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January 4, 2021

ELECTRONIC MAIL

NEVADA CANNABIS COMPLIANCE BOARD
555 E. Washington Avenue, Suite 4100
Las Vegas, Nevada 89101
Electronic Mail: regulations@ccb.nv.gov

Re: **JANUARY 19, 2021 WORKSHOP ON REGULATION 12.065**;
Comments of Ziel Equipment, Sales & Services, Inc.

Dear Sir or Madam:

We represent Ziel Equipment, Sales & Services, Inc. ("**Ziel**" or the "**Company**"). The purpose of this letter is to provide the Company's written comments on Regulation 12.065, which will be the subject of the Nevada Cannabis Compliance Board's ("**CCB**") workshop on January 19, 2021.

IDENTITY AND INTEREST OF THE COMMENTER

Ziel is a leading developer of Radio Frequency ("**RF**") equipment for the reduction of microbial pathogens, (ziel.com). The food and cannabis industries across North America, Europe, South America, and Australia utilize RF technology to safely remediate products intended for human consumption or ingestion.

Ziel has developed and designed the APEX branded line of RF equipment for microbial pathogen reduction in food and cannabis with its strategic manufacturing partner STALAM, the world's largest manufacturer of RF devices with more than 2,200 RF units deployed globally over more than 40 years (Stalam.com). APEX devices are approved for commercial use to pasteurize almonds, cashews, macadamias, sesame and chia seeds with installations in the United States, Mexico, Chile, and Australia. Beginning in 2016, Ziel also began working with licensed cultivators to apply RF treatment to cannabis. By utilizing Ziel's established and reliable RF pasteurization technology, cannabis cultivators and producers are able to achieve up to 99.99% reduction (also known as a "**4-log reduction**") in bacterial and fungal pathogens. While Ziel's technology is intended to supplement good manufacturing practices, APEX devices help cannabis licensees ensure that they are providing a safe product that meets the highest quality standards for the consumer. Moreover, APEX devices allow operators to satisfy these standards through a method that is compatible with the requirements for organic certification.

The Company maintains its headquarters in San Francisco, California, with an additional location in Fresno, California. Communications regarding these comments should be addressed to:

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SUMMARY OF COMMENTS

CCB Regulation 12.065 requires that any cannabis or cannabis product treated with "radiation" be labeled with a notice advising that the product has been "treated with irradiation." This regulation further requires that the label also include the Radura symbol "as used by the U.S. Food and Drug Administration." CCB personnel have advised that this labeling requirement applies to products treated with ionizing radiation as well as products treated with non-ionizing radiation, or RF.[1] Regulation 12.065 should be amended to provide that cannabis and products containing cannabis treated with *ionizing* radiation must be labeled with symbol requirement, consistent with federal law.

Food treated with ionizing radiation must be labeled in accordance with U.S. Food and Drug Administration ("**FDA**") regulations because "the ability to reliably differentiate between irradiated and non-irradiated foods or ingredients is in the interest of government agencies, food processors, and consumers."[2] Importantly, the FDA *does not* require special labeling or the use of the Radura symbol for products treated with non-ionizing radiation like RF. Similarly, Ziel is not aware of *any* state or country that requires food or cannabis treated with non-ionizing RF to carry a radiation notice label or utilize the Radura symbol. Moreover, the labeling and Radura symbol requirements are inconsistent with federal law and mislead consumers about the distinct methods used to remediate harmful pathogens and the risks associated with each of those processes. The amendment to Regulation 12.065 proposed herein resolves this conflict and creates a labeling regulation that mirrors the FDA's requirements and is grounded in the well-

[1] RF technology treats cannabis with non-ionizing radiation to safely remediate microbes or other potentially harmful pathogens.

[2] Kim M. Morehouse and Vanee Komolprasert, *Irradiation of Food and Packaging*, ACS Symposium Series 875, Chapter 1 (2004) *available at* https://www.fda.gov/food/irradiation-food-packaging/overview-irradiation-food-and-packaging. Included here as Exhibit 1.

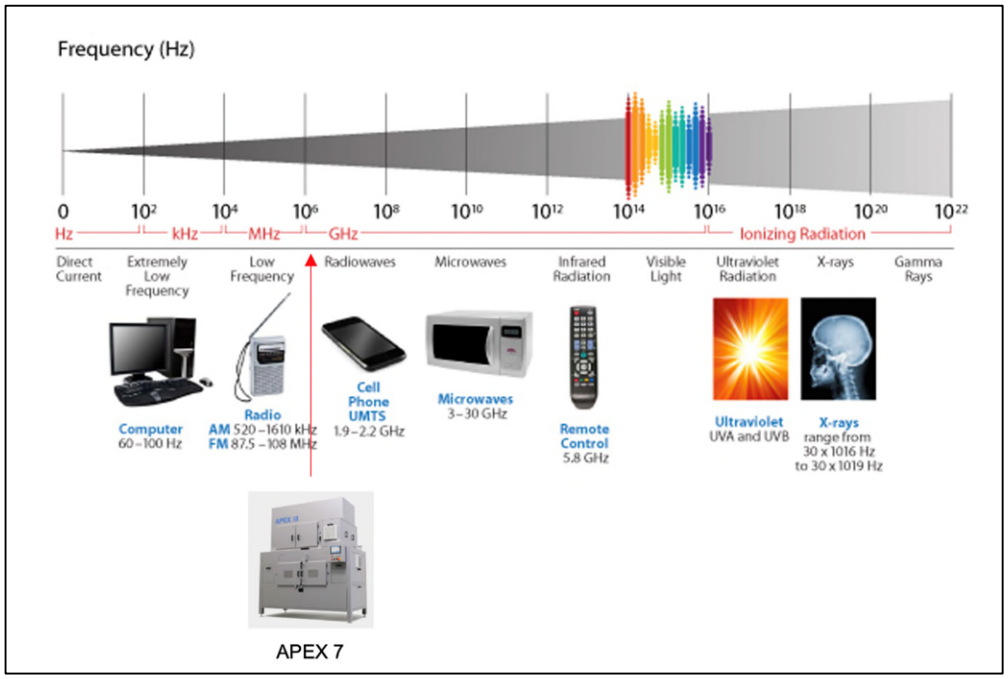
established scientific distinctions between ionizing and non-ionizing radiation. This proposed amendment advances public health by empowering consumers to make informed choices about their health and the products they ingest.

