THE 6th NATIONAL MONITORING PLAN FOR RESIDUES IN HONEY FROM ETHIOPIA

presented by

The Animal Health Regulatory Directorate

under

THE MINISTRY OF AGRICULTURE (MoA)

Addis Ababa, Ethiopia

March 2013

Executive Summary

This document aims at developing and enhancing the export potential of Ethiopia's major bee product, honey. It highlights the interests, the needs and the requirements of all the stakeholders, particularly the honey producer and processor enterprises with membership to the Ethiopian Honey and Beeswax Producer and Exporters Association (EHBPEA) as they are directly involved in the 6thResidue Monitoring Plan (RMP) for Ehiopian honey. The primary aim of promoting export for honey trade is geared to identifying the conditions and market requirements of the European Union (EU), one of Ethiopia's leading export markets. Ethiopia since February 2008 has been added to EU's third country listing for exporting honey (Commission Decision 2008/105/EC) through its consecutive RMP by establishing procedures to monitor the residues of veterinary drugs and pesticides including Polychlorinated Biphenyls (PCBs) as well as heavy metal contaminants in accordance with EU directive 96/23/EC. The 5thRMP was submitted in March 2012, which still allowed Ethiopia to be retained among the third countries to export honey through the registered companies involved in the process. The EU must annually receive the RMP for licensing the export of honey by the participating honey producers and processers under the EHBPEA, after reassessing the requirements for EU's third country listing. This document, therefore, lays the basis of the 6thRMP for Ethiopian honey to be submitted by Ethiopia's Ministry of Agriculture (MoA) to EU's competent authority (CA), the Food and Veterinary Office .

According to the most recent report of the CSA in 2010, the national honey yield is estimated at 53.68 thousandtons per annum. The largest volume of honey (97%) is collected from traditional hives while the remaining percentage is from frame and intermediate hives.

The statistics just presented, highlights that Ethiopia has a high potential for raising its national revenue through exporting honey. Within2008/9-2011/12Ethiopia exported an average of 306.8 tons/year of honey and 207.6 tons of beeswax. Ethiopia's honey export was limited to Saudi Arabia, Kuwait, United Arab Emirates, Iran, Yemen and others like Djibouti, Sweden, Israel, Japan,Germany, Norway, United Kingdom, United States of America and Canada. The nation's honey export has mainly increased as a result of the EU permit. This has encouraged the exporting companies to be annually included in the RMPs. The current RMP, the 6thin the series, targets 810 tons and it involves six honey/beeswax producer/processor companies.

The 810 tons of honey in the current export plan for 2013is only about 1.51% of the estimated national honey yield. Despite the leap from the earlier negligible export volume of honey until 2004, the amount in the current plan of the enterprises is still small compared to the country's actual production of 53.68thousand tons/year without considering the effect of development projects upon apicultural production growth.

Constraints affecting the apiculture sector in Ethiopiaoccur at all levels of the value chain. They range from low capacity honey production and processing methods, hygiene, packaging technology and lack of accredited laboratories for verifying the quality and safety of raw and processed honey. The situation is not different from the other agricultural and food sectors which are the major export earning commodities.

Significant changes have taken place in the last few years to support and strengthen the Ethiopian Sanitary and Phytosanitary (SPS) Measures in terms of legal and instutional frameworks relating to food and drug safety and quality requirements. The stated

changes in this RMP-2013 report signify the following developments including the most recent publications of Ethiopian laws and regulations (i-xv).

i. Establishment of the Livestock Development Sector at a State Ministerial level under the Ministry of Agriculture (MoA), 2013.
ii. Establishment of the Animal Health Regulatory Directorate(AHRD) under the Livestock Development Sector (2013) –a Competent Authority responsible for monitoring the progress and submitting the RMP to the EU.
iii. Establishment of the Livestock and Feed Resources Directorate (LFRD, 2013).

iv. Launcing of ASPIRE Project The largest apicultural development project so far, the ASPIRE project (Apiculture Scaling – Up for Rural Income and Employment), with approx. 7 Million EUR in grants and loans, addressing tens of thousands of beekeepers in a value chain approach, with the Netherlands government as the main donor, was launched on March 28th, 2013

v. Establishment of a Centre for a Satellite Laboratory of Honeybee Diseases and Pollination Research in the country with a grant of EU, an*icipe*& AU-IBAR coordinated project (2013).
vi. Proclamation 728/2011 to provide for the *Veterinary Drug and Feed Administration and Control*
vii. Guidelines for*Import and Export of Animal and Animal Genetic Materials* which includes import of drone semen and export of live queen bees and drone semen.
viii. Proclamation 674/2010 to provide for the *Registration and Control of Pesticides,* repealing Decree No. 20/1990.
ix. Regulation 196/2011 for the *Establishment of Ethiopian Conformity Assessment Organization*
x. Regulation193/2010 for the *Establishment of Ethiopian Standards and Technology Agency*
xi. Regulation195/2010 for the *Establishment of Ethiopian Accreditation Bureau*
xii. Proclamation 661/2009 *to Provide for Food, Medicine,and Health Care Administration and Control which led to the formation of Food, Medicine, and* Health Care Administration and Control Authority relpacing the DACA (Drug Administration and Control Authority).
xiii. Proclamation 660/2009 *to Provide for Apiculture Resources Development and Protection*
xiv. Draft regulation on apiculture resources development and protection.
xv. Establishment of a new Apiculture Research Division at a national level
xvi. Direct involvement of honey exporting enterprises in the current RMP.
xvii. Establishment of Ethiopian Apiculture Board (EAB), an apex private public body to coordinate activities related to honey production and marketing in cooperation with the MoA and other key stakeholders.
All the current exporters except Rahi are certified for conformity. Certification against ISO 9001:2000, Fair-trade, and organic certificationof the processing packaging plant of Beza Mar Agro-industry PLC and certification of ISO ISO:22000:2005 and HACCPof Apinec Agro-industry, Tutu and His Family, Dimaand Comel PLC are seen in Annex VI).

Other institutions and development activities towards mitigating the constraints relating to apiculture and enhancement of honey quality and safety are further reflected below:
xviii. Attention given by the MoA to increase honey production in the coming 5 years(2010-2015) of the Programme for Agriculture Growth and Transformation Plan (GTP), which is the third phase of the Millennium Development Goal, to control quality of animal products and to increase export of honey by volume and value.

xix. Expansion project of the Holeta Bee Research Center (established in 1964) to possess a laboratory for testing honey quality parameters.

xx. Presence of a well-equipped laboratorywith planned activities for accreditation, quality assurance and document preparation projects that includes drugs and pesticide residue analyses

xxi. Publications of Ethiopian standards (2005) for honey, beeswax and beehives

xxii. Establishment of Multi Stakeholder Platform of Honey along the Honey Value Chain since 2010which is currently run by the EAB.

xxiii. Establishment of the EHBPEA (see sub-section 1.2.2) and the Ethiopian BeekeepersAssociation, EBA, the latter about a decade ago.

xxiv. Support of the SNV-Ethiopia and lately ACDI/VOCA for sponsoring the Residue Monitoring plan which commenced in 2006/2007 and continued until the current one for 2013.

xxv. Other NGO supports for the sector to enhance the production capacity, quality andsafety of both honey and beeswax

xxvi. Local and local/foreign joint venture investments from production to final processing (see Annex V)

Acronyms

AAS	Atomic Absorption Spectrophotometer
ADR	Adverse Drug Reaction
AHRD	Animal Health Regulatory Directorate
Apinec	Apiculture Development and Trading PLC
ASPIRE	Apiculture Scaling-up Programme for Income and Employment
BSE	Bovine spongiform encephalopathy
CA	Competent Authority
CODEX STAN	Codex Alimentarius Standards
DACA	Drug Administration and Control Authority
DDT	Dichloro-diphenyl-trichloroethane
DG	Director General
EAB	Ethiopian Apiculture Board
EBA	Ethiopian Beekeepers Association
ECAE	Ethiopian Conformity Assessment Enterprise
EHBPEA	Ethiopian Honey and Beeswax Producers and Exporters Association
EHNRI	Ethiopian Health and Nutrition Research Institute
EIAR	Ethiopian Institute of Agricultural Research
ELISA	Enzyme linked Immunosorbent Assay
ESBA	East Showa Beekeepers Association
EU	The European Union
FAO	Food and Agricultural Organisation
FMHACA	Food, Medicine, and Healthcare Administration and Control Authority
FTIR Spec.	Fourier Transform Infrared Spectrophotometer
GAP	Good Agricultural Practices
GC	Gas Chromatograph
GC MS	Gas Chrmatograph-Mass Spectrometer
GICO	Ghion Industrial & Commercial PLC
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practices
GTP	Growth and Transformation Plan
GIZ	German Technical Cooperation
HMF	Hydroxymethylfurfuraldehyde
HPLC	High Performance Liquid Chromatograph
HPTLC	High Performance Thin Layer Chromatography
ISO	International Organisation for Standardisation
PU hives	Polyurethane hives
IAF	International Accreditation Forum
IEC	International Electrotechnical Commission
ILAC	International Laboratory Accreditation Cooperation
LC – MS	Liquid Chromatograph-Mass Spectrometer
LFRD	Livestock and Feed Resources Directorate
LIDE	List of Drugs for Ethiopia
MoA	Ministry of Agriculture.
MoH	Ministry of Health
MLs	Maximum Levels of contaminants
MRL	Maximum Residue Limit

MRPL	Minimum Required Performance Limits
MSH/RPM+	Management Science for Health/Rational Pharmaceutical Management Plus
NGO	Non - Governmental Organisation
NMI	National Meteorolgy Inistitute
OIE	Office International des Epizooties (English: World Organization for Animal Health)
PASS	Pharmaceuticals Administration and Supply Services
PCBs	Poly Chlorinated Biphenyls
PHARMID	Pharmaceutical & Medical Supplies Import & Wholesale Share Co.
PLC	Private Limited Company
POP	Persistent Organic Pollutants
QC	Quality Control
QSAE	Quality and Standards Authority of Ethiopia
RMP	Residue Monitoring Plan
SABS	South Africa Bureau of Standards
SNNPR	State Southern Nations, Nationalities and Peoples Regional State
SNV	The Netherlands Development Organisation
SOPs	Standard Operating Procedures
SPS Measures	Sanitary and Phytosanitary Measures
UNDP	United Nations Development Programme
UV-Vis spectrophotometer	Ultra Violet-Visisble spectrophotometer
WHO	World Health Organisation

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produced by the

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1. Introduction and general information

Beekeeping is among the vibrant agricultural enterprises practiced throughout the country for its significant contribution to economic and social development at the household and national level. It provides direct income benefit to beekeepers and to Tej (Local honey wine) brewers through sales of hive and value added products and to beekeeping equipment manufacturers and craftsmen. Candle makers and retailers of these items do also benefit from the sales of the item. Beekeeping creates job opportunity to the majority of the rural mass and youth groups and over 1.5 million people are involved along the apiculture value chain. According to reports of the Ministry of Agriculture (2010) a household income from apiculture is estimated at over $US 60 million/annum. The role it plays in enhancing food security, poverty reduction and food production through pollination of crops has become substantial in the recent years.

