



**A PROPOSED COORDINATION STRUCTURE FOR
BIOSAFETY REGULATORY AGENCIES
IN KENYA**

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THE NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

(NCST)

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Acronyms and Abbreviations

COMESA	Common Market for Eastern and Southern Africa
DVS	Department of Veterinary Services
EIA	Environmental Impact Assessment
ELISA	Enzyme -Linked Immunosorbent Assay
EMCA	Environment Management Coordination Act
GMOs	Genetically Modified Organisms
IBC	Institutional Biosafety Committee
ISAAA	International Service for the Acquisition of Agribiotech Applications
KEMRI	Kenya Medical Research Institute
KEPHIS	Kenya Plant Health Inspectorate Service
LMOs	Living Modified Organisms
MOU	Memorandum of Understanding
NBC	National Biosafety Committee
NCST	National Council for Science and Technology (NCST)
NEMA	National Environment Management Authority
PBS	Program for Biosafety Systems
PCPB	Pest Control Products Board
PCR	Polymerase Chain Reaction
SPS	Sanitary and Phytosanitary Measures
USAID	United States Agency for International Development

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1.0 Introduction

Fostering coordinated and mutually acceptable approaches to decision making among regulatory agencies is one of the critical areas identified within the broader agenda of building and strengthening a functional national biosafety system under the PBS Kenya Associate Award. PBS is an IFPRI-managed program that supports partner countries in Africa and Asia in the responsible development and safe use of agricultural biotechnology. PBS effectively addresses biosafety through an integrated program of research, capacity development and outreach.

In response, to the need for a coordinated and harmonized approach to biosafety decision making, the National Council for Science and Technology (NCST) and the Program for Biosafety Systems (PBS) initiated the process of facilitating regulatory agencies to delineate their roles and responsibilities. The key biosafety regulatory agencies including the Department of Veterinary Services (DVS), Kenya Plant Health Inspectorate Service (KEPHIS), National Environment Management Authority (NEMA), Pest Control Products Board (PCPB), Public Health Department and Kenya Bureau of Standards (KEBS) were asked to develop a coordination structure (document) that outlines their regulatory roles, procedures and decision making mandates.

The following Terms of Reference (TORs) were drafted to guide the agencies on this task. An outline was also drafted to ensure that a standard format is applied by all the agencies.

Overall task

Develop a coordination structure (document) that outlines the regulatory roles, procedures and decision-making mandates of each biosafety regulatory agency.

Specific tasks

- Define and harmonize the decision-making process and roles of each regulatory agency in handling introduction, trials and commercial release of GM plants.
- Define and demarcate the decision-making process and roles of each regulatory agency in handling introduction, trials and commercial release of transgenic animals and microorganisms
- Define and harmonize the decision-making boundaries and roles of each regulatory agency in handling food and feed commodity imports and exports including food aid.
- Define and harmonize the decision-making boundaries and roles of each regulatory agency in the approval of biopesticides, biofertilizers, veterinary inputs and products.

This document has been prepared through a number of consultative meetings in line with the above TORs.

2.0 The biosafety regulatory system in Kenya

Kenya's national biosafety system has evolved over the years to respond to challenges from scientific developments in the field of modern biotechnology. The National Council for Science and Technology (NCST) is the designated competent authority that handles all matters pertaining to biosafety. The objects of the Council established under the Science and Technology Act of 1980 is to coordinate, guide, advise and promote the application of

science, technology and innovations for accelerated national development. In 1995, the NCST initiated a process of developing the national biosafety guidelines and regulations under the Science and Technology Act, chapter 250 of the laws of Kenya. These were issued in 1998. The guidelines and regulations made a provision for the establishment of a National Biosafety Committee (NBC) to serve as the technical arm of the Council in overseeing coordination and implementation of biosafety issues. The membership of NBC comprises of regulatory agencies and key stakeholder groups. The Biosafety Act 2009 makes provision for establishment of a competent authority to be known as the National Biosafety Authority (NBA). The Authority will replace the NBC and shall be under the Ministry responsible for Science and Technology. It will be managed by a board of eminent scientists, permanent secretaries from key ministries, the secretary NCST, directors of biosafety regulatory agencies and representatives of farmers, consumers and the private sector. Key functions of the authority embrace overall supervision and control of the development, transfer, handling and use of genetically modified organisms for research or commercial purposes.

2.1 The mandate of regulatory agencies

The following regulatory agencies are identified in the Biosafety Law, and therefore we summarize their mandates and legal jurisdiction.

The Kenya Plant Health Inspectorate Service (KEPHIS) is a state corporation established under the State Corporations Act (Cap 446). KEPHIS offers inspectorate and vigilance services on all matters related to plant health and quality control of agricultural inputs and produce. The authority to execute and enforce regulatory activities under the jurisdiction of KEPHIS is prescribed in the following laws of Kenya

- The Fertilizer and Animal Feedstuffs Act Cap 345 of 1962
- The Seeds and Plant Varieties Act, Cap 326, of 1972, (1975) Rev. 1991 - Seed Regulations incorporated.
- The Plant Protection Act (Cap 324) – (1937, 1962 Rev. 1979). Rules for prevention of introduction and spread of pests and diseases destructive to plants. Amended 1955, 1960, 1961, and 1971, 1979).
- Suppression of Noxious Weeds Act: Cap 325 of 1960. Provides for the suppression of noxious weeds.
- The Agricultural Produce (Export) Act. Cap 319 (1923 Amended 1955, 1960): Provides for the grading and inspection of agricultural produce for export.

The Kenya Bureau of Standards (KEBS) was established by an Act of parliament, the Standard Act- Chapter 496 of the Laws of Kenya. It started its operations in July 1974 as the National Standards body established to promote standardization in industry and trade, through standards development, conformity assessment, testing, and metrology. KEBS regulatory role is based on conformity to standards.

The Pest Control Products Board (PCPB) is a Statutory established body under an Act of parliament, the Pest Control Products Act, Cap 346, Laws of Kenya in 1982 to regulate the importation and exportation, manufacture, distribution and use of pest control products.

The Department of Veterinary Services (DVS) is under the Ministry of Livestock Development. The Department is charged with the responsibility of preventing and controlling animal diseases and pests to safeguard human health, improve animal welfare, increase livestock productivity, ensure high quality livestock and their products and facilitate domestic and international trade.