DISCUSSION AND RECOMMENDATION

1. Non-Ionizing RF Versus Ionizing Radiation

Electromagnetic waves transmit energy through space. Energy transmitted via these waves is referred to as electromagnetic radiation. Electromagnetic waves have a very wide spectrum (range of frequencies), with low frequency waves having longer wavelengths and high frequency waves having ultra-short wavelengths. For all practical purposes the electromagnetic radiation, based on their frequencies, are differentiated as non-ionizing radiation and ionizing radiation. The difference between these two types of radiation is based on the amount of energy emitted. Ionizing radiation emits enough energy to remove tightly bound electrons from an atom thus creating ions (*i.e.*, atoms with a charge). Non-ionizing radiation does not have sufficient energy to cause ionization. Examples of ionizing radiation include gamma rays, x-rays, and electron beam radiation. Non-ionizing radiation includes microwaves and RF, which emits even less energy than microwaves.

The Electromagnetic Spectrum & Real-world Applications (Source: National Institutes of Health)



Frequency of Apex shown on frequency spectrum from NIH

As shown on the above image, Ziel's RF technology is on the non-ionizing radiation spectrum. This technology pasteurizes food and cannabis through a thermal process. RF heating in APEX devices works by placing the cannabis in an electromagnetic field at 27.12MHz. This process exposes the dipoles (molecules with separated positive and negative charges, e.g., water) to an oscillating electromagnetic field, causing the dipoles to continually align themselves with the field. This continuous rotation and friction of the dipoles and molecules generates heat. Notably, RF technology *does not* involve the use of any hazardous substances regulated by the State of Nevada under Chapter 459 of the Nevada Revised Statutes ("**NRS**") or Nevada Administrative Code ("**NAC**"). Indeed, the independent organic certification organization EcoCert[3] has determined that cannabis treated with RF is consistent with standards for organic certification. Almonds pasteurized with Ziel's APEX devices have also received USDA organic certification.

Ionizing radiation is also a method utilized to treat cannabis, and the FDA allows the use of ionizing radiation on food in *limited* circumstances. Because of the energy emitted by ionizing radiation, this method has the potential to produce a chemically unstable state in the material at which it is directed. Accordingly, FDA regulations establish the food products permitted to be irradiated, as well as other conditions of use such as the purpose of irradiation, the maximum absorbed dose, and labeling requirements.[4] Nevada also recognizes the inherent risks associated with equipment that generates ionizing radiation. Unlike Ziel's APEX device, cannabis treatment devices utilizing ionizing radiation are regulated under the state of Nevada's Radiation Control Program and require certification from the Nevada Division of Public and Behavioral Health.[5]

2. No State or Federal Agency Requires Radura Labeling for Non-Ionizing RF

Given the fundamental differences between ionizing radiation and non-ionizing RF, as well as the different risks associated each type of radiation, the FDA and other federal and state regulatory authorities have developed distinct regulatory requirements for ionizing and non-ionizing radiation. Most notably, food treated with ionizing radiation must be labeled in accordance with FDA regulations because "the ability to reliably differentiate between irradiated

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[3] EcoCert is one of the largest organic certification organizations in the world and conducts inspections in more than 80 countries for compliance with 150+ standards in the food, farming, forestry, textiles, cosmetics and eco-products sectors.

[4] *See generally*, 21 C.F.R. Part 179.

[5] *See* NEV. ADMIN. CODE § 459.150.

and non-irradiated foods or ingredients is in the interest of government agencies, food processors, and consumers."[6]

> As explained by the FDA in a set of frequently asked questions:
>
> **Do foods have to be labeled indicating they have been treated with irradiation?**
>
> Labeling is required when the food product has been treated with ionizing radiation in accordance with 21 CFR 179.26. As a condition of use for ionizing radiation (i.e., gamma rays, x-rays, or e-beam sources), the treated food product must be labeled with the radura symbol and with the statement "treated with radiation" or "treated by irradiation." ***This labeling requirement does not apply to the treatment of foods with non-ionizing radiation***. (See applicable provision in 21 CFR 179.26)[7]

Other national and state regulatory agencies have similarly concluded that non-ionizing RF technology does not merit the same level of regulatory scrutiny as ionizing radiation. None of the U.S. states or countries where Radio Frequency devices are used require food or cannabis products treated with the devices to bear a radiation or Radura symbol label. Any decision by the CCB to apply such a requirement to cannabis treated with RF runs counter to the weight of the scientific studies, data and conclusions of other public health regulatory agencies.