In Ethiopia, identification and study of honeybee diseases and pests started in 1989. Since then, a number of surveys and studies were conducted (Gezahegne and Amssalu 1991[1]; Dessalegn and Amssalu 2000[2], Dessalegn and Amssalu 2005[3], and Dessalegn and Yosef 2005[4]). These studies revealed the occurrence of adult and brood honeybee diseases, pests. Honeybee diseases identified include: *Nosema,Amoebaand Chalk brood*while dangerous diseases like *American foul brood, European foul brood and Acarine*and others are reported to be absent. *Varroatosis* has bee identified in neighbouring countries, therefore, its presence in the country needs to be investigated.Their non-existence may be due to prohibition and control of importation of used beekeeping equipment, live honeybees and other bee species such as bumblee bee. Although the existence of *Nosema* and *Amoeba* honeybee diseases in the country had been reported in 1991 , they have not presented any negative effect on local honeybee colonies due to the lower number of Nosema spores per infected individual honeybees than the critical level causing negative effects.This may be attributed to the climatic condition of the country which allows bees defecate outside the hive even during the rainy season and minimize the risk of infection. Chalk brood is known to be more serious inreducing honey production than the adult honeybee diseases found in the country. No chemotherapy is registered in the world against chalk brood disease. None of the aforementioned diseases are treated using drugs other than exercising colony manipulation practices and hence, there is no chance of honey contamination with veterinary drugs in Ethiopia.

Ants, wax moths, small and large hive beetles, death head hawk moths, bee-eater birds, lizards, toads, spiders, honey badgers and wasps are the reported pests for honeybees. Like the honeybee diseases, these pests are controlled by colony manipulation.

Applications of drugs and pesticides for protection against plant and animal pests and diseases are becoming a major global concern as hazards to safety in food commodities for government food regulators and risk management organizations. This is so because of lack of good agricultural practices which can be preventive measures to maintain pesticides and veterinary drugs below the Maximum Residue Levels (MRLs). These cannot be changed immediately through short production cycles. To provide safe food to consumers, it is essential that adequate monitoring is in place to eliminate the possibility of the presence of the residues and contaminants in food commodities in amounts less than the regulated

[1]Gezahegne and Amssalu, *Preliminary Survey & Diagnosis of Nosema, Amoeba, Acarine Diseases at Holetta Bee Research Center*, 1991
[2]Dessalegn and Amssalu, *Pest and Pathogen Survey in South and Southwest parts of Ethiopia*, 2000
[3]Dessalegn and Amssalu, *Distribution of Nosema Disease in Ethiopia*, 2005
[4]Dessalegn and Yosef, *Pest and Pathogen Surveys in Addis Ababa* 2005

residue levels. This is still one of the major challenges for developing countries. Despite all these risks from hazards, it is gratifying to note that Ethiopia's honey export access to the European Union market has been sucessful because apiculture is mostly a traditional practice and the apiaries are far from industrial and agro-industrial areas.

To verify residue levels of pesticides and drugs (such as organochlorine and organophosphorous compounds, antibiotics including chloramphenicol) and heavy metal concentrations, test results of baseline samples taken from time to time (yearly) show that the honey produced in Ethiopia must be below the specified maximum residue limits (MRLs) or Maximum Levels (MLs) of contaminants. Monitoring tests conducted from the 1st to the 5th RMP for honey in Ethiopia since early 2007 have favourably reflected this which has therefore exhibited successes in the RMPs with regard to Council Directive 96/23/EC..

Asuccessful RMP for honey as an animal product is the central requirement for exporting the productto the EU countries on the basis of Council Directive 96/23/EC which lays the requirements that must be met in relation to the planning and execution of national residue control plans for live animals and products of animal origin. The principal objective of the legislation is to detect illegal use of substances in animal production and the misuse of authorised veterinary medicinal products and to ensure the implementation of appropriate actions to minimise any recurrence of all such residues in foods of animal origin.

Consignments of foods which contain residues in excess of the EU Maximum Residue Limits (for pesticides and veterinary medicines), Maximum Limits (for contaminants e.g. heavy metals, toxins etc) or contain residues which do not have a Community MRL or ML may not be legally placed on the EU market and will be rejected.
The fifth plan for 2013that had been submitted to the Food and Veterinary Office still kept Ethiopia in the third country listing. This annual submission of plan aims at evaluating conformity to the Ethiopian official regulations to ensure safety of honey with regard to the levels of residues and contaminants of chemical substances in it. As stated in Directive 96/23/EC, the RMP has to be updated every year. From the outset the Ethiopian RMP for honey was accepted by the FVO of the EU in accordance with Commission Decisions[5].This document and the test certificates of the residues and contaminants in honey constitutes the 6thRMP forsubmission to the Commision not later than 31st March 2013.

1.1 Competent authorities - contact details

The Animal Health Regulatory Directorate (AHRD) of the MoA is designated as the **"competent authority**"(see Organogram I).

Name and address of the CA

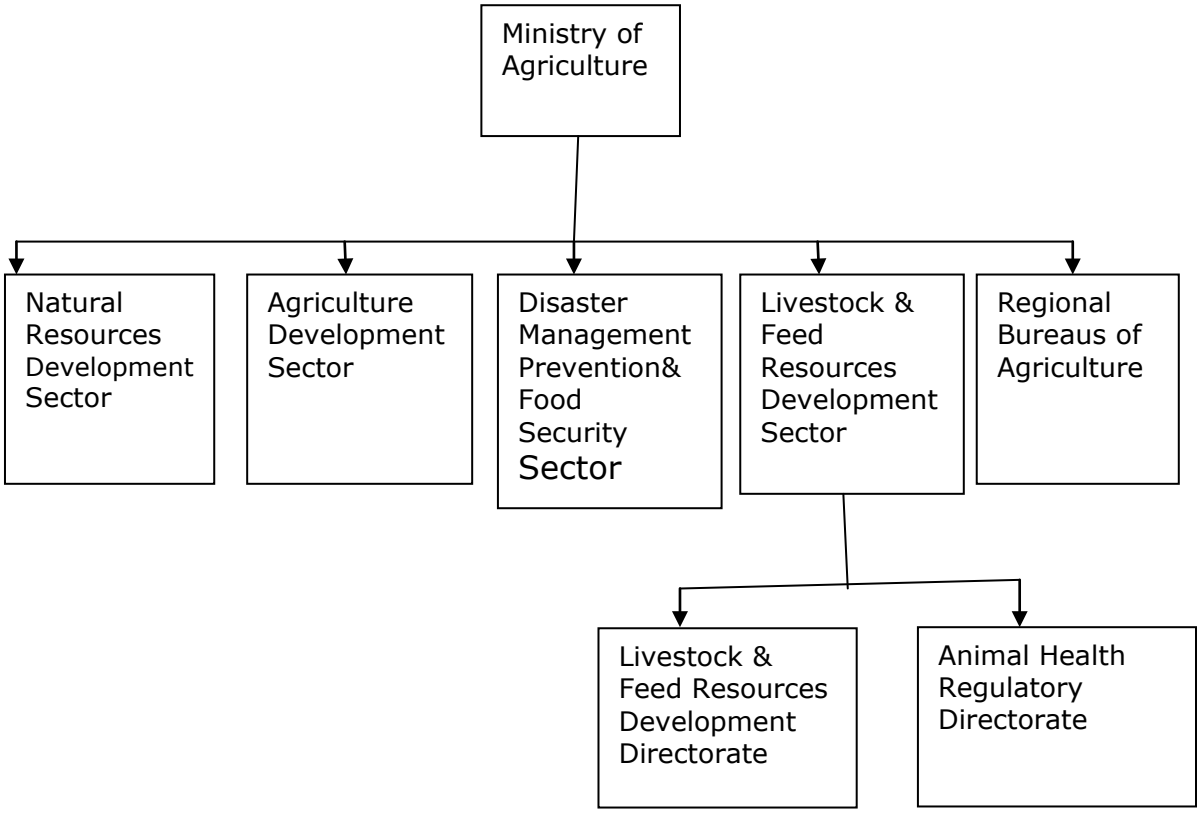
[5]2008/105/ECamending Decision 2004/432/EC on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC

Animal Health Regulatory Directorate,
Ministry of Agriculture
P.O.Box: 62347
Addis Ababa, Ethiopia
E-mail:bsiraw@yahoo.com
Tel: +251 116 461277
Faxes: +251-116 462003

1.2 The structure of the CA, MoA

The AHRD of the MoA is the Directorate*, inter alia*, responsible to ensure that only healthy, safety and wholesome foods of animal origin reach the market and are placed in the hands of consumers and exporters. It is the institution for implementing national Sanitary and Phytosanitary (SPS) Measures which aims at protecting plant and animal life or health within the country including from risks arising from animal and plant diseases, food additives, toxins, residues, pests, microbial and heavy metal contaminants. It monitors the development of these sub-sectors and ensures and maintains the quality and safety of animal and animal products, both for domestic consumption and export. Beside these, the authority coordinates, supervises and monitors residue and contaminant testing activities at all levels and develops proclammations and regulations related to food quality and safety of animal origin. The Directorate is also responsible to develop, monitor and evaluate Internal Control System, ICS, and its implementation at the grass root level.

