposed to irradiation). Therefore, the FDA did not specify a minimum or maximum UV dose by regulation but concluded that this should be achieved for individual usage situations in a manner consistent with good manufacturing practice.

In addition, the FDA expects that the maximum dose applied to the juice will be economically self-limiting due to the costs associated with UV irradiation. Also, the levels of UV irradiation applied to the juice will be limited by the possible alterations in quality, nutritional and organoleptic characteristics of the juice (i.e., changes in taste or color) after UV irradiation, and changes that may result in decreased consumer acceptance.

Surface and potable water

Other approved applications of UV radiation for the

page 15 ▶

◀ page 13

processing and treatment of foods are surface microorganisms control and sterilization of potable water. Low-pressure mercury lamps at 253.7 nm are approved as radiation sources with the limitations in terms of ozone production.

The essential treatment conditions in terms of intensity, flow patterns and product requirements are outlined in the US FDA CFR 21 179.39 (Table 1) (US FDA 2001).

UV pasteurized water for dairy industry
In 2009, FDA Pasteurized Milk Ordinance (PMO, 2009) approved UV disinfection to create pasteurized equivalent water for use in cleaning and rinsing applications. The regulation states that UV light shall be applied so that the entire volume of water receives at least the following dose when used as pasteurized water:

- Low-pressure UV at 254 nanometers at a UV dose of 186 mJ cm^{-2} or a 4-log adenovirus equivalent.
- Medium-pressure UV at 120 mJ cm^{-2} or a 4-log adenovirus equivalent.

Other requirements include various control elements to ensure the all water volume receives the minimum dose of UV light, real-time monitoring to ensure the dose is consistent and cleaning protocols to ensure the system always works at peak performance.

Baking yeasts
The US FDA has approved UV light treatment of baker's yeast to convert endogenous ergosterol to vitamin D2. The FDA concluded that the use of UV light-treated baker's yeast does not pose a safety concern, since the UV light treatment has been shown not to produce any new components of toxicological concern that could be introduced into the diet (US FDA, 2012, 21 CFR Part 172, 381). Vitamin D2 baker's yeast may be used safely in foods as a source of vitamin D2 and as a leavening agent.

Novel foods regulations
In six countries, UV treated food products belong to the category of Novel Foods, including the EU, Great Britain, Canada, Australia, New Zealand and China. Novel foods and ingredients are regulated in a varying manner in each country with the majority of systems based on a risk or safety assessment review model and most countries also requiring notification and approval. In general, foods that result from a process that has not been previously used for food production are considered as novel foods. Novel foods are also products that do not have a long history of safe use as a food.

Health Canada/Canadian Food Inspection Agency

Apple juice and cider
Foods and feed that result from a UV process that has not been previously used for their production are considered as novel foods and novel feed. Companies are required to submit detailed scientific data for review and approval by Health Canada or Canadian Food Inspection Agency (CFIA) before such products can be sold. In 2004, Health Canada determined that there are no safety concerns, and it has no objection regarding the sale of UV-treated apple cider using commercial Cider Sure 3500 unit (FPE, Rochester, NY) to achieve a reduction in the microbial load of apple juice and cider products (Health Canada, 2004).

European Union (EU)

Novel food regulations that came into effect in 2018 specify that a food product should be considered a novel food when

page 16 ▶

Table 1. US FDA CFR 21 179.39 – UV for treatment and processing foods

Irradiated food	Limitations	Use
Food and food products	Without ozone production: high-fat content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 253.7 nm radiation) per 5 to 10 ft^2.	Surface microorganism control
Potable water	Without ozone production; absorption coefficient, 0.19 cm^{-1} or less; flow rate, 100 gal/h per watt of 253.7 nm radiation; water depth, 1 cm or less; lamp-operating temperature, 36 to 46°C	Sterilization of water used in food production
Juice products	Turbulent flow through tubes with a minimum Reynolds number of 2,200	Reduction of human pathogens and other microorganisms

◀ *page 15*

it results from a production process not used within the Union before 15 May, 1997, and which gives rise to significant changes in the composition or structure of a food affecting its nutritional value, metabolism or level of undesirable substances (REGULATION (EU) 2015/2283).

