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Food and Feed Safety Law

Report Categories:

Sanitary/Phytosanitary/Food Safety

FAIRS Subject Report

SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports

Livestock and Products

Poultry and Products

Dairy and Products

Fishery Products

Dried Fruit

Fresh Fruit

Grain and Feed

Oilseeds and Products

Planting Seeds

Snack Foods

Tree Nuts

Vegetables

Retail Foods

Food Processing Ingredients

Food Service - Hotel Restaurant Institutional

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Report Highlights:

This report contains an unofficial translation of Tunisia's draft law on food and feed safety, approved by the People's Assembly on February 12, 2019. The law now currently awaits the President's signature. Key measures in the law include the creation of a National Authority for Food Safety as well as a National Agency for Risk Assessment, both of which would report to the Minister of Health. The law allows for a two-year transitional period and repeals and replaces a number of measures in Tunisia's Law on Animal Husbandry. Once finalized, effectively all of Tunisia's current underlying regulations on food and feed safety will remain in force until replaced by the new authority. The law has not yet been notified to the WTO. Tunisia's imports of affected food and feed products total over \$2 billion annually with the United States accounting for five percent market share.

LAW ON FOOD AND FEED SAFETY

TITLE I

General Provisions

Article 1 - The purpose of this Law is to ensure the safety of food and feed in order to ensure a high level of protection of human and animal health and safety, to protect the economic interests of the consumer, and to develop exports.

Article 2- This Law establishes:

- the general principles governing food and feed safety.
- the general obligation of food and feed safety.
- the obligations of operators in the food and feed sector.
- the general rules of official controls.

Article 3 - This Law applies to all stages of the primary production, production, processing, transport, storage and distribution of food and feed including import and export transactions and related advertising.

This Law applies as well to food in restaurants, coffee shops, and in all public and private entities including hospitals and public and private healthcare institutions.

It does not apply to primary production for private domestic use or to the preparation, handling and storage of food for private domestic consumption.

Article 4 - For the purposes of this Law, the following definitions shall apply:

1- Foodstuff: any substance or product, processed or unprocessed, intended to be ingested or likely to be ingested by humans.

The term covers beverages, chewing gum and any substance, including intentionally integrated water in foodstuffs during its manufacture, preparation or processing. It includes bottled waters and mineral waters.

The term 'food' does not cover:

- a) Feed for animals;
- b) Live animals not intended for human consumption;
- c) Plants before harvesting;
- d) Medicines;
- e) Cosmetics;
- f) Tobacco and tobacco products;
- g) Narcotic drugs and related substances;
- h) Residues and contaminants.
- <u>2- Feed</u>: any substance or product, including additives, processed or unprocessed, intended for oral feeding to animals producing food products.
- <u>3- Safe product</u>: any food or feed complying with the safety's legal and regulatory provisions in force.
- <u>4- Danger</u>: Any biological, chemical or physical agent present in food or feed or any food or feed state such as petrification, contamination, mold, or any others similar state that may have harmful effects on health.
- <u>5- Risk</u>: the probability that a harmful effect to health comes into effect and the severity of this effect due to the presence of a danger.
- 6- Risk analysis principle: principle based on three linked components, which are risk assessment, risk management, and risk

notification.

- <u>7- Precautionary principle</u>: principle based on temporary measures taken when the available information shows that the food and feed can harm human or animal health without any irrefutable scientific proof pending more necessary scientific information which will allow a better risk assessment.
- 8- Transparency principle: principle based on public consultation and notification in the cases stated in this Law
- <u>9-Traceability</u>: the ability to track, through all stages of production, processing and distribution, the movement of a foodstuff, animal feed, food-producing animal or a substance intended to be incorporated or capable of being incorporated in a food or feed
- 10- Operator: Any natural person or legal entity exploiting in an effective way a company in the food or animal sectors
- 11- Food business enterprise: any public or private enterprise that carries out, either for profit or not, activities referred in Article 2 of his Law and related to food.
- <u>12-Food chain</u>: all stages of primary production, production, handling, processing, packaging, transport, warehousing and distribution, sale, display, and export or import.
- 13- Animal feed business: any public or private enterprise that carries out, for profit or not, activities referred in Article 2 of his Law and related to feed.
- <u>14- Establishment</u>: any unit for production, processing, packaging, distribution, storage or preservation of food and feed, including slaughterhouses and their annexes, meat cutting and packing plants, fish market, fishing vessels, boats, catering facilities, and animal by-product processing units.
- <u>15- Approval</u>: official recognition from the National Authority for Food Safety that allows the operator to carry out its activities subject to approval.
- <u>16- Registration</u>: official recognition from the National Authority for Food Safety that allows the operator to carry out its activities not subject to approval.
- <u>17- Primary production</u>: a step from the food chain consisting specifically in cattle rearing, cultivation of primary products harvesting, milking, and any animal products prior to slaughter. It also covers hunting, fishing, and harvesting of wild products.
- <u>18- Retail</u>: Food processing, storage at the selling points or delivery to the final consumer including distribution points, catering facilities, restaurants, other food service providers, and retailers and wholesalers.
- 19- Market display: the handling of foodstuffs or feed for sale, distribution or transfer, free of charge or for a fee.
- <u>20- Withdrawal</u>: means the withdrawal from sale of foodstuffs or feed that are or may present a danger to consumers or animals.
- <u>21- Recall</u>: action consisting of returning unsafe food and feed, or potentially unsafe food and feed on the human and animal health, from the consumers or animals tenants.
- <u>22- Final consumer</u>: the last consumer of a foodstuff, which does not use it in the context of a production operation or an activity of a food business.
- <u>23- Consumer</u>: any natural or legal person who acquires, for a fee or free of charge, a product intended for a final use, for his own or family needs or for the need of another person or an animal for which he is responsible.
- <u>24- Private family consumption</u>: production, preparation, or storage of a product for the purpose of consumption to meet private family need without selling it or granting it for free.
- 25- The authority: the National Authority for Food Safety.

