



Original research

Functional Food Safety and Product Liability in Iranian Legal System

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ABSTRACT

The approach of the legal system is very important in the field of Product Liability especially in relation to "Functional Food" safety. Regulations originate from legal approaches. So, it is important how the legal system thinks? In this regard, two theories of "Fault" and "Strict Liability" have emerged among jurists. The study of civil liability of Iranian legal system has shown the lack of a specific and comprehensive system of civil liability governing on food industry. What stands out is that this legal system in the field of food production is mainly focused on the traditional theory of fault, which needs to be reformed to ensure food safety, foster innovation in the food industry, and emphasize consumer protection.

Keywords: Civil Liability, Functional Foods, Consumer Law, Fault, Strict Liability

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1. Introduction

Governments have the duty to ensure food security, meaning all people, always, have physical, social, and economic access to sufficient, safe, and nutritious food. In this direction, the world has faced developments in the field of innovation of food and agricultural products. The production of Functional Foods is one of the results of such an approach (Sokolowski, 2020). According to Iran's legal document, Functional Food is defined as "Functional Foods" are "foods that have a similar appearance to common foods that are consumed in the daily diet. Available valid scientific evidence confirms that these foods, in addition to their basic nutritional value, at least have a specific and proven health-promoting and disease-preventing effect"¹.

What is important is that the changes that have occurred in the field of food affect its legal aspects, including the change in the traditional view of civil responsibility. On the one hand, innovation

is one of the important and influential factors on the efficiency and competitive advantage of businesses. Therefore, manufacturers are redoubled efforts in producing innovative food products, including Functional Foods, that are differentiated from normal food products with basic nutritional value. On the other hand, this innovative effort toward consumer protection needs special supervision (Ibid; Volkhardt et al, 2017). Because even though the consumption of new and unknown products, as an innovation, is a response to challenges, the possibility of facing the risk of negative effects on the health and life of consumers cannot be ignored (Katouzian, 2012). It should be noted that the combination of product liability, governmental regulations, and market forces provide the level of food safety (Buzby and Frenzen, 1999). Therefore, the legal system, while honoring the emergence of innovation in food production, deals with appropriate legislation in this field and emphasizes compliance with product quality standards (Dinu, 2012).

When the innovative functional food product purchased by the consumer is unsafe or its production is associated with non-compliance with regulations, we face the civil liability of the

¹ Article 3 of the Executive Directive on Functional Foods and Optional Enrichment of Food and Beverages (2017).

producer. In addition, in the industrial society, the consumer, who is the weak party, should be protected against the producer, because in most cases, the injured party cannot prove the fault of the producer and huge food industries. In the traditional legal view, fault must be proven to show the burden of responsibility. But can justice always be achieved with this approach? The implementation of justice and the protection of public interests require that the traditional legal system be viewed, and new rules be introduced (Katouzian, 2012).

This article is an attempt to answer the question of what approach Iranian legal system has in dealing with the producer of unsafe Functional Food. For this purpose, three sections have been designed and presented: The first section describes key relevant concepts, including "Food Security", "Functional Food" and "Civil Liability". The second part, while explaining the basics of civil liability of manufacturer, deals with the basis of civil liability of functional food manufacturer in Iranian legal system. The final part also gives suggestions for reforming Iranian legal system in this regard.

1. Key Concepts

For a better understanding of the topic, an overview of three key concepts is provided:

1.1. Food Security

"Food security is defined as a situation that exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life" (Peng and Berry, 2019). The concept of food security has evolved over time. The four pillars of food security include availability, access, utilization, and stability (FAO, 2009). In addition, there are two more dimensions that are important: agency and sustainability. These six dimensions of food security are reinforced in conceptual and legal understandings of the right to food (FAO, IFAD, UNICEF, WFP and WHO. 2021; HLPE Reports. 2020).

A look at the evolution of the definition of the term "food security" shows the expansion of the elements of this concept from quantity to quality. The definitions always refer to the access of everyone to food and places to the description of the quality of healthy and nutritious food in the shade of stability and sustainability (Peng and Berry, 2019).

According to paragraph 1 of Principle 43 of the Constitution of Iran, providing the basic needs of the society, including food for everyone, as one of the criteria of the economy of the Islamic Republic of Iran to ensure the economic independence of the society and eradicate poverty and deprivation and meet human needs during growth, while maintaining her/his freedom is explained. In addition, Article 11 of the International Covenant on Economic, Social and Cultural Rights (1966), which Iran has also ratified, refers to the right to food security (Ebrahim-Gol, 2008). According to Clause C, Article 1 of the Executive Regulations of the Supreme Council of Health and Food Security (2017), the term "food security" is defined as "sustainable access of all people at all times to healthy and sufficient food based on proper nutritional culture".