The mandate of the Department is enforced by a number of legal instruments including the Animal Diseases Act Cap 364, the Public Health Act Cap 242 and the Food, Drugs and Chemical Substances Act Chapter 254.

- The Animal Diseases Act CAP 364 deals with matters relating to the diseases of animals.
- The Meat Control Act Cap 356 -enables control to be exercised over meat and meat products intended for human consumption, and over slaughterhouses and places where such meat is processed; and to provide for import and export control over such meat and meat products; and for matters incidental to and connected with the foregoing.
- The Public Health Act Cap 242- secures and maintains health
- The Food, Drugs and Chemical Substances –concerned with prevention of adulteration of food, drugs and chemical substances and for matters incidental thereto and connected therewith.
- The Dairy Act Cap 336- provides for the improvement and control of the dairy industry and its products

The Public Health Department is under the Ministry of Public Health and Sanitation. The Department safeguards the health of consumers through food safety and quality control, surveillance, prevention and control of food borne diseases/illnesses. The principal pieces of legislation under which the department operates include the Public Health Act Chapter 242, the Food, Drugs and Chemical Substances Act Chapter 254 and the Meat Control Act Chapter 316.

The National Environment Management Authority (NEMA) was established through the Environmental Management Coordination Act of 1999. The Act confers NEMA with the authority to exercise general supervision and coordination over all matters relating to the environment and to be the principal instrument of the government in the implementation of all policies relating to the environment including approval of LMOs intended for release into the environment.

3.0 Biosafety issues under the mandate of the institution

KEPHIS

- KEPHIS is the lead agency in implementing the national policy on the introduction and use of genetically modified plant species, insects and micro-organisms of plant health concern
- Handles GM crops, seeds and microorganisms for environmental release (of plant origin that may pose SPS risks)
- Issues import permits for plant material including seed, grain, propagating material and conducts inspections of confinement facilities for GMOs
- Safeguards against importation of unauthorized LMOs (plants and biocontrol agents) into Kenya
- Inspections of quarantine facilities for certification before importation
- Inspection and approval of containment facilities (laboratories, screen houses and open quarantine facilities) for handling genetically engineered organisms as set out in the existing regulations and guidelines.

- Satisfactory inspection report of the containment facilities required before an importation permit is issued.

KEBS

KEBS promotes standardization in industry and trade through standards development, conformity assessment, testing, and metrology. As far as biosafety issues are concerned, the role of KEBS will be to develop standards that the rest of regulatory agencies need to execute and enforce their respective mandates. For instance, KEBS is expected to:

- Coordinate development of standards including GMO and GMO products
- Monitor GMO food, feed and fertilizers for compliance to standards
- Participate in evaluation of food safety assessment data provided by organizations intending to commercialize GMO for food, feed and for processing

PCPB

- Microorganisms for use directly or as active agents in pest control products including genetically modified organisms
- Macrobials for use directly or as active agents in pest control products including genetically modified organisms
- Biochemicals derived from genetically modified organisms used directly or as active ingredients or in pest control products.

DVS

- Control of imports/exports to ensure safety of animal health inputs such as feed, drugs and vaccines including GMOs.
- Control of imports/exports and certification of food of animal origin
- Control of animal genetic and other biological material

Public Health Department

- safeguards the health of consumers through food safety and quality control, surveillance, prevention and control of food borne diseases/illnesses.
- Sampling of GMO food for analysis and issuance of import and export certificates after ascertaining that food is safe for human consumption.
- Inspection of food and food establishments of GMO origin.

NEMA

- Coordinate Environmental Impact Assessment (EIA) on all LMOs or GMOs intended for introduction into the environment before the proposed NBA issues permit (s) for environmental release. Unless exempted, all programmes, projects or activities intended to introduce LMOs into the environment are subject to EIA and audit.

4.0 Biosafety approval channels

All the agencies follow the system for handling notifications and requests laid down by the NBC in their regulatory approvals. The following procedures are followed:

- a. After screening by the IBC, requests are submitted to the National Biosafety Committee (NBC).
- b. The NBC will screen for completeness and after acknowledgement (to the notifier) for completeness, the request will be examined by a panel of experts from NBC and where necessary by external experts, the panel will evaluate the risk assessment carried out by the applicant, and send its findings to the NBC.
- c. Upon receiving the opinion of the panel, the NBC shall submit its recommendation to the NCST, which shall issue the decision document to the notifier.

5.0 Areas of interaction/intersection among regulatory agencies

The biosafety regulatory agencies introduced above are represented on the NBC and they participate jointly in decisions that touch on regulatory approvals for GMOs. In this respect, the NBC is a key point of convergence and interaction. In addition KEPHIS and DVS attend Institutional Biosafety Committee (IBC) meetings in an advisory/observer capacity. Most of the regulatory agencies are also members of the Kenya Standing Technical Committee on Imports and Exports (KSTCIE – coordinated by the Ministry of Agriculture), the National Food Safety Coordination Committee (the Ministry of Public Health and Sanitation is the Secretariat for this committee) and the National Codex Committee under the Ministry of Trade.

The status of existing capacity for biosafety both in terms of facilities and human resources strongly indicate that KEPHIS is ahead of other agencies. At least five KEPHIS staff have been trained on various aspects of detection and more than ten in the area of monitoring. The KEPHIS seed testing laboratory and the analytical chemist laboratory have received international accreditation by the International Seed Testing Association and the South African National Accreditation system respectively. The laboratories have modern molecular biology equipment such as PCR, ELISA, rapid diagnostic kits and spectrophotometers. KEPHIS is also the designated regional reference laboratory on matters of plant health in the COMESA region.

6.0 Areas of potential overlaps among regulatory agencies

KEPHIS does not directly get involved in clearing and certifying milled or processed food imports. It is not a concern for KEPHIS because they don't pose any plant health risks. The mandate of KEPHIS mainly touches on the issuance of permits for importation of unmilled food that may pose plant health (SPS) risks.

KEBS and KEPHIS interact in decision-making and regulatory approvals of unmilled food imports or food aid. At the ports of entry, both KEBS and KEPHIS have specific mandates. For instance, imported grain has to comply with the KEPHIS requirements for SPS while KEBS ensures that the grain meets the standards that have been set.