The Ministrycurrently builds a quality control laboratory to ensure the quality and safety of seeds, meat, milk, honey and beeswax produced in any parts of the country in order to deliver support for Sanitary and Phytosanitary measures to the commodities prior to distribution to local and international markets.
The AHRD prior to or during the submission of the RMP to the EU**,** may submit an updated list of pesticides and registered and used in Ethiopia including information on the MRLs. The MRLs of pesticides and vet-drugs of importing countries or the Codex Alimentarius, may be adopted until a government-approved regulation enters into force. This will allow the selected testing laboratory involved to adopt the requirements of the importing country (e.g. EU Member States) with regard to the maximum permitted Residue Limits (MRLs) or the MLs. The EU action limits are used for unauthorised or prohibited substances.
The original of this document encloses Annex IB encloses an Excel plan template for the substances tested. The difficulty reflected in the absence of Community or the EU Maximum Residue Limits for many of the trace chemicals specific for honey is understood.
The veterinary services under the same Directorate of the CA ensure that only healthy, safety and wholesome foods of animal origin reach the market and are placed in the hands of consumers and exporters. The responsibility of registering, administering and controlling veterinary drugs has nationally been decided to be the responsibility of the CA which regulates on the basis of a new Proclamation 728/2011 to provide for Veterinary Drugs and Animal Feeds Administration and Control. The Livestock and Feed Resources Directorate (LFRD) of the same Ministry works closely in coordination with the AHRDto develop and coordinate government policies, strategies, proclamations regulations and guidelines related to livestock, fisheries, poultry, apiculture and sericulture. In addition, the Directorate in cooperation with the Regional Agricultural Bureaus works aggressively to increase honey production by 20% in the third 5 years of theAgriculture Growth and Transformation Plan.



Organogram I: Minsitry of Agriculture, MoA (**Note**: *an Authoritywhich regulates veterinary drugs and animal feeds is established)*

1.2.1 The local authorities - structure and resources of the subordinate organisations

The CA, MoA, is in close cooperation with other authorities, mainly with the new Food, Medicine, and Health Care Administration and Control Authority to make sure that all requirements concerning RMP for Ethiopian honey can be fully covered and controlled.

Food, Medicine, and Healthcare Administration and Control Authority

- The Food, Medicine, and Healthcare Administration and Control Authority, FMHACA, under the Ministry of Health, is the responsible institution to ensure the quality and safety of foods as well as the quality, safety and efficacy drugs, traditional medicine, medical supplies and instruments, cosmetics, and their labeling and packing materials through evaluation and certification. The FMHACA was established during 2009 to accommodate regulatory powers on food safety and administration and control of pharmaceuticals and traditional medicines as well as health services, health and health-related institutions and health professionals.

Annex VII. **Oranogram II:**The current structure of the FMHACA

The Food, Medicine, and Health Care Administration and Control Proclamation *(No. 661/2009)* mandates the Ministry of Health to issue food safety regulations and directives for processed foods as well as for therapuetic and supplimentary foods. The competent

ministry regulates foods safety, including acceptability of locally produced, imported and exported foods for consumption.

Contact Details

The Food, Medicine, and Healthcare Administration and Control Authority
Ministry of Health
P. O. Box 5681
Addis Ababa (Ethiopia)
Tel No.: 00251 – 11 - 5524122
Fax No.: 00251 – 11 - 5521392
e-mail.: daca@ ethionet.et

The National Quality Infrastructure of Ethiopia

As at late 2010, the Quality and Standards Authority of Ethiopia, QSAE, has been legally abolished and replaced by four new institutions as the pillars of the National Quality Infrastructure**.** The four institutions are empowerd by the following separate regulations, each headed by a Director General with appropriate number of Directorates. The regulations are, namely:

i. Regulation193/2010 for the Establishment of Ethiopian Standards and Technology Agency
ii. Regulation194/2010 for the Establishment of National Metrology Insitute
iii. Regulation195/2010 for the Establishment of Ethiopian Accreditation Bureau
Regulation 196/2011 for the Establishment of Ethiopian Conformity Assessment Enterprise

It is expected that the two technical and non-tariff trade barriers, namely the Technical Barries to Trade (TBT) and Sanitary and Phytosanitary Measures which relate to qualty and safety of agro-products and foods will be better addressed with these new legal and institutional frameworks of the National Quality Infrastructure.

The Ethiopian Standards and Technology Agency, ESTA

- Regulation193/2010, issued by the Council of Ministers hereby establishes the ESTA. All standards set and published, or adopted, by the former QSAE are administered and revised by the*ESTA.* The Ethiopian Standards for honey, beeswax, and beehives [Annex IV: specification (beehives, honey, beeswax)] were published in 2005 and retain their validity with the new Agency. The specifications in the Ethiopian honey and beeswax standards are found comparable to the Codex requirements and EU legislations. The honey standard has also fixed specified test methods for each required component (moisture content, reducing sugars, sucrose, acidity, ash, HMF, diastase activity and water insoluble matter). No national databases are available currently regarding levels of residues and contaminants. Codex Alimentarius and EU regulations are used for levels of residues and contaminants. The country mostly verifies local export products by certificates from accredited laboratories abroad to make sure the levels abide by international regulations.

The Ethiopian Conformity Assessment Enterprise

This organization constitutes the Testing Laboratory Directorate under the new Ethiopian Conformity Assessment Enterprise in accordance with Regulation 196/2010. The objectives of the Ethiopian Conformity Assessment Enterprise are detailed in the regulation as follows:

i. Provide certificate for manufacturing industries and service sectors by assessing their conformity in accordance with the necessary quality requirements.

ii. Provide certificate for export products by inspecting their conformity based on Ethiopian standard or international standard or other countries standard.
iii. Provide certificate for manufacturing industries or service sectors or management systems or personnel by assessing their competence in accordance with national and international standards.
iv. Provide certificate for import products by inspecting their conformity in accordance with technical regulations or national, regional and international standards.
v. Provide strict testing and inspection service for those products, services and management systems that should subject to the mandatory standards.
vi. Organize testing laboratories which are essential for the fulfillment of the objectives according to the existing situation of the regions and increase conformity assessment services.
vii. Participate in inter laboratory comparisons and proficiency test scheme between various regional and international testing laboratory institutions, in order to prove the testing laboratory services provided by the Organization.

The Ethiopian Metrology Institute

- This institute is established under the new *Regulation No. 194/2010 for Establishing National Metrology Institute* (the NMI) with an overall aim of establishing measurement traceability in order to enhance comparability among measurements conducted by national and international institutions. Both scientific and legal metrology are covered under the functions of this institute.

- **The Ethiopian National Accreditation Bureau**

The Accreditation Bureau is established as of 1 Feb 2011 and is empowered by a new Regulation195/2010 *for the Establishment of the Ethiopian Accreditation Bureau* as an independent body and with its own legal personality as part of the federal government. Regulation195/2010 sets the following Objectives and Powers.

Objectives

i. Contribute its part for the acceptance and appreciation of Ethiopian products and services in domestic and international markets by developing appropriate infrastructure of national accreditation system, which comply with international requirements.
ii. Establish and implement a management system that can enable to develop a conformity assessment and consultancy services which complies with international practices.
iii. To prepare requirements and guidelines which verify the relevance and quality of the provisions of education and health services and also to ensure the compliance of education service standard with regard to the regulations in place.
iv. Represent and maintain the interest of Ethiopia in international and regional accreditation organizations regarding accreditation activities.

The power and duties of the Accreditation Organization, *inter alia*, include

i. To provide a sole accreditation service to organizations that are involved or going to be involved in conformity assessment activities based on national and international requirements.
ii. To hold, administer and permit the use of national accreditation marks or certificates of conformity assessment, education and health and if necessary to cancel or to suspend on the use of the mark or certificate whenever those requirements are no longer maintained.
iii. Based on rules and regulations to be issued, provide accreditation service, and when necessary cancel or impose sanction on the issued recognition to those bodies that are involved in conformity assessment activities within the country.
iv. To provide registration service for bodies those are already involved and have a desire to involve in management system consultancy service.

v. To prepare and publicize directives related to recognition and registration of services and accreditation service for conformity assessment, education, and health sectors.
vi. Undergo surveillance audit on those bodies that are already received a conformity assessment, education and health accreditation and also on bodies that received recognition and registration for consultation services.
vii. Keep a book of registration, for organizations locally accredited in conformity assessment, education and health sector, those recognized and registered and also those organizations which are received, canceled or suspend from the body's recognition and publicize and inform to regulatory enforcement and if necessary to other concerned bodies.
viii. Represent the benefit of the country in international and regional accreditation organizations related to accreditation activities.
ix. Implement national accreditation systems that fulfill/comply the requirements of international laboratory accreditation cooperation (ILAC) and International accreditation forum (IAF).

Melkasa National Bee Research Division

The Melkasa National Bee Research Division is a bee research division under the Melkasa Agricultural Research Centre of the Ethiopian Institute of Agricultural Research (EIAR). It is the centre of excellence for overall apiculture research and responsible to coordinate all apicultural research activities at a national level.

Bureaus of the Agriculture of the Regional NationalStates

The bureausand their subordinate offices are responsible for the development of beekeeping in their respective regions. These offices plan activity programmes, supply required beekeeping equipment and accessories, render training and extension services at all levels, supervise and render technical assistance and advice to the farmers including those invloved in apiculture .