- <u>26- The competent authority</u>: For the purposes of this Law, the competent authority is the National Authority for Food Safety or any other mandated authority.
- 27- The authority in charge of risk assessment: National Agency for Risk Assessment.
- 28- The accredited laboratory: the laboratory that was accredited according to the legislation in force.
- <u>29- The approved laboratory</u>: the laboratory designed by the authority to conduct official analyses.

TITLE II

General principles governing the safety of food and feed

Article 5 – Food and feed safety is based on the following principles:

- risk analysis principle
- precautionary principle
- transparency principle

CHAPTER 1

Principle of risk analysis

Article 6 – The authority in charge of risk assessment, conducts risk assessment in an independent, transparent and unbiased way. Risk assessment is a science-based process based on four components: danger identification, danger description, assessment of the danger exposure probability, and risk description.

Article 7- The authority manages the risk based on possible options in consultation with stakeholders after consideration of the risk assessment result, in particular the opinions of the authority responsible for risk assessment and any other legitimate factors in relation to the issue, with a view to taking appropriate preventive and control measures. The authority is also responsible of managing the national early warning network.

Article 8 - Risk communication is based on:

- the interactive exchange between the authority, the authority in charge of risk assessment, the consumers, the organizations representing consumers, food and feed companies, and other interested parties of information and advice on dangers and risks, factors related to risk, and probability analysis.
- the explanation of the results of the risk assessment and the basis for the decisions taken by the authority.

CHAPTER 2

Precautionary principle

Article 9- The authority may take provisional measures based on the precautionary principle according to the provisions of Chapter 2 of Title VI of this Law. The provisional measures taken by the authority shall be proportionate to the degree of probable risks to achieve the high level of human and animal health protection taking into account the technical and economic possibilities and other factors considered legitimate in the light of the circumstances in question.

The authority is required to review the provisional measures taken within a specific time depending on the nature of risk on human and animal health and the type of scientific information needed to remove the scientific uncertainty and to carry out a more comprehensive risk assessment.

CHAPTER 3

Transparency principle

Article 10- The competent authority shall directly consult the public and representing bodies in an open and transparent manner during the preparation, evaluation and revision of related regulations.

Article 11- Where there are reasonable grounds to suspect that a food or feed may pose a risk to human or animal health, the authority shall take appropriate measures , , to inform the public of the nature of the risk on health depending on the nature, severity, and the risk level, by identifying the food or feed or its type, the risk that it may present and the measures taken or to be taken to prevent, reduce or eliminate that risk.

TITLE III

General safety commitment and food and feed compliance

Article 12- Food and feed imported, exported, or placed on the market shall, under normal or expected conditions of use, provide legitimate safety and not pose a threat to human or animal health.

Article 13- No food shall be imported, exported, processed, re-exported, or placed on the market if it is dangerous. A food is said to be dangerous if it is considered to be: detrimental to health, or unfit for human consumption.

Article 14- In determining whether a food is dangerous, account shall be taken of:

- a) the normal conditions of use of the food by the consumer at each stage of production, processing and distribution,
- b) information provided to the consumer concerning the prevention of adverse effects on the health of a particular food or a particular category of food.

In determining whether a food is detrimental to health, account shall be taken of:

- a) the immediate, short-term or long-term likely effect of that foodstuff on the health not only of a person consuming it but also of its offspring,
- b) probable cumulative toxic effects,
- c) the particular health sensitivities of a specific category of consumer when the food is intended for him.

In determining whether a food is unfit for human consumption, account shall be taken of whether the food is unacceptable for human consumption in view of the intended use for contamination reasons of external origin or by putrefaction, deterioration or decomposition.

Article 15- No feed shall be imported, exported, processed, re-exported or placed on the market if it is dangerous.

An animal feed is said to be dangerous given the intended use if it is considered to:

- a) have an adverse effect on human or animal health,
- b) render foodstuffs derived from food-producing animals for human consumption dangerous.

Article 16- When dangerous food is part of a batch or lot of foodstuffs of the same category or the same description, it shall be presumed that all the foodstuffs in that batch or lot are also dangerous, unless a detailed assessment shows the opposite

Article 17- When a dangerous animal feed is part of a batch or lot of the same category or the same description, it shall be presumed that all the feed of that batch or lot are also dangerous unless a detailed assessment shows the opposite

Article 18- The import, export, processing, or placement on the market of any food or animal feed not in compliance with the regulations is prohibited. If the importing country regulations allow the opposite, the operator shall inform the authority and obtain an authorization prior to the export or re-export.

Article 19- It is prohibited to store dangerous, unsafe, non-conforming food and feed in all production, processing, storage, distribution and sale areas, transportation means, open markets, stables, and slaughterhouses. If the operator proves that he took measures to prevent the sale or use of these products, he is allowed to store it in the places referred above.

