Directive Issued for Feed Risk Assessment, Risk Management and Risk Communication (Directive No. 291/2021)

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Veterinary Drug and Animal Feed Administration and Control Authority

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DESCRIPTION

Cognizant of the importance of measures for government assurance of the quality and safety of domestically produced, exported and imported feed, build the confidence of local and export customers about the quality and safety of Ethiopian Live animals and animal products and foster competitiveness in the world market to enhance foreign exchange earnings from exports;

Cognizant ofthe fact that Ethiopia is due to join the World Trade Organization (WTO) where Sanitary and Phytosanitary (SPS) is a requirement for international trade in agricultural products, it has been found necessary to assure the free movement of safe and wholesome feed

WHEREAS, it has been found necessary to protect the livestock population directly consuming feed, economic risks to livestock producers,the health of the human population consuming animal products and the environment through ensuring the safety of compound feeds and feed ingredients produced, imported, distributed, exported, retailed and utilized;

WHEREAS, it is found necessary to ensure that imported and exported compound feeds and feed ingredients fulfill the necessary safety requirements and the functioning of feed markets in an orderly manner by prohibiting the production and sale of unsafe feed products and fraudulent acts committed on feeds;

WHEREAS, it is found necessary to guide appropriate feed risk analysis taking into account the farm feed production to utilization continuum, put a standard and acceptable guidance for follow up and self-regulation by feed ingredient and compound feed producers, importers, distributors, exporters, retailers and users in place so that safe feed and consequently safe food is produced; and identify the roles of different stakeholders when a need to respond to feed safety related emergencies arise;

NOW, THEREFORE, in accordance with the duties and responsibilities given to the Authority under Sub-article 2 of Article 28 of Proclamation number 728/2011to issue directives necessary for the implementation of this Proclamation and other regulations therefrom, this Directive is issued to guide Feed Risk Assessment, Risk Management and Risk Communication to safeguard animals from health risks; humans from economic and health risks; and to ensure the functioning of feed markets in an orderly manner by prohibiting the production and sale of unsafe feed products and fraudulent actions committed on feeds.

PART ONE

GENERAL

1. Title

This Directive may be cited as "Veterinary Drug and Animal Feed Administration and Control authority Directive issued to guide Feed Risk Assessment, Risk Management and Risk Communication No. 291/2021".

2. Definitions

Notwithstanding the definitions provided under Proclamation No.728/2011 article 2, unless the context requires otherwise:

1. **Adulteration of Feed or Feed Ingredients**- means mixing of a compound feed or feed ingredient of standard quality and safety with sub-standard materials.

2. **Audit**- a systematic and functionally independent examination to determine whether activities and related results comply with planned food safety management objectives.

3. **Authority -**means the Veterinary Drug and Animal Feed Administration and Control Authority (VDFACA)

4. **Biological or biohazards -**include bacteria, viruses, fungi or their toxins that pose a threat to the health of animals and humans.

5. **Chemical hazards** –Includes heavy metals, pesticide residues, alkaloids, free gossypol and chemical substance that pose a threat to the health of animals and humans.

6. **Communiqué -**Information issued in any format by the competent authorities, giving it an official status.

7. **Competent body -** A body officially recognized and overseen by the competent authority to undertake specified feed hygiene and safety activities.

8. **Competent person -** A person who has the training, knowledge, skills, and ability to perform an assigned task, and who is subject to requirements specified by the competent authority.

9. **Compound Feed or Feed Ingredient Health Certificate -**means a legal certificate that confirms that a compound feed or feed ingredient is safe and that it does not cause any side effect or cause health problems on the livestock fed or on humans that consume animal products from such livestock.

10. **Compound feed or Feed Ingredient standards** - mean quality and safety requirements of compound feed and feed ingredients defined and approved through the procedures of the Ethiopian Standards Agency (ESA) and accepted as the official national quality and safety standards.

11. **Consignment -** The quantity of product dispatched or received at one time and covered by a particular contract or shipping document.

12. **Contaminant -**Any biological or chemical agent, foreign matter or other substance not intentionally added to feed that may compromise feed and food safety.

13. **Critical control point (CCp) -** A point, step or procedure in a feed or food process at which control can be applied and, as a result, a feed or food safety hazard can be prevented, eliminated or reduced to acceptable levels.

14. **Critical limit -** The maximum or minimum value to which a physical, biological or chemical hazard must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified feed or food safety hazard.

15. **Economic impact -** The effect that a food/feed incident event will have on the national and international sales or potential sales of the product and possible related products.

16. **Exposure assessment-**The qualitative and/or quantitative evaluation of the exposure of a food-producing animal to a hazard and to an evaluation of the likely amount of a hazard in feed that can transfer to an edible product.