Holeta Bee Research Centre

The Holeta Bee Research Centre under the Oromia Agriculure Research Institute of the Oromia Regional State is the poineer centre responsible for apiculture research in the country. It undertakes adaptive and applied research on bee botany, bee biology, hive products, bee health, bee management and beekeeping equipment. It also coordinates national apicultural research projects mainly honeybee diseases and pests and popularize technologies. Beside these, the center holds beekeeping training for beekeepers, development agents and other extension staff and investors. At present apiculture research has begun in SNNPR, Amhara, Tigray, Gambella and Beneshangul Gumuz Regional States

1.2.2 Relationship with other agencies –civic organisationsand development partners

The Ethiopian Apiculture Board (EAB)

This is the national apex body dedicated to promoting the apiculture sector in the country and creation of market access for Ethiopian honeybee products. It was launched on 6th of February, 2009. It is a private/public partnership organization with the Patronage of the Minister of Agriculture. The objectives include:

- Encouraging the production and marketing of diversified hive products;
- Promoting sufficient supply of quality bee products by increasing productivity and production of hive products;

- Enhancing capacity building and contributing to poverty reduction through appropriate environmental management;
- Ensuring good agricultural practices;
- Lobbying and advocating to build competitive industry in Ethiopia;
- Addressing barriers to market access;
- Facilitating networking among members and other stakeholders.

The EAB has established 4 subordinate offices at regional levels in the Regional National States of Tigray, Amhara, Oromia and SNNPR. These branch offices are responsible to undertake all the apiculture development and research activities in their respective regional states ofcourse with a strong support from the EAB. All the regional chapters of EAB have organized an awareness creation forum to all the stakeholders in their respective regions.Some have started registration of members.

Honey and Beeswax Producers and Exporters Association (EHBPEA)

Ethiopian honey and beeswax processors have formed the EHBPEA with the aim of establishing uniform quality control throughout the honey and beeswax industry in order to enhance the reputation and acceptability of Ethiopian honey and beeswax. This association forms the national apex body for producing, processing and export of bee products in Ethiopia.The Residue Monitoring Plan is still a matter of priority for the honey producing/processing members.At the moment the EHBPEA has 19 membercompanies which are located all over the country (see part in Annex V). In the first RMP for honey, the number of companies covered 6 out of the then 11 EHBPEA members. In 2010, seven companies have been perimitted to move 700 tons of honey for export. The 4th RMP involved6 enterprises out of which were 5 who had taken part in the third plan and one additional enteprise which did not take part in all the earlier plans.In the5th RMP 5 companies were involved to export 810 tons of honey to EU member countries.In the current RMP 6 companies are involved to export 810 tons of honey to EU member countries.

Ethopian Beekeepers Association (EBA) and East Showa Beekeepers Association (ESBA)

EBA and ESBA are non-profit oriented associations involved in creating a common forum to exchange experiences and views to all members, encouraging beekeeping research, improving the quality, safety and quantity of bee products and in the promotion of marketing these products. All together both organisations over700 registered members.

International Centre for Insect Physiology and Ecology (ICIPE)

The ICIPE, is a development partner based in Nairobi, Kenya has commenced scaling up beekeeping project in Tigray regional state of Ethiopia with the objectives to

1. help programme communities develop coping mechanisms and diversify livelihoods, improve their incomes from sustainable use of natural resources through beekeeping;
2. provide training and infrastructure support for farmers groups and field officers in appropriate scaling up technology for apiculture including crop pollination services;
3. provide support to process organic certification in two pilot project weredas of Tigray region;
4. Monitoring and evaluation of project activities. One of the components of the project focuses on accessing the global market through fair trade and organic certification of the honeybee products;
5. Provide to support the establishment of a satellite laboratory for investigating and controlling honeybee diseases, pests, pollination research and quality of hive products.

2. The National Residue Monitoring Plan, based on Council Directive 96/23/ EC

Residue levels of veterinary drugs, pesticides and contaminants in food commodities are becoming a major global concern for government food regulators. This is so because of the lack of good agricultural practices which can be a preventive measure to maintain pesticides and veterinary drugs below the maximum residue levels (MRLs) and contamiants below their maximum levels (MLs). These cannot be changed immediately through short production cycles. To provide safe food to the consumers, it is essential that adequate monitoring is in place to eliminate the possibility of the presence of the residues and contaminants in food commodities in amounts less than the official and regulated residue levels.

To verify residue levels of pesticides and drugs [such as organochlorine and organophosphorous compounds as well as antibiotics (including chloramphenicol)] and heavy metal concentrations, test results of baseline samples taken from time to time (e.g. yearly) must show that honey produced in Ethiopia is below the specified MRLs or maximum levels (MLs).

2.1 The legal basis of the competent authorities - policy and regulation

Proclamation 728/2011 to provide for the *Veterinary Drug and Feed Administration and Control* is the recent proclamation.*Proclamation 674/2010 for the Administration and Control of Pesticides*,is the legal basis for controlling pesticides in Ethopia which replacesthe 1990 "Pesticide Registration and Control, Council of State, Special Decree No. 20/1990". Besides these there are other proclamations and regulation put into law, "Food, Medicine, and Health Care Administration and Control, *Proclamation No. 661/2009*" and regulating the use of foods, drugs, vaccines, export and import of live animals and animal products on animal health, Proclamation No. 267/2002. Proclamation 661/2009 issued on 13 Jan 2010 is a one to Provide for Food, Medicine, and Health Care Administration and Control superseded the former *"Drug Administration and Control Proclamation No. 176/1999" of* 29 June 1999. The latter replaced the regulation called"*Pharmacy Regulation No. 288/1964"*, which had formed the legal basis for official establishment of drug regulation in Ethiopia. The"Pharmacy and Laboratory Department", which was the first drug regulatory body established under the Ministry of Health had beenempoweredby the Pharmacy Regulation No. 288/1964.Drug regulatory activities as well as the registration of pharmacy personnel have, therefore, taken place with emerging developments since 1964.

Under Proclamation No. 661/2009, the competent body which covers foods, human drugs and healthcare is the FMHACA, which became operational during 2010. The FMHACA inspects food and medicine manufacturers, importers, wholesalers, drug retail outlets as well as pharmacy units in health care facilities. It issues certificates of competence to private manufacturers, wholesalers and drug retail outlets while trade licenses are issued by the Ministry of Trade. In accordance with Proclamation 661/2009, the FMHACA can establish its own branch offices in the regions for the control of foods, medicines and health care systems. The Regional Health Bureaus are delegated to undertake inspection and licensing of foods trade, drug retail and health care service outlets.

2.2 Authorisation and legislation concerning the use of substances

The following ministries and authorities are involved in food and quality control programmes to guarantee agro-products and semi-processed and processed food safety at all levels – from the producer to the consumer (see Organogram I).

A. The Ministry of Agriculture (MoA)

i. Animal Health Regulatory Directorate (development of Proclamation 728/2011 to provide for the *Veterinary Drug and Feed Administration and Control)*
and
ii. Livestock & Feed Resources Development Directorate (development aspect of Proclamation 660/2009)

B. The Ministry of Health

i. Food, Medicine and Healthcare Administration and Control Authority, FMHACA

The Ministry of Agriculture (MoA)

The following national legislations are applicable to the MoA institutions

Proclamation 728/2011 ,the **Veterinary Drugs and Animal Feeds Administration and Control** Proclamation aims at improving the on-going animal health program to enable the country to produce animal and animal products compliant with the standard of world market requirements. The proclamation shall be applicable throughout the country to regulatory activities of veterinary drugs, feed veterinary drug professionals and institutions dealing with veterinary drugs and feed.
According to the proclamation an Authority shall be formed to take all the necessary Sanitary and Phytosanitary measures and execute duties and responsibilities listed under the Article of Powers and Duties of the Authority. Registration and control of locally produced and imported veterinary drugs and animal feeds and ensuring the quality, safety and efficacy of the veternary drugs are two of the regulatory functions of the Authority.
The importanttwo Articleson powers and duties of Proclamtion 728/2011 for Veterinary Drugs and Animal Feeds Administration and Control include:
Article 20, empowering the Authority to conduct the following.

- Prepare & submit to the competent organ standards for safety, efficacy and quality of veterinary drugs and the safety and quality of feeds & feed additives and upon arrival, follow up the implementation & observance of same
- Evaluate laboratory and clinical studies in order to ensure the safety, efficacy and quality of traditional veterinary drugs and veterinary services
- Organize quality control laboratories required to carry out its duties
- The appropriate organs shall appoint veterinary drug & feed inspectors to ensure compliance of the provisions of this proclamation & regulations & directives issued hereunder.

Article 21 empowers the inspector to conduct the following:

- Enter during working hours, any premise where veterinary drug or feed is carried out or veterinary drug or feed is stored or stop any carrier loaded with veterinary drug or feed and undertake inspection;
- Inspect records, documents, prescriptions and computers related to veterinary drug and feed and take copies of such documents as may be necessary;
- Take samples of veterinary drugs, feeds or feed additives in accordance with directives issued by the Authority;
- Subject to quality control veterinary drugs, feeds or feed additives suspected to be adulterated, spoiled or counterfeited, contaminated or those suspected to be dangerous to users and order quarantine of such items until the results are known;
- Inspect the proper disposal of veterinary drugs, feed or feed additives or those determined to be unfit for use in accordance with this proclamation.

▪ **Apiculture Resources Development and Protection Proclamation No. 660/2009**
This promotes apiculture development and protects apiculture natural resources with regard to commercial, urban, peri urban and migratory beekeeping. One of the purposes of this

proclamation is to ensure a sustainable contribution to maintaining quality and sanitation standards in honey. Inspection of any apiaries, honeybee products processing, storage transportation and taking close down or suspension measures where such facilities are found unfit to comply with the necessary requirements are two of the powers and duties of apiculture resources development inspectors under this proclamation. The most important articles are summarized below:

- Article 3(2) Any person who wishes to undertake beekeeping development activities in natural resource rehabilitation area enclosure, community forest, state forest or wildlife park and protection area shall obtain written permit from the body that is authorized for the administration of such land.
- Article 3(3) Any person who wishes to undertake commercial beekeeping development or commercial queen bee rearing shall obtain a business license issued pursuant to the relevant laws.