3. Recommended Amendment to Regulation 12.065

Different cannabis treatment methods should be assessed individually and evaluated according to the unique risks associated with each process. The FDA has developed a comprehensive regulatory structure for food additives, including ionizing and non-ionizing radiation, founded on decades of scientific research and data. Based on this data, the FDA has concluded that products treated with *ionizing* radiation warrant special labeling, while products treated with *non-ionizing* radiation do not.[8] While cannabis is not itself a "food," Nevada cannabis licensees incorporate cannabis into products intended for human inhalation and consumption. Accordingly, ensuring the safety of cannabis sold by Nevada licensees to consumers is a fundamental and relevant area of concern for the CCB,[9] and it is appropriate to look to the

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[6] Kim M. Morehouse and Vanee Komolprasert, *Irradiation of Food and Packaging*, ACS Symposium Series 875, Chapter 1 (2004) *available at* https://www.fda.gov/food/irradiation-food-packaging/overview-irradiation-food-and-packaging. Included here as Exhibit 1.

[7] FDA, Understanding Food Irradiation: What Industry Needs to Know, https://www.fda.gov/food/irradiation-food-packaging/understanding-food-irradiation-what-industry-needs-know (emphasis added).

[8] *See* 21 C.F.R. § 179.26.

[9] *See* NEV. REV. STAT. § 678A.005(4).

approach utilized by the FDA and other public health agencies in addressing the use of radiation on food.[10]

CCB labeling regulations related to radiation treatment should be consistent with FDA labeling requirements, which are premised on decades of data considering the potential impact of ionizing and non-ionizing radiation on public health. The scientific consensus is that ionizing radiation merits more rigorous review and labeling. The public health concerns underpinning the FDA's decision to require labeling for ionizing radiation simply do not apply to RF technology. Requiring radiation labeling for products treated with RF incorrectly implies equivalency between ionizing and non-ionizing radiation and harms Ziel's ability to accurately market its APEX devices in Nevada. Applying a misleading radiation label on products treated with RF harms Ziel's business and is not supported by any established public health concerns about using RF to treat food or cannabis.[11]

Furthermore, any requirement to use the Radura symbol should also be consistent with federal law. The Radura symbol has an established and commonly understood meaning. For more than three decades, the Radura symbol has been applied to food products treated with *ionizing* radiation. Requiring the Radura symbol on cannabis treated with RF and other non-ionizing radiation inappropriately alters the purpose of this symbol and undermines its established meaning and the intent behind its use. Utilizing the Radura symbol outside the context of ionizing radiation misleads and confuses consumers about the meaning of this symbol and deprives consumers of "the ability to reliably differentiate between irradiated and non-irradiated" products.

For the reasons explained herein, the following proposed amendment to Regulation 12.065 achieves those goals:

> **12.065 Cannabis treated with radiation.** If any cannabis or cannabis product has been treated with ***ionizing*** radiation at any time, any and all packaging of the irradiated cannabis or cannabis product must include labeling that contains the following statement: "~~NOTICE:~~ This product contains ingredients that have been

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[10] Suggestions that cannabis and edible cannabis products are more akin to over-the-counter ("**OTC**") drugs than food are misplaced. Unlike cannabis and food products, OTC drugs are subject to a number of rigorous additional safety and efficacy requirements. Cannabis and food products do not receive this same level of regulatory scrutiny and scientific review. *See, generally*, FDA, *Drug Applications for Over-the-Counter (OTC) Drugs*, https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs.

[11] *See* Flamingo Paradise Gaming, LLC v. Chanos, 125 Nev. 502, 520, 217 P.3d 546, 558 (2009) (classifications of businesses must not be arbitrary and must bear a rational relationship to the articulated purpose).

treated with ~~ir~~radiation" in bold lettering, along with the Radura symbol ***identified in 21 C.F.R. § 179.26*** ~~as used by the U.S. Food and Drug Administration~~.

These amendments mirror the FDA's requirements for radiation labeling and require the same label language established in 21 C.F.R. § 179.26. By creating consistency with existing federal requirements, this amendment will allow consumers to identify ionize radiated cannabis products in the same manner as ionize radiated food products. Eliminating any labeling requirement for ionizing radiation deprives Nevada consumers of the ability to make educated and informed decisions about their health and strips consumers of their right to choose to avoid irradiated cannabis.

Ziel respectfully recommends that the CCB revise Regulation 12.065 as set forth in this letter. We look forward to participating in the workshop on January 19th and appreciate this opportunity to work with the CCB to bring clarity and consistency to the regulations addressing cannabis labeling. Please advise if you have any questions or require additional information.

Sincerely,

FENNEMORE CRAIG, P.C.

