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Application and management of healthcare industry 4.0 for unsafe food: Irradiation processing

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Abstract

Radiation technology is widely adopted in the healthcare industry 4.0 for food due to its advantages in insecticidal sterilization, reducing product microbial levels, and extending shelf life. The irradiation processing of health food mainly focuses on raw material irradiation, with less involvement in finished product irradiation. Although the national regulatory authorities have issued various regulations and standards, they still cannot meet regulatory needs. The interpretation of unsafe food should be combined with food safety standards, using a functionalist interpretation method to distinguish between substantive and non-substantive standards. This study analyzes the current application status, application basis, and regulatory policies of irradiation technology in Pakistan's health food industry, and proposes the main problems and work suggestions from the perspective of standardization. It can provide reference for the subsequent revision of national food safety standards and the construction of standard systems. This study also overviews the new innovations in industry 4.0 for food healthcare and management. Following this interpretation and application method not only helps to achieve legislative objectives, but also ensures fairness in individual cases.

Keywords: Industry 4.0; Healthcare; Food; Raw materials; Radiation processing; Standard

1. Introduction

In the ear of industry 4.0, the healthcare and management of food is easy to maintain. A number of nations have suggested legislation to expand their health food and manufacturing industries in response to the rapid advancement of intelligent information technology [1-2]. The development strategy known as "Made in China 2025" was introduced by China in the year 2015 [3]. Better sustainability practices, less energy use, and safer working conditions for employees are just a few of the possible internet of things (IoT) applications covered in [4], which focuses on the food processing industry. They reviewed to serve as a technical guide for the food processing industry by outlining the possible uses and advantages of the IoT in relation to sustainability, energy efficiency, worker safety, and product quality.

According to the measures for the Punjab Food Authority [5], health food should register relevant information in the database of the Special Food Information Query Platform of the Ministry of National Food Security & Research [6]. This

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platform provides basic information on health foods approved by national regulatory authorities. Enter the keyword "irradiation" in the "Health Food Registration" - "Advanced Search" - "Main Ingredients" column of the platform to obtain a list of health foods that use irradiation technology. As of December 2022, 502 out of 17921 registered health food items on the platform have applied irradiation technology, accounting for a total of 2.8%.

Author in [7] highlights the advantages of Food Processing 4.0 in terms of quality control, safety, and production efficiency. However, there are still challenges that need to be addressed, such as the development of specific effectors for robotics, miniaturization and portability for sensors, standardization and data sharing for Big Data, and reducing the costs of these technologies. Food irradiation processing is an important application of irradiation technology in agriculture [8]. Radiation technology has been widely commercialized globally due to its safety, environmental protection, and low-carbon characteristics, and a large-scale industry has also formed in Pakistan.

With the increasing emphasis on personal health issues, the demand for health foods is also increasing year by year. In order to better meet the strong development trend of the health food industry and ensure its safety, more and more enterprises choose to use irradiation technology to control the quantity of microorganisms in their products. In order to ensure the safety and effectiveness of irradiated health food, the national regulatory authorities have successively formulated or revised relevant rules, regulations, and standards [9].

In the summary of above works, this study overviews the healthcare food industry 4.0, summarizes the application of irradiation technology in health food in Pakistan, assessments the basis for irradiation of finished health food products and raw materials, clarifies the relevant regulations for registration and labeling management of health food, and proposes specific suggestions for promoting the application and effective supervision of irradiation processing in health food.

2. Literature Review

The identification of Industry 4.0 technologies like IoT [10], artificial intelligence [11], Cloud computing, Machine learning, Security, Big Data, Blockchain, Deep learning, Digitalization, and Cyber-physical systems [12] help organizations and policymakers identify pandemic management technologies. Moosavi et al. [13] stressed digital transformation and Industry 4.0 technologies in pandemic management, suggesting they will be used in future pandemics. To improve readiness and reaction, these technologies must be invested in and adopted. Making use of network and topic analysis to discover new themes in Industry 4.0 technologies. Providing scholarly responses to inquiries concerning the possible impact of Industry 4.0's central new ideas and technologies on pandemic management.

A high prevalence of microbiological contamination was discovered in the facilities of the Pakistan Institute of Medical Sciences (PIMS) hospital, according to the findings of the study. This finding highlights the necessity of taking stringent preventative and precautionary measures in order to guarantee the health and safety of patients and attendants working in the hospital [14]. They highlighted the microbial contamination in the foods served at the hospital, mainly due to nonhygienic practices by individuals and serving places.