Article 20- Without prejudice to the legislation in force, the labeling, advertising and presentation of food and feed, including the form, packaging, packaging materials used or the manner in which they are presented, as well as the information disseminated, must not mislead the consumer, in any of the following elements:

- a) the nature, composition, substantive qualities, content of useful principles, species, origin, date of manufacture, shelf life, or method of production and production technique,
- b) conditions of use and expected results,
- c) the identity, quality or suitability of the advertiser

Article 21- The Minister in charge of health may, after consultation with the consulting commission referred in Article 45 of this Law, regulate aspects relating to:

- a) the microbiological specifications of food and feed.
- b) composition, physico-chemical, biological and organoleptic specifications, useful components, labeling, additives, contaminants, pesticide residues, residues of veterinary drugs and other food and feed specifications or their treatment, according to their nature and category.
- c) conditions of food and feed production, processing, import, export, storage, distribution, and sale.
- d) conditions and procedures for the control of food and feed.
- e) set the general criteria to produce, use, and trade the products and materials to be in contact with the food.

TITLE IV

Obligations of operators

Article 22 - Every operator shall notify the authority of any establishment under its responsibilities.

The operator shall also notify the authority of any change in its activities or the addition of new tasks in the course of its activity or the closure of the establishment.

The notification content and procedures are set in an order of the Minister in charge of health.

Article 23- If the approval or the registration is required, every operator shall ensure that the establishment is approved or registered by the authority before the first placing the food or feed on the market.

The list of sectors subject to registration and approval is set by order of the Minister in charge of health.

The authority shall draw up and keep up to date in its website a list of establishments, which have been approved or registered.

The conditions and procedures for approval and registration are set by governmental decree.

Article 24- Every operator shall comply with the good practices of health protection, and establish and implement a self-control program based on the good practice guide referred in Article 34 of this Law to verify food and feed safety before placing it on the market.

Every operator is required to record, in documents, all procedures taken pursuant to this Article and shall present them upon request from the authority.

Article 25- Except for retail, every operator must set up, implement, and maintain permanent rocedures based on the principles of the Hazard Analysis Critical Control Point (HACCP) system. This shall be conducted by qualified persons with the required skills.

The list of food and sectors subject to this procedure are set by order of the Minister in charge of health.

Article 26- Before a product is placed on the market, an operator must obtain a health certificate issued by the authority.

The list of food concerned by this procedure and the conditions and procedures for granting the health certificate shall be laid down by order of the Minister in charge of health.

Article 27- Every operator shall establish a traceability system for foodstuffs, feed, and any other substance intended to be incorporated or capable of being incorporated in foodstuffs or in animal feed.

The traceability system must be adapted to the nature of the activity and the products manufactured or placed on the market by the operator.

The list of food and sectors subject to this procedure are set by order of the Minister in charge of health

Article 28- Every operator must cooperate with the authority in compliance with the provisions of this Law.

Article 29- Every operator in the food sector and responsible for retail or distribution must withdraw unsafe food from the market and contribute to food safety by sending the necessary information related to the traceability to producers, processors, and the authority, and collaborate with them in the taken measures.

Article 30- Every operator shall immediately withdraw the specific food or feed from the market and notify the authority if he considers, or has reasons to believe that the produced, processed, imported, distributed food and feed is not safe.

The operator shall also inform the feed consumer or user in an efficient way of the withdraw operation and clarify the reasons. When needed, the operator shall recall the food that was presented to the consumer or the supplied feed if the taken measures are not sufficient to reach a high level of human or animal safety.

Article 31- Every operator shall immediately notify the authority if he considers, or has reasons to believe that the food placed on the market may be dangerous to human health or the feed that was placed on the market is unsafe.

The operator shall inform the authority on the measures taken to protect the consumer from the risk resulting of the feed use. The operator shall not prohibit any person to cooperate with the authority if this person's purpose is the protection from risk, or minimizing or eliminating it.

- **Article 32-** The operator shall ask the authority for opinion and cooperate with it to decide on the future of the withdrawal and recalled food and feed, in accordance with procedures previously set.
- **Article 33-** The conditions of the good practices of health protection, self-control, traceability, and notifications to the authority and consumer are set by governmental decree.
- **Article 34-** The operator may implement the guide of good practices prepared by professional and inter-professional organizations that establish and disseminate the guides.

The guides are prepared after consultations with consumer's representatives in accordance with the legislation in force and with the international specialized organizations' notices.

The authority in charge of risk assessment evaluate the cited guides.

The authority assess and approve the guides of good practices and make sure that they comply with the provisions of the Paragraph 2 of this Article and that its contents can be enforced in the specific sectors, following the concurrence of the consulting committee referred in Article 45 of this Law.

TITLE V

National Agency for Risk Assessment

Article 35- A public institution is created, of a non-administrative nature, endowed with civil personality and financial autonomy, called the "National Agency for Risk Assessment" and placed under the supervision of the ministry in charge of health.

The administrative and financial organization and the modalities of operation of the National Agency for Risk Assessment are set by decree.

Article 36- The National Agency for Risk Assessment shall be responsible for the following tasks:

- provide advice and scientific and technical assistance to the risk managers in the sectors that present risks on human health and product safety.
- collect and analyze information to assess and identify the risk that has impact on human health and product safety.
- conduct or order the needed scientific studies to achieve its mission and report its results.
- facilitate the transmission of trustworthy, unbiased, and clear information to concerned parties in their respective assigned areas.
- communicate in an independent way about its specific analysis and orientations in regards to its prerogatives.
- contribute in the drafting of laws and regulations in its fields of competence.
- establish relationships with authorities that conduct similar missions in other countries and cooperate with them.
- provide the needed training in its fields of competence.
- receive and review technical and scientific enquiries coming from professional organizations and business actors in the field of risk assessment.