/s/ *Katherine Hoffman*
Katherine L. Hoffman

Enclosures: Exhibit 1

Exhibit 1

Exhibit 1

Overview of Irradiation of Food and Packaging

With Permission from ACS:
ACS Symposium Series 875
Irradiation of Food and Packaging
2004, Chapter 1, Pages 1-11.

Kim M. Morehouse[*] and Vanee Komolprasert[**]

The information and conclusions presented in this book chapter do not represent new Agency policy nor do they imply an imminent change in existing policy.

Ionizing radiation can extend shelf life and improve the quality and safety of foods. National and international organizations and regulatory agencies have concluded that irradiated food is safe and wholesome. A brief background of the food irradiation issues leading to these conclusions is given. Despite its limited use in the past, use of food irradiation is increasing as consumers are beginning to appreciate the benefits of irradiated food. Interest in the use of food irradiation increased following the 1997 US Food and Drug Administration approval of irradiation for pathogen control in unprocessed red meat and meat products. This approval led to numerous studies on a variety of food irradiation applications. Since food is usually prepackaged prior to irradiation, the possibility of radiolytic products being released from packaging materials into food requires a safety evaluation. Therefore, the use of these packaging materials is subject to regulatory review and approval prior to their use.

I. Ionizing Radiation

Radiation for the treatment of food is achieved through the application of gamma rays (with Co-60 or Cesium-137 radioisotope), electron beams (high energy of up to 10 MeV), or X-rays (high energy of up to 5 MeV). Radiation principles explain how the gamma rays, e-beams and X-rays interact with matter. These interactions result in the formation of energetic electrons at random throughout the matter, which cause the formation of energetic molecular ions. These ions may be subject to electron capture and dissociation, as well as rapid rearrangement through ion-molecule reactions, or they may dissociate with time depending on the complexity of the molecular ion. Effects of radiation on matter depend on the type of the radiation and its energy level, as well as the composition, physical state, temperature and the atmospheric environment of the absorbing material. The chemical changes in matter can occur via primary radiolysis effects, which occur as a result of the adsorption of the energy by the absorbing matter, or via

secondary effects, which occur as a result of the high reactivity of the free radicals and excited ions produced as a result of the primary effects. These highly reactive intermediates can undergo a variety of reactions leading to stable chemical products. In general, it is these chemical products that are detected and referred to as radiolysis products. For living things, these chemical changes can ultimately have biological consequences in the case where the target materials include living organisms.

II. Irradiation of Food

The use of ionizing radiation for food preservation began in the early 1920s. Later, during the 1950s-1960s, the US Army conducted research into low-dose and high-dose irradiation of military rations [(1)]. These experiments prompted similar studies in other countries, and the interest in food irradiation has grown ever since. With proper application, irradiation can be an effective means of eliminating and/or reducing microbial and insect infestations along with the foodborne diseases they induce, thereby improving the safety of many foods as well as extending shelf life.

1. Safety for Consumption of Irradiated Foods

The safety of irradiated foods for human consumption has been questioned because ionizing radiation can lead to chemical changes. The wholesomeness of irradiated foods has, therefore, been the subject of considerable national and international research, which has been reviewed and evaluated by joint expert committees of the International Atomic Energy Agency (IAEA), the World Health Organization (WHO), and the Food and Agricultural Organization (FAO) of the United Nations. These expert groups have uniformly concluded that the food irradiation process does not present any enhanced toxicological, microbiological, or nutritional hazard beyond those brought about by conventional food processing techniques [(2)]. These organizations, along with the Codex Alimentarius Commission and numerous regulatory agencies, have endorsed the safety of food irradiation, providing that Good Manufacturing Practices (GMPs) and Good Irradiation Practices (GIPs) are used. This has resulted in the approval of irradiated foods by many national governments, although not all of these approvals have led to use of irradiation in the marketplace.

2. Identification and Detection of Irradiated Foods

The ability to reliably differentiate between irradiated and non-irradiated foods or ingredients is in the interest of government agencies, food processors, and consumers. In addition, detection tests can be used to enforce the labeling requirements (see below) for identifying irradiated foods. Labeling will enhance consumer confidence by providing assurance of the consumer's right to choose. Furthermore, the knowledge of radiation-induced chemical changes in food provides the scientific basis for the safety evaluation of the consumption of irradiated food [(3)].

Several detection methods have been subjected to interlaboratory collaborative studies including electron spin resonance (ESR), luminescence methods, physical methods, chemical methods, and biological methods ([4], [5]). ESR measures the concentration of free radicals in irradiated matter. The luminescence methods measure the presence of excited molecules such as light emission upon heating material (thermoluminescence, TL). The physical methods are based on changes in physical properties of matter e.g. viscosity [(6)]. The chemical methods are based on measurement of radiolytic products, e.g., using gas chromatography (GC) to measure volatile radiolytic products such as alkanes, alkenes and 2-alkylcyclobutanones in fat-containing food, or to measure non-volatile compounds such as 6-ketocholesterol and o-tyrosine. The biological methods are based on measurements of changes in viable microorganisms or changes in plant germination as a result of irradiation. The most practical methods are ESR (for foods containing bones, shells, or other particles), TL (for foods containing mineral dust particles), and GC (for fat-containing food) [(7)]. Continuing efforts to develop detection methods are focusing on the DNA comet assay [(8, 9, 10, 11)], and the changes in protein molecular mass distribution measured by discontinuous SDS-polyacrylamide electrophoresis (SDS-PAGE) and quantified by laser scanning densitometry [(12)].