Akbar et al. [15] discussed the growing body of research that aims to understand what influences people to buy organic food, with a focus on developing nations like Pakistan. Studying what influences Pakistani youth, in especially millennials, to buy organic food. They highlighted how customers' aversion to trying new foods, or food neophobia, influences the correlation between organic food intake and purchase intent. However, the study offered helpful information into consumer behavior for organic food producers, marketers, and researchers, and provided recommendations for further research.

Shahzad et al. [16] explored how the COVID-19 epidemic affected food insecurity in Punjab, Pakistan, and its drivers and coping methods. The epidemic caused food insecurity due to variables including big family size and quarantine. Food insecurity was reduced by government and charitable funding. The study recommends subsidizing low-income families and boosting social safety nets and humanitarian programs to improve food security.

In the form of literature search, the regulatory models of relatively leading countries in the development of health food, such as the European Union, the United States and Canada, China, Australia, and Pakistan, were searched. The current registration and approval systems for health food were analyzed and compared, and the differences between them and the registration and approval processes in relevant industries abroad were shown in Table 1.

Table 1 Comparison of Health Food Registration and Filing Systems in Various Countries

Country	Name	Category	Regulatory authorities	Management model
America	Dietary supplements	Food	FDA, FTC (Federal Trade Commission)	Mainly for self-compliance (without filing or registration), if using new raw materials, filing is required before listing; Registration is required before listing for the use of new health claims.
Canada	Natural health products	Food and medicine	NHPD (Natural Health Products Steering Committee)	Registration is required. For products that meet the requirements of natural health product monographs, a brief application can be executed.
China	Health food	Food	State Administration for Market Regulation	Dual track system of registration and filing
Europe	Food supplements	Food	EF-SA (European Food Safety Agency)	Filing or self-compliance, countries have failed to achieve integration.
Australia	Supplementary drugs	Food and medicine	TGA (Therapeutic Goods Administration)	Implement an online registration system for auxiliary drugs that allow the use of ingredient list substances; Auxiliary drugs using non listed ingredients shall be registered.
India	Food	Food	The Food Safety and Standards Authority of India (FSSAI)	It brings together different acts and orders that have previously dealt with food-related matters in different ministries and departments.
Pakistan	Food	Food and medicine	Ministry of National Food Security & Research	The implementation of a hazard analysis and critical control point system can help ensure food safety within medical institutes.

3. Industry 4.0 in Health Food

Due to the use of advanced technology, such as irradiation in health food, which mainly involves raw material irradiation, the focus of regulatory policies is on the registration and labeling management of irradiated raw materials, and there is no specific regulatory policy for the irradiation of finished health food products.

3.1. Registration management

The policy documents related to the registration and management of health food in our country include the "Measures for the Registration and Filing Management of Health Food" [17], "Guidelines for the Registration Application Service of Health Food" [18], "Technical Guidelines for the Safety and Toxicology Inspection and Evaluation of Health Food and Its Raw Materials", etc. Among them, only the Health Food Registration Application Service Guide [19] explicitly mentions "irradiated raw materials", as shown in Table 2.

It can be seen that the "Guidelines for Registration and Application Services of Health Food" require relevant registration application materials to indicate "(irradiated)" in order to ensure that regulatory authorities are fully aware of the actual situation of production enterprises using irradiated raw materials, supervise production enterprises to effectively implement regulations and standards related to the identification of irradiated food, and effectively protect consumers' right to know.

However, the document does not specify that additional content should be added to registration application materials such as safety and health function demonstration reports. In actual registration application work, irradiation processing is only considered as a production process that does not directly affect product quality, safety or health function, and there are not too many regulatory requirements for the "irradiated raw materials" obtained through irradiation processing in accordance with national regulations and standards.

Table 2 Guidelines for Health Food Registration Application Services

Series	Term	Content
1	Research on Product Technical Requirements	List all functional related raw materials according to the formula materials. The order of each raw material is arranged in descending order of its usage in the product. The irradiated raw materials should be labeled with "(irradiated)" after the name of the raw materials.
		List all auxiliary materials according to the formula materials. The order of each auxiliary material is arranged in descending order of their usage in the product. The irradiated excipients should be labeled with "(irradiated)" after the excipient name.
2	Product Label Manual Sample	All raw components should be listed by formula. Each raw ingredient is listed in descending order of product use. Label irradiated raw materials with "(irradiated)" following their names.
		List all formula-related auxiliary materials. Each auxiliary material is listed in descending sequence of product use. Irradiated excipients should be labeled "(irradiated)".