Also, in paragraph 4 of the General Policies of the Resistance Economy (2012) issued by the Supreme Leader of Islamic Republic of Iran, it is mentioned to "ensure the security of food and treatment and create strategic reserves with an emphasis on increasing the quantity and quality of production". In paragraph 6 of the General Health Policies (2013) issued by the Supreme Leader of Iran, it is also referred to as "providing food security and equitable benefit of the people from a healthy, desirable and sufficient food basket, clean air, public sports facilities and safe health products along with compliance with national, regional and global standards" has been mentioned.

1.2. Functional Foods

One of the achievements of the need to pay attention to the existence of sufficient, safe, and nutritious food for an active and healthy life in the scope of implementing food security is the design and development of the complex concept of Functional Foods. Functional Foods are innovative foods that provide a solution for maintaining nutritional health.

In the definitions of the terms under Article 3 of the Executive Directive on Functional Foods and Optional Enrichment of Food and Beverages (2017)², "Functional Foods" are "foods that have a similar appearance to common foods that are consumed in the daily diet. Available valid scientific evidence confirms that these foods, in addition to their basic nutritional value, at least have a specific and proven health-promoting and disease-preventing effect". Thus, these types of foods will be associated with an innovative approach compared to normal foods. It seems that the abovementioned definition has a kind of complexity and ambiguity in the definition and classification of functional food

Undoubtedly, how a functional food product is described and classified affects almost every aspect of product development, marketing and regulatory compliance. Unfortunately, "there is still no consensus on the definition of "Functional Foods" and accordingly many institutions lack a comprehensive process for its classification" (Martirosyan, 2020). For example, the balance between food and medicinal products should be considered, especially for the development of innovative health-related products (Volkhardt et al, 2017).

1.3. Civil Liability

The meaning of liability is the duty of a person to compensate for the damage caused to another due to an illegal act. If the responsibility is caused by the non-performance or delay in the performance of the contract, it is called "contractual responsibility" and means the obligation of the offender to compensate for the damage caused by the non-performance of the contractual obligations. If the obligation to compensate the loss is caused by an illegal harmful act that occurred outside the contractual relations, it is called "Civil Liability" (Katouzian, 2013).

2. Legal Accountability of the Producer of Unsafe Functional Food

The importance of ensuring food security places a heavy duty on the shoulders of the legal system to facilitate the implementation of this vital goal by formulating appropriate laws. The responsibility of manufacturers and suppliers of unsafe food products as a

² The latest version is approved in 2017.

defective product has several stages of development: It started from the basis of contractual responsibility and led to the basis of strict liability (Katouzian, 2012).

2.1. Manufacturer's Contractual Responsibility

The responsibility for the sale of defective goods is based on the contract and is limited to the relationship between the two parties. The civil law allows the buyer of defective goods to cancel the sales contract or to reduce the price difference between healthy and defective goods. But the risks caused by industrial products may be more than the price of trade and beyond it, and harm the life and property of other consumers. In other words, innocent people with no legal relationship with the producer may be at risk (Ibid). Therefore, the limitation of liability within the framework of the contract does not cover all the losses of the buyer, nor the rights of the group that did not participate in the contract. In the recent past, consumer claims have been handled based on contractual liability. But with the passing of time and the revelation of the disadvantages and weaknesses of this approach, the attitudes were directed towards non-contractual responsibility, because people often suffered from food consumption who did not have any contractual relationship with the food manufacturer. In addition, often the amount of damage caused was more than the amount of food purchased. As a result, the approach of dealing based on contractual responsibility is considered only in favor of food producers and to the detriment of consumers (Afzali Hoseini et al., 2014).

2.2. Manufacturer's Non-contractual Responsibility

Social changes and the production of many industrial products, including the production of various types of innovative food, led to the creation of relationships with the origin of non-contractual responsibilities, which, as a result, has also changed the foundations of the legal responsibility of manufacturers (Sokolowski, 2020). In this way, considering the important role of food production in the life of every person, the civil liability of the cause of damage should not be considered subject to contractual liability, even if there is a contract, due to the importance of food production and its place in health and macro policies. countries, justice requires that this issue be subject to the principles of non-contractual responsibility (Afzali Hoseini et al., 2014; Jafari Tabar, 1996).

2.2.1. Philosophical Foundations of Civil Liability

In the context of this article, two types of non-contractual liability are important: responsibility based on fault and strict liability.