3. Labeling

Like other forms of processing, irradiation can affect the characteristics of food. Consumer choice mandates that irradiated food be adequately labeled and under the general labeling requirements, it is necessary that the food processor inform the consumer that food has been irradiated. Labeling of irradiated foods however, is undergoing reevaluation in the US. If whole foods have been irradiated, FDA requires that the label bear the radura symbol and the phrase "treated with radiation" or "treated by irradiation." Yet, if irradiated ingredients are added to foods that have not been irradiated, no special labeling is required on retail packages. Special labeling is required for foods not yet in the retail market that may undergo further processing in order to ensure that foods are not irradiated multiple times. In this regulation, FDA advises that other truthful statements, such as the reason for irradiating the food, may be included [(13)].

Because the words "radiation" and "irradiation" may have negative connotations, the labeling requirement has been viewed as an obstacle to consumer acceptance. Many in the food industry believe that an alternative wording, e.g. "electronically pasteurized," would be helpful. In 1997, Congress attempted to resolve this issues in two ways. First, it mandated that the FDA could not require print size on a label statement to be larger than that required for ingredients and second, it directed the FDA to reconsider the label requirement and to seek public comment on possible changes. The FDA had not in fact mandated a type size but did require a statement that would be "prominent and conspicuous." In response to this congressional directive, the FDA published an Advance Notice of Proposed Rulemaking (ANPR) in 1999 seeking public comment on the labeling of irradiated food, particularly on whether the current label may be misleading by implying a warning and invited suggestions of alternative labeling that would inform consumers without improperly alarming them. Thousands of comments were received, with a

large number compiled into a categorical database for further examination by the CFSAN's Office of Nutritional Products, Labeling, and Dietary Supplements. This leading office for labeling policy has not yet determined whether there will be a change in labeling requirements.

4. Consumer Acceptance

Consumer advocacy groups have expressed their perception that consumers do not want irradiated food products [14]. Consumer acceptance is based on a complex decision-making process weighing the perceived risks and benefits of food irradiation compared to the existing alternatives. The acceptance is related to the needs, beliefs and attitudes of the individual consumer and the nature of the economic, political and social environment in which food choices take place [15]. Even though the benefits and safety of food irradiation have been scientifically documented, public awareness of such information has been limited. Consumers consequently reject food irradiation due to consumer confusion over what food irradiation is [16]. Lack of knowledge of food irradiation and how it works generates fear that irradiated food is radioactive. Another concern is that irradiated food contains free radicals and radiolytic products. Food and health professionals could take an instrumental role in educating the consumer about the advantages and limitations of food irradiation and thus facilitate consumer acceptance of irradiated food products [17]. The advantages of food irradiation (process safety, reduction of chemical use, and improved quality and safety of foods) over other food preservation techniques such as canning, freezing, or chemical treatment far outweigh the drawbacks - a slight reduction in nutrients (vitamins) [18].

Though the levels of consumer acceptance vary among countries, consumers in North America are rapidly increasing their acceptance of irradiated foods [19, 20]. Consumer education has resulted in an appreciation of the benefits of irradiated foods. Survey results indicated that consumers develop a positive attitude toward food irradiation after receiving information on product benefits; safety and wholesomeness; environmental safety issues; and endorsement by recognized health authorities. A positive response to irradiated foods can be enhanced if the consumer is allowed to compare irradiated and nonirradiated foods side by side. Increasing numbers of consumers are willing to purchase irradiated food because they prefer the advantages irradiation processing provides. Further promotion of irradiated food has been achieved by marketing tests in various countries [21].

5. Food Irradiation Regulations

Governmental regulation of irradiation of food varies considerably from country to country. Where irradiation is permitted, regulations are needed to license the plant, radioactive materials or process; to ensure radiation safety, environmental security, and general health and safety during plant operation; and to provide for safe disposal of any hazardous materials at the end of the operation. Each country has adopted its own unique approach to the introduction, approval, and regulation of the technology for food production. Although there is an agreement among

international committee experts that food is safe and wholesome for consumption after irradiation up to a dose of 10 kGy, there is no approval for irradiation of all foods up to this limit in any country. Most countries approve food irradiation on a case-by-case basis.

In the US, the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1958 places food irradiation under the food additive regulations. It is because of this act that the FDA regulates food irradiation as a food additive and not a food process. Congress explicitly defined a source of radiation as a food additive when it stated that "Sources of radiation (including radioactive isotopes, particle accelerators, and X-ray machines) intended for use in processing food are included in the term 'food additive' as defined in this legislation." The Food Additives Amendment states that a food is adulterated (thus it cannot be marketed legally) if it has been intentionally irradiated, unless the irradiation is carried out in conformity with a regulation prescribing safe conditions of use. For clarification, the statute does not define the form of energy or the process as an additive, but rather the equipment used to irradiate the food as it may affect the characteristics of the food.