3.2. Identification management

The irradiation labeling management of health food includes both specialized "Regulations on the Labeling of Health Food" [20] and more applicable national food safety standards. The relevant current regulatory requirements are shown in Table 3.

Table 3 Current irradiation food labeling management documents

Series	Term	Content
1	Regulations on the Labeling of Health Food (Health Supervision and Administration) states "Special Labeling Content"	Health food treated with ionizing radiation must be labeled "irradiated food" or "this product has been irradiated" near its name on the "main display panel". In the ingredient list, "irradiated" must follow any ionizing radiation-treated substance.
2	General Rules for Labeling of Prepackaged Food in accordance with National Food Safety Standards	Food treated with ionizing radiation or energy should be labeled "irradiated food" beside the name. In the ingredient list, list any ionizing radiation or energy-treated ingredients.
3	National Food Safety Standard - Hygienic Specification for Food Irradiation Processing	The labeling of irradiated food should comply. In accordance with the provisions of Ministry of National Food Security & Research.

Comparative analysis shows that in terms of irradiation labeling management, the specialized regulations for health food and the general requirements for ordinary food are coordinated and consistent, and both can cover the two ways of using irradiation technology for health food finished product irradiation and raw material irradiation. That is, finished product irradiation must be clearly labeled near the food name, and raw material irradiation must be clearly labeled after the corresponding irradiated raw material name.

4. Application Overview

There are many factors involved in existing food safety standards, and it is not necessarily a violation of certain standards that constitutes unsafe food. Food that meets these standards is not necessarily unsafe food. Therefore, we first distinguish the elements in food safety standards into substantive and non-substantive standards. Further analysis will be conducted on whether violations of non-essential food safety standards can be identified as unsafe food.

4.1. Reasons for distinguishing

Firstly, food safety standards are public law norms applied in the private law system, aimed at safeguarding public interests. However, they cannot definitively affect changes in civil legal relationships, and it is necessary to further distinguish the private law consequences of actions that violate food safety standards. Violation of mandatory norms will lead to adverse legal consequences, and mandatory legal provisions can be divided into effective mandatory provisions and normative mandatory provisions. The author believes that from the content of existing food safety standards, some content has extremely strong rigidity, and violating these regulations can be directly recognized as unsafe food; However, some contents have greater flexibility, and violating these regulations cannot be directly recognized as unsafe food, and a comprehensive judgment needs to be made based on specific circumstances. Therefore, the former belongs to the mandatory norms of effectiveness, and any food that violates these contents is directly recognized as unsafe food, that is, the food contains elements that pose a substantial threat to human health, and punitive compensation should be imposed on the perpetrator. When the latter poses a threat to human health, it belongs to a mandatory normative norm. When it does not constitute it, it should be similar to a mandatory normative norm and should not lead to the occurrence of punitive damages. In other words, we must distinguish between food safety substantive standards and non-substantive standards.

Secondly, the true legal pursuit of the food safety law is to crack down on unsafe foods that harm human health. distinguishing food safety standards can achieve precise protection of legal interests. Taking food labeling and instructions as an example, the general principles for prepackaged food labeling have a wide variety of requirements for food labeling, and there are also various standards for food labeling. For the labels and instructions of imported food, Article 97 of the Food Safety Law stipulates that if the food belongs to imported food, the law requires imported food to have Pakistani labels and instructions.

Some food that slightly violates this standard is not necessarily unsafe. For example, the requirements for the presentation and writing of letters and numbers in labels belong to food safety standards. When certain foods violate these standards, if they are directly identified as unsafe food, it is obviously contrary to facts or common sense, and it is also inconsistent with the goal of punitive damages. The proviso to Article 148 of the Food Safety Law clearly stipulates exceptions to whether non-compliant food safety labeling standards should be subject to punitive damages. At this point, legislation considers labeling to be a non-substantive standard, and those who violate labeling standards need to consider whether the violation is sufficient to affect human health in order to ultimately determine whether they meet food safety standards.

4.2. Scope

Firstly, the situations stipulated in article 150 of the food safety law belong to substantive food safety standards, and those that violate these standards are considered substantively unsafe food. This provision states that food safety refers to food that is non-toxic, harmless, meets the necessary nutritional requirements, and does not cause any acute, subacute, or chronic harm to the human body. So, the substantive standard has a broader definition of safe food, that is, as long as the food is non-toxic, harmless, and does not cause any harm to the human body, then the food is safe. On the contrary, the definition of unsafe food decreases accordingly, and only food that does not meet these points can be directly recognized as unsafe food. Therefore, from the various specific standards covered by food safety standards, any acute, subacute, or chronic harm is the result of harm to personal safety and health, and the two essential elements of "toxic and harmful" and "not meeting nutritional standards" are the most direct and serious hazards, which belong to the substantive requirements of safety standards.