Milk

In January 2016, the European Food Safety Authority (EFSA) approved usage of UV light as a milk post-pasteurization treatment due to the nutritional value of such a treatment (EFSA, 2016). The novel food is cow's milk (whole, semi-skimmed or skimmed) to which a treatment with ultraviolet (UV) radiation at 253.7 nm is applied after pasteurization to extend the shelf life of the milk and to increase vitamin D3 concentrations by conversion of 7-dehydrocholesterol to vitamin D3. The EFSA panel concluded that the novel food, UV-treated milk, is safe under the intended conditions of use as specified by the applicant.

Bread

In 2014, the EFSA (EFSA, 2018) approved application of the equipment manufacturer for UV treatment of bread. The permission was issued for sale of yeast leavened bread and rolls that can be UV treated after baking to convert ergosterol to vitamin D2 (ergocalciferol) at the maximum level of 3 µg vitamin D2 per 100 g. The permitted UV irradiation process is within the wavelength of 240 to 315 nm for maximum of 5 s with a UV dose of 10 to 50 mJ cm^{-2}. Other authorized UV-treated products that are included in the new EU union list include mushrooms and baker's yeast (EFSA, 2018).

Food Safety and Standard Authority of India

Milk

The Food Safety and Standard Authority of India (FSSAI) regulates and defines novel foods as "an article of food for which standards have not been specified but is not unsafe; provided that such food does not contain any of the foods and ingredients prohibited under this Act." In 2013, based on the application and supporting documents, the scientific committee of the FSSAI gave raw milk treated with a SurePure UV system the status of "Process Approval."

Israeli standard

Milk

The Israeli standard is based on Israeli standard 82 and codex 247-005, both of which state that the pasteurization of milk is determined based on the quality of the treatment. That is, the reduction of microorganism to a set standard and is not dependent on the method (i.e., temperature). In 2017, the Israeli food regulations agency approved the use of UV light to reduce microbial load in pasteurized milk. The health committee approved the application from the AseptoRay Company to treat pasteurized milk with UV at 200 to 300 nm using a turbulent flow regime. The treated milk must be free from microbial contamination and will be labeled according to Israeli regulation as "UV-treated" and will be subjected to any changes in the Israeli regulation. In case of increase of vitamin D3 in the milk, it will be labeled as "Vitamin D content was produced by UV treatment" or similar statement. The manufacturer is responsible for the product safety and quality.

Conclusions

Growing interest and fast spreading of UV technology in food production and processing around the globe dictates a need for acceleration of regulatory approvals, harmonization and globalization of regulations. There are several UV-treated products – such as juice products, raw and pasteurized milk, mushrooms, bread and bakery yeasts – that received regulatory approvals and can be sold around the globe. The EU, Canada, Australia and New Zealand have broadly similar approaches in the regulation of novel foods. Pre-market safety assessment is required before the UV-treated foods can be sold to consumers in the US. However, the identification of these foods, the form of pre-market assessment, the level of regulatory oversight and the legislated powers of regulators do vary between countries. Understanding the regulations for each country will assist equipment manufacturers in getting their products and technology on markets faster and at the lower costs. ■

References

EFSA, 2016. Safety of UV-treated milk as a novel food pursuant to Regulation (EC) No 258/97. http://www.efsa.europa.eu/en/efsajournal/pub/4370. EFSA Journal 2016;14(1):4370

EFSA. 2018. EU authorized list of UV treated Novel Foods https://ec.europa.eu/food/safety/novel_food/authorisations/list_authorisations_en

Health Canada. 2004. Ultraviolet light treatment of apple juice/cider using the CiderSure 3500.Novel Food Information. http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/dec85_rev_nl3_e.html. Accessed Feb. 29, 2008.

REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015.

U.S. Food and Drug Administration. 2001. 21 CFR Part 179. Irradiation in the production, processing and handling of food. Fed. Regist. 65: 71056-71058.

U.S. Department of Health and Human Services, 2015 Public Health Service.

Food and Drug Administration. The Grade "A" Pasteurized Milk Ordinance (PMO) 2009. 182-184.

U.S. Food and Drug Administration. 2012. 21 CFR part 172. § 172.381 Vitamin D2 baker's yeast. Federal Register /Vol. 77, No. 168 / Wednesday, August 29, 2012 /Rules and Regulations 52229. Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D2 Baker's Yeast.