



A Continuing Controversy: Labeling Requirements on Irradiated Foods

Citation

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A Continuing Controversy: Labeling Requirements on Irradiated Foods

Introduction

For the average American, the words radiation and irradiation are apt to conjure up images of nuclear weapons, radioactive waste, x-rays, and other unpleasant materials associated with health dangers. Yet these words are also displayed on the labels of food products treated with a irradiation process which made the foods safer for consumers to eat. Food irradiation, currently approved for use on several foods, kills microorganisms and insects which could pose substantial health risks to consumers. Irradiation can also be used to retard spoilage and ripening of fruits and vegetables to increase their shelf life.

Despite its potential benefits, irradiation and the labeling of irradiated foods has been a subject of controversy since its inception. Since 1966, the Food and Drug Administration (FDA) has required irradiated foods to be labeled as such, but because the initial foods approved for irradiation treatment were limited to potatoes and wheat, the process was not widely publicized. In 1986, however, FDA expanded the list of approved foods to include fruits, vegetables, and spices, and revised its labeling regulations to require that irradiated products be labeled at both the wholesale and the retail level. The promulgation of these guidelines drew criticism from the food industry, Congressmen, and several consumer groups, and remains a hotly debated topic today.

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This paper provides a brief introduction to the controversy surrounding labeling requirements for irradiated foods.¹ I will attempt to explain the rationale behind FDA's labeling guidelines for irradiated foods, and its legal authority for the requirements. Part I discusses the historical background leading to the present labeling requirements. Part II explains the legal authority of the FDA to mandate labeling. Part III argues that FDA's

¹While the safety of the irradiation process also merits discussion, that debate is outside the scope of this paper. I focus specifically on the labeling issue of irradiated foods.

labeling requirements could be extended to encompass irradiated ingredients as well as irradiated foods. Finally, I conclude not only out of respect for the public health and safety mandate of FDA but also in the interest of free choice for American consumers, that current labeling requirements are valid, essential, and should be expanded in order to allow consumers to make an informed choice on the foods they eat.

I: Backaround

A. History of Irradiated Foods

Food irradiation is not new technology in food processing. To the contrary, irradiation represents one of the most intensely studied technologies in the history of food processing. As early as the 1930's, the U.S. government recognized the potential benefits of radiation treatment and began experimenting with the use of radiation to preserve food. From 1953, the government allocated \$80 million through the Atoms for Peace program on irradiation research, and learned enough so that GI's and astronauts could be fed irradiated food rations.² And as the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act (the Act) indicates, Congress was well aware of the potential use of irradiation in the processing of foods for consumers.

For all of the debate and discussion surrounding irradiated foods, irradiation is a relatively simple method of food preservation. Food placed on a conveyor belt is exposed to gamma rays from cobalt 60 at ionizing radiation doses high enough to destroy insects and bacteria but low enough to prevent significant molecular changes. The bombardment by gamma rays also prevents or retards cell division, slowing down the ripening of fruits and vegetables.³ irradiation leaves no residue in food, and does not destroy as many nutrients as other types of conventional food processing such as canning.

²Sharon Begley and Mary Bruno, A High-Energy Food Fight, Newsweek, March 28, 1983, at 72.

³Interestingly enough, the process does not work on all foods: it causes leafy vegetables to lose their green color, grapes to become soft, and bananas to develop brown spots.

The potential benefits of food irradiation are numerous. The Institute of Food Technologists reports that irradiation could reduce the need for nitrates in cured meats, and pesticides such as ethylene dibromide in produce. Both of these chemical preservatives have both been found to cause cancer in animals. And according to a U. S. Department of Agriculture study, permitted doses of radiation could eliminate between 99.5 and 99.99 percent of Salmonella microorganisms in poultry.⁴ in addition, at high dosage levels not yet approved by FDA, the process could sterilize food so that it could be stored for years without refrigeration.