17. **Feed** - means a material that includes commercialgrass hay and crop residues, concentrates used for feeding animals produced, imported, and transported from one region to another or exported to other countries for commercial purposes.

18. **Feed additive** - means a product that may or may not have nutritional contributions added to mixed feeds in small quantities during feed processing as a sweetener, to improve coloration, or as a binding agent and does not have any deleterious side effects on the animals that feed on it or consumers of animal products produced therefrom.

19. **Feed Raw Material or Feed Ingredient** - means a product that could be a mixture or a single ingredient or a feed additive that is used to constitute compound rations. It can include sugar factory by-products (cane tops, Bagasse, molasses); oil milling and flour milling by-products (Oil cakes/meals, bran, shorts, grain screenings, cassava processing by-product); brewery and distillery by-products (Brewer's grain, distiller's grain, malt by-products); Forage (wet, hay, chopped, pellet); slaughterhouse by-products (blood, bone, meat, offals); Fish processing by-products; poultry litter/manure; Mineral supplement sources like lime, *bole*, diatomous earth,

and salt; microbiological feed improvement inputs like Effective Microorganism-EM, enzymes, probiotics.

20. **Good Agricultural Practice (GAP)**- a collection of principles to apply for on-farm production and post-production processes, resulting in safe and healthy food and non-food agricultural products, while taking into account economic, social and environmental sustainability.

21. **Good Hygienic practices (GHp) -** All practices regarding the conditions and measures necessary to ensure the safety and suitability of feed or food at all stages of the food chain.

22. **Good Manufacturing Practices (GMP) -**A series of procedures in a branch or sector in which the standard of conduct is laid down.

23. **Hazard -** a biological**,** chemical or physical agent in, or condition of, feed with the potential to cause an adverse health effect;

24. **Hazard Analysis and Critical Control points (HACCP) -** A method to identify process steps where a loss or significant deviance from the required product quality and safety could occur if no targeted control is applied.

25. **Hazard characterization -** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in feed.

26. **Hazard identification -** The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular feed or group of feeds.

27. **Incident -**Any event where there are concerns about actual or suspected threats to the safety of feed that could require intervention based on the information available.

28. **Inspection** - is the examination of feed or systems for control of feed, raw materials, processing, and distribution, including in-process and finished product testing, in order to verify that they conform to requirements.

29. **Label** - means any material which is printed or affixed to a packing material which provides the necessary information about a veterinary drug or feed and includes an explanatory note attached therein

30. **Legislation** - acts, regulations, requirements or procedures, issued by public authorities, related to foodstuffs and/or feedstuffs and covering the protection of animal and public health, the protection of consumers and conditions of fair trading.

31. **Maximum Residue Limit (MRL) for pesticides -**The maximum concentration of a pesticide residue (expressed as mg/kg) recommended by the Codex Alimentarius Commission to be legally permitted in or on animal feeds.

32. **Official accreditation -**the procedure by which a competent authority formally recognizes the competence of an inspection and/or certification body to provide inspection and certification services.

33. **Package or Container** - means a material or container used to pack, transport or store compound feed or feed ingredients.

34. **Physical hazards** – include glass, metal, wood plastics, stones, and any other similar materialthat pose a threat to the health of animals and humans.

35. **Proclamation** - means veterinary drug and feed Administration and control proclamation no.728/2011.

36. **Quantitative risk assessment** - structured science-based processes based on numerical data that estimate the probability and severity of illness from consuming feed containing biological, chemical or physical hazards.

37. **Qualitative risk assessments** - are non-numeric processes commonly used for screening risks to determine whether they merit further investigation, and can be useful in preliminary risk management activities.

38. **Risk -**A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in feed.

39. **Risk analysis** - a process consisting of three interconnected components: risk assessment, risk management, and risk communication;

40. **Risk assessment -** A scientifically based process consisting of four steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization.

41. **Risk characterization -** The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment.

42. **Risk communication -** The interactive exchange of information and opinions concerning risk, risk-related factors, and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of

risk assessment findings and the basis of risk management decisions throughout the risk analysis process.

43. **Risk estimate**- The quantitative estimation of risk resulting from risk characterization.

44. **Risk management** - the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, relevant for the protection of the health of consumers and for the promotion of fair-trade practices, and, selecting appropriate prevention and control options as needed;

45. **Risk perception -** The judgment that people make about the characteristics, likelihood, and severity of a specific risk.

46. **Risk profile -** The description of the feed safety problem and its context.

47. **Traceability/product tracing -** The ability to follow the movement of a feed through a specified stage(s) of production, processing, and distribution.

48. **Undesirable substances -** Contaminants and other substances which are present in and/or on feed and feed ingredients and which constitute a risk to consumers' health, including -related animal health issues and food safety.