A food additive regulation, in general, may be established or amended in one of two ways: by the FDA's own initiative to propose a regulation, or in response to petitions filed by proponents of an additive's use. A petition, the more common method of regulatory alteration, is a scientific and legal document that forms the basis for the administrative record under-pinning the Agency's decision. This decision must be based on an explicit, complete, and unassailable record. The record must contain adequate information to demonstrate that the additive is safe under all conditions of use that would be permitted. When authorized, the regulation is granted generically; anyone can use the additive in conformance with the specified conditions of use permitted under the regulation.

The Food Additives Amendment does not exempt the foods that are regulated by other authorities. Meat or meat food products are subject to the Federal Meat Inspection Act. Poultry products are subject to the Poultry Products Inspection Act. Irradiated meat and poultry are then subject to the requirements of the Acts, which are administered by the Food Safety and Inspection Service (FSIS) of the Department of Agriculture (USDA). In addition, the USDA's Animal and Plant Health Inspection Service (APHIS) administers the law that quarantines certain crops from transport into the country. Irradiation is one quarantine treatment method that can be used with some foods to protect US agriculture from the import of exotic pests; therefore, such a use must also meet the requirements of APHIS.

At the recent international conference on ensuring the safety and quality of food through radiation processing [(22)], it was evident that food irradiation regulations in several countries have been or are being harmonized through compliance with the Codex General Standard for Irradiated Foods and the relevant recommendations of the International Consultative Group on Food Irradiation (ICGFI). The participants of the Conference agreed that national regulations need not stipulate maximum dose limits from a toxicological and nutritional perspective under

good manufacturing and irradiation practices. The regulations should focus on the production of microbiologically safe products that meet the stated technical purposes, should provide appropriate flexibility for processors, and should be in conformity with Codex as well as the World Trade Organization (WTO) agreement on the sanitary and phytosanitary measures. These measures are required to protect human, animal and plant health and must be based on the standards and recommendations of the recognized international authorities including the Codex Alimentarius Commission.

6. Emerging Food Irradiation Applications

Irradiation is an effective form of food preservation that extends the shelf life of the food and therefore reduces the spoilage of food. The process also benefits the consumer by reducing the risk of illnesses caused by foodborne diseases. Food irradiation may be achieved using low-dose, medium-dose, or high-dose levels of radiation. Low dose irradiation (< 2 kGy) is used to delay sprouting of vegetables and aging of fruits; medium dose (between 1 and 10 kGy) is used to reduce the levels of pathogenic organisms, similar to pasteurization; and high dose (>10 kGy) is used to achieve sterility of the product. Ahmed [23] reported that 37 countries have approved one or more items of irradiated food products for human consumption, and 25 countries have commercialized the irradiation process.

Since worldwide foodborne diseases are increasing and attempts to reduce them have been unsuccessful, the World Health Organization considers food irradiation important toward ensuring food safety and reducing food losses [24]. Irradiation can be a useful control measure in the production of several types of raw or minimally processed foods such as poultry, meat and meat products, fish, seafood, and fruits and vegetables [25]. The US sets an example for the increase in permitted food irradiation uses as exemplified by the 1997 FDA approval of the irradiation of unprocessed red meat and meat products [26] and the 1999 FSIS/USDA approval of plant facilities [27]. The list of FDA-approved, irradiated foods for pathogen control has recently been amended to include fresh shell eggs [28] and seeds for sprouting [29]. There is continued interest in using this technology, as suggested by the pending petition submitted by the Food Irradiation Coalition to amend the permitted use of ionizing radiation to treat a variety of human foods to a maximum irradiation dose of 4.5 kGy for non-frozen and non-dry products, and 10.0 kGy for frozen or dry products [30].

As the outbreaks of foodborne pathogens continue, an increase of food irradiation research also continues. Irradiation is being considered as a method to ensure the hygienic quality of food, as a legitimate sanitary and phytosanitary treatment of food and agricultural commodities, as a quarantine treatment of fresh horticultural commodities, and as a substitute for fumigants in Asian countries and the USA. Low-dose and medium-dose irradiation applications are currently being investigated with food products [31], but the use of irradiation in combination with other processes [32], and high-dose food irradiations are beginning to emerge [33]. Strategies for food irradiation continue to evolve and are updated periodically [34, 35, 36, 37, 38, 39, 40, 41, 42].

III. Irradiation of Food Packaging

To prevent recontamination, food is usually packaged prior to irradiation. Therefore, the effects of radiation on the food-packaging materials must also be considered when evaluating the safety of irradiated foods. Irradiation can cause changes to the packaging that might affect integrity as a barrier to microbial contamination. Irradiation might also produce radiolysis products that could migrate into food, affecting odor, taste, and possibly the safety of the food.

Many food-packaging materials are made of polymers. Radiation effects on polymers are the result of competing crosslinking or chain scission, i.e., degradation, reactions. Crosslinking is the joining of two polymer chains via a bridge-type chemical bond, leading to an increase in molecular weight. Crosslinking in many plastics and rubber is essentially a curing process that modifies the physical and mechanical properties of the polymer. Radiation-induced crosslinking dominates under vacuum or an inert atmosphere. Chain scission, on the other hand, is the fragmentation of polymer chains, which leads to a decrease in average molecular weight and dominates during irradiation in the presence of oxygen or air. Both reactions are assumed to be random and are generally proportional to dose, as well as dependent on dose rate and the oxygen content of the atmosphere in which the polymer is irradiated. Radiation does not affect all the properties of a polymer to the same degree. Therefore, when selecting a polymer for a particular application, the effect of radiation on the overall stability of the material must be considered.