FDA became officially involved in the regulation of irradiated foods in 1958 when Congress passed the Food Additives Amendment to the Federal Food Drug and Cosmetic Act. The amendment established a licensure system which prohibited the use of a food additive until its sponsor established the additive's safety and FDA issued a regulation specifying its conditions of use. Congress also included any source of radiation in food processing in its definition of a food additive. In the decade that followed, FDA permitted the use of irradiation to control insects in wheat and to inhibit sprouting in potatoes. In 1985 and 1986, FDA approved the use of irradiation to control trichinosis in pork, to slow ripening and to control insects in fresh fruits and vegetables, and to control microorganisms in spices and seasoning. Most recently, in May 1990 FDA approved irradiation for raw chicken, turkey, and other poultry.⁵

Irradiation is currently used worldwide. Today between 15% and 20% of the spices sold in the U.S. are exposed to irradiation to control bacteria, insects, and filth.⁶ in the Netherlands and South Africa, irradiation is in commercial use and carries a value-added perception to consumers there.⁷ Irradiated foods are also commonplace in France,

Produce and pork can be treated with radiation before marketing, but consumers are leery: Irradiated food: Is it safe?, U.S. News & World Report, August 11, 1986 at 58. 457 Fed. Reg. 19460. .. (May 6, 1992).

~ Fed. Reg. 18538. (May 2, 1990).

⁶Daniel P. Puzo. Irradiation: The Waiting Game, Los Angeles Times, at H2. Col. I.

⁷Daniel Best. Marketing Irradiation, Prepared Food. January 1989, at 66.

Japan and Thailand. To date some 36 countries have obtained various clearances for the processing of some 50 food items.⁸

Food irradiation is not without many critics. Several Congressmen and consumers groups have voiced their concern over its safety. They claim that irradiation depletes foods of essential nutrients, and produces trace amounts of radiolytic products in foods which pose a health risk to consumers. In addition, some consumer groups such as the Food Irradiation Project for the New York Public Interest Research Group have expressed concern that there is no mechanism to monitor the level of irradiation to which foods would be exposed, and thus irradiation could become a quick fix for covering up quality deficiencies of food manufacturers.¹⁰ In the face of scientific uncertainty, Great Britain and West Germany moved to ban the sale of irradiated foods.

Moreover, consumer surveys suggest that public reaction to food irradiation is mixed. A 1985 poll found that only 28.2% of 900 people surveyed said they would buy food irradiated by gamma radiation, even assuming that the food did not spoil and would cost no more than food treated in other ways.¹¹ On the other hand, a 1989 USDA Economic Research Service survey indicated that 66% of consumers would even be willing to pay a higher price for chicken with Salmonella levels greatly reduced by irradiation, and only 14% said they would not buy irradiated chicken at all.¹² A recent survey conducted in 1992 by the Food Marketing Institute revealed that 35% of

⁸James O. Mason, *Food Irradiation—Promising Technology for Public Health*, 1992

U.S. Department of Health and Human Services: Public Health Report 1992, September

1992/October 1992, at

⁹See The Status of the Technical Infrastructure to Support Domestic Food Irradiation, Hearing before the Subcomm. on Energy Research and Production of the House Comm.

on Science and Technology, 98th Cong., 2d Sess. (1984); Federal Food Irradiation

Development and Control Act of 1985, and Hearing before the Subcomm. on Department Operations, Research, and Foreign Agriculture of the House Comm.

on Agriculture, 99th Cong., 1st Sess. (1985); Food Irradiation, Hearing before the Subcomm. on Health and the Environment of the House Comm. on Energy and

Commerce, 100th Cong., 1st Sess. (1987).

¹⁰See Marketing Irradiation, note 7, at 66.

¹¹Francesca Lunzer, Atomic Lunch, *Forbes*, September 9, 1985, at 119.

¹²Irradiation of Poultry to Control Foodborne Pathogens, Food Safety and Inspection Service, U.S. Department of Agriculture: Fact Sheet, June 1990 at

consumers consider food irradiation a serious hazard, 28% of consumers thought irradiation was something of a hazard, 10% said it was not a hazard at all and 27% were not sure.¹³

B. History of Labeling of Irradiated Foods

In addition to the controversy surrounding the safety of food irradiation, debate continues regarding the labeling of irradiated foods. Since July 1966, the FDA has required that all irradiated food be labeled as such, but it was not until 1986 when the FDA approved the use of irradiation in several food products that labeling drew much attention. In April 18, 1986, FDA published a final rule which permitted the use of irradiation for produce and spices, and created new labeling requirements which are in effect today.¹⁴ FDA ordered that food which had been irradiated must, on the wholesale label, bear either the statement "Treated with radiation, do not irradiate again" or "Treated by irradiation, do not irradiate again." At the retail level, FDA required the inclusion of the international Radura logo indicating irradiation, and for a two year experimental basis a written statement on the label that the product had been treated with radiation or treated by irradiation.¹⁵ For individual items of un packaged irradiated foods such as fruits and vegetables, FDA allowed the required logo and statement to be prominently displayed to the consumer as a point-of-purchase counter sign or on the labeling of the bulk container.