Food safety is a point of convergence for many regulatory agencies including KEPHIS, the public health department, KEBS, DVS and even the fisheries department. While the overall mandate of the public health department is to ensure food safety for human consumption potential overlaps in regulations can occur with DVS which handles food of animal origin, the fisheries department which looks at fish disease aspects and KEPHIS which pays attention mainly to food of plant origin. The government has taken cognizance of the fact that the national food safety system in Kenya is managed by various agencies under different

ministries and laws. Each agency operates independently to fulfill the function for which it was established. However, the activities at each level require integration into a coordinated system. As a result, the National Food Safety Coordination Committee (NFSCC) was formed to enhance coordination and minimize overlaps.

The Ministry of Special Programmes under the office of the President handles importation of food aid particularly during times of emergency and humanitarian crisis. Food aid donations in many cases originate from countries such as the US which plant GMOs on a large scale. In situations of emergency, the President can authorize importation of emergency food aid with guidance from the relevant authorities. For instance the Ministry of Special Programmes and the Office of the President is expected/requested to consult the NBC before making a decision to import food aid that may contain GMOs. KEPHIS does not regulate animal feeds but plant materials which may be used as animal feed such as seed cotton cake. Overlaps are likely to be encountered with DVS which is charged with the responsibility of controlling imports and exports and ensuring the safety of animal health inputs such as feeds, drugs and vaccines including genetically modified ones.

The Pest Control Products Board (PCPB) regulates the importation and exportation, manufacture, distribution and use of pest control products including microorganisms, macrobials and biochemicals derived from GMOs. KEPHIS is involved in the regulatory approval of biofertilizers and biopesticides. The focus of KEBS is mainly on compliance with standards. The institution is expected to develop standards for all GM products and support monitoring and inspection of the same. The Biosafety Law will guide the development of relevant standards.

The involvement of KEPHIS in the regulatory approvals of microorganisms for environmental release interfaces with the mandate of the PCPB. Some of the pest control products are biological in nature e.g. pests which might cause diseases or become predatory pests in the environment. A major distinction that should be noted here is that KEPHIS only deals with biopesticides which address plant health issues e.g. microorganisms and insects. Microorganisms which address animal health issues are under the mandate of DVS.

The Environmental Management Coordination Act, 1999 mandates NEMA to exercise general supervision and coordination over all matters relating to the environment and to be the principal instrument of the government in the implementation of all policies relating to the environment. The EMCA Act mandates NEMA to make guidelines for environmental release of GMOs. Applicants will be expected to satisfy the NEMA requirements for Environmental Impact Assessment (EIA) in the initial stages. The NBC will take into consideration recommendations from NEMA before approval is given and a license for environmental release issued. While the aforementioned provisions of the EMCA Act are clear, KEPHIS is actively involved in implementing the national policy on the introduction and use of genetically modified plant species, insects and micro-organisms of plant health concern. This is not necessarily an area of overlap. In decision making on environmental release of GMOs, NEMA will be expected to seek expert advice and guidance from KEPHIS.

It is anticipated that the Biosafety Act will help minimize overlaps through creation of a National Biosafety Authority (NBA) that will stipulate and coordinate the regulatory functions of each agency. In the process of drafting the “Biosafety Bill” about 25 pieces of legislation were reviewed to ensure harmony and minimize conflicts. Practical challenges are expected to emerge in the course of implementation. They will be sorted out on a case-by-case basis and the necessary adjustments made based on lessons learnt and experiences gained.

7.0 Coordination structure matrix for biosafety regulatory agencies in Kenya

Activities presented in the matrix are those being performed by the regulatory agencies under the existing laws and regulations or those expected to be performed by the regulatory agencies after the enactment of the anticipated Biosafety Act.

	Activities	KEPHIS	KEBS	PCPB	DVS	Public Health	NEMA	Remarks including identified gaps and proposals for filling them
1	Mandate of the institution	<ul style="list-style-type: none"> -Vigilance on matters of plant health and quality control. -Plant variety protection-testing and release of new varieties. -Seed inspection and certification. 	<ul style="list-style-type: none"> -Promote standardization in industry and trade by: -Development of standards. -Conformity assessment -Testing -Metrology 	<ul style="list-style-type: none"> -To regulate the importation and exportation, manufacture, registration, distribution and use of pest control products. 	<ul style="list-style-type: none"> -Prevent and control animal diseases and pests to safeguard human health, improve animal welfare, increase livestock productivity and quality and facilitate trade. 	<ul style="list-style-type: none"> -To ensure safety and quality of food meant for human consumption - Surveillance, prevention and control of food borne diseases/illnesses 	<ul style="list-style-type: none"> -Supervision, coordination and implementation of all policies and matters relating to the environment. 	<p>Fertilizers, animal feeds and related plant regulations are not clearly mandated to any of the regulators and there is some confusion regarding the roles of KEPHIS, DVS, MoA etc in this area though there is potential of GM products coming in the FFP (food, feed or processing) chain</p>
2	Biosafety issues under mandate of the institution	<ul style="list-style-type: none"> -Oversight of plant related national biosafety regulations. -Inspection of trials of GMOs of 	<ul style="list-style-type: none"> -Development of standards for GMOs and ensuring conformity to the GMO standards 	<ul style="list-style-type: none"> - Microorganisms for use in pest control products including 	<ul style="list-style-type: none"> Regulate import/export and ensure safety of animal health and production 	<ul style="list-style-type: none"> - Surveillance, prevention and control of food borne diseases/illnesses 	<ul style="list-style-type: none"> -Coordinate EIA on all LMOs or GMOs intended for introduction 	<p>GM products that are on the boundary of medical and plant/animal are not clearly defined and therefore may not</p>