49. Any expression in the masculine gender includes the feminine.

3. Purpose of the Directive

The purpose of this Directive is to ensure the supply of safe animal products to consumers through guiding the feed and food safety regulatory bodies on the appropriate assessment, management, and communication of risks related to feeds as the basis for risk management recommendations.

4. Scope of Application

This Directive shall be applicable to risk analyses at all stages of the feed production continuum, processing, storage and distribution (wholesale, retail trade, import, export) and utilization of feed ingredients and compound feeds. The directive will also establish principles, responsibilities, and procedures to support decision-making on matters of feed risk analysis.

PART TWO

FEED RISK ANALYSIS

5. General Feed safety requirements

1. Feed safety requirements shall be those set in the Ethiopian Animal feed standards or international standards accepted or adopted by Ethiopia.

2. Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe. Feed shall be deemed to be unsafe for its intended use if it is considered to:
   a) have an adverse effect on animal and consequently human health;
   b) make the food derived from food-producing animals unsafe for human consumption.

3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless proven otherwise following a detailed assessment.

4. Feed that complies with the specific provisions governing feed safety shall be deemed to be safe insofar as the aspects covered by the specific provisions are concerned.

5. Conformity of a feed with the specific provisions applicable to that feed shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the feed is unsafe.

6. General considerationsin feed risk analysis

1. Feed safety measures to achieve the general objective of an appropriate level of protection of animal, human and environmental health shall be based on risk analysis as appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. A feed safety situation may range from a no risk situation and progressively to an "emergency" and may not be clear whether the risk represents a serious threat to animal and consequently human health until information is gathered.

4. The feed safety regulatory Authority and all its organs should have response plans in place that define the roles and responsibilities of those involved in managingemergencies in

sufficient detail so that individuals clearly understand their roles, andambiguity and duplication are prevented.

5. Feed risk analysis shall be conducted in a systematic manner under the following categories:

   a. ***Risk Assessment:***the magnitude of the risk to consumers should be evaluated once an incident is recognized. At this stage, the main goal will be to collect all the information needed to evaluate the situation in a timely and effective manner as the next steps will depend on the results of the risk assessment.

   b. ***Risk management:***response measures depending on issues like the type of hazard, level of risk and possible negative effects on health,economy, and trade.

   c. ***Risk communication:***A well-established communication strategy throughout the management of a feed safety incident depending on the level of risk is necessary. An assessment of all steps taken to manage it should be conducted during the incident and soon after it is over to make corrective measures in the course of managing the incidence at hand or draw lessons for managing similar future incidents.

7. Initiation of a feed risk analysis process

1. First notice of an incident may come from many different sources. Information about a possible feed safety risk can come from feed producers, user complaints, media reports, laboratory test results, and/or from the routine supervision or planned assessments by the Authority or other sources.

2. The informants shall, as soon as reasonable, inform the competent authority or its representative if they consider that a feed or feed ingredient does not satisfy feed safety requirements.

3. The information shall be as detailed as possible and should at least contain a description of the nature of the problem, a description of the type of feed or feed ingredients, the species for which it is intended, the lot, the name of the manufacturer and/or the place of origin.

4. The initial information on a risk shall first be verified/validated through quick on-site visits followed by tests that may include checksabout whether the feed is potentially contaminated with the suspected hazard; whether severe ill health or death has occurred; whether the incident appears to be localized or widespread; whether the source of the hazard has been identified; likely extent of distribution of the product; the need to take interim measures.

5. Once the event has been established to be an emergency, the feed safety emergency response plan should be activated and an internal multi-directorate or multi-agency coordination group established as the type and extent of the emergency warrants.

6. The competent authority and operators should immediately take effective measures at the appropriate level to avoid further danger and initiate a risk assessment process.

7. As soon as it becomes likely that a particular feed or feed ingredient is to be traded internationally and may pose a danger, the competent authorities of the exporting countries should notify, at least, the competent authorities of the relevant importing countries. The notification should be as detailed as possible.