The subarticles under Article 4 of Proclamtion 660/2009 for Apiculture Resources and Protection state the following:

- 4(1) Any beekeeper shall, in the course of his operations, protect and conserve the apiculture resources.
- 4(2) Any person who practices honey hunting from forest, rock or cave nested honeybee colonies shall keep the removal of honey without causing any damage on the honeybee colonies and natural resource ecology of the area.
- 4(3) To protect indigenous honeybee species from communicable honeybee diseases:
  a. importation of live bee species or used beekeeping or processing equipment or materials shall be prohibited;
  b. Hygiene certification may be requested or inspection may be required on any used beekeeping equipment in transit to the country unless the packaging requirement is recognized.
- 4(4) Unless licensed for queen bee rearing activity, no person shall be allowed to export live honeybees for development or research purposes.
- 4(5) Any person engaged in crop protection undertakings shall have the responsibility to take proper precaution to avoid poisoning fatalities that may occur on honeybees due to improper use of pesticide chemicals

▪ ***Prevention and Control of Animal Diseases, Proclamation No. 267/2002***

This Proclamation regulates animal health, use and application of veterinary drugs, vaccines, the export and import of live animals and animal products to establish the traceability of residues in animals and animal products. The proclamation complies with the OIE, Codex Alimentarius and WHO. The Animal and Plant Health Regulatory Directorate under MoA is the responsible institution for the implementation.

Aditionally, proclamation ***267/2002*** regulates movement of animals and products by establishing:

i. Quarantine; Inspection and conditions of quarantine stations to control animals and animal products (Article 10)
ii. Entrance and exit posts (Article 11)
iii. Export of animals, animal products and byproducts (Article 12)
iv. International animal health and sanitary certificates (Article 14 (1)
v. Animals Movement permit (Article 15)
vi. Powers to the Animal Health Officer to cover inspection of animals and products (Article 8, Parag. 1-9)

▪ ***Proclamation 674/2010 for the Administration and Control of Pesticides***

The provision of this new Proclamation for the control and administration of pesticides replaces***Special Decree No. 20/1990,*** to lay an elaborated scheme of adminstrationn, registration and control which would make it possible to minimize the adverse effects caused by utilization of pesticides, to the extent realizable, that might cause damage to the health of human beings, animals, plants and the environment.

The MoA is the responsible institution for the implementation of the Animal Disease Proclamation, No. 267/2002 and Proclamation No. 674/2010 for the Control of Pestcides to consolidate the powers of the MoA with regard to adminstration registration and control, quality control of imported products and the uses of legal sanitary and phytosanitary measures.

Regarding Pesticide Registration, Article 3 (1) states that 'No pesticide shall be registered unless the efficacy, safety and quality is tested under field or laboratory conditions are approved by the Ministry. No person may formulate, manufacture, import, pack, re-pack, label, sell, distribute, store or use a pesticide not registered by the Ministry or contrary to the conditions of its registration.' Article 15 (1) pertains to a requirement for Certificate of Competence relating to manufacturing, formulating import & export and application 'Any person who intends to manufacture, formulate, pack, repack, label, import, export, store, sell, distribute, transport, or offer pesticide application services shall obtain a certificate of competence, which shall be a precondition for the issuance of a business licence.'

Further, Article 31 of Proclamation 674/2010 prohibits the following

i. No person shall import, store, transport or offer for sale any pesticide unless it is packed and labeled in accordance with this Proclamation.
ii. No person shall adulterate a pesticide or sell or store a pesticide which he has reasonable grounds to believe may be adulterated.
iii. No person shall formulate, manufacture, import, export, pack, re-pack, label, sell, distribute, store, or use a banned pesticide under any circumstances.
iv. No person shall formulate, manufacture, import, export, pack, re-pack, label, sell, distribute, store, or use a severely restricted pesticide without written authorization from the Ministry.

- **Establishment of Supervising Authority for Proclamation 728/2011**

A Supervising Authority as per the Veterinary Drug and Feed Administration and Control Proclamation has been established (2012). Strengthening a National Quality and Residue Control Laboratory which is under construction and manpower and/or technical operators required to implement i*s one of the*duties and responsibilities of the Authority. It is known that all the necessary laboratory facilities are ready.

- **Draft decree on apiculture resources development and protection (2011)**

The draft decree on honey and beeswax quality assurance, drafted in 2006, has been merged with the newly developed Decree on Apiculture Resources Development and Protection (2011) submitted to the Council of Ministers for endorsement.

The draft decree has 24 articles out of which Article 5, Article 8, Article 10, Article 11, Article 12, Article 14 and Article 15 deal on marketing of bee products; protection of bees; bee products processing, packaging and transportation; safety and quality protection of bee products; qualification certification and cancellation, designation of supervising authority and its duties and responsibilities and duties and responsibilities of inspectors respectively.

Some of the statements in these Articles include:

- Any marketable bee products shall meet quality and hygiene standards.
- With exceptions for small scale producers or traders, the processing and packaging of bee products shall be undertaken by a competent processing organization at the appropriate processing site and according to the established standards.
- Any international circulation of bee product supplies shall be subject to possession of valid hygiene certificate issued from the relevant supervising body of the country of origin.

- Any processor and /or exporter of bee products shall develop internal control system for farm gates to effect traceability of bee products when not comply to the standard.
- Any person who wishes to engage in bee products trading shall fill an application and is required to obtain a qualification certificate issued by the supervising authority, business license or registration certificate whenever appropriate.
- Commercial sale or exchange of adulterated bee's products for human consumption and other uses by way of trade or otherwise is prohibited.
- The supervising authority shall issue qualification certificate to bee products processing plants and products marketing institutions thereby confirming compliance with the provisions of this regulation.
- Inspector designated by the supervising authority shall take test samples on the basis of inspection manual to determine the safetyof honeybees' products for human consumption or where it is found or suspected to be adulterated with beeswax product determine confiscation of the product, and take disposal measure on the product when it is found contaminated.
- Any bee's product marketed to the EU member states, USA and Japan shall comply the standard requirements supported with approved residue monitoring plan.

This draft Decree on apiculture resources development and protection establishes a Regulatory Authority and defines its function (Articles 14-18) including the appointment of competent inspectors (Article 16).

Article 17 empowers the inspector to conduct the following:

i. inspect facilities of honey and beeswax business operators (processing, packing, labeling, storage and transport) to establish whether they are compliant or non-compliant with the safety standards.
ii. whenever necessary, take honey samples for tests by a designated laboratory for proper sanitation standards in the hygiene and disinfecting works and to determine the safetyof honey for human consumption where it is found or suspected to be adulturated.
iii. take disposal measures on honey when it is found contaminated.
iv. has the authority to destroy honey if found unfit for human consumption and if verified by a designated laboratory.
v. conducts inspection duties at any place where honey is stored so as to determine their compliance with the requirements set forth in the decree.
vi. reports the action taken to the Inspectorate.
vii. produces identity and responsibilities prior to conducting inspection of the facilities of honey business operators.
viii. Additionally, annexes 1 and 2 of the Decree consist of:
    - Hygienic requirements for honey and beeswax
    - License requirements for honey and beeswax business operators (processing, packing, labeling, storage and transport)
    - Application form to receive certificate of competence for honey and beeswax business operators both for internal trade and export.
    - Certificate of competence for honey and beeswax operators
    - Licenses for honey business operators both for internal trade and export if verified by an inspector and the Inspectorate.

- ***The Ethiopian Organic Agriculture Systems Proclamation No. 488/2006***
  This Proclamation aims at (a) facilitating international acceptance and market access (b) value addition (c) ensuring traceability from farm to market through inspection (d)

ensuring that product labels are genuine as well as (e) the harmonization of organic production.

The functional use of regulatory recognition of internationally accredited Organic Certification Bodies in awarding Organic Certification is clearly emphasized.

- ***The Plant Quarantine Regulation No. 04/1992***

  This self descriptive regulation is implemented by the same APHRD, under the MoA for exporting animals and animal products like honey without a health certificate.

- ***Establishment of Centre and satellite stations for bee diseases and pests***

  A Centre for bee diseases and pests at *ICIPE* Kenya and four satellite stations (one each in Ethiopia, Cameroon, Burkina Faso and Senegal) will be established. It is an*ICIPE*& AU-IBAR coordinated project along the bee health service chain to establish an African innovation centre for research, development, advocacy, capacity building & strategic networking for honeybee diseases and pests for food security in Africa.

  This proposal is in line with the European Union's strategy as per the Advancing African Agriculture (AAA) document. The EU/AAA provides a long-term framework for assistance, has a continental scope with a focus on S*ub-Saharan Africa* (SSA), and is aligned with the AU and related organisations such as AU-IBAR**.**

  The goal of the establishment is to contribute to reducing the incidence of bee diseases and pests to improve honey production and pollination services for income generation and harmonise procedures and legislation relating to bee health issues in Africa and in Ethiopia in particular. Accordingly its objectives are to develop modules for bee diseases and pests management with policy options to protect bee colonies and scale up honey production and pollination services for crop production and access to markets in Africa and beyond (export).

  The project is designed to achieve four results which include:

  1. Facilities for innovative technologies development for surveillance and provision of baselines and benchmarks of bee diseases and pests risk analysis established.
  2. Development of validated bee disease and pest management modules with efficient field based diagnostic tools.
  3. Enhanced awareness on the honeybee health and create conducive environment for enhanced bee disease control, access to markets, and consumer safety.
  4. Capacity of beekeepers/farmers federations and national agricultural research centers on bee health management systems and policy options strengthened.

  The following are some of the activities to attain the above mentioned results.