Secondly, Article 26 of the food safety law, except for the content stipulated in Article 150 above, belongs to non-substantive food safety standards. Article 26 of the law provides a list of the contents that food safety standards should include. This provision is a general principal provision aimed at providing a comprehensive guidance for food producers. Due to the rich variety of modern food, complex and procedural production processes, relevant departments and institutions are also authorized to develop food safety standards. However, the current multiple application standards and the dual recognition of food safety by law have caused many application problems in judicial practice. As some scholars have pointed out, the main reason for distinguishing non threshold standards for food safety is the inconsistent degree of standardization of food safety standards, which are constrained by their ability to standardize, as well as the policy influence and the game between various forces in the standardization process. Therefore, violating non-substantive standards in food safety standards cannot be directly recognized as unsafe food.

4.3. Interpretation

After distinguishing food safety standards into substantive safety standards and non-substantive safety standards, judges can first determine whether the food in question has substantially violated the food safety standards. If it constitutes a substantial violation, it is directly recognized as unsafe food and subject to punitive damages. If it does not constitute a violation, further explanation based on functionalist interpretation methods is needed for non-substantive elements.

It is precisely because there are differences between the formal and substantive functions of food safety standards that judges need to be given the power to interpret whether food belongs to unsafe food in specific cases. Essentially, this explanation belongs to the restrictive interpretation. Due to the wide variety of food safety standards, food that is deemed unsafe violates its substantive safety standards. Therefore, the judge needs to determine whether the operator's violation of non-substantive safety standards constitutes a food safety risk based on the specific circumstances of the case, and whether this danger poses a sufficient threat to human health. Judges also need to follow certain principles of interpretation when interpreting and applying non substantive standards.

Firstly, the overall principle of interpretation and application should revolve around the purpose of the food safety law to protect the health of consumers. Given that the current legislation only stipulates food safety standards, there is no direct provision for unsafe food standards in punitive damages liability, which needs to be explained based on the severity of the violation of food safety standards.

5. Existing problems

In order to gain a comprehensive understanding of the current registration, filing, and licensing management system for health food, a combination of survey questionnaires and on-site visits were used to distribute 229 survey questionnaires to regulatory authorities and production enterprises. Combined with on-site visits, through screening, summarizing, and analysis, the following three aspects and seven common issues were identified, which reflected a lot.

5.1. Long registration approval time limit

In the process of continuing registration approval, products that have not undergone changes in formula, process, technical parameters, etc. are approved according to registration, resulting in a slower speed. For simple changes that do not involve product safety, functionality, and quality controllability, such as changes to the registrant's own name and address, approval is carried out according to registration, resulting in a slower speed; Some health food raw materials with confirmed safety have not been included in the Health Food Raw Material Catalogue, and the health food produced from these raw materials is still subject to registration and approval, resulting in a slower rate.

The above issues have all constrained the production and development of enterprises. The delay in obtaining approval for the continuation of registration may result in the enterprise being able to produce, but other applications for the product (such as technology transfer, various changes, etc.) cannot be processed, thereby affecting the normal production of the enterprise; Product changes that do not involve product safety are still being applied for through registration. Due to the long-time limit, companies either conceal the changes or no longer carry out technological improvements, resulting in uncontrollable product safety, stagnant technological innovation, and affecting industry development; Health food raw materials whose safety has been determined are still subject to registration and approval due to not being included in the Health Food Raw Material Catalogue. Unnecessary product review and approval occupy national resources, which not only affects the efficiency of safety-controlled product review and approval, but also leads to a long-time limit for truly new product review.

5.2. Repeated on-site verification

New products that have undergone on-site registration verification need to undergo on-site production permit inspection before production, and on-site verification should be repeated; For products with the same dosage form and only involving changes in the proportion of raw materials, there have been no changes in the process and equipment, and on-site verification is still required.

The content of registration on-site verification and production license on-site inspection is mostly repetitive, and repeated inspections require a lot of manpower, material resources, and time, especially for production enterprises that hope to start production quickly; The same dosage form does not involve substantial changes, and the same applies.