8. Incident Categorization

1. Incidents shall be categorized to allow the advance identification of the types of risk management options and communication strategy appropriate to the level of incident.
2. A scoring system may be used to quantitatively assess the factors contributing to the severity of the incident to determine its status. A classification matrix, taking into account different factors and considering real and potential risk may include the following factors:
   a. Effects on animal and subsequent consumer health.
   b. Number of affected animals and people
   c. vulnerable groups
   d. Public perception
   e. Distribution along the feed/ food chain
   f. Extension /complexity
   g. Economic Impact

3. The Authority shall regularly review the categorization of the incident as the escalation or de-escalation of its status may vary with time and location. For the purpose of this directive, incidents may be classified into low, medium and high.

   a. **Low (Mild incident):**An incident with mild effects on animal health; no veterinary attention is required; public perception of risk is low; Minimal effects to sales of feed and animal product. This level of incident may be considered as routine and managed with low risk management intervention and fewer resources within the Authority's jurisdiction and doesn't thus require extraordinary management or communication.

   b. **Medium (severe)incident:**Incident with effects on animal health where a medium to high number of animals require veterinary attention

or even deaths may occur; might be widespread, difficult to control or have severe consequences; medium / high public perception of risk; some media impact; noticeable loss in sales, large expensefor recovery. A task force for internal coordination within the authority and cross-organizational collaboration is required.

c. **High(emergency):**Incident with serious effects on animal health involving major illness and deaths that might be very widespread, difficult to control or have severe consequences; high number affected; possible effects on human health; high public perception of risk; high media impact; economic impact with substantial losses or closure of businesses. A high level or emergency situation cannot be handled within the Authority feed safety organization and it requires extraordinary tools such as the establishment of an emergency unit.

4. There may be a need to scale up the response (management options) and/or communication strategy if there is a high level of concern from the general public and/or media.

5. The authority shall appoint the risk manager, and/or establish relevant focal points, task forces, an emergency unit for the purpose of risk analysis as appropriate.

6. The Authority shall sign covenants or Memoranda of Understanding (MoU) with relevant bodies to lay the ground for formal collaboration and cooperation in risk analysis as required

7. The Authority shall organize and ensure availability of resources for risk analyses from internal and external sources

PART THREE
Feed Risk Assessment

9. Information file for Feed Risk Assessment

1. The Authority shall create a harmonized information file for an effective and fast collection of information. The file should include the following information:
   a. The health effects on consumers; severity, symptoms, illness description.
   b. Risk assessment.
   c. Possibility of spreading along the feed/food chain and the possibility/probability of spreading to other administrative regions and countries.
   d. Traceability
   e. Images/photos of feed /batch numbers/labels.
   f. All relevant data from the information sources
   g. Relevant scientific information.
   h. Consumer reactions, risk perception, complaints.
   i. Effect on media.
   j. Information gathered from the stakeholders involved (feed/food sector).
   k. Information on similar cases and the actions taken in those situations.

10. The Risk Assessment Process

1. The scope and purpose of a particular risk assessment being carried out shall be clearly stated, the data that need to be gathered identified.

2. Risk assessment experts shall be selected in a transparent manner on the basis of expertise and objectivity in their scientific work. The need to include external expertise and institutions needs to be assessed.

3. Risk assessment shall be based on scientific data and use available quantitative and qualitative information to the greatest extent possible. The assessment methodology employed should be consistent with internationally accepted approaches.

4. Routine monitoring of compound feed and feed ingredients, whether by industry or official inspection bodies, shall include inspection and sampling and analysis to detect unacceptable levels of undesirable substances

5. Limitations in the process having an impact on the risk assessment shallbe explicitly considered at each step should be quantified to the extent that is achievable and documented in a transparent manner.

6. The process shall follow a structured scientific approach incorporating the following four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization.

1. Hazard Identification

1. Identification of possible hazards in feed shall include undesirable substances that could be physical, biological or chemical agents. Biotransformation products present in products also need to be considered.

2. Existing data, complemented with expert opinion may be used as a surrogate to address scientific questions in cases where the hazard is not fully identified, existing data are insufficient and when there isn't enough time to generate the data.

3. Hazard identification shall take factors that can markedly influence the occurrence of a given hazard in feed like environmental conditions and interactions with other materials during growth, harvesting, drying, processing, storage, handling, and transport into account.

4. The hazard identification shall consider useful information on the presence of the hazard in feed from regulatory surveillance samples and investigative work, published data from government agencies, scientific peer-reviewed publications, industry self-monitoring programs, etc.

5. Consideration should be given to the evaluation of the source of feed ingredients and environmental conditions and interactions; the possibilities for the introduction of hazards during theirmanufacture, preparation, transportation, handling, storage and use in order to evaluate which feed ingredients may contain a given hazard.

2. Hazard Characterization

1. Aqualitative and/or quantitative evaluation of the nature of the adverse health effects associated with hazards in feed should be conducted for any hazard identified, including biotransformation products.

2. Information/data on the existing characterization of specific hazards, toxicity studies, may be obtained from international reports and monographs from risk assessment bodies and/or in peer-reviewed scientific literature. Sources of information shall be documented.

3. If scientific data are not available or are inadequate to characterize a hazard, it may be necessary to consider generating such data to resolve the data gaps. Any generation of new data shall be based on relevant scientific principles and procedures.