Article 37- the National Agency for Risk Assessment cooperates with the National Authority for Food Safety and specialized control authorities to reach a balance between the risk assessment, risk management and risk notifications.

Article 38- To carry out its mission, the National Agency for Risk Assessment can, further to its request, access the needed information, which is under the possession of public entities, corporations, or persons, and this without being stopped by professional, medical, trade, or industrial secrecy.

In this case, the agency cannot divulge these secrecies to others if they are not proven to be dangerous.

Article 39 - In the framework of its mission, the National Agency for Risk Assessment can contract with experts chosen based on their qualification and experience in the field of risk assessment according to the legislation in force.

The funds are fixed by governmental decree.

Article 40- The employees and contractors of the National Agency for Risk Assessment referred in the Article 39 of this Law shall abide by the professional secrecy related to the operations and information they were aware of when conducting their official business.

Article 41- The National Agency for Risk Assessment prepares an annual report on its activities published on its official site.

TITLE VI

The National Authority for Food Safety

Article 42 - A public institution is created, of administrative nature, endowed with civil identification and financial autonomy, called the National Authority for Food Safety. The headquarters of the authority is located in the capital Tunis and the authority may have regional representations in all Tunisia.

The authority benefits from professional independence when conducting its missions referred in this Law and is under the administrative and financial supervision of the ministry in charge of health.

The National Authority for Food Safety's employees abide by <u>Law #1985-78</u> dated August 4, 1985, related to the general basic organization for the employees of the public-owned enterprises that have a industrial, commercial nature and the corporations that are majority owned by the state directly or indirectly.

The administrative and financial organization and the modalities of operation of the authority are set by governmental decree.

Article 43- The authority shall be responsible for the following tasks:

- implement the state policy in the field of consumer protection; animal and plant safety; animal welfare; and the safety of food, feed and agricultural inputs, from primary production to the final consumer and contribute in elaborating the policy
- identify and monitor the plant and animal health status
- design and set strategies, orientations, and programs related to pest management; animal and plant diseases control; animal welfare; the safety of food, feed, and agricultural inputs; and monitor the implementation and the assessment.
- propose, prepare, and review legal and regulatory texts within the scope of its competency.
- control the safety of food, feed, raw materials, and agricultural inputs; animal welfare; animal and plant safety in all stages from primary production to distribution including import and export.
- control the quality and safety of seeds, seedlings, fertilizers, and pesticides for agricultural use and trade.
- control the quality and safety of drinking water and wastewater used in agriculture.
- control materials and objects intended to be in contact with food.
- control the safety of food supplied to restaurants and bars in public and private structures and institutions, including public and private hospitals and health institutions.
- ensures the integrity of economic transactions and protect the interests of the consumer in the field of its competency.
- control pet food.
- grants accreditations, registrations, authorizations, and certificates in the field of its competency
- approve seeds and seedlings and agriculture pesticides and prepare a special manual.
- participate in the approval process of veterinary drugs, veterinary biological products and cleaning materials.
- manage its laboratories and appoint the laboratories that can conduct analysis for the benefit of the authority.
- contributes to the activity of specialized international and regional authorities and develop programs of cooperation and technical support in their fields of competency.
- represents Tunisia at the international and regional authorities active in its field of competency.

The authority shall exercise its functions in accordance with the provisions of this Law and all legal provisions related to drinking water and the protection of plants, animals, fisheries products, and pet food.

Article 44 - The authority may delegate some of its official control functions to a public structure other than the functions provided in Chapter 2 of Title VI of this Law.

The conditions for delegation are set by governmental decree.

The authority may also designate a special institution to deliver services related to its activities.

Article 45 - A consultancy committee is charged with advising the authority on all areas of its competency, including the policy to be followed.

This committee includes representatives from the relevant ministries and structures; the authority; the competent authority in charge of risk assessment; and professionals and consumer organizations as well as experts.

The modalities and composition of the consultancy committee shall be regulated by governmental decree.

Article 46 - The authority shall prepare an annual activity report and send it to the President of Parliament and the Head of Government during the first semester of the following year.

The annual report is also published on its website.

Article 47 - The authority's resources consist of:

- credits and grants from the State
- the taxes and fees paid to the operators for the services rendered
- the revenues of the laboratories under its supervision
- amounts from reconciliation

- donations and wills
- income obtained from the disposition of its properties
- benefits from the delays of payments
- cost of investing their financial savings
- incidentals income

The taxes and fees, referred in the second point of the first Paragraph of this Chapter, shall be equivalent to the real value of the expenses made and determined by the authority, as well as the methods and date of their payment are set by governmental decree after consultation with the consultancy committee of the authority.

If the authority is dissolved, its properties shall be returned to State, which carries out its obligations in accordance with the legislation in force.