  - Raise awareness of the role and importance of bees in food security and as important pollinators in the region, including media engagement;
  - Provide policy makers and regulators with advice with the aim of harmonizing procedures and legislation relating to bee health issues, and developing a regional and continental framework on bee health;
  - Establish multi-stakeholder partnerships and mechanisms for the development of policy, and institutional and market options (a decision making matrix) for bee health and pollination services (*the Market Options Matrix can assist a farmer to develop a plan that incorporates most of the elements of production, marketing and business*)*;*
  - Practical demonstration of reduction in bee diseases and pests in beekeepers/farmers' apiaries through workshops;
  - Identify market constraints and opportunities for honey and hive products and pollinated food crops, including an analysis of existing agricultural policy related to these issues;

- strengthen the capacity of national veterinary authorities for bee disease detection, and timely notification and reporting.
- Develop mechanisms to disseminate the project results to improve regional and international trade;
- Harmonize and operationalize the framework and procedures for quality control;
- Provide training to increase the capacity of identified stakeholders to acquire information and utilize improved bee health technologies/innovations to produce, develop, process and market beehive and additional agricultural products;
- Identify the constraints, needs and opportunities for national information and communication systems;
- Develop a regional database on pollination services and bee health research and development outputs;
- Strengthen the capacities of stakeholders to analyze the value chain of pollination services and priority beehive products, and the commercial policies of the agricultural sector;
- Develop and promote bee health knowledge management systems.

In general AU-IBAR incorporates this knowledge into each participating country development strategies so that African nations can achieve their development goals in beekeeping and prevent/protect past investments in the bee sector.

- ***Implementing the Stockholm and Rotterdam Conventions***

  Ethiopia is party to both the Rotterdam and the Stockholm Conventions whose implementation require the control or banning of mostly pesticides and certain toxic industrial chemicals.

  - **The Stockholm Convention** deals with banning and restricting the use of **Persistent Organic Pollutants** (POPs) [aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene and the PCBs, hexachlorobenzene (also a pesticide), and dioxins and furans].
  - **The Rotterdam Convention** promotes shared responsibility and cooperative efforts among parties in the international trade of certain hazardous chemicals, comprising 22 pesticides and five industrial chemicals including PCBs.

The MoA is the implementing organization of the Conventions while the Ethiopian Environmental Protection Authority is the focal point for the Convention Headquarters. It is interesting to note that B3 chemicals under Directive 96/23/ECincludes the PCBs and the organochlorine pesticides aldrin, DDT, dieldrin, endrin and heptachlor (see annex 1A) are part of the pesticides which are also covered under the Rottterdam and/or Stockholm Conventions. One of the requirements for the Ministry to authorize registration of a pesticide is that the pesticide is not banned or severely restricted by an international convention or in another country with an equivalent registration scheme (Pesticide Proclamation 674/2010, Artcile 5 Section 1j). This strongly reflects the coherence and synergy between the Ethiopian law, the two Conventions and the RMP on the basis of Directive 96/23/EC.

The Ministry of Health

The following national legislation is applicable for the MoH regulatory role.

- **Food, Medicine, and Healthcare Administration and Control *Proclamation No. 661/2009***

  From 1999-2009, the Drug Administration and Control Proclamation No. 176/99 of June 1999, was used to regulate human and veterinary drugs which was comprehensive enough

to control the entire life cycle of pharmaceuticals. The new proclamation 661/2009 defines the objectives, powers and duties as well as the need for a new organization of the competent authority for Food, Medicine, and Healthcare Administration and Control. The proclamation empowers the competent regulatory body to additionally control and administer food safety, which are in line with the principles of Sanitary and Phytosanitary Measures. Worker's health, zoonotic and other communicable diseases are included. The products covered are: foods, human and traditional medicine, pesticides for home use, food additives, poisons, blood and blood products, narcotic and psychotropic substances, vaccines, sera, radioactive pharmaceuticals, cosmetics, sanitary items, medical instruments and medical supplies. The new Proclamation is issued to make the fragmented and poor quality administrative and regulatory system in the food and health sector efficient and effective. This necessitated the establishment of a new and coordinated food, medicines and healthcare regulatory system.

The proclamation has provisions for regulatory activities such as registration, inspection, quality control of foods (Articles 7 and 10), water (Article 12), drugs (Article 13), post marketing surveillance and control of clinical trials (Article 15), drug and food information as well as advertisement, packaging and labelling of products. It also states the need for obtaining license for import, manufacture, wholesale and retail activities. For obtaining food production licenses, regulations based on the Proclamation 661/2009 have been drafted for approval by the Council of Ministers.
Proclamation 661/2009 stipulates that any form of drug and food advertisement must be approved in advance by the regulatory authority. A drug information and Adverse Drug Reaction (ADR) monitoring unit has been established and ADR monitoring as well as dissemination of food and drug information to health professionals has been launched.
A Food and Medicines evaluation and registration system has been launched. The process involves assessment of the food safety as well as efficacy, safety and quality of pharmaceutical products through clinical and pharmaco-chemical data evaluation as well as laboratory quality control. Submission of WHO-type certificate is a requirement for products to be imported. There is a written guideline indicating the above and other requirements. The registration process is linked to Good Manufacturing Practice (GMP) and inspection of manufacturing plants.
According to the proclamation any food may not manufactured, imported, exported, stored, distributed transported or made avaliable for sale or use to the public without permit of the appropriate organ (Article 6, Registration and Licence). It is establishing procedures for food safety and quality control. No food or its raw material shall be put into use unless it complies with international or national safety and quality standards (661/2009 Article 7: Food Safety and Quality Control). Additionally the folowing sub-articles are quoted to illustrate the power of the regulatory system.

- No food or its raw material, additive or packaging material shall be put into use unless it complies with international and national safety and quality standards (1).
- Any food shall be preserved in accordance with the standards set or adopted by appropriate organ (2)
- Any person may not operate a laboratory established for food quality control unless it is receives certificate of competence from the executive organ (3).
- A certificate of competence issued in accordance with sub-article (4) of this Article shall be renewed every year (5).

Regarding food import and export, Article 10 of Proclamation 661/2009 states the following in its two subarticles:

- 10(1) -Any imported food shall be accompanied by a certificate of quality and safety authenticated by the concerned government organ of the exporting country.
- 10(2) -The executive organ may issue safety certificates for export foods that need the same.

Article 13(1) of the proclamation states '***no medicine shall be produced locally or imported, and put to use unless it is duly registered by the executive organ'.***

The authority shall assure the quality of drugs as per its own pharmacopoeia or the pharmacopoeia of other countries which are recognized by it. No drug, raw material or packing material which fails to comply with its quality specifications shall be put into use.
The authority shall carry out post-marketing surveillance in order to ensure the safety, efficacy and quality of drugs that are put into use. The authority shall have the power to ban the use, or to revoke the registration, of a drug that was put into use when, later on, it is proved to be ineffective or its risk outweighs its benefit.
The new Proclamation 661/2009 has more provisions to prescriptions and dispensing under Article 39 (subarticles 1-6), 'Prescribing and Dispensing of Medicines'. The FMHACA adopted former DACA records including "guidelines for the control and use of prescription paper". These guidelines enable the authority to trace the use of medicines back to all levels of consumption, which means more security, better documentation, more transparency and product traceability concerning the use of drugs. http://www.daca.gov.et/Documents/Guidprescription2.pdf.
Article 53 (section g) pertains to the violation of Article 7(1) and(2) about food safety and quality and Article 8 relating to food packaging and labelling. Violation to these articles shall be punishable with imprisonment of not less than 2 years and not exceeding 5 years and a fine ranging from Birr 20,000 to 50,000.
Article 53(1) c and d relate to measures or punishment taken in the case of a illegal drug and trade or clinical trial which defines imprisonment of 7 years and fine ranging within Birr 50,000 -100,000.

2.3 Health constitution of bee colonies and national production data for honey and beeswax

Ethiopia is currently known to be one of the ten leading producers of honey and beeswax in the world and has the top honey production volume in Africa.

- There are no serious honeybee diseases and pests reported in Ethiopia. In the country, identification and study of honeybee diseases and pests started in 1989. Since then a number of surveys and studies were conducted (Gezahegne and Amssalu 1991[6]; Dessalegn and Amssalu 2000[7]; Amssalu and Dessalegn 2005[8], Dessalegn and Amssalu 2005[9], and Dessalegn and Yosef 2005[10]). These studies revealed the occurrence of adult honeybee diseases namely: Nosema, Amoebaand Chalk brood.

Nosema and Amoeba are seasonal bee diseases that prevail during wet seasons. These diseases are found to be diminished even without taking any management practices to arrest the infestation. A survey result conducted in 2009 on occurrence and degree of infestation of chalk brood diseases in the country revealed that there was chalkbrood in the country. Absence of American foul brood, European foul brood and others is also reported. Their non-existence may be due to prohibition of importation of used beekeeping equipment and live honeybees. The existence of Varroatosis is to be investigates as it is found in neighbouring countries.Although the existence of Nosema and Amoeba honeybee diseases in the country had been reported in 1991, they presented no negative effect on local honeybees. This may be attributed to the climatic condition of the country which allows bees to defecate outside the colony even during the rainy season and minimize the infection of the diseases. The chalk brood is more serious than the adult honeybee diseases found in the country. No chemotherapy is registered in the world against the chalk brood disease.
Concerning beekeeping problems, ants, wax moths, bee lice, large hive beetles, small hive beetles, death head hawk moths, bee-eater birds, lizards, toads, spiders, honey badgers and wasps are reported as honeybee pests.

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[6]Gezahegne and Amssalu , *Preliminary Survey & Diagnosis of Nosema, Amoeba, Acarine Diseases at Holeta Bee Research Center*, 1991
[7]Dessalegn and Amssalu , *Pest and Pathogen Survey in South and Southwest parts of Ethiopia*, 2000
[8]Amssalu and Dessalegn
[9]Dessalegne and Amssalu, *Distribution of Nosema Disease in Ethiopia*, 2005
[10]Dessalegn and Yosef, *Pest and Pathogen Services in Addis Ababa*, 2005

2.3.1 Application of veterinary drugs and pesticides

None of these pests and honeybee diseases found in Ethiopia are treated using drugs other than exercising colony manipulation practices and hence there is no chance of honey and beeswax contamination with veterinary drugs in Ethiopia in this respect.