3. Exposure assessment

1. Exposure assessment to a hazard in feed shall be undertaken in a two-step process. The first step concerns the exposure of the food-producing animals to the hazard(s) through the feed.
2. The second step shall be an evaluation of the transfer of the hazard(s) to edible product(s) from the food-producing animal if such exposure is present.
   a. The animal exposure assessment shall include the formulation of the feed, the use patterns for the animal, and the exposure scenarios.
   b. Assessment of the transfer of the hazard to the edible animal products from exposed animals shall be accomplished through appropriate procedures.

3. Published, peer-reviewed, toxicokinetic or other models that can predict the transfer of hazard from feed to edible products, may be used or adapted for a given exposure assessment. Sources of information should be documented.

4. Risk Characterization

1. Risk characterization, in a feed risk assessment, shall consider the outcomes from the hazard characterization and the exposure assessment to derive a risk estimate for feed safety.

2. A risk estimate may be performed by a comparison of the predicted levels of the hazard in feed with existing national or international maximum levels.

3. When the hazard is also present in environmental sources such as water and air, other exposure assessments on these sources should be taken into consideration for the risk characterization and subsequent risk management options.

5. Reporting

1. The risk assessment shall be fully and systematically documented and communicated to the risk manager tasked by the Authority for the purpose, Taskforce or emergency Unit as the case may be.

2. The risk assessment report should indicate any constraints, uncertainties, assumptions and their impact on results of the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager/ Task force/ emergency Unit, not the risk assessor.

3. The conclusions of the risk assessment shall be made available to other risk assessors and interested parties for possible review.

PART FOUR

Feed Risk Management

11.Risk management

1. General considerations

1. **Preparedness:** The Authority shall, under situations of no incident, prepare itself for a possible emergency situation when decisions must be made quickly. Some such measures include:

    a. Creation of various tools such as templates for data gathering, situation report templates and decision trees, clear and concise reference materials for use during emergencies; Risk categories, including definitions, descriptions and examples; Risk ranking/risk maps; Risk management options appropriate to individual risk categories; Implementation approaches; Communication approaches appropriate to individual risk management options, including communication with international bodies and other governments; Pre-defined roles and responsibilities of the emergency management team members; National feed safety incident contact list. Tools already developed could be useful in assessing risk rapidly in the absence of complete information.

    b. A database on structural groups of similar chemical substances for which toxicological proxydata that can be used to infer hazard characteristics for substances for which no data are available. Develop a prior awareness of the existence and causes of uncertainties in existing data, thus the robustness of the risk assessment during an emergency through regular dialogue;

    c. Establish formal and informal relationships/partnerships with external experts, institutions, countries to obtain relevant data, information and also forge their collaboration. Signing Memoranda of Understanding (MoUs) may need to be in place for formal collaborative arrangements.

2. The Authority shall regularly revise risk assessment data and knowledge as new data and knowledge become available.

3. The Authority shall put an emergency response plan for feed risk emergency response at all levels in place.

4. The regulatory authority can develop or encourage the development of specific documents and guides on good practices like Good Agricultural Practices (GAPs), Good Hygienic Practices (GHPs), and Hazard Analysis and Critical Control Point (HACCP) plans to reduce the occurrence of hazards and support risk assessment measures.

5. The Authority shall in collaboration with relevant stakeholders like associations also encourage, provide technical support and training to actors along the feed production to utilization continuum to apply HACCP principles and procedures to reduce feed risk incidence.

2. Choice of risk management options

1. Risk management shall take the results of risk assessment, other factors legitimate to the incident under consideration and precautionary principle to achieve the general objectives of feed safety management into account.

2. Available management options shall be evaluated to identify a preferred option or a combination of options are selected as necessary.

3. The choice of a risk management option shall be based on a number of factors including the severity of the health risk, the probability of its occurrence, the number of individuals potentially affected, the level of protection required/ desired, and the anticipated effectiveness of the proposed risk management option(s) on the reduction or elimination of a health risk. Such options could include:
   a. Collection and analysis of affected or potentially implicated product(s);
   b. Stopping further production and distribution
   c. Voluntary or mandatory removal of the product(s) from the market;
   d. Posting of public alerts and warnings
   e. Using other active communication strategies;
   f. Detention or seizure of product(s);
   g. Reconditioning of the product(s);
   h. Destruction of product(s);
   i. Criminal prosecution of offenders.

4. Considerations shall be made of the capacity to implement, level of certainty about the risks, assessment of public expectations and perceptions, the extent of legal support, Risk management approaches taken by other countries, and trade implications, should also be considered.

3. Implementation of identified risk management options

Risk management options shall be implemented by a variety of parties, including government, the feed industry, feed users, each of which has different responsibilities depending on the risk management option to be implemented.