Title VII

Official control of the food chain

Chapter 1

Organization of official control

Article 48 – the authority regularly ensures and organizes the official food chain controls according to the risks and based on the principle of risk analysis to achieve the specific goals, taking into account the following elements:

- a) identifies the risks associated with food, feed, animals, plants, or agricultural inputs; active institutions in the mentioned sectors; use of food, feed, and all productive processes; equipment, material, and activity that can affect the human health or health safety of the food, feed, and agricultural inputs; and that affects animal health, plant health, and animal welfare.
- b) the operators' precedents in the food and feed sectors with regard to the legal provisions and health safety regulation related health safety and food and feed compliance, or other actors in the food chain that are important to animal health and welfare, plant health, and agricultural inputs.
- c) the effectiveness of the previous monitoring operations carried out by the authority.
- d) any information regarding the possibility of a breach in the legislative and regulatory provisions in force.
- e) any information related to the emergence of health risks arising from local, regional or international health surveillance and early warning network.

Article 49 – The authority prepares an official monitoring plan for a period of three years, which shall be evaluated and reviewed on a regular basis. It also carries out monitoring operations whenever necessary, without complying with the plan.

Article 50 – Official control are carried out without prior notice, but the authority can inform the operator in advance when appropriate in accordance to the laid down procedures.

The official control methods and procedures for the food chain are regulated by a governmental decree.

Article 51 – The authority ensures the official control at import and export to verify the health safety and the plant and feed health in view of potential risks.

The official import and export control methods and procedures are set a by a governmental decree.

Article 52 – The authority ensures the coordination and cooperation between the various structures entrusted with certain official monitoring functions.

Chapter 2

Measures taken related to food and feed

Article 53- The conformity of a food or feed with relevant legal and regulatory provisions does not preclude the competent authority from taking all appropriate measures to impose restrictions on its placement on the market, its importation, its withdrawal, or to prohibit its exportation, if the said authority, under the precautionary principle, has legitimate reasons to suspect that, despite its safety, the food or feed concerned is likely to be dangerous to human or animal health.

Article 54 - If it is established that the food or feed displayed on the market, imported, or exported is unsafe and present a threat on human or animal health, the competent authority may after hearing the operator take the following measures:

- suspends the manufacture, import, export or placement in the market for free or with charge.
- engages the recall, withdrawal from any place where it is found or destroys when it is the only means of putting an end to the danger.
- orders the dissemination, via the appropriate means of information, of warnings or precautions for use.
- orders the recall for exchange, modification, or a total or partial reimbursement.

The terms of withdrawal and recall are set by order of the Minister in charge of health.

The governmental decree referred in Article 50 of this Law set the cases of suspected dangerous products and the measures that need to be taken, the duration, the complementary measures needed to have a final decision on the suspected products, and the measures and procedures needed to bring back the safety qualification to the product.

Article 55: The authority can order the use of the unsafe food or feed that do not present a threat to the human or animal health for purposes other than the expected ones.

However, when the operator proves that the products is safe, the authority can order the re-displaying of the product on the market.

Article 56- The authority may request the operator to carry out, in a specific time and according to the procedures set by the authority, an inspection on his own expense by the laboratories referred in Article 73 of this Law if there are sufficient elements that could question the safety of a food or feed and the operator is not capable to prove that he conducted inspection operations, or when the specificities of a new products requires it.

Pending inspection's results, the authority may suspend the placement on the market of the food or feed.

The authority may as well put the establishment under official intensive controls on the operator expenses if there are an infraction recurrences, disobedience, absence of the required self-control program, or inappropriate implementation of the required self-control program.

Article 57: The authority re-conduct control on the operator expenses to check if he took the needed corrective measures following a prior official control that proved the food or feed to be unsafe.

Article 58- The competent authority may, after hearing the operator, suspend the authorization or registration for a specified period during which he must take the necessary measures to meet the legal requirements.

Ifat the end of the specified period, the operator has not taken the necessary measures, the approval or registration shall be withdrawn by the authority.

Article 59- The authority can, after the danger is proven, take the decision to close the establishment for a period not exceeding six months.

The authority can as well order the posting of the closure decision on the main entrance of factories, the operator stores entrance, and at the municipality where the establishment headquarter is located and this on the expenses of the operator.

Article 60- The authority can send a warning to the operator to take the needed complementary measures if there is an infraction to legal provisions that not present danger on the human and animal health.

The warning includes the infraction, the legal provisions that was violated besides the granted time to stop the infraction.

When the deadline is over and in the case of not compliance an investigation report is prepared.

CHAPTER 3

Early Warning Network and Crisis Management

Article 61- An early warning network shall be established to notify of a direct or indirect risk to human, animal, and plant health. This network is established as the national early warning network.

The national early warning network procedures and management are set in a governmental decree.

Article 62- The purpose of this network is to:

- collect and communicate information and warnings on the national territory, in another country, or in group of countries.
- exchange data with counterpart organizations in other countries or group of countries,
- inform the competent institutions of other countries when a severe risk threatening human, animal, or plant health was found during or after import, or during or after export of food, feed, agricultural inputs, animals, or plants.
- inform the competent international organizations.

Article 63- The authority shall draw up an intervention plan in case of crisis that specifies:

- the administrative authorities to intervene,
- the prerogatives and responsibility of each intervening authority,
- the ways and procedures to be followed for the exchange of information between the concerned actors.

These plans are regularly updated by the authority.

TITLE VIII

Violations and Sanctions

CHAPTER 1

Violation Investigations

Article 64- The violation investigations in the provisions of this Law shall be established by:

- the judicial police officers referred to in Paragraphs 1, 2, 3 and 4 of Article 10 of the Code of Criminal Procedures,
- the agents from the National Authority for Food Safety from doctors, veterinarians, pharmacists, engineers, technicians, public health technicians, and agents of the Economic Inspection Department, who are sworn in and empowered for this purpose by the Minister in charge of health.