2.3.2 Petsticideresidues

The use of pesticides by farmers is very minimal because

- farming is for subsistence for communities with an average cultivated land of less than 0.2 hectares.
- the mainly used herbicide to protect farmer's crops from weeds is 2-4D, which is biodegradable.
- high-potential areas for beekeeping and sources of honey and beeswax for the EHBPEA members are far from areas where pesticides are intensively applied.
  African bees are known to be very aggressive what means that they are kept far away from the fields to prevent attacks against people and animals.
- in earlier years, the coffee growers of South-western Ethiopia were aggressively using pesticides for treating coffee berry disease. At present, due to the market demand for organic coffee, most of the farmers who grow coffee ceased to use pesticides for treating coffee plantations. Currently the Farmers Union in the coffee growing areas and the government are encouraging farmers to produce organic coffee for attractive prices and this has created an opportunity to harvest residue-free honey and beeswax from these areas. Since 2007/2008, honey produced by outgrower cooperative in Southern Ethiopia, also a coffee growing area, have been Organic Certified by BCS Oko-Garantie (Germany) under the project of Beza Mar Agro-industry PLC, one of the honey exporting companies to the EU Countries. More recently, organic certification of the apiary of Apinec Agroindustry and its out-growers has also been awarded.

2.3.3 Honey production

The CSA,2010 Report records that the national average honey yield is estimated at 53.68 thousand tons per annum. Until now, Ethiopia's honey export is negligible compared to the estimated production per year.
The exported honey and the value generated from this commodity during 2008/9-2011/12is indicated in Table 1. The amount of exported honey increased, though not steadily, during the few last years compared to the few tons of honey exported during 2008/9. Honey Export is destined to the Middle East Countries namely Saudi Arabia, Kuwait, United Arab Emirates, Iran, Yemen and others like Djibouti, Sweden, Israel, the UK, Canada. The Ethiopian honey external trade has shown remarkable effect since2010 export as a result of sucessive EU permits since February 2008, which is expected to rise annually if the EU listing of Ethiopia continue to be a success. The newer markets are the EU, non-EU European as well as non-European countries. This includes the United Kingdom, Norway,the United States, the United Arab Emirates and Yemen .

Table 1: Export of Honey and Beeswax in tones & values in $USD

Year	Honey		Beeswax	
	Qty	Value	Qty	Value
2008/09	179.5	880,195	195.65	1,061,899

2009/10	359.99	2,106,453	274.38	939,083
2010/11	310.51	2,407,375	163.04	1,669,982
2011/12	377.21	2,796,912	197.46	2,046,837

Source: Ministry of Iindustry, 2012

2.3.4 Total figures of honey production planned to be exported to the EU

MoA has recently developeda five year development and marketing plan to alleviate poverty through the agricultural Growth and Transformation Plan (GTP). The necessary strategies that would bring about a tremendous increase in quality, safety and quantity of the products has been developed and is under implementation.
The current and marked increase of traditional, intermediate and frame hives set for honey and beeswax production in beekeeping potential areas will definitely maximize the amount produced, and improves the quality and safety of the products. This will provide ample opportunity to the producers, increase their production and ultimately their income and contributes to increased supply of raw materials to the processing plants of the exporters.
On 11 February 2008, the EU approved the first RMP for honey upto at 300 tons. The exporting companies plan was to rise the volume to 3,000 tons within the next 10 years. The 2009 RMP was for 1,200 tons for seven EHBPEA member companies. . The current Residue Monitoring Plan for the six companies (below) targets 810 tons of honey.

I. Apinec Agro Industry Plc 150 tons
II. Beza Mar Agro Industry PLC 210 tons
III. Tutu and Family PLC 150 tons
IV. Comel PLC 120 tons
V. Rahi Mar 60 tons
VI. Dima PLC120 tons

The amount from last year's plan has the same although the number of exporting enterprises has gone upfrom fiveto six.

2.3.5 Proportion of the export data concerning the national production data of honey and beeswax

On the assumption that the honey production in Ethiopia is the current updated estimate, 53.68 thousand tons, the honey export will be only about about 1.8% of the current (2011) national average for the 2010 honey yield.
With respect to honey, the residue monitoring plans will be based on these export data.

2.4 Selection of groups of residues for the residue monitoring plan

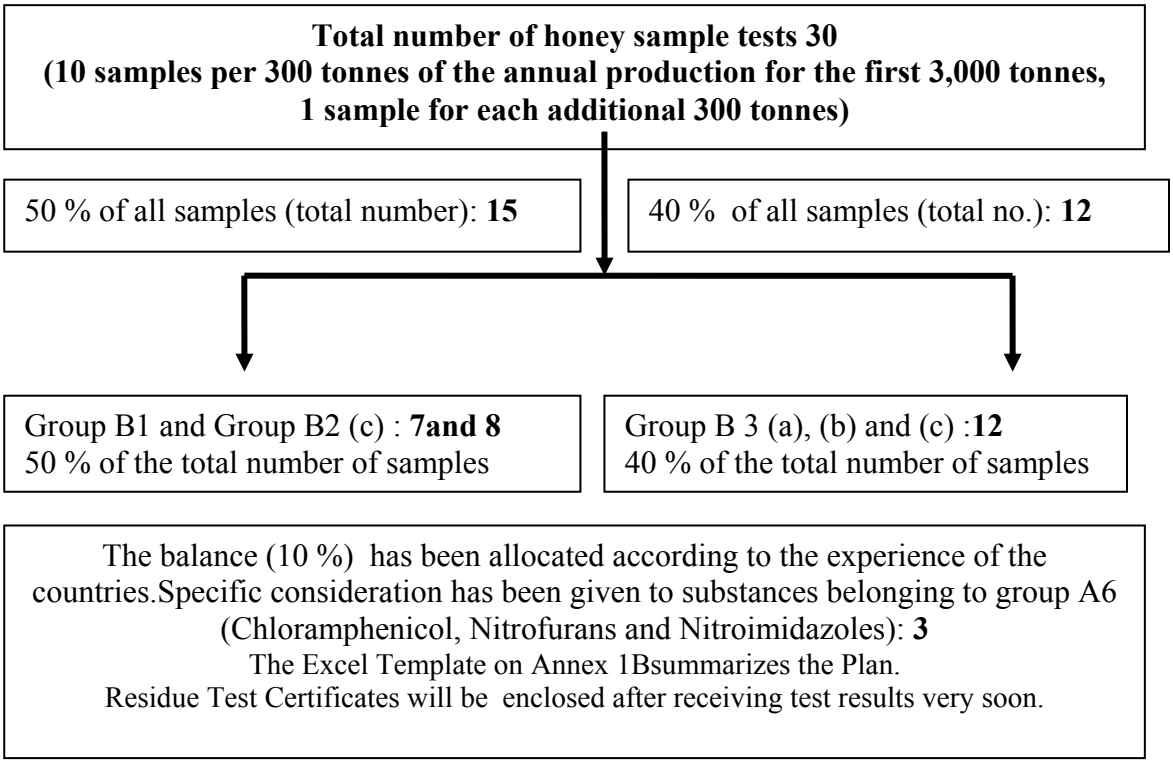
The national residue control plan for honey and beeswax is based on Council Directive 96/23/EC. Commission Decision 97/747/EC (chapter 4, honey) that fix the levels and frequencies of sampling of honey for monitoring certain substances and residues thereof in certain animal products. The sample size will depend on the analytical methods used.
For constructing the residue monitoring plan, the Microsoft Excel templates supplied by DG SANCO for third country control data have been used. The number of samples to be taken for each of the relevant subgroups of substances is automatically calculated. In the current plan, 27 sampleswere collected from the candidate enterprises and their outgrowers and for testing 30 substance groups (i.e. Group B1 in 7 samples, Group B2c in 8 samples, Group B3 (a, b,c) in 12 samples and Group A6 in 3 samples), This is still in excess of the minimum number of tested samples, which is 27, in accordance with Commission Decision 97/747/EC.

2.4.1 The national residue control plan

The sampling levels and frequencies are based on annual national production figures and on the structure of the apiculture and honey production enterprises in Ethiopia. According to Commission Decision 97/747/EC, the number of samples are 27 for 810 tons of honey. In the present plan 27 honey samples have been collected at different locations from different members of EHBPEA and are under test for 30 substance groups by the designated accredited laboratory.The sampling plan (represented in Annex VIII) ensures that the results are representative of the overall honey quality and safety under consideration.
The samples were taken at any point in the production chain, because it is possible to trace the honey back to the original producer. The residue monitoring plan is based on export data. The sampling level and frequency are shown below.

2.4.2 Sampling level and frequency

The number of samples that have to be controlled for the residue monitoring plan is fixed in Directive 96/23/EC and Decision 97/747/EC. There is no split system in place for export to the EU, i.e. honey from all farms is eligible for export to the EU. Hence, the national production data has been used for calculating the minimum number of samples which is 10 per 300 tones of annual production for the first 3000 tonnes and 1 sample per additional 300 tones. The breakdown in the following flow diagram has been respected:
Twenty seven (27) official samples were collected and sent by the CA via courier service (TNT) directly to the accredited laboratory. The coded samples and substances under the groups to be tested, which number 30, are presented in Annex VIII).



The test results by the designated laboratorywill be submitted to the FVO as soon as received.