4. Monitoring and review of the results of the feed risk management measures

1. The results of the implementation of the risk management options and the effectiveness in controlling the hazard and the risk shall be monitored to see whether the hazard is being controlled effectively or whether additional or follow up measures are required.

2. Review of the whole risk management process after conclusion of the incident and the lessons therefrom shall be used toimprove the effectiveness of similar future incidents.

5. Management of medium and high feed risk Incidents

1. Pending further scientific information for a more comprehensive assessment, provisional risk management measures necessary to ensure protection shall be adopted in specific circumstances where, following an assessment of available information, the possibility of harmful effects on health are identified but scientific uncertainty persists.

2. Provisional measures adopted shall be proportionate and no more restrictive of trade than is required to achieve the appropriate level of health protection with due regard to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration.

3. The provisional measures shall be reviewed within a reasonable period of time depending on the nature of the risk identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.

6. Management of a medium (Sever) level feed riskincident

1. Thedecisionmakingandmanagementofmedium level feed risk incidentshall reside within the authority.Additional Measuresincluding the establishment of a task force for coordination internally and cross-organizational collaborationshall be sought to deal with the incident.

2. The Task Force, set up by the authority, shall have a specific mandate and be in charge of dealing with the incident in a more responsive, more coordinated, and as a centralized unit for dialogue and coordination with all parties involved in the particular incident such as other competent authorities, stakeholders, laboratories, scientific support or any other.

3. Thecompositionandterms of referenceof the Taskforce could vary depending on the nature of therisk, but some basic duties oftheTaskForceshall include:

   a. Centralize the collection of data and monitoring relevant information sources such as scientific literature, rapid alert systems for feed, trade data and official bulletins, laboratory results.
   b. Organize timely and comprehensive situation reports.
   c. Traceability.
   d. Promoting internal communication.
   e. Sharing information and dialogue with stakeholders.
   f. Organize and facilitate risk communication through appropriate channels as appropriate.
   g. Organizingqualitybased Information management (decisions, measures taken, monitoring, conclusions, lessons learned).
   h. Risk Assessment coordination.
   i. Coordination of Scientific and laboratory support (techniques, sampling methods, etc.).
   j. Continuous monitoring of the management measures by the use of indicators and written reports, quality standards,and records of relevant information
   k. Design thecommunicationstrategytomediaandconsumers.

7. Management of a high (Emergency) level feed risk Incident

1. ThedecisionmakingandmanagingresidewithinanEmergency Unit since the situationcannotbehandledwithintheauthorityandrequires an additionalresponse.The unit whichshould be a multi-disciplinary and multi-organization group shall operate as the designated focal point for emergency management and communication.

2. The Unit shall allowthe useof efficient communication policies with consumers as consumer perception and media attention become very important. Centralization of the decision making within the Unit shallbe effectively used to avoid the potential for diverging messages.

3. Composition and function the Emergency Unit shall be specifiedto allow a fast and efficient decision process. Its membersshould,therefore, have a high level of responsibility in the feed/food sector.

8. Composition of the Emergency Unit

a. Head of the Unit
b. Representatives of competent authorities within the feed/ food chain.
c. Representatives of competent authorities for public health.
d. Representatives of competent authorities in border controls for feed.
e. Representatives of the relevant scientific community and laboratory.
f. Representatives of relevant competent national/regional authorities.
g. Communication expert.
h. Legal advice.
i. Any other expert; police, military authorities, civil defense.

9. Functions of the Emergency unit

a. Recognition of an emergency situation and communication to the Authority.
b. Ensuring scientific including laboratory support
c. Establishment of an "investigational tracing unit" for feed flow analysis of supply chains within areas of outbreak batch-precise trace-back in combination with epidemiological information on feed preparation practices.
d. Ensuring the involvement of all competent organizations involved in the response to the feed/food incident and in the coordination of the overall response arrangements.
e. Design the communication strategy to media and consumers and ensuring an optimal flow of informationas appropriate
f. Compilation of situation reports.
g. Continuous monitoring of the management measures by the use of indicators and situation reports.
h. Mobilizing additional resources if needed.
i. Organizing quality-based Information management (decisions, measures taken, monitoring, conclusions, lesson learned).
j. Proposes official declaration that the emergency situation has ceased as and when appropriate.

PART FIVE

Feed Risk Communication

12.Risk Communication

1. Feed Risk Communication Considerations

The Authority shall make advance preparation to have an effective communication system in place to provide timely, open and accurate exchange of information to all stakeholders and partners and impacted parties in a feed safety emergency situation including between competent authorities of different countries because of international trade.Any research and/or assessment results regarding feed hazard risks, conducted by government or nongovernment bodies should not be communicated to the public without the consent of the communications wing of the Authority. Hence, such a body is expected to sign a covenant/MoU for communication of the results of the research/assessment to the public.