	Activities	KEPHIS	KEBS	PCPB	DVS	Public Health	NEMA	Remarks including identified gaps and proposals for filling them
		<p>plant origin.</p> <p>-Safeguard against importation of unauthorized LMO (plants and biocontrol agents) into Kenya.</p>		<p>GMOs.</p> <p>-Microbials for use as pest control products including GMOs.</p> <p>-Biochemicals derived from GMOs</p>	<p>inputs such as feed, drugs and vaccines including GMOs.</p> <p>-Regulate import/export and certification of food of animal origin</p> <p>-Control of animal genetic and other biological material.</p>	<p>sses</p> <p>-Sampling of GMO food for analysis</p> <p>-Issuance of import and export certificates for GMO food</p> <p>-Inspection of food and food establishments of GMO origin</p>	<p>into the environment before the lead agencies issue permit (s) for environmental release</p>	<p>be regulated as such</p> <p>Products and commodities that move through the special programmes may be outside these structure .e.g. relief consignments under the ministry of special programmes.</p>
3	GM products and regulatory activities handled under the mandate of the institution	<p>-GM crops, unmilled food aid and imports, seeds, microorganisms and regulated articles e.g. soil</p> <p>-KEPHIS issues importation permits for unmilled food</p>	<p>-Inspection of GMOs (including food imports, feeds and fertilizers) to ensure conformity to standards</p>	<p>-Pest control products of GM nature (microorganisms, macrobials and biochemicals)</p>	<p>- Transgenic animals</p> <p>-Animal health inputs derived from GMOs</p> <p>-Food derived from transgenic animals</p> <p>-Regulation of importation, exportation,</p>	<p>-GM food meant for human consumption including food aid and locally produced and marketed, imported and exported</p>	<p>All programmes, projects or activities intended to introduce LMOs into the environment are subject to EIA and</p>	<p>GMO products may appear duplicated/crosscutting in each of the regulatory agencies but each agency has a specific aspect of concern e.g. KEPHIS looks on plant health issues (SPS) while</p>

	Activities	KEPHIS	KEBS	PCPB	DVS	Public Health	NEMA	Remarks including identified gaps and proposals for filling them
		-Inspection and approval of plant quarantine and containment facilities for GMOs			registration and use of the above. -Monitoring and inspection for animal research	food.	environmental audit	KEBS focus is mainly on standards.
4	Point of interaction with other agencies	-Member of NBC and serves as an observer/advisor at IBCs -Member of KSTCIE -Member of National Food Safety Coordination Committee -Member of National Codex Committee	-Member of NBC -Member of National Food Safety Coordination Committee -Secretariat of biotech technical committee -Secretariat of National Codex Committee	-Member of KSTCIE -Member of National Food Safety Coordination Committee -Member of National Codex Committee	-Member of NBC and several IBCs -Member of National Food Safety Coordination Committee -Member of National Codex Committee -The Ministry of Health is mandated to ensure safety of all foods while the DVS handles food of animal origin. -Collaboration with the with	-Member of NBC -Secretariat of National Food Safety Coordination Committee -Member of National Codex Committee -Public health interacts with KEPHIS on safety of food aid and with DVS on food of animal origin -The	NEMA interacts with all the regulatory agencies in accordance with the National Environmental Management Act (EMCA)	-All regulatory agencies follow NBC/NBA approval procedures according to their respective mandates

	Activities	KEPHIS	KEBS	PCPB	DVS	Public Health	NEMA	Remarks including identified gaps and proposals for filling them
					the Ministry of Agriculture in handling animal feed of plant origin especially grain and with KEBS on issues of standards	Ministry of Health under which the department falls is the Secretariat of the Food Safety Coordination Committee		
5	Food safety assessments	Unmilled grain and unprocessed foods are checked for presence of unauthorized genetic material	-Unmilled and processed GM food. -Auditing of GM food safety assessments based on the codex guidelines	All pest control products meant for use on edible crops or domestic animals are subjected to health and environmental risk assessment	-Food safety assessment of food of animal origin according to local and international regulations and protocols	-Participates in safety assessment of GM foods	-Collaborate with other relevant regulatory institutions in cases where unmilled materials may find their way into the environment	
6	Monitoring and inspection of contained and confined field trials.	All the trials with plants are so far considered as quarantine facilities and are	Not applicable	All pest control products are expected to undergo local biological	-Monitoring and inspection of contained and confined field trials for	Not applicable	-Collaborate with relevant agencies within the framework of	

	Activities	KEPHIS	KEBS	PCPB	DVS	Public Health	NEMA	Remarks including identified gaps and proposals for filling them
		approved and monitored through KEPHIS		efficacy trials before registration. Monitoring is also carried out at the time of testing. Some special conditions may be attached to products with high risks as per conditions set by the KSTCIE	research in animals and animal health and production inputs		the NBC	
7	Release and post environmental release monitoring	Release of new varieties. These should be undertaken according to the variety release system which is supervised by KEPHIS	Not applicable	Inspection of premises where pest Control products are manufactured, packaged and sold.	-Release and post release surveillance and monitoring to ensure safety of GMOs. -Inspection of animal health and production inputs manufacturing facilities	-Surveillance of GMO foods after placement on the market to ascertain human safety after consumption	-Monitoring of release and post release of GMOs to the environment to ensure no negative impacts on the environment	