However, in the case it is proven by the judicial police officers referred to in Article 10 of the <u>Code of Criminal Procedures</u> in their investigation of committed crimes in other cases to find a violation of the provision of this Law, it can take precautionary measures and release the preliminary inspections before the agents of the national authority have agreed to the investigation.

Article 65. The agents appointed to inspect violations in the exercise of their duties:

during the normal hours of opening or working, access professional premises, workshops and warehouses and all other places associated with professional premises. They may also perform their duties during the transportation of

food and feed.

However, in the event of an emergency, they are allowed to intervene outside normal business hours or working hours.

- where appropriate, access living quarters, in accordance with the conditions referred to in the <u>Code of Criminal</u> <u>Procedures</u>, after being authorized by the territorially competent State Prosecutor.
- make all the investigations and obtain at the first request and without displacing the documents, electronic files, and records necessary for their investigations and findings and make copies of them.
- seize the necessary documents, electronic files, or equipment used to prove the violation or to search for accomplices of offenders in exchange of a delivery voucher.
- seize foodstuffs and feed in accordance with the provisions of Articles 68 and 69 of this Law.
- take samples according to the methods and conditions stipulated in the regulations in force.
- consult all the documents necessary for the accomplishment of their duties with the public administrations, institutions and organizations subject to be controlled by the State in accordance with the legislation in force.
- use the findings and results of analysis and research carried out by other institutions.
- require the advertiser of an advertisement to make available to them all the elements necessary to justify the allegations, indications or advertising presentations. They may also require the advertiser, the advertising agency or the person in charge of the support to make available to them the messages broadcast.
- request documents proving the identity of the actual directors, legal directors and representatives of the institutions subject to control.
- prepare hearing minutes of the violator and any person connected to the facts or in possession of information useful and if necessary a copy of each hearing minute shall be forwarded to the person heard no later than 30 days after the date of publishing the minutes.
- where necessary, act as a client during the control process in cases in order to detect the violations.

In case of crime case which requires imprisonment, the agents, referred to above, shall notify immediately the State Prosecutor in accordance with the provisions of Chapter 13 and beyond of the <u>Code of the Criminal Procedure</u>.

Article 66 – Public, security and military officials shall, upon request, assist the agents referred to in Article 64 of this Law when carrying-out their duties.

The owners of transport establishments shall not obstruct the control, inspection, sampling, or seizure operations and present transport documents, consignments, receipts and statements in their possession.

Article 67- Without prejudice to the obligation to provide information, the agents assigned to inspect the violations and all persons who have access to the files of violations, shall be bound by professional secrecy. The disclosure of the professional secrecy is subject to the penalties provided for in article 254 of the Code of the Criminal Procedure.

Article 68- The agents referred to in Article 64 of this Law may make a temporary seizure on foodstuffs and feeds suspected of being dangerous or unsafe,

The minutes for seizure will be processed for that purpose and shall include the time, date, the names and the quality of the agents, the place of inspection, the identity and description of the holder of the seized goods and, where appropriate, identity and description of the person present at the time of the inspection, the legal reference of the seizure, the statement of the seized goods, the quantity, the identity and description of the person from whom the goods were seized, the signatures of the agents, and the person present during the inspection and, where appropriate, the person from whom the goods were seized. In case of refusal of signature, this shall be indicated in the minutes.

The minutes may include any other provisions that the verbalizing agents deem useful in the investigation and the precautions to be taken to avoid any change in the seized goods or their defectiveness or their mixing with other products.

Pending the results of the inspection, the seized food or feed shall be left in the custody of its holder.

The seized period may not exceed two months without the authorization of the State Prosecutor from the Court of First Instance that shall issue a decision in the matter at the request of the authority.

At the expiry of this period and in the absence of authorization of extension by the State Prosecutor, this procedure legally expires.

The authority may at any time authorize the lifting of the temporary seizure.

Article 69 - Food and feed that have been found to be dangerous or unsafe, or present danger to human or animal health, or are harmful to human or animal health shall be seized by the agents referred to in Article 64 of this Law.

The contents of the minutes for seizure drafted for this purpose shall be the same as that provided in the second paragraph of Article 68 of this Law.

A copy of the minutes for seizure shall be sent to the holder of the seized goods. If the holder of the seized goods is not the offender, the offender shall be notified by registered letter or any other means leaving a written record not later than seven days.

Minutes of seizure of perishable food or feed shall be sent within 48 hours to the State Prosecutor at the competent court.

The concerned food or feed shall be stored in the premises of the concerned person and, in the case of refusals, stored in good conditions in a place chosen by the reporting agents.

Article 70 - Agents, referred to in Article 64 of this Law, may proceed to the destruction of the seized goods, after obtaining the permission of a competent judge if that is the only way to put an end to the danger.

The holder must be notified of the authorization to destroy.

Minutes of destruction shall be drafted and signed by the agents, referred to in the first paragraph of this Article, and the holder or whoever may represent during the destruction process. If the minutes are drafted in the absence of the holder or the latter refuses to sign it during his presence, this shall be stated in the minutes.

In all cases, the holder must provide the necessary means for the destruction. The destruction shall be carried out in accordance with the regulations in force, in particular with regard to the environment, at the expense of the holder.

Article 71- Samples taken by agents referred to in Article 64 of this Law shall be subject to the required analyses conducted by accredited laboratories. In the absence of accredited laboratories, it is possible to carry out the analyses in qualified laboratories.