2. Communication during normal situations

1. Communication policies shall be designed to create trust and provide transparency and openness to the work of the national competent authorities with open dialogue with stakeholders.
2. Risk assessments shall be published regularly and communication channels should be open.
3. The Authority shall conduct impact studies to evaluate the effects of its risk communication on the target audience to see if the message(s) have been appropriately delivered and had the desired impact.

3. General Guidelines for Communication during Medium and High Levelsof Incident

1. Communication needs to occur more frequently during an emergency because there is usually an urgent demand from various stakeholders for timely up-to-date situation reports
2. Communicating with the media, the affected population, and the public during medium and high levelsof incident shall be harmonized with some common basic guidelines to avoid mistakes that may lead to more economic losses or loss of consumer confidence.
3. The communication will be activated either by the Coordinator of the Task Force (Medium Level) or by the Head of the Emergency Unit (High Level). Basic general guidelines that should be taken into account shall include:

a. The communication strategy should be agreed in close collaboration and under the coordination of the leading Task Force or Emergency Unit as the case may be.
b. All risk communication should be coordinated through one individual or office to ensure consistency of messaging and to avoid confusion.
c. The exchange of information shall be between official contact points designated by the relevant stakeholders.
d. Communication messages may need to change rapidly as more information is obtained or as risk management actions are changed under situations where an emergency may not be fully understood.
e. The emergency response team needs to include members who have good knowledge of effective risk communication methods and who can provide advice to the spokesperson delivering the public messages to make sure that appropriate messages reach the target audience.
f. Feed safety risk communication shall be a two-way process. The Authority shall, therefore, provide a mechanism for seeking assistance or information and also to provide information for example through a telephone helpline, call center or web portal.
g. Specific care shall be taken for communicating uncertainties.Lack of scientific evidence or variability should be communicated together with the incident, but do not justify the withholding of information if the target audience is at risk and need to be informed.
h. Information flow shall be transparent and continue during all phases of the feed emergency situation to enable continuous evaluation and development of the emergency response.

4. The information provided shall provide a clear and complete description of the nature and extent of the incident where possible including information on:
   a. What is known about the feed safety emergency;
   b. Types of feed products involved;
   c. Types of risks and location;
   d. harmful levels of exposure;
   e. Advisable measures in cases of exposure;
   f. Sources and channels for additional information

5. Under circumstances when identification a feed safety emergency is identified and the risk is suspected to have gone beyond the country's boundaries, the competent authority, shall,exchange information with all

known to be affected and potentially affected countries, as relevant. The information shall include:

a. The nature of the feed safety emergency including the hazards and risks identified, the methodology used and any assumptions made;
b. Detailed identification of the feeds concerned including product markings, certificate information;
c. Affected and potentially affected populations group(s);
d. Shipping and related information, e.g. name and contact information exporter, importer, consignee, and shippers;
e. Action taken to reduce or eliminate the hazard;
f. Full details of the designated official contact point and the relevant competent authority.

4. Communication channels

1. No one channel of communication may be adequate to ensure that communication reaches all target audiences
2. The communication vehicle and the way information is presented should be tailored to the needs of the audience, including targeting those at greatest risk and considering literacy and the languages spoken.
3. A Combination of channels shall, as much as possible and appropriate, be employed. These channels could be:
   a. Radio, television, and print media
   b. Official press release and conferences.
   c. Partners/stakeholder networks.
   d. Meetings, workshops, focus groups.
   e. Information days/meetings.
   f. The internet: Active posting and advice on websites, Use of social media (Facebook, Twitter, etc.)
   g. use of health or field officers and organizations
   h. Open consumer information phone "*hotline",* smartphone applications.

5. Communiqué Content

1. Special care should be taken in the elaboration of the messages to consumers or media during severe incidents or emergencies.
2. The contents of the Communique should allow creating awareness without generating excessive alarm.
3. Should contain enough information that will allow the consumer to take the right choices. This could include:
   a. Description of the risk (nature, characteristics, etc.)

b. Description of the product affected as images/photos/batch numbers/labels of the product, and distribution channels.
c. Description of health effects on users or consumers (risk population or groups involved, where applicable, possible health effects on these groups, sourced information.
d. Measures already taken and those planned.
e. What to do if the affected feed is in your possession.
f. What to do if you have used the feed to feed your animals.
g. Telephone numbers, Web page, e-mail address, fax number, etc. to permit an adequate exchange of general information and queries as necessary.