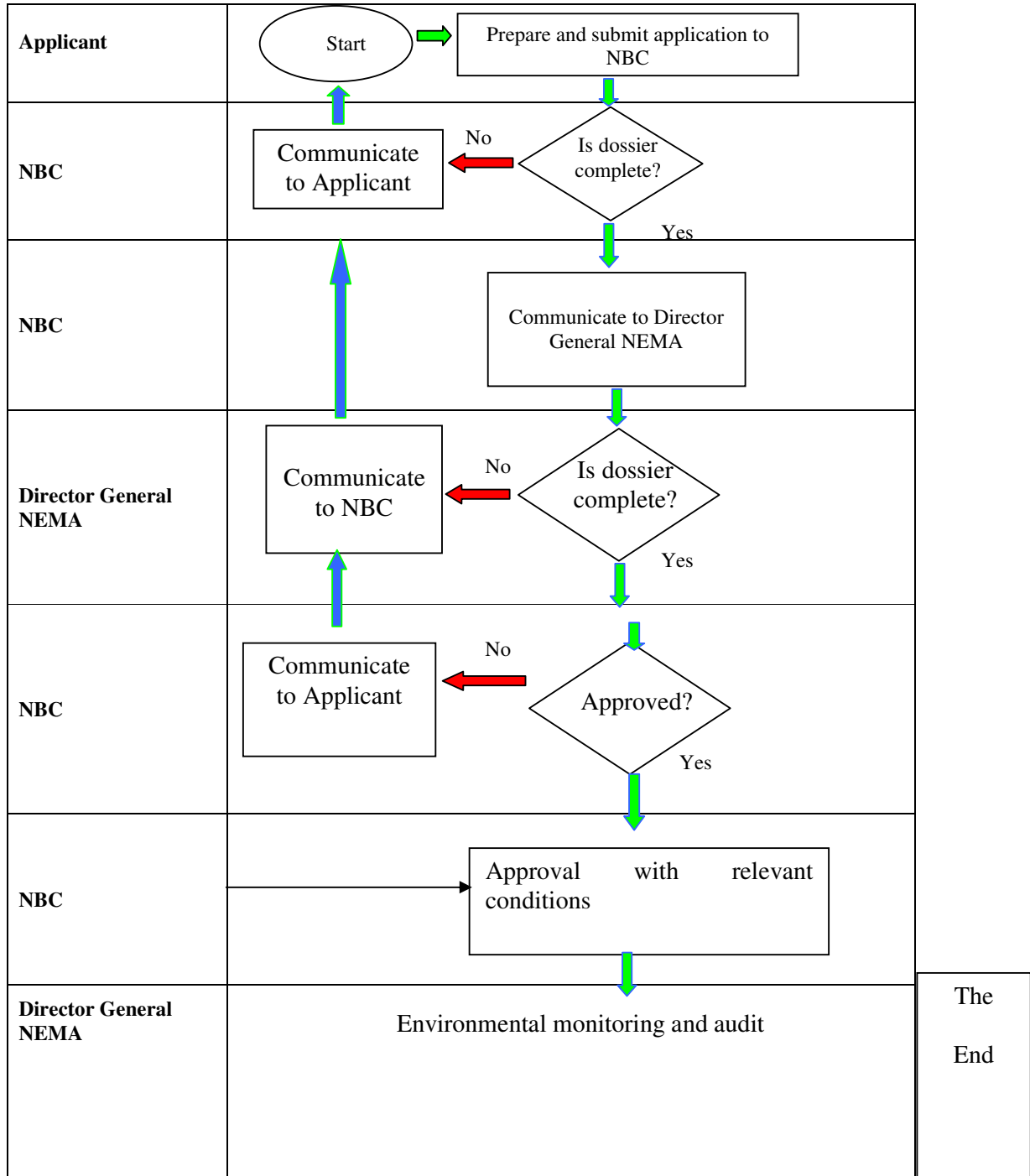
8.0 Coordination structure flow diagrams

The coordination structure flow diagrams have been developed to illustrate how different categories of GM products flow through the regulatory system. As indicated earlier on in this document, the regulatory agencies have specific mandates as summarized below.

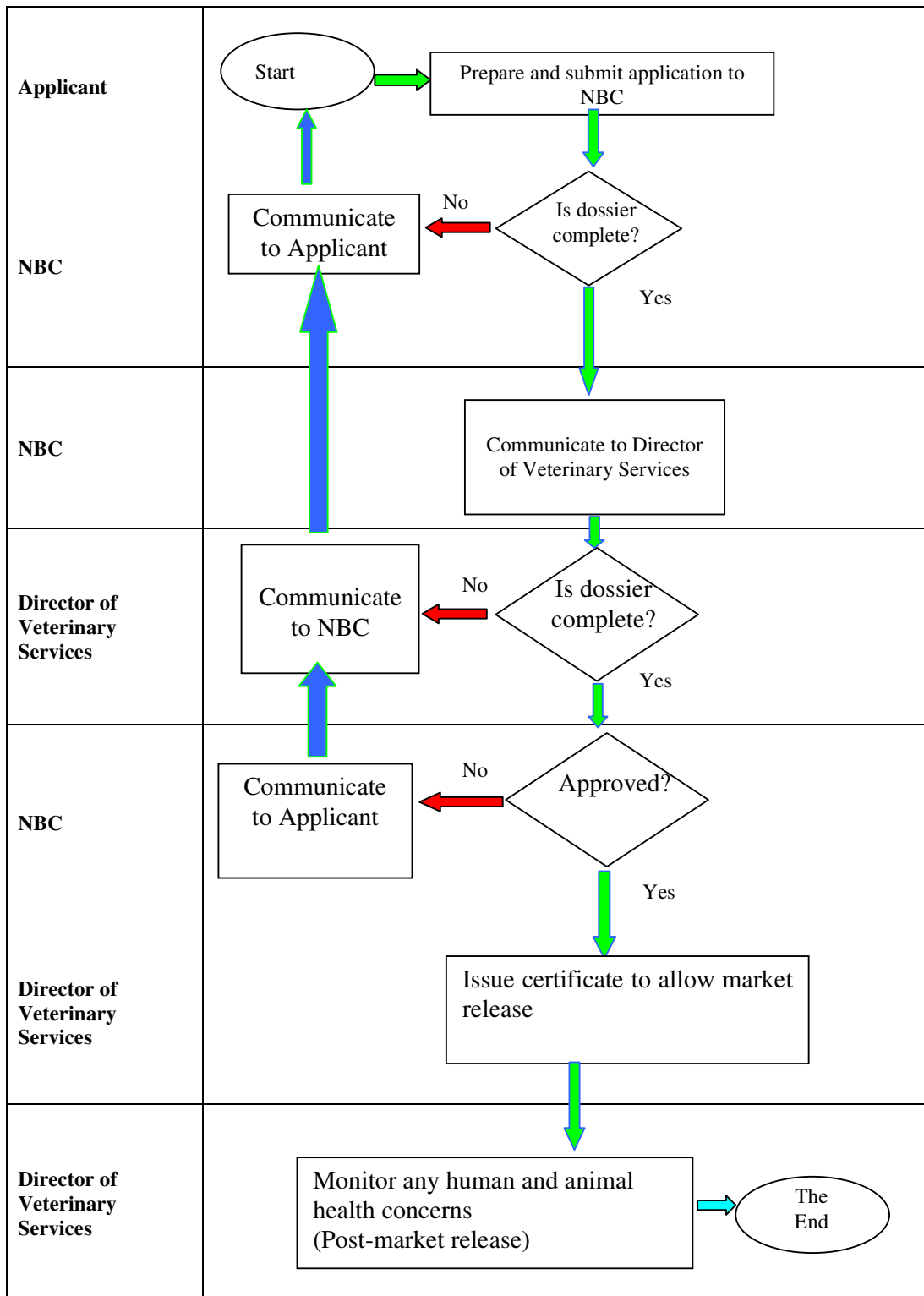
- Kenya Plant Health Inspectorate Services (KEPHIS)-regulates all aspects of plant health
- Public Health-regulates food safety matters.
- Pest Control Products Board (PCPB)- responsible for regulation and registration of pest control products.
- Kenya Bureau of Standard (KEBS)- development of standards
- National Environment Management Authority (NEMA)- coordinating all issues related to the environment
- Department of Veterinary Services-regulation of animal health matters.