1. Regulatory Requirements-Chemistry Considerations

Both crosslinking and chain scission reactions can occur during irradiation of food-packaging materials. If crosslinking dominates, the migration of packaging components is not expected to increase and, in fact, is likely to decrease compared to that observed for unirradiated packaging. In contrast, if chain scission dominates, lower molecular weight molecules are formed, and these potentially mobile molecules may migrate into food. The safety of these compounds must be evaluated because, in the U.S., all commercial facilities that irradiate food and other bulk materials such as medical supplies are currently irradiating in air. In addition, the migration of low-molecular-weight radiolysis products into food could affect the odor and taste of the irradiated food.

In the U.S., components of packaging used to hold food during irradiation must undergo premarket approval by the FDA and may be used only if they comply with the regulations in 21 CFR 179.45 or are the subject of an effective food contact notification or Threshold of Regulation exemption. Regardless of the review channel, chemistry data supporting the identity of and human dietary exposure to a new food-contact substance intended to be used during the irradiation of prepackaged food, as well as its radiolysis products, must be submitted to the

FDA. If the packaging material is already approved for unirradiated uses, comparisons can be made to an unirradiated control to determine exposures that would result from the new irradiated use.

2. Evaluation of Irradiated Food-Packaging Materials

Studies of the effects of radiation on polymeric food-packaging materials have been limited compared to those for medical devices and pharmaceutical products. Ionizing radiation for sterilization of medical devices and pharmaceuticals provides advantages over traditional heat and chemical sterilization methods. Radiation sterilization has been successfully applied to medical products and their packaging, which is made of both thermoplastics and thermosets and includes polyesters, polystyrenes, polyethylenes, elastomers, Nylon, acrylics, and cellulose and their copolymers. Since several thermoplastics are used with both food and medical devices, similar radiation effects on these polymers are anticipated. However, the typical dose used on medical devices is 25 kGy [(43)], whereas a dose less than 10 kGy is usually applied to food. This means that the levels of radiolysis products should be proportionately lower in food-packaging polymers as compared to medical devices. The observation of radiation-induced alterations in medical products focuses mainly on the physical and performance changes of the devices. Therefore, there are limited quantitative chemical data available to aid in the analysis of the migration of radiolysis products from polymers into food. Additional investigations are needed to evaluate the suitability of modern food- packaging materials and adjuvants intended for use during the irradiation of prepackaged food.

Most of the packaging materials listed in 21 CFR 179.45 are films and homogeneous structures that were approved in the 1960s. These materials do not fully meet today's needs, as modern materials are more desirable to the food industry. Many modern materials have not yet been evaluated by FDA. These materials may contain adjuvants that prevent undesirable reactions from occurring during polymer processing and subsequent irradiation. Adjuvants may be added to minimize the loss of chemical and physical properties, e.g., antioxidants are added to polymers to prevent the polymer from oxidizing, UV stabilizers are added to prevent discoloration of polymers when exposed to light, and release agents are added to enable high-speed production. Adjuvants are especially prone to degradation upon irradiation because they degrade preferentially over the polymer. Therefore, the radiation-induced degradation of various polymer adjuvants, including antioxidants, plasticizers, coatings, release agents, and stabilizers must be evaluated as well [(44, 45)].

References

(1) Diehl, J.F. Safety of Irradiated Foods, Marcel Dekker, Inc., New York, **1995**, pp 1.

(2) Diehl, J.F. Safety of Irradiated Foods, Marcel Dekker, Inc., New York, **1995**, pp 283-289.

(3) Diehl, J.F. *Safety of Irradiated Foods*, Marcel Dekker, Inc., New York, **1995**, 144.

(4) Haire, D.L; Chen, G., Janzen, E.G.; Fraser, L.; Lynch, J.A. *Food Res. Int.* **1997**, *30,* 249-264.

(5) Delincée, H. *Trends in Food Sci. Tech.*. **1998**, *9,* 73-82.

(6) Chabane, S.; Pouliquen-Sonaglia, I.; Raffi, J. *Canadian J. Physiology and Pharmacology*.**2001**, *79,* 103-108.

(7) Cerda, H.; Delincée, H.; Haine, H.; Rupp, H. *Mutation Research/Fundamental and Molecular Mechanisms of Mutagenesis*, **1997**, *375,* 167-181.

(8) Marchoni, E.; Horavatovich, P.; ndiaye, B.; Miesch, M.; Hasselmann, C. *Rad. Phys. Chem.* **2002**, *63,* 447-450.

(9) Marin-Huachaca, N.S.; Lamy-Freund, M.T.; Mancini-Filho, J.; Delincée, H.; Villavicencio, A.C.H., *Rad. Phys. Chem.* **2002**, *63,* 419-422.

(10) Barros, A.C., Freund, M.T.L.; Villavicencio, A.C.H.; Delincée, H.; Arthur, V. *Rad. Phys. Chem.* **2002**, *63,* 423-426.