PART SIX

Feed Risk Analysis Monitoring and Evaluation

13. Monitoring and Evaluation

1. Adetailedrecordshall be keptduring the course of anincident for the purpose of monitoring and Evaluation.
2. A continuous assessment of management and communication activities shall be done in the course of an on-going incident and corrective measures taken timely.
3. A report that reviews and analyses the whole process, including lessons learned and recommendationsshall becompiled especially when a Medium(Severe) or High (Emergency)incident isclosed.Examplesofissuesthatshouldbeincludedinthedocumentare:
   a. Assessment of Information file
   b. Assessment of incident management
   c. AssessmentofCommunicationtomediaandconsumers
   d. Assessment of Traceability exercises.
   e. Assessment of internal procedures.

14.Feed Risk Analysis and the Inspection and Certification System

1. The Feed Processor/producer, Importer, Distributor, and Exporter Registration and Certification Directive 02/2018 of the Authority shall apply regarding the inspection and certification system. Feed Risk Analysis shall utilize the procedures set therein with due consideration to:
   a. Inspection and certification systems for ensuring feed safety shall be designed and operated on the basis of objective risk assessment appropriate to the circumstances and based on current scientific evidenceavailable.

b. Consistent and transparent risk analysis shall apply to facilitate trade to increase confidence in the feed safety and inspection systems by trading partners and enable inspection resources to be targeted effectively on hazards to animal and public health arising at any stage of the feed production and distribution chain.
c. The Authority shall, in addition to regular inspection, conduct assessments at times and places where risk is presumed to be prevalent

2. Feed and feed ingredient manufacturers and other relevant parts of the industry shall be encouraged to practice self-regulation to secure compliance with required standards for feed production, storage, and transport. Official inspectors shall be trained in the assessment of the application of HACCP principles.
3. Adequate sampling andappropriately validated analytical methods in the appropriate Ethiopian national standards and international standards accepted in the Ethiopian standards shall be used to ensure that the results are representative and reliable.
4. The elements of a control program shall as appropriate include inspection/auditing; sampling and analysis; checks on hygiene, including personal cleanliness and clothing; examination of written and other records; examination of the results of any verification systems operated by the establishment; audit of establishments by the national competent authority; national audit and verification of the control program.
5. Administrative procedures shall be in place to ensure that controls are carried out by the inspection systemand where non-compliance is suspected.
6. Controls shall, as appropriate, cover establishments, installations, means of transport, equipment and material; raw materials, ingredients, technological aids and other products used for the preparation and production of feedstuffs; semi-finished and finished products; materials and objects intended to come into contact with feedstuffs; cleaning and maintenance products and processes, and pesticides; processes used for the manufacture or processing of feedstuffs; the application and integrity of health, grading and certification marks; preserving methods; labeling integrity and claims.

PART SEVEN
Capacity Development for feed risk analysis

15.Developing Capacity of the Authority

1. The Authority shall develop its working modalities by thoroughly evaluating the human and infrastructural capacity at all levels, identify gaps and make the necessary adjustments commensurate to required standards to cater for its responsibilities of maintaining feed safety and respond to possible safety incidents.

2. The technical and infrastructural capacity of the Authority to institutionalize feed risk analysis and upholding feed safety shall be given utmost priority. The following shall be the measures in this regard:

a) Building the skills and knowledge of relevant staff of the Authority in feed safety risk assessment, management, and communication throughmeasures likeformal training, on-the-job training, experience sharing.
b) Upgrading the infrastructural capacity of the Authority in terms of the required facilities including Information Technology (IT), communication, laboratory capabilities to cater for an array of hazards, mobility, etc. required for rapid response to feed safety risk incidents.

16.Developing Capacity of Stakeholders

1. The Authority shall uphold the importance of education and training in feed safety for all stakeholders involved in the whole continuum of feed production and utilization including industry, agriculture, trade and the public at large.
2. Extension services, including provisions for practical educational training at colleges and universities,shall be mobilized to support the education of relevant groups.
3. Every possible avenue for reaching out to stakeholders to maximize the education message(s), e.g., online capabilities and networks, public meetings, etc. shall be utilized to build stakeholder capacity in feed safety.
4. Feed Industries shall be supported to establish their own internal safety and quality assurance and monitoring capabilities and play their roles in feed safety assurance

PART EIGHT

Miscellaneous provisions

17.Inapplicable Directives

No Directive, circular, letter, customary practice, in so far as it is inconsistent with this Directive, be applicable with respect to matters covered in this Directive.

18.Amendment of this Directive

The Veterinary Drug and Animal Feed Administration and Control Authority may when it finds it necessary, amend this Directive.

19.Effective Date

This Directive shall enter into force from _____.

Terzu Daya Degaga (Dr.)

Executive Director

Veterinary Drug and Animal Feed Administration and Control Authority