For all the products, the first stage entails submission of the request by the applicant to the NBC. The application/dossier is then examined for completeness. Applicants are requested to provide additional details in cases where dossiers are incomplete. Those that meet the requirements of NBC are cleared to proceed to the next stage. In stage two, NBC consults the relevant regulatory agency (e.g. KEPHIS on matters of plant health) for expert advice. On the basis of the feedback received, NBC makes a decision to either reject or accept the application. Once the application is approved, the relevant agency issues the applicant with a permit and this now enables the individual or institution to proceed with research or commercial release. Monitoring by the relevant regulatory agencies to ensure conforming to biosafety requirements becomes an important activity after approval. The next section presents flow diagrams with detailed approval channels for GM products handled by different regulatory agencies.

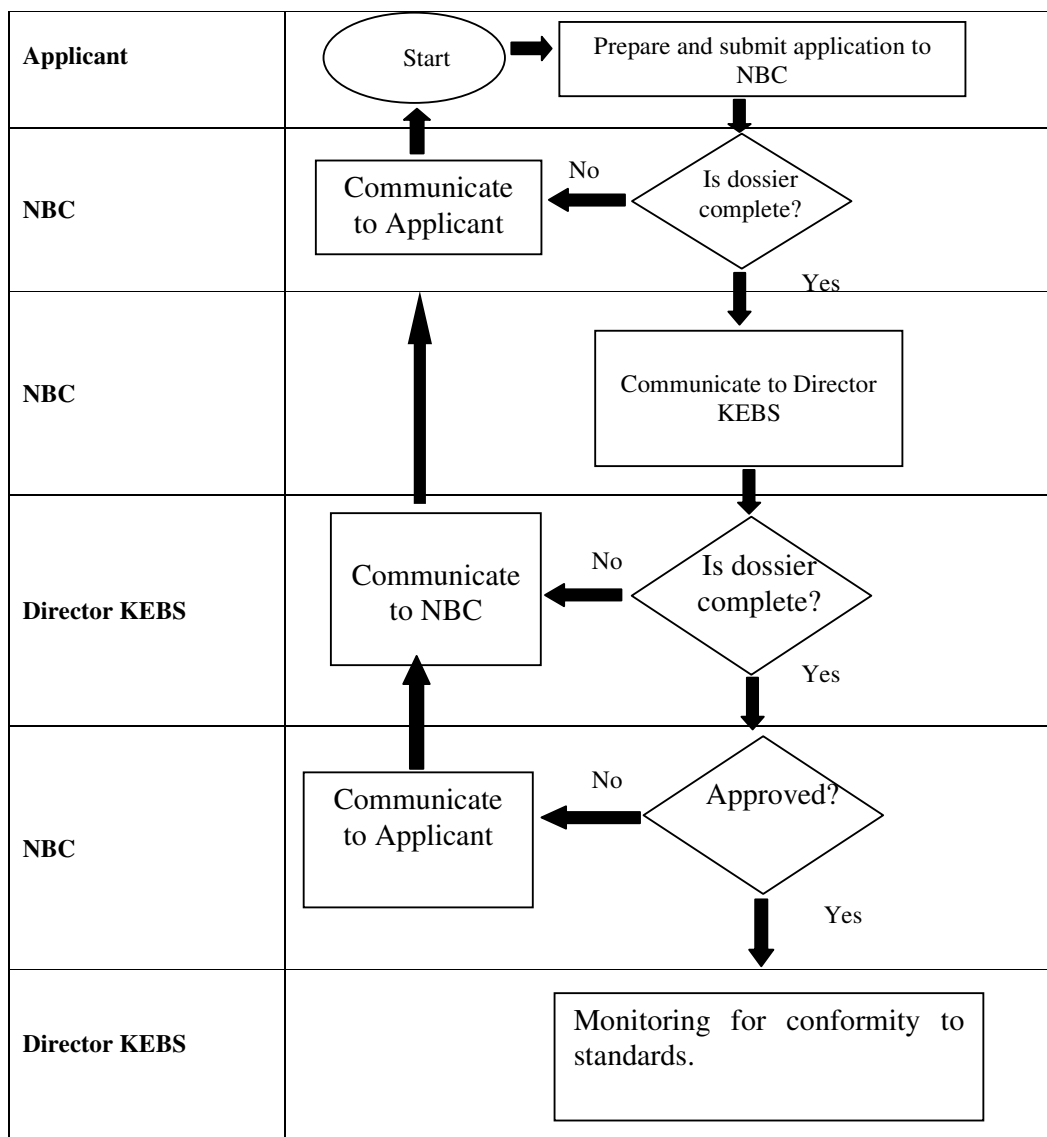
8.1 NATIONAL ENVIRONMENT MANAGEMENT AUTHORITY FLOW DIAGRAM FOR RELEASE OF GM PRODUCTS OR CROPS INTO THE ENVIRONMENT