The analyses shall be carried out on the remaining samples taken by the agents referred to in Article 64 of this Law in accordance with the provisions of the <u>Code of Criminal Procedure</u>.

The methods and procedures of sampling shall be determined by order of the Minister in charge of health.

Costs of analysis of samples taken during official controls at the time of import or export are borne by the importer or exporter.

Article 72- The Authority shall prepare the laboratories according to the corresponding opinion of the Advisory Committee provided for in Article 45 of this Law.

The conditions and methods of rehabilitation of the laboratories shall be determined by decree of the Minister in charge of health.

Article 73- The analysis is not mandatory if the inspection of the control agents, statements by the operator or legal representative, the results of the risk assessment, or the information gathered through the early warning network indicate that food and feed are dangerous or unsafe and poses a threat to human or animal health.

Article 74- Violation investigations of the provisions of this Law shall be established by minutes drafted by at least two agents referred to in Article 64 of this Law, who have personally contributed to the investigation constituting the violation after having made known their qualifications and the presentation of their professional cards.

All minutes shall include the identity of the authorized agents, their signatures, the identity of the offender or the legal representative of the legal persons, his statements, and the conclusion of the authority responsible for the agents.

The minutes must also indicate the date, place, nature of the inspection or control carried out and the legal authority and

indicate that the offender was notified of the date and place of its drafting and that the offender was invited by registered letter.

The minutes shall state, where appropriate, that the person concerned has been notified of the seizure and that a copy of the minutes of the seizure has been sent to him by registered letter or by any other means leaving a written record which includes the date, the description of the seized goods, and any other necessary information.

The offender or his representative, present at the time of the drafting of the minutes, shall be required to sign it. In case the minutes are drafted in his absence or the latter refuses to sign it during his presence, this shall be stated in the minutes.

Minutes fulfilling the conditions laid down in this Article shall be submitted by the authority to the State Prosecutor at the competent court within a period not to exceed one month following the finalization of the minutes of the offense accompanied by the requests of authority.

CHAPTER 2

Sanctions

Article 75- One shall be punished with imprisonment of one year to three years and a fine of fifty thousand (50,000) dinars to one hundred thousand (100,000) dinars or one of these two penalties only, for those who deceive or tempt to deceive, by any means or process in the use capacity or the risks resulting of the use of the product or the control, the manual of use, or the precautions that should be taken.

The amount of the fine referred in the paragraph one of this Article can be calculated in accordance with the results of the infraction.

The provisions of the Article 215 of the <u>Penal Code</u> are applicable if the cations cited above harm human or animal health, if the infraction is a part of an organized crime, or was carried out under an organization and agreement.

Article 76- Any person that commits the following infractions is punishable by the penalties refereed in Article 310 of the Penal Code:

- broke the general safety commitment as stated in Article 12 of this Law;
- produced, processed, imported, exported, stored, transported, distributed, displayed on the market dangerous or unsafe food or feed, not in compliance, subject to suspension from displaying on the market, withdrawn, or recalled;
- displayed food or feed on the market without checking if its safety and compliance;
- displayed food or feed on the market without obtaining the health safety certificate;
- did not take the needed measures to prevent, decrease, or eliminate the risk in a voluntary way, or did not abide by the measures taken by the authority;
- did not notify the authority, cooperate with it, or prohibited a person from cooperating with the authority

without prohibiting the enforcement of Articles 215, 218, and 219 of the Penal Code.

Article 77- Any person that commits the following infractions is punishable by a fine of ten thousand (10,000) dinars to fifty thousand (50,000) dinars:

- the use of an establishment without notifying the authority or failing to notify the authority about a change in activities or the closure of the establishment.
- the use of an unapproved or un-registered establishment
- the non-use or non-implementation of a self-control program
- the non-use of the traceability system or the infraction to the related legal provisos
- the non-respect of the good practices of health protection
- the non-use, or the non-implementation of permanent measures based on the HACCP system
- failure to notify the consumers or feed users

Article 78- A prison sentence from 1 month to one year and a fine of between five thousand (5,000) dinars and fifty thousand

(50,000) dinars or one of these two penalties only shall be punishable, to anyone who hinder or attempt to obstruct the agents referred in Article 64 of this Law to carry on their missions.

Article 79- A prison sentence of one month to one year and a fine of between ten thousand (10,000) dinars and fifty thousand (50,000) dinars shall be punishable or one of these two penalties only, each person who handles product seized by the agents referred to in article 64 of this Law without authorization.

Article 80- Anyone who has committed the following offenses shall be liable to a fine ranging from ten thousand (10,000) dinars to thirty thousand (30000) dinars:

- mislead the consumer by labeling, advertising or presentation of an unsafe food
- not retain the information and documents relating to the self-checking program or the traceability system.
- not give the authority or the agents referred in Article 64 of this Law the needed document and information when requested or not divulge the requested evidence.

Article 81- The term of imprisonment shall be increased to perpetuity if the person in charge displayed a product in the market that caused death and up to 20 years if the product caused permanent incapacity.

Article 82- The court may order the publication of its judgment in its entirety or in extracts from the newspapers it designates, and display it in the places indicated by it, in particular at the main gates of the convicted person's factories or workshops and its stores for a period not exceeding six months.

Article 83- The penalties of imprisonment provided for in this Law shall apply to legal persons, personally to their president, agent, and any other person entitled to represent the legal person, and whose liability in the committed acts is established.