In addition to the mandatory statements, the FDA's final rule also permitted manufacturers to use additional labeling as part of a consumer education effort. The rule allowed food producers to state on the wholesale or retail label the purpose of the

¹³Irradiation: The Waiting Game, supra note 6, at H2, Col. I.

1449 Fed. Reg. 5714 (February 14, 1984); 51 Fed. Reg. 13376 (April 18, 1986).

¹⁵51 Fed. Reg. 13376, 13387.

¹The Radura logo was developed in the Netherlands in the early 1980's to identify a food that has been irradiated.

1751 Fed. Reg. 13376, 13387-88.

treatment process or expand upon the kind of treatment used. For example, the manufacturers could put treated with radiation to extend shelf life or treated with radiation to inhibit maturation, provided the statement truthfully described the primary purpose of irradiation.¹⁸ In addition, in the interest of allaying consumer misconceptions concerning food irradiation, manufacturers could state on the food label that 'this treatment does not induce radioactivity.'¹⁹

FDA later made permanent the obligation to include the words 'Treated with radiation or Treated by' irradiation at the retail level. In 1988, FDA extended the two year experimental period included in its 1986 final rule for an additional two years because the agency believed that most consumers have had no opportunity to associate the required information logo with irradiation treatment. 2t) In a subsequent rule published in 1990, FDA eliminated the expiration date for the wording requirement, making the radiation statement a permanent fixture at least until it can be shown that the logo alone is sufficient to convey to consumers that the product has been irradiated.²¹

Not surprisingly, many in the food industry have been adamant opponents of labeling. Food producers worry that mandatory labeling does not provide the necessary education about the process of irradiation. and only caters to the prejudice of consumers who associate irradiation with health risks. The United Fresh Fruit and Vegetable Association, which supported labeling at the wholesale level to prevent reirradiation of produce, also expressed its concern that mandatory labeling at the retail level would unfairly put retailers into situations where they could not control possible misbranding 22 Association representatives testified before Congress that the frequency of shipments made it difficult to segregate produce loads in the back room, that open displays

1851 Fed. Reg. 13376. 13388.

1⁹5J Fed. Reg. 13376. 13388-89.

2053 Fed. Reg. 4856 (February 18, 1988); 53 Fed. Reg. 12756 (April 18, 1988).

2155 Fed. Reg. 646 (January 8, 1990), 55 Fed. Reg. 14413 (April 18, 1990).

²²Federal Food Irradiation Development and Control Act of 1985, and Hearing before the Subcommittee on Department Operations, Research, and Foreign Agriculture of the House Committee on Agriculture, 99th Cong., 1st Sess. (1985).

commonly used created the danger of switching fruits and vegetables by consumers. and that labeling of produce at the retail level would not be enforceable. FDA responded to these arguments by stating that any confusion and mistrust by consumers could be corrected by proper consumer education programs, and that labeling of fruits and vegetables in nonpackage form could be labeled individually or in bulk similar to the current labeling practice on bulk on waxed or coated fruits and vegetables.

III. Le2al Authority To Requiire Labels On Irradiated Foods

Any legal analysis of regulation of food labels must begin with a discussion of the ori2inal 1906 and 1938 Food and Drugs Acts. When Congress drafted the 1906 Act. it delegated to FDA the authority to regulate food labels. This early legislation, however. focused only on prohibition of false or misleading claims and did not impose an affirmative duty by manufacturers to provide information to consumers. When Congress later passed the 1938 Act, it expanded the provisions of the 1906 Act to provide FDA with two additional powers. First. Section 403 mandated that certain essential information be included on food labels. And second. Section 201(n) empowered FDA with authority to require additional information in food labels to assure that consumers are not harmed or misled by claims of the food manufacturer.