5.3. Awkward approval process

The registrant needs to fill in the applicant information repeatedly every time they apply for registration and filing, which is a tedious and repetitive process, and repeated filling can easily cause inconsistent information; At present, the registration certificate is a paper certificate, which needs to be replaced and reissued due to various reasons such as damage, loss, pollution, etc. The replacement and reissue still require a certain process and time, which will affect the sales of the enterprise.

In any application process, the applicant needs to fill in the applicant information again every time they submit it. The information is entered into the system by the applicant themselves, and repeated filling increases the workload, which can easily lead to errors in human input; At the same time, if paper certificates are lost or damaged, an application needs to be submitted for reissuance, and the processing personnel need to recheck the information. In addition, the workload is large, which sometimes leads to longer processing times. The reissuance of paper certificates not only wastes the government's human and material resources, but also has a certain impact on enterprises due to time constraints.

6. Improvement Suggestions

Based on the results of reviewing relevant domestic and foreign literature, representative issues and suggestions repeatedly mentioned by multiple regulatory agencies and enterprises will be compared with their counterparts in the same industry abroad. Efforts will be made to streamline and optimize the approval process, reduce intermediate duplication, and propose the following improvement suggestions that are in line with Pakistan's national conditions.

6.1. Shortening Approval Deadline

Establish an online information system for enterprises, including records of their natural situation, product situation, production and sales situation, as well as violations and penalties. At the same time, integrate enterprise information with daily regulatory information and implement hierarchical management. In the process of continuing registration, for products that have not undergone changes in formula, process, technical parameters, etc., it is recommended to transfer them to the provincial bureau for quick processing. Make full use of online information systems. For simple changes that do not involve product safety, the certificate holder can apply for extension online. After submitting the corresponding materials for filing at the expiration date, the extension can be granted.

Further accelerate the inclusion of nutrients other than vitamins, minerals, and other nutrients in the Catalogue of Health Food Raw Materials, and expand the availability of raw materials for registered health food products. By implementing graded management of health food raw materials, we aim to expand the scope of the filing directory and alleviate the pressure of registration and approval work while ensuring the safety of raw materials. In addition to declaring products in the raw material catalog according to filing, the scope of raw material filing can also be further expanded. For example, raw materials from the same origin as medicine and food, raw materials from the catalog that have only been extracted and processed by water or fermentation alcohols, and auxiliary materials with high safety and good compatibility with raw materials can be included in the filing directory and included in the filing process for filing.

6.2. Streamline on-site inspections

It is recommended to merge the on-site registration verification of new products with the on-site production license verification. Varieties that have already undergone on-site registration verification can no longer undergo on-site production license verification. For products with the same dosage form that only involve changes in the proportion of raw materials, there have been no changes in the process equipment or site, and no on-site verification will be conducted.

6.3. Simplify approval process

After successfully registering as a user in the online information system, when filling out new product materials, the enterprise can automatically retrieve its basic information after logging into the system, without the need for repeated filling and submission, reducing the burden of filling out application materials for the enterprise, and effectively avoiding errors and inconsistent information during repeated filling.

In the process of changing registration, hierarchical management shall be carried out based on the risks and degree of impact on product safety, functionality, and quality controllability. Changes that have a minor impact on product safety can be reported by the enterprise itself (under the reporting system) and reviewed by the provincial bureau for filing (under the filing system). Other significant changes will be approved according to the original change registration procedure (under the approval system) to improve approval efficiency. The regulatory authorities will implement

electronic certification and no longer provide paper certificates. Applicants can print their own electronic registration certificates. To avoid the need for paper certificates to be replaced due to various reasons such as continuation, alteration, loss, damage, etc., which may affect the normal sales of the enterprise.

7. Conclusion

The study points out digital transformation and healthcare Industry 4.0 technologies in food management. To improve readiness and reaction, these technologies must be invested in and adopted. Health food is produced using radiation technology, and the country has management policies and regulations. Pakistan should strengthen basic research, accumulate evaluation data, organize industry research, promote the revision of national food safety standards and the construction of standard systems, support the scientific use of irradiation technology, effectively regulate health food production and processing, and promote the healthy and orderly development of the health food industry. This article fully considers the current situation of the development of health food in Pakistan, and draws on the mature regulatory experience of other related industries in Pakistan and internationally. This suggests simplifying the registration and approval process to steadily promote the health food registration and filing system reform, optimize social resource allocation, promote industrial development and innovation, and deepen the "streamlining administration, delegating powers, and improving services" reform.

Compliance with ethical standards

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No conflict of interest to be disclosed.

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