2.2.1.1 Theory of Fault

The theory of fault is known as a traditional theory that prevailed until the late 19th century. According to this theory, responsibility is based on fault (whether intentional or unintentional), and only someone who has committed a fault can be held responsible, and the proof of this is primarily the responsibility of the victim (Safai and Rahimi, 2013). For example, in this context, Article 6 of the

Food, Beverage, Cosmetic, and Hygiene Act (1967)³, by mentioning the statement of carelessness, puts the burden of proving fault on the consumer.

This process causes problems for the aggrieved consumer. Including the fact that proving the manufacturer's fault is a specialized and technical matter and it is not within the power of the consumer to prove it, and it depends on getting an expert theory, which is a technical matter and imposes a huge cost on the victim.

So, according to the social changes and the industrial revolution, the transformation of industries, and the increase in losses to individuals, it became clear that this theory alone is not sufficient and responsive to social needs. Because perhaps the accidents and damages that are caused by the world of industry and assuming that the cause is to blame, the victim cannot prove the fault. As a result, the damage remains uncompensated, and this is also against justice and fairness (Safai and Rahimi, 2013). In other words, the consumer class could not prove the manufacturer's fault in the lawsuit for compensation, and as a result, the theory of fault lost its moral appeal. To deal with such issues and help the victims, legal ideas, laws, and judicial procedures faced significant changes. These developments led to the presentation of new proposed theories, including the "Strict Liability Theory", which is important to protect the consumer against the producer.

2.2.1.2. Strict Liability

The importance of legal and economic policy, as well as facing the challenges caused by the application of the theory of fault, led legal attitudes towards responsibility for the manufacturer of defective goods. This type of liability is called "Strict Liability" due to its lack of dependence on fault and contractual relationship, and it can somehow implicitly indicate the manufacturer's guarantee of the health and safety of goods (Katouzian, 2012).

In the case where there is no fault; That is, in the assumption that the benefits of the desired behavior are greater than its harm, the social benefits justify its encouragement, a situation that may be a harmful behavior. So, the question is whether such a loss should be compensated? If the answer is yes, who should compensate it? If the answer is that the compensation should be done by someone whose behavior is the only cause or one of the causes of the loss, the basis of that is the theory called "Strict Liability Principle". Strict liability for damages caused by special risks of a person's behavior or activity. In other words, everyone is responsible for damages and risks caused by his behavior and activities. But what is important, in the theory of strict liability, it is assumed that the perpetrator includes the cost of compensating the incurred losses in the price of her/his product. Then, if the desired activity is socially useful (that is, its benefits are greater than its costs), it is traded in the market and remains, even if it finds a higher price due to compensation costs. If this additional price is more than the market price, it turns out that behavior or activity is not useful from the social point of view and should be abandoned. Therefore, the theory of strict liability is used to provide appropriate means of compensation, eliminate anti-social behavior and to help the society to consciously choose the desired behavior from the undesirable one (Katouzian, 2013; Badini, 2013; Coleman, 1992).

The responsibility arising from the production of pharmaceutical and food products is justified by strict liability. Of

course, it should be added that in the case of products, since the risk may arise due to subsequent product defects or other circumstances, such as abnormal use, the scope of strict liability is also limited. In other words, if such events are proved, the principle of strict liability will be lost by cutting the relationship of causality between the perpetrator and the damage (Katouzian, 2013).

Among the strong and solid reasons for adopting the approach of strict liability for manufacturer, the following can be mentioned (Badini, 2013; Badini and Panahi Osanloo, 2012; Kionka, 2006):

- 1- Customer trust and expectation: By offering the product to the market, the producer implicitly guarantees that the product is safe and healthy. As a result, customers justifiably rely on this implied action.
- 2- Manufacturer's responsibility: The most economical means of distributing the cost caused by the injuries of defective products is to impose the costs on the product manufacturer, which can spread these costs among all the consumers.
- 3- Deterrence: Strict liability provides an incentive for the manufacturer to make her product as safe and healthy as possible.
- 4- Burden of proof: Even though the product manufacturer is at fault in most cases, it is difficult for the consumer or buyer to prove the product manufacturer's fault, and it may have happened that the lawsuit against the guilty manufacturer has been met with failure and various obstacles.
- 5- Fairness: The producer imposes non-reciprocal responsibility and risk on the consumer but obtains an important economic benefit from the supply of the product to the market. Therefore, it is fair to be the guarantor of the danger that he creates, not to impose the cost of the danger to the society in general or to the victim.

2.2.2. Elements of Civil Liability

For a person to be considered responsible and obligated to compensate the damage caused to another, basically three conditions or elements are necessary for proof (Safai and Rahimi, 2013):

2.2.2.1. Loss

There must be a loss. loss has a common meaning that includes any material or spiritual damage to a person. Also, the loss must be compensable, and this compensability has five conditions: 1- The loss must be certain (not probable). 2- It is directly derived from the action of the defendant. 3- The loss must be personal; This means that the person who claims damages must be the victim herself/himself or her/his representative (such as heirs). 4- The loss must occur because of the harm that has been done to the right or legitimate interest of the claimant, 5- The loss must not have been compensated before, and 6- The loss must be foreseeable.