Neither the 1906 Act nor the 1938 Act specifically addressed risks posed by substances that were not added to food. a concept which was not defined in the original Acts but was understood to embrace substances incorporated as ingredients or used during processing. In 1958 Congress drafted the Food Additives Amendment to the Federal Food, Drugs, and Cosmetics Act to address the problems of food additives in processed foods in depth. The Amendment created a license system for substances intended to be used as ingredients in processed food, and provided that any product that contained a food additive whose use had not been approved by FDA would be considered adulterated under section 402(a)(2)(C).

When FDA published its final rule governing the labeling of irradiated foods in the April 18, 1986 Federal Register, the agency turned to Sections 409, 403(a) and 201(n) of the Act to justify its authority to mandate labeling. Section 409(c)(3)(B) of the Act prohibits approval of a food additive if a fair evaluation of the data before the Secretary shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of the Act. Because Section 201(s) specifically defines food additive to include any source of radiation in food processing, Section 409(c)(3)(B) subjects irradiated food to the adulteration and misbranding analysis of Sections 403(a) and 201(n).

Sections 403(a) and 201(n), which set forth when a food is considered to be misbranded, has been invoked by FDA in the past to require a seller to reveal facts to prevent consumers from being deceived. Section 403(a) states that a food is misbranded if its labeling is false or misleading in any particular way. Section 201(n) clarifies this provision by providing that in determining whether labeling is misleading, the agency shall take into account if the labeling or advertising fails to reveal facts material in light of...representations in the labeling of a food. Thus, as applied to irradiated foods the issue of labeling hinges on whether irradiation as a food additive is a material fact that must be disclosed to the consumer to prevent deception.

In its discussion of its 1986 final rule, FDA answered in the affirmative. FDA first acknowledged that irradiation, while safe to consumers, could cause changes in the organoleptic or storage properties of finished foods. Because these changes were not immediately apparent to consumers, the agency then argued, they represented a material fact that must be disclosed under Section 201(n). As an agency report explained, knowing that a food has been processed by radiation could be important to many consumers:

Changes in organoleptic properties (taste, color, smell, texture) may make the processed food more or less desirable to individual consumers. These changes may well be significant to prospective purchasers of irradiated food. Thus, knowing that a food has been processed by radiation may be important to many consumers. Unless the label indicates otherwise, these consumers would be likely to assume that food has not been processed or has been processed by traditional means. It follows that the label of a food that has been irradiated but that does not state this fact is misleading, because the label fails to inform that consumers that the food has been processed, and that it has been processed in a nontraditional fashion. FDA believes that changes in food caused by the irradiation allowed under the proposed regulation, although of no safety concern, are sufficiently important that the consumer should know that this process has been used?³

In short, the agency feared that the absence of a label statement on irradiated foods would incorrectly suggest that the irradiated food product was essentially unprocessed.

Some opponents of labeling requirements submitted several comments in response to FDA's proposed regulations. They argued that FDA did not have the authority to require a retail label because labeling was not a prerequisite for safe use under section 409(c)(1) and (d) of the Act.²⁴ FDA responded to these comments by emphasizing that because the retail label requirements were predicated on misbranding considerations and not on food safety or health risk considerations, Section 409(c) did not apply.

In addition, some comments argued on consistency grounds that if the agency interpreted the Section 403(a)(1) standard as changes in organoleptic properties, then the presence of additives now commonly used in foods should be highlighted? Moreover, they stated, because most conventional food-processing also affect the organoleptic properties of food, they deserve highlighting as well. FDA responded to these concerns by stating that although most conventional food processing affects the organoleptic properties of food, the processing is either obvious to the consumer or

^{2,3}George H. Pauli and Clyde A. Takeguchi, *Irradiation of Foods - An FDA Perspective*, Food Reviews International, 1986, at 100.

2451 Fed. Reg. 13376, 13388.

2551 Fed. Reg. 13376, 13388.

conveyed to the consumer through labeling or packaging. The agency cited as examples products which do not require labels, such as canned food, which is obviously heat processed. and frozen foods, which is obviously frozen. On the other hand. where food processing not visible, such as pasteurization or sterilization, the agency mandates labeling. Thus, labeling of irradiated foods is not inconsistent with past FDA regulation.