(11) Delincée, H. *Rad. Phys. Chem.* **2002**, *Vol. 63,* 443-446.

(12) NiÄ‡iforoviÄ‡, A.; RadojÄï¿½iÄ‡, MilosavljeviÄ‡, B.H. *Rad. Phys. Chem.* **2001**, *55,* 731-735.

(13) Morehouse, K.M. *Rad. Phys. Chem.* **2002**, *63*, 281-284.

(14) Satin, M. *Food Irradiation: A Guidebook;* Technomic Publishing Co., Inc., 1993, pp 95-151.

(15) Henson, S. *Food Policy*. **1995**, *20*, 111-127.

(16) Thomas, P.A. Part C. *Rad. Phys. Chem.* **1990**, *35*, 342-344.

(17) Weaver, V.M.; Marcotte, M.L. *Int. J. Rad. App. Instr. Part C. Rad. Phys. Chem.* **1988**, *31*, 229-234.

(18) Fox, J.A. *Food Tech.* **2002**, *56*, 34-37.

(19) Kunstadt, P. *Int. J. Rad. App. Instr. Part C. Rad. Phys. Chem.* **1990**, *35*, 248-252.

(20) Marcotte, M; Kunstadt, P. *Rad. Phys. Chem.* **1993**, *42*, 307-311.

(21) Frenzen, P.D.; DeBess, E.E.; Hechemy, K.E.; Kassenborg, H.; Kennedy, M.; McCombs, K.; McNees, A.; FoodNet Working Group. *J. Food Prot.* **2001**, *64*, 2020-2026.

(22) Summary of the conference and the conclusions. In Irradiation For Food Safety and Quality, Proceedings of FAO/IAEA/WHO international conference on ensuring the safety and quality of food through radiation processing. Eds: Loaharanu, P.; Thomas, P. 2001, Technomic Publishing Co., Inc., v-xv.

(23) Ahmed, M. *Rad. Phys. Chem.* **1993**, *42*, 245-251.

(24) Diehl, J.F. *Safety of Irradiated Foods;* Marcel Dekker, Inc., New York, 1995, pp 291-293.

(25) Molins, R.A.; Motarjemi, Y.; Käferstein, F.K. *Food Control.* **2001**, *12*, 347-356.

(26) Food and Drug Administration. *Final Rule*, Federal Register, 1997, 62(232), 64107-64121.

(27) Food Safety and Inspection Service. *Final Rule*, Federal Register, 1999, Vol. 64, 72150-72166.

(28) Food and Drug Administration. *Final Rule*, Federal Register, 2000, 65(141), 45280-45282.

(29) Food and Drug Administration. *Final Rule*, Federal Register, 2000, 65(210), 64605-64607.

(30) Food and Drug Administration. *Notice*, Federal Register, 2000, 65(3), 493.

(31) Urbain, W.M. *Food Irradiation;* Academic Press, Inc., New York, 1986, pp 124-236.

(32) Farkas, J.; Adrassy, E., Nanati, D.; Horti, K.; Meszaros, L; Reichart, O. In *Combination Processes For Food Irradiation*, the proceedings of the final research co-ordination meeting of the co-ordinated research programme on irradiation in combination with other processes for improving food quality organized by the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture, IAEA, Vienna, 1998, 15-32.

(33) *High-Dose Irradiation: Wholesomeness of Food Irradiated with Dose above 10 kGy*, Report of Joint FAO/IAEA/WHO Study Group, WHO Technical Report Series 890, World Health Organization, 1999, 1-37.

(34) Derr, D.D.; Engel, R.E. *Rad. Phys. Chem.* **1993**, *42*, 289-296.

(35) Derr, D.D.; Engeljohn, D.L., Griffin, R.L. *Rad. Phys. Chem.***1995**, *46*, 681-688.

(36) Giddings, G. *Rad. Phys. Chem.* **1996**, *48*, 364-365.

(37) Derr, D.D. *Rad. Phys. Chem.* **1996**, *48*, 362-363.

(38) Neyssen, P.J.G. *Rad. Phys. Chem.* **2000**, *57*, 215 -217.

(39) Kalman, B.; Szikra, L.; Ferencz, P. *Rad. Phys. Chem.* **2000**, *57*, 281-283.

(40) Diehl, J.F. *Rad. Phys. Chem.* **2002**, *63*, 211-215.

(41) Ehlermann, D.A.E. *Rad. Phys. Chem.* **2002**, *63*, 277-279.

(42) Luckman, G.J. *Rad. Phys. Chem.* **2003**, *63*, 285-288.

(43) Burg, K.J.L.; Shalaby, S.W. In *Irradiation of Polymers: Fundamentals and Technological Applications;* Clough, R.L.; Shalaby, S.W., Eds.; ACS Symposium Series 620; American Chemical Society, Washington, DC, 1996, pp 240-245.

(44) Pauli, G.H., C.A. Takeguchi. *Food Rev. Int.* **1986**, *Vol. 2*, 79-107.

(45) Kuznesof, P.M. Irradiation of packaged foods: FDA perspectives on packaging materials. Paper presented at Engineering Foundation Conference on Advancing Food Technology with the Irradiation Process, 1987, November 15-20, Santa Barbara, California.

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