Article 84- Anyone who voluntarily proceeds to the suppression, concealment or total or partial laceration of the posters affixed in accordance with the provisions of Articles 59 and 82 of this Law shall be liable to a fine of one thousand (1000) dinars to three thousand (3,000) dinars 74 of this Law, during the period fixed for posting, and the bill will be re-issued at the expense of the offender for the re-posting.

Article 85- In the case of a second offense, the penal sanctions provided for in this Law shall be doubled.

Article 86- Regarding the infractions refereed in Articles 77 and 80 of this Law, the Minister in charge of health can order a settlement, following the offender's request before or after the public prosecution as long as a final judgment has not been pronounced.

The amount of the settlement cannot be less than 50% of the requests of the authority. It may not be less than the minimum threshold of the fine set in this Law.

The settlement commits the parties and cannot be withdrawn or presented to the court for any reasons

The transaction must be in writing and in as many copies as there are parties with a separate interest. It must also be signed by the offender or his legal representative and include his undertaking to pay the amount covered by the transaction within the specified period.

During the period of completion of the reconciliation procedures and the period fixed for its execution, the limitation periods for the public action will be suspended. The payment of the amount set out in the deed of transaction will result in the termination of the proceedings and the stay of the prosecution or judgment or the execution of the sentence.

The transaction procedure is exempt from registration and stamp fees.

The transaction cannot be concluded with a repeat offender.

TITLE IX

Transitional Provisions

Article 87 – Articles 18, 19, 21, 37, 38, 39, 40, the first paragraph of Article 41, 42, 43, 44, 45 of the Animal Husbandry <u>Law</u> #2005-95, dated October 15, 2005, are repealed.

The mission of bottled water control referred in <u>Decree #2011-52</u>, dated June 6, 2011, that updated and completed <u>Law</u> #1975-58, dated June 14, 1975, related to the creation of the Mineral Water Board, is withdrawn from the prerogatives of the Mineral and thermal Water Board

The application texts resulting from the Articles cited above remain effective until replacement.

Article 88- In the sense of this Law, food and feed are exempted from the application of:

- The provisions of the <u>Law #1992-117</u>, dated December 7, 1992, related to the consumer protection, and its texts remain effective if not replaced.
- Article 8, 9, 10, 11 of the <u>Law #1994-41</u>, dated March 7, 1994, related to the foreign trade, and the applications texts related to the import and export technical control remains effective until the publication of the governmental decree stated in Article 51 of this Law.

The provisions of <u>Law #1999-24</u>, dated March 9, 1999, related to the import and export veterinary inspections and its implementing texts remain effective until the publication of the two governmental decrees referred in Articles 50 and 51 of this Law.

Article 89- The effective decrees and orders related to fishery products and live bivalve mollusks are considered implementing texts of this Law.

The orders related to the approval of the book of specifications related to the organization of semi-canned plant origin products, the creation of a committee in charge of the technical control and organization of the activities of the units producing semi-canned plant origin products, the creation of a committee in charge of dates, fruit and fresh vegetables packaging, the creation of a committee in charge of the technical control and organization of the activities of vegetable oil packaging, and the creation of a committee in charge of technical control, are considered implementing texts of this Law until the publication of a governmental decree referred in Article 23 of this Law.

Article 90- Decree #1995-1474, dated August 14, 1995, designating the competent authority for the technical control of the import and export of fishery products and the approval of premises, remains effective until the publication of the two governmental decrees referred in Articles 23 and 51 of this Law.

Article 91- Agents that belong to the corps of public health physicians, veterinarians, pharmacists, public health technicians, nurses holding social, public, and animal health protection diplomas under the supervision of the ministries in charge of health, agriculture, and trade and in charge of the health safety control, plant health and the quality of food products are transferred to the authority.

A committee in charge of finalizing the agents compulsory transfer is created according to joint order by the Ministers of health, agriculture, and trade.

The directorates under supervision of the ministries cited above in the first paragraph of this article continue to fulfil its mission until the authority is established and supersedes the directorates.

Equipment, tools, and files belonging to these directorates are transferred to the authority according to the legislation in force.

The authority replaces all the transferred directorates in terms of rights, duties, and commitments.

Article 92- The laboratories under the supervision the ministries in charge of health and agriculture and under the supervision of the directorates that will be transferred to the authority, are transferred to the authority.

Equipment, tools, and files belonging to these laboratories are transferred to the authority according to the legislation in force

A list of the laboratories that will be transferred is set in a governmental decree.

Article 93- Every operator of an establishment or a food or feed company shall abide by the provisions of this Law since it publication with a maximum delay of two years from its publication.

The laboratories are granted a maximum of five years from the publication of this Law in the Official Gazette of the Republic of Tunisia to obtain the accreditation certificate according to the legislation in force. Meanwhile, working with these laboratories continues according to the legislation in force as it was before the publication of this Law.

Article 94- The Agency for the Products Health and Environmental Control is dissolved and all its assets are transferred to the National Agency for Risk Assessment that replace it in terms of rights, duties, and commitments.

With consideration of Article 31 of this Law, the agents of the Agency for the Products Health and Environmental Control are incorporated in the National Agency for Risk Assessment.

The Agents of the National Agency for Risk Assessment abide by <u>Law #1985-78</u>, dated August 4, 1985, related to the general basic organization for the employees of the public-owned enterprises that have industrial, commercial nature and the corporations that are majority-owned by the state directly or indirectly.

In the case of dissolution of the National Agency for Risk Assessment, all its assets are transferred to the State which commits to execute its commitments.