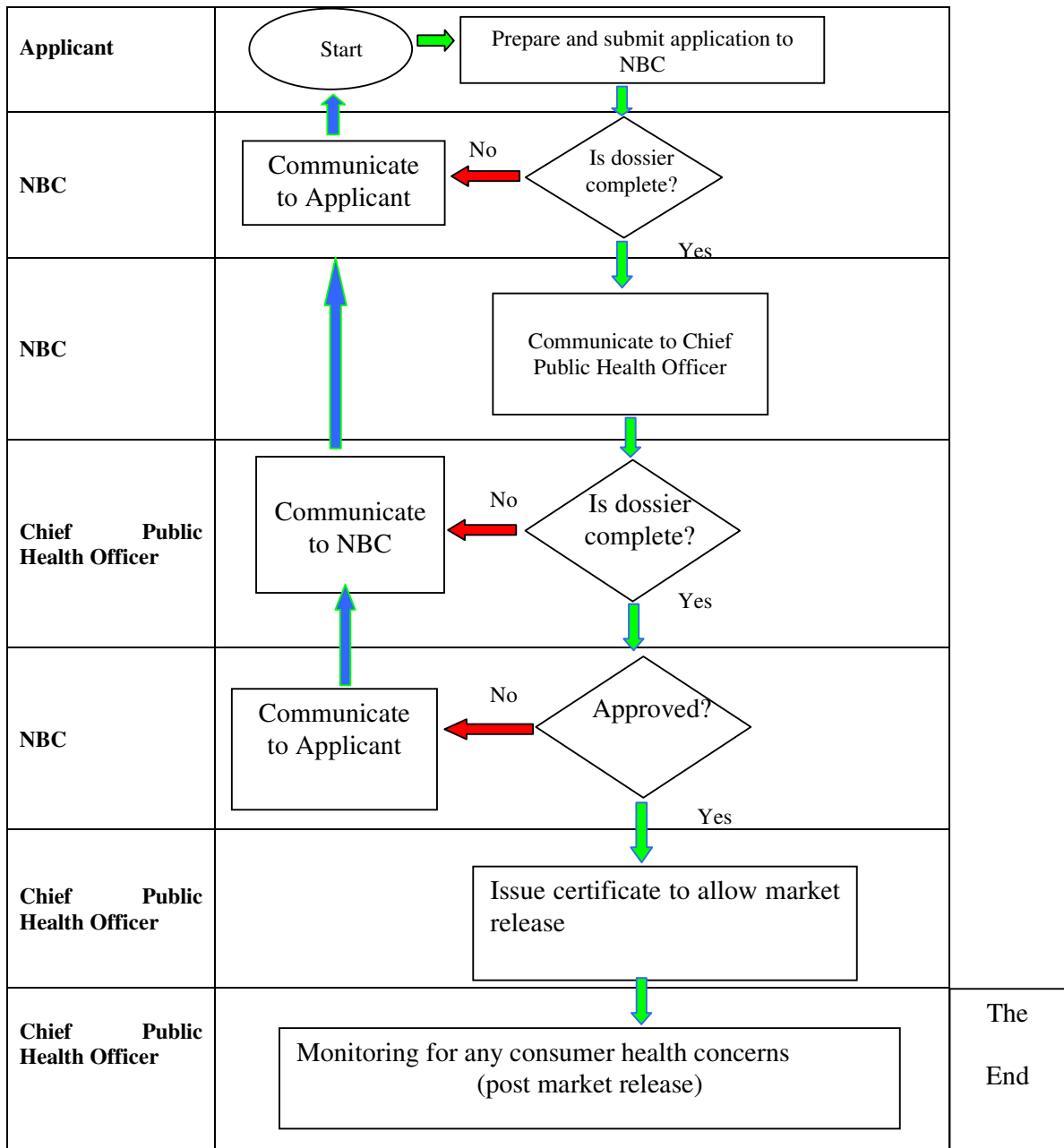
8.2 DEPARTMENT OF VETERINARY SERVICES PROCESS FLOW PLAN FOR GM ANIMAL PRODUCTION INPUTS.



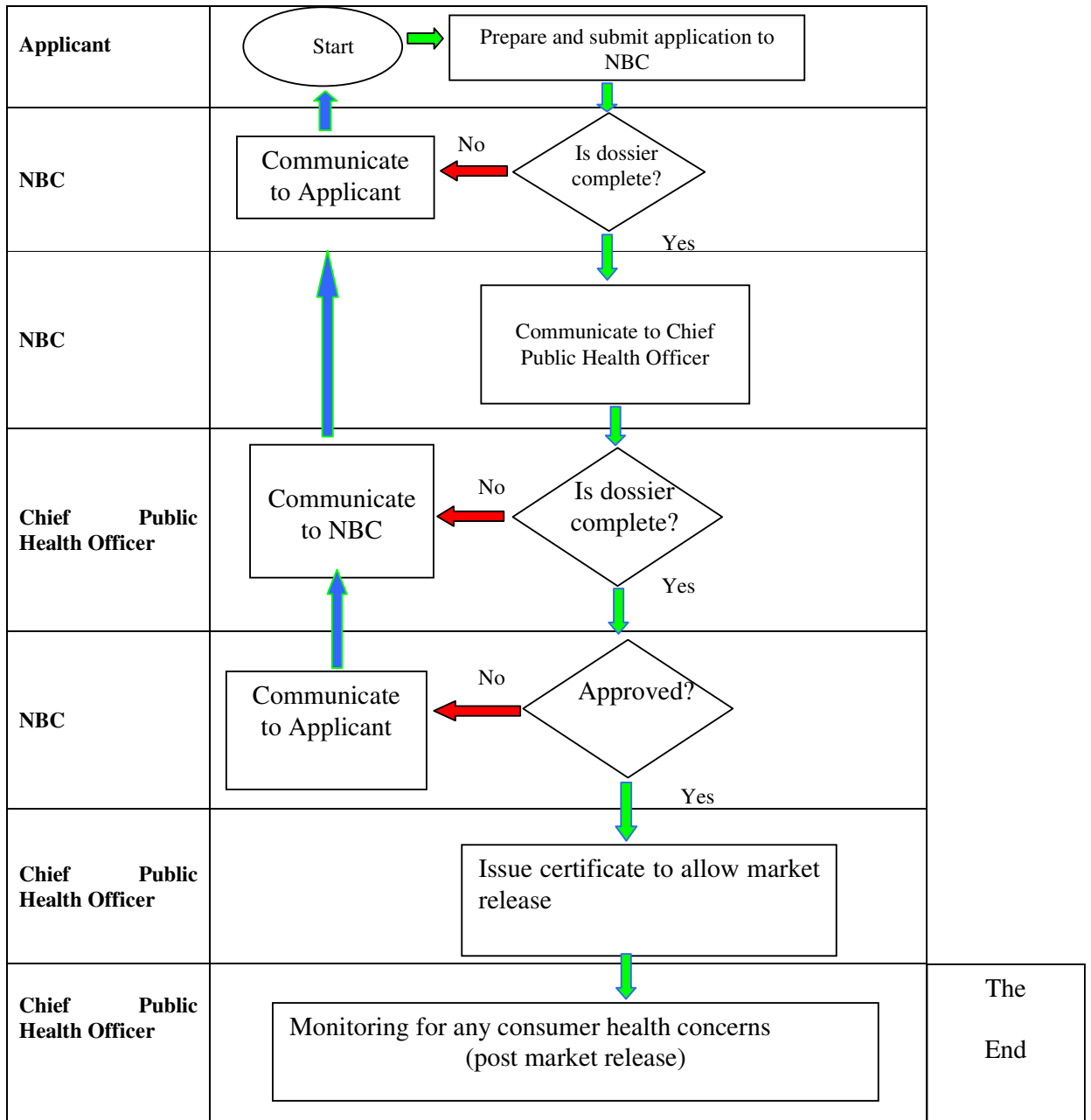
8.3 KENYA BUREAU OF STANDARDS PROCESS FLOW PLAN FOR ASSESSMENT OF GENETICALLY MODIFIED ORGANISMS AND DERIVED PRODUCTS FOR CONFORMITY TO STANDARDS