Finally, some comments suggested that food irradiation is a food-preservation process which should be considered a process instead of a food additive.²⁶ FDA dismissed this claim, stating that there is no statutory exemption for a process being declared on a food label, and thus it was irrelevant whether irradiation is a process in determining whether retail labeling is appropriate.²⁷

III. Labels On Foods With An Irradiated Ingredient

FDA labeling requirements has not satisfied all consumer groups; some groups believe labeling must go further. Petitioners in Maine protested that Menus and catalogs offering irradiated products should also be marked as such. and any business institution, or organization serving, selling, or donating. directly or indirectly irradiated food items should have signs on their front doors²⁸ Meanwhile, The National Coalition to Stop Food Irradiation lamented that shoppers are kept in the dark because prepared foods that include irradiated ingredients are not required to be labeled.²⁹ While this author believes that current requirements should not extend to restaurant menus. I would argue that the requirements should be altered to include foods containing an irradiated ingredient.

The 1986 final rule applied only to food that had been irradiated (first generation food), and exempted from labeling food that merely contains an irradiated ingredient

²⁶5J Fed. Reg. 13376. 13389.

2749 Fed. Reg. 5718.

²⁸Petition Urges Labeling Of Radiation-Treated Food: Consumer Group Pushes For Menu Warnings. Nation's Restaurant News Newspaper. March 10, 1986. at 33.

²⁹Peter Dworkin. Produce and Pork Can Be treated With Radiation before Marketing. But Consumers Are Leery U.S. News & World Report, August 11, 1986. p. 58.

second generation food). FDA distinguished labeling of irradiated foods from irradiation of one ingredient in a multiple-ingredient food by reasoning that ...such a food has obviously been processed. Consumers would not expect it to look, smell, or taste the same as fresh or unprocessed food, or have the same holding qualities.³⁰ The agency had no evidence that irradiation of an ingredient would affect the characteristics of a multiple ingredient food in any significant way and with respect to food labeling, the consumer's right to know has been defined by the Federal Food, Drug, and Cosmetic Act, and the agency' has no basis to impose additional requirements when a manufacturer has met the statutory obligation³¹.

As alluded to in Part 11. where safety is not an issue. FDA's authority to require special labeling is much less expansive. For example. when FDA was asked to require ingredient labeling for tampons, and the agency' was not aware of any data showing a health risk, the agency concluded that it did not have the legal authority to impose an ingredient labeling requirement on products.³² In addition, the agency has on occasion expressed concern that to require labels to announce the presence of specific ingredients would overexpose and desensitize consumers to warnings and decrease the labels' effectiveness.³³

Nevertheless, a plausible argument for labeling of irradiated ingredients might be crafted from other provisions in the Act and the agency's own logic surrounding labeling for first generation foods. Section 402(i) of the Act requires that any food made from two or more ingredients must have a label with the common, or usual name of the ingredient. Although the agency stated in 1988 and again in 1993 that the common or usual name of

3051 Fed. Reg. 13376. 13389.

³¹Final rule. denial of request for hearing. and response to objections on irradiation in the production. processing. and handling of food. 53 Fed. Reg. 53176, -- (December 30. 1988).

³²See Final rule on labeling for menstrual tampons. 54 Fed. Reg. 43766. -- (October 26. 1989).

³³See Final rule, food labeling, declaration of ingredients. 58 Fed. Reg. 2850 (January 6.

1993): see ~ Proposed rule. 56 Fed. Reg. 28592 (June 21. 1991).

an ingredient would not include additional information on processing. the Act defines broadly an ingredient to include all those substances that have been used to manufacture a food, including all added substances.³⁵ And under Section 201(s), all added substances would entail all substances that may be reasonably expected to become components of food with the exception of those that are an inherent natural constituent. Conceivably, because irradiation is not an inherent natural constituent, it should be listed in some form as an added food-processing substance.