2.2.2.2. Fault

The general rule in civil liability, which includes most cases of civil liability, is liability based on fault and the fault causing the damage must be proven (Article 1 of the Civil Liability Act approved in 1339). But in the no-fault liability raised in today's law, it is accepted as an exception to the general rule.

2.2.2.3. Causality

There must be a causal relationship; That is, it must be proven that the damage caused to the claimant is caused by fault or in exceptional cases caused by the harmful act of the defendant. In this way, they say that there must be a relationship of causality between the damage caused and the fault or harmful act. In other words, it talks about citing or attributing harm to a person's actions.

However, in a lawsuit based on strict liability, it is enough to prove: 1- The defect and insecurity of the product existed initially and at the time of delivery and did not occur later. 2- The defect and insecurity of the product that existed from the beginning caused the damage. 3- The occurrence of damage and danger caused by the defect was predictable. As a result, the basis of this lawsuit is the manufacturer's legal responsibility against any defect and insecurity that makes the supplied food product dangerous, whether the defect is caused by the manufacturer's fault or caused by another factor (Katouzian, 2014).

2.2.3. Basis of civil liability of Functional Food manufacturer in Iran's legal system

Now the question is, based on Iran's legal system, which legal approach has been adopted for the civil liability of producers of unsafe functional food? The answer to this question is important because it plays role in the country's food security policy. By studying the legal system of Iran in this field, it seems that the following points can be considered:

In this regard, what attracts attention of the legal point of view is a general and vague definition of the specialized and broad term "Functional Food". The mentioned definition creates ambiguity in judicial decisions and weakens the process of realizing justice.

Also, by studying the legal system of Iran, it seems that the approach of the Iranian legislator in the field of civil liability of food manufacturers has a kind of fragmentation and inconsistency in the organization of legal provisions (Alizade, et al, 2021). For example, the literature of Article 6 of the Food, Beverage and Cosmetics Law (1967) is designed based on the theory of "Fault", and far from consumer law, the burden of proving fault is on the claimant. Also, it was announced based on a study of the cases presented in the Tehran Medical and Pharmaceutical Affairs Prosecutor's Office, "responsibility based on fault in this matter is accepted by the courts" (Afzali Hoseini et al., 2014).

On the other hand, the legal system is faced with Article 2 of the Consumer Rights Protection Act (2009), which implies the application of the theory of "Strict Liability" by the Iranian legislator. Of course, according to some research, the recent Act not only does not involve any innovation in the legal system in the field of responsibility of the suppliers of goods and services, but it has also added to the existing ambiguities and has raised many questions for lawyers (Badini, 2012).

As stated, the application of the theory of strict liability does not have the problems caused by the application of the theory of fault. In addition, the cost of preventing harm caused by unsafe innovative substances on the part of the producer of functional food is certainly lower than the cost of compensating for the harm to people's health. Therefore, it is recommended to design a coherent legal system based on the strict liability approach for the field of civil liability of food producers. (Alizade, et al, 2021).

Another thing that should be added is the formulation and clear explanation of the legal duties and stronger supervision of

governmental supervisory bodies. For example, it is suggested to propose appropriate legal penalties with more details for supervisors' violations in the relevant laws. Also, according to the support policies, it has been emphasized to design and create a fund to compensate for the physical damages caused by the production of functional foods. Because the performance of such a fund is important when the government regulatory body has acted weakly, or the loss cannot be attributed to a person (Dehghanzadeh, M. H., Khadem, M. 2016; Afzali Hoseini et al., 2014).

3. Conclusions

With an interdisciplinary perspective and focusing on justice about food security policies, this research achieved the following results, which hopefully will be a way forward in the path of legal reforms of Iranian laws in the field of functional foods production:

1- Studying the technical terms contained in the legal documents of the food and drug field, including the definition of functional food, implies the presentation of general and vague definitions without paying attention to its details. Therefore, it is recommended to provide comprehensive definitions with more details in the legal reforms to avoid differences of expert opinions and to facilitate the path for the relevant executive and judicial bodies.

2- Due to the old laws governing the field of food production, it is suggested to draft and approve a comprehensive new law in the field of food and medicine that can respond to the challenges of innovative food production. What is very important in this structure is the focus on the strict liability approach in line with the consumer law. Such a view leads to more producer responsibility, more consumer trust, increasing the producer's motivation to produce safe and healthy food and respect fairness.

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