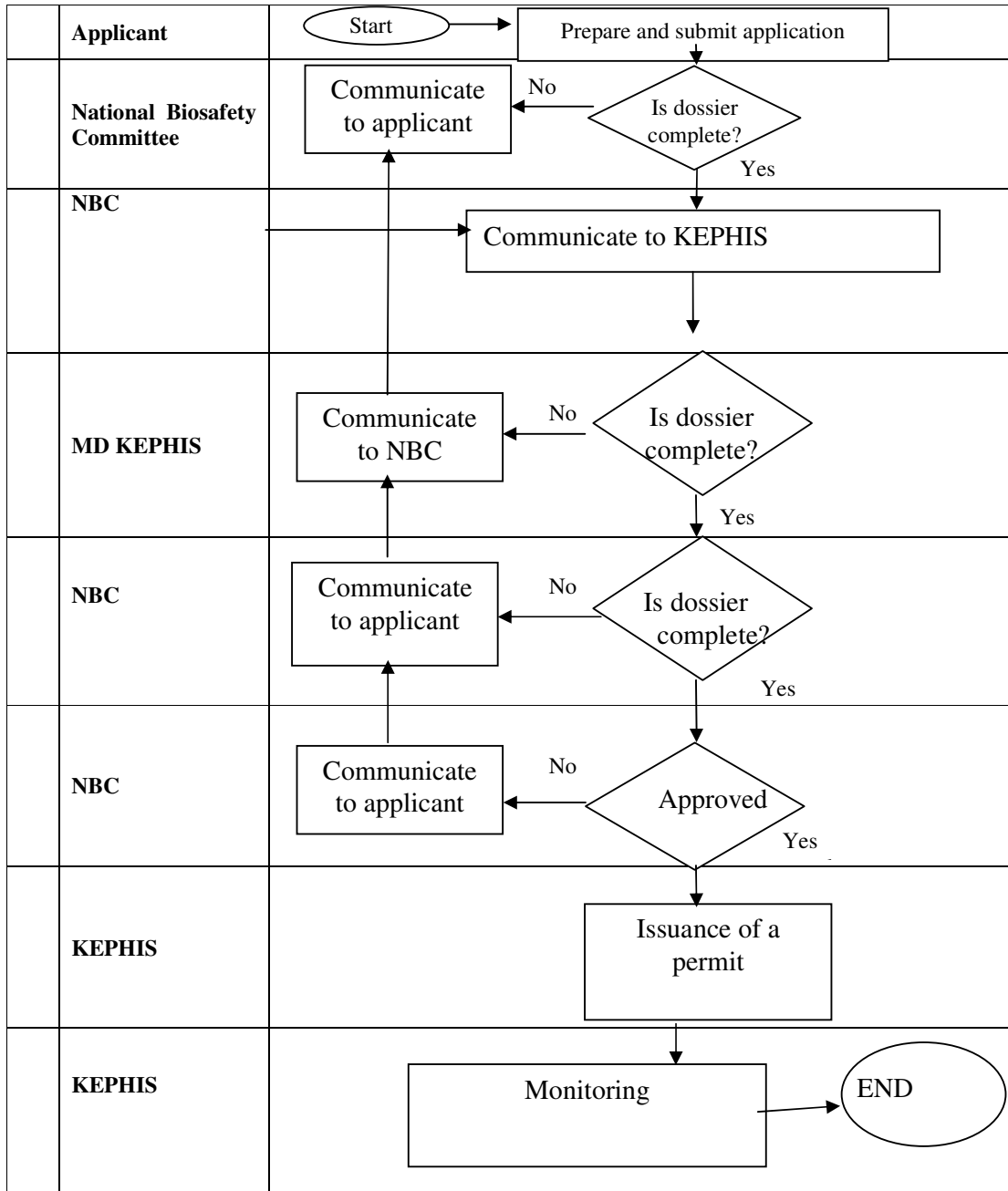
8.4 PUBLIC HEALTH GM FOOD SAFETY PROCESS FLOW PLAN



8.5 PUBLIC HEALTH GM FOOD SAFETY PROCESS FLOW PLAN



8.6 KEPHIS PROCESS FLOW PLAN FOR HANDLING GM PLANT PRODUCTS



9.0 Conclusion and recommendations

The development of the coordination structure commenced before the Biosafety Bill was presented and passed in parliament in December 2008. To a large extent, this document gives a reflection of how the current biosafety system is organized in terms of mandates and decision making procedures followed by the various regulatory agencies. After the President signed the Biosafety Bill into law in February 2009, modalities of establishing and streamlining the technical and administrative operations of the NBA have been initiated. This document will be useful in the formative stages of the NBA in terms of defining the existing arrangements for conducting business.

Once all the organs of the NBA are up and running smoothly, it is recommended that this document should be revised and aligned to the new structures and decision making channels. . It is expected that the transition process will provide clarity on the how the regulatory agencies currently represented on the NBC will relate and interact with the NBA.