As FDA noted in the Federal Register, the agency has historically required the disclosure of a food-processing agent whenever it is material to the processing of foods:

...flour is required to be modified by the term 'bleached' if bleaching agent are used in processing and modified by the term 'bromating' if potassium bromate is used in the processing of the flour.³ Requirements also exist for enriched farina, processed orange juice, and orange juice from concentrate to allow consumers to be able to distinguish between different processing methods of specific ingredients.³⁷ Similarly, food represented to be a traditional food must disclose processing differences (e.g. potato chips made from dehydrated potatoes, onion rings made from minced onions, etc.)^{3x}

To be consistent in its goal to prevent deception, irradiated ingredients should be similarly labeled. As FDA has stated: Food ingredients, including food additives that have a functional effect in food, are required to be disclosed on food labels....additives such as aspartame that are present as ingredients are required to be included on the

³⁴See 53 Fed. Reg. 53176; 58 Fed. Reg. 2873.

³⁵What's Biotechnology Got To Do With Food Labeling?, Food & Drink Daily, June 14, 1993.

³⁶51 Fed. Reg. 13376, 13388.

³⁷See 51 Fed. Reg. 13376, 13388; see also Final rule for Food Labeling: Declaration of Ingredients; Common or Usual name for Nonstandardized Foods; Diluted Juice

Beverages: Technical Amendments. S Fed. Reg. 44059 (August 18, 1993); see also 58

Fed. Reg. 2897 (January 6, 1993).

385j Fed. Reg. 13376, 13388.

ingredient labeling statement on the food's label. ~ Notwithstanding the fact that consumers know that second generation food is processed, and that irradiated ingredients are safe, consumers have a right to know whether an ingredient has been altered by irradiation. As the agency itself admits, irradiation does cause some changes to the food, and when the consumer is informed of the presence of these ingredients, the possibility of misrepresentation is removed.~
Moreover, although the Act does not provide FDA with unfettered discretion to require food labels to bear what ever information the agency believes some consumers might wish to know, FDA itself has stated that whether information is material Ifor disclosure under Section 201(n) of the act depends not on the abstract work of the information, but on whether consumers view the information as important and the omission of label information may mislead a consumer.⁴¹ Consumer demand for labeling of irradiated ingredients is high; in the 1990 proposed rulemaking removing the expiration date for labeling 72 of the 167 comments which agreed with FDA's 1986 labeling proposal advocated that an explicit statement be included whenever an irradiated ingredient is used in a foodi²

Conclusion

Despite industry fears that consumers would associate the consumption of irradiated foods cancer or other health risks, evidence exists which suggests that some consumers now accept the foods as safe and reliable. In January 1992 the nation's first facility designed specifically to irradiate food opened near Tampa, Florida.⁴³ And one of

~5I Fed. Reg. 13376. 13388.

⁴⁰FDA's conclusion in 1993 that it did not have a legal basis for requiring labeling for milk from cows treated with BST is not applicable here, because unlike the situation with irradiated foods, there is no difference between BST milk and that from untreated cows. Thus, under Sections 403(a) and 201(n) there would not be any misleading representation about milk from cows treated with BST unless accompanied by the information that BST was used.

⁴¹Irradiation of Foods - An FDA Prespective, supra note 23, at 101.

⁴²~ Fed. Reg. 14413. 14414 (April 18. 1990).

⁴³Food Irradiation-Promising Technology for Public Health, supra note 8.

the first grocers to offer irradiated vegetables. Carrot Top of Glenview, Illinois, reported that by early 1993 the ratio of sales of irradiated versus nonirradiated strawberries had risen to approximately 20 to 1. and that sales of irradiated chickens were also brisk⁴⁴ Perhaps similar to the controversy surrounding microwave ovens several years ago, over time increased education about the safety and usefulness of irradiated foods will allay public fears and misconceptions about irradiation.

Increasing sales success, however, should not signal a retreat from requiring logos and written statements to identify food that has been exposed to irradiation. Because it is undisputed that irradiation causes some changes, albeit harmless and invisible, in the character of treated foods, labeling is needed to prevent irradiated food materials from masquerading as unprocessed materials in both irradiated foods and irradiated ingredients. Labels on irradiated foods also serve to inform and instruct consumers on the technology of irradiation. And most importantly, labeling empowers consumers, who already possess an array of concerns based on fairness, economic, animal and human safety, moral, and religious beliefs, with the necessary information to make an informed independent choice on the foods they eat.

⁴⁴Retailers Begin Stocking Poultry. More Planned. Nuclear News. October 1993. at

64.