2.5 Reasons for the selection of substances for inclusion in the residue control plan

The Food and Medicine and Healthcare Administration and Control Authority (FMHACA) of Ethiopia has kept a list of Veterinary Drugs that can be permitted for import into Ethiopia[11]. However, the currently registered veterinary drugs[12] that have been imported by drug companies are far smaller in number. Group A6 substances (chloroamphenicol, nitrofurans, nitrofurazone) are not registered in Ethiopia since no company has imported them so far, although they are in the 2002 official "List of Veterinary Drugs for Ethiopia"[14].
The national Drug Policy gives priority to selection of drugs based on the country´s animals health problems, trained manpower, financial resources, infrastructure with full consideration of safety, efficacy, quality and cost.
The national drug list serves as a useful guide for procurement, distribution and prescription of drugs in the country. The development of a national drug list is an ongoing process. Hence the list will be subjected to contineous deletion and inclusion: as the pharmaceutical industy introduces new medicines, they will be critically evaluated in terms of, *interalia*, their potential to safety and efficacy, better patient compliance and other drug qualities.
The list contributes making the use of patterns of veterinary medicines and agrochemicals (pesticides) readily comprehensible.

2.6 Veterinary drugs andPesticides registration and controls

In order to provide appropriate health care to animals in Ethiopia, the provision of veterinary drugs of proven safety, efficacy and quality is indispensable. One important method of ensuring the safety, efficacy and quality of these products is through evaluation and registration of veterinary products, which are to be imported or locally produced before they are offered for use in the country.
The new FMHACA of Ethiopia adopted the former DACA guidelines and data for the registration of veterinary drugs with the objective of providing applicants with information concerning documentation to be submitted for registration of veterinary products.
The guideline consists of the following four sections:

- requirements for abbreviated registration of veterinary drugs (section I)
- requirements for registration of new veterinary drugs (section II)
- requirements for re-registration of veterinary products (section III)
  requirements for various other forms of registration of veterinary drugs(section IV)

After a veterinary product is registered, its registration is valid for five years only. It is mandatory for manufacturers to apply for re-registration by submitting the required documents before the due date.
Samples of various standard forms have been annexed to the guideline and applicants are advised to use it whenever they apply.
The requirements for registration of veterinary drugs demand a lot of information like "chemical and pharmaceutical documentation"(chemical data on active ingredient, molecular formula, chemical name, structure, physico-chemical properties, synthesis, nalytical specifications and test methods, key raw materials, key intermediates, degradation

[11] List of Veterinary Drugs for Ethiopia" First Print Edition, DACA, Addis Ababa, 2002
[12] DACA, "Registered Veterinary Drugs in Ethiopia", from 2002-2007; also available online, List of Drugs and Formularies, http://www.daca.gov.et/Documents/lvd4.pdf (Accessed 20Feb 2011)

profile, including analytic procedures used in the detection and determination of by-products), data on composition (complete qualitative and quantitative composition of the finished product, including quality specifications and control methods), analytical and stability report etc.

The Plant Health Regulatory Directorate (PHRD) office has already established and used procedures for inspection of pesticides at customs and the regional stores prior to their dispatch for use. The inspectors collect and document data including pesticide specifications, classification, batch, supplier/manufacturer, expiry date and third party certification of QC tests.

There are about 295 pesticides registered in Ethiopia[13]. (PHRD March 2012) out of which are 123 insecticides, 72 herbicides, 71 fungicides, 29 rodenticides, miticides, avicides, adjuvants, PGL, sticker, nematocides, plant growth regulators and 8 household pesticides including those combinations in formulations with two or more chemicals (partially listed under annex ID). All the registered pesticides are imported from abroad by 40 legally registered companies. Only one public company is formulating limited number of plant protection chemicals. An average of 1,262 tonnes of various pesticides had been imported and used every year[14] (MoA, 2010). The demand for using pesticides in the country is increasing from time to time although complete information is not avalable for the more recent years.

The new Pesticide Proclamation[15] empowers the competent Ministry, MoA, to designate any public or private laboratory as an official laboratory for the purpose of conducting tests and issue Certificates of Analysis stating the method used and other information that may be prescribed by directives of the Ministry. It also sets a requirement for registration and licencing pesticdes to any conditions including:

- limitation or prohibition of the use of the pesticide in a specified area;
- limitation of the use of the pesticide to specified times of the day or of the year;
- requirement to notify beekeepers of neighbouring areas before application of the pesticide;
- prohibition of application of the pesticide when certain plants are in bloom;
- limitations on sale of the pesticide to persons holding a certificate of competence;
- limitations on use for certain purposes.

2.7 Comparison of registered pesticides vs the 96/23/EC list

The table in Annex ID compares the pesticides registered and controlled for use in Ethiopia with those listed under 96/23/EC. The following are the conclusions from the comparison.

Organophosphorus pesticides:
Comparison of the organophosphorus pesticides registered in Ethiopia and those under 96/23/EC (Group B3b) for the RMP show that there are seven pesticides, namely:
Diazinon, Dimethoate, , Malathion, Pirimiphos-Methyl, Chlorpyrifos, Ethoprophos, Methidathion

Organophochlorines:
2 pesticide are registered (Endosulphan, *Dicofol*) in Ethiopia out of the 15 under 96/23/EC (Group B3a). Hence common to both systems are:
Endosulphan, Dicofol

[13] APHRD "List of Registered Pesticides, Sep 2010"
[14] MoA, Report of the APHRD March,2012
[15] *PROCLAMATION 674/2010, TO PROVIDE FOR THE REGISTRATION AND CONTROL OF PESTICIDES*, 2010

Carbamates and Pyrethroids:
14 of these pesticides are registered in Ethiopia and 6 under 96/23/EC (Group B2c). Common to both systems are three Pyrethroids, namely:*Deltamethrin, α-Cypermethrin and Cypermethrin.*
Flumethrin and Permethrin are not registered for use in Ethiopia.

(i) These twochemicals Flumethrin andPermethrin, under 96/23/EC, *Annex IA* to this document, *are not considered to pose any risk of contamination in Ethiopian beeswax and honey and they are not as well registered and not imported for use in Ethiopia. These residues mostly would occur in beeswax and honey as residues if colonies were treated against varroa mite species. (ii) Varroa mites have not been detected so far in Ethiopia. (iii) The type of beekeeping in Ethiopia is the traditional fixed comb 95% of hives occupied by wild swarms. (iv) It is not feasible to administer bee medicines prophilactically.*

2.8 Maximum Residue Limits (MRLs)and Maximum Levels (MLs)

Maximum Residue Limits (MRLs) are not yet established for veterinary drugs and pesticides applied in Ethiopia. Adopting EU MRLs has been an option, until Ethiopia approves its own MRLs, based on international guidelines.
Article 26 of Proclamation 674/2010 states the details on pesticide residue analysis designates the MoA to collaborate with relevant authorities in establishing the maximum residue limits for agricultural products.
Maximum levels (MLs) for contaminants (e.g. natural food toxins, bacterial infections and heavy metals) are not as well established in Ethiopia. Adopting the EU maximum contaminant levels may be an option until Ethiopia accepts its own MLs based on international guidelines. The MRLs of pesticides and drugs of other countries that may be adopted until a government-approved regulation enters into force. This will allow the selected testing laboratory involved to adopt the requirements of the importing country (e.g. EU Member State) with regard to MRLs or MLs.
As already reflected in section 2.3, none of the pests and honeybee diseases are treated using drugs other than exercising colony manipulation practices and hence there is no chance of honey and beeswax contamination with veterinary drugs in Ethiopia in this respect.
EU action limits are used for unauthorised substances corresponding to the EU minimum required performance limits, MRPL set by Decision 2002/657/EC.

Pesticide residues
The use of pesticides by farmers is very minimal (a) because farming is at subsistence level for communities with an average cultivated land of less than 0.2 hectares. (b) The mainly used herbicide is 2-4D, which is biodegradable, to protect farmer's crops from weeds (c). High potential areas for beekeeping and sources of honey and beeswax for the EHBPEA members are far from areas where pesticides are intensively applied. In accordance with Proclamation 674/2010, pesticide residue analysis and monitoring on processed agricultural products and human beings shall be conducted by the concerned appropriate organs.

2.9 Measures for non-compliance against legislation

a. Honey and beeswax offered for sale must be safe, not altered and not adulterated. Additives must not alter honey. Bioactive ingredients like enzymes must be traced in honey and the honey must be free from risks from biological hazards (vermin, bacteria, mould), toxicological (pesticides, veterinary drugs and heavy metals) or physical (smoke, foreign particles) risks. Towards measures for non-compliance, Article 8 of the *Apiculture Resources Development and Protection* Proclamation No. 660/2009(Dec 2009) has the following provisions:Any person who commits hazard on natural habitat while operating beekeeping or cause to spread honeybee diseases to healthy colonies or induce harm on beekeeping and bee products due to improper

use of pesticides or cause damage on the honeybee colonies and ecology of the area due to fire hazard while honey hunting is punishable with a fine from Ethiopian Birr 5,000-10,000 ($ US 284.09-568.18.)or imprisonment from three up to five years or both.

b. Any person who defy, threatens or put in danger the supervising authority is punishable with a fine from Birr 2000-5000 ($ US113.64 -284) or imprisonment from two up to five years or both.

c. Any person found in act of processing, transporting or market supplying to the market place or consumer market sale or transfer of adulterated, contaminated or poisoned bee products authority is punishable with a fine from Birr 10,000-15,000 ($ US 568.18- 852.27)or imprisonment from five up to ten years or both.

d. Any person who imports or exports or attempts to import or export live bee species or honeybee races or used beekeeping equipment or goods without the operating permits or contrary to the conditions thereof, or any person who commits or attempts any honeybee races smuggling is punishable with a fine from Birr 15,000-20,000 ($ US 852.27- 1136.36) or imprisonment from ten up to fifteen years or both.

e. Any person who violates the provisions of this proclamation or any regulations and directives to be issued according to this proclamation or causes any obstruction in the implementation process is punishable with imprisonment up to five years.

Additionally, Section g under Article 53 of Proclamation 661/2009 for Foods and Medicines prohibits the violation of Article 7(1) or (2): food safety and quality or Article 8: food packaging and labelling shall be punishable with imprisonment of not less than 2 years and not exceeding 5 years and fine ranging from Birr 20,000 to Birr 50,000($ US 1136.36-2840.90)

2.10 Measures of punishment taken in the case of a illegal drug trade and handling

If the test result of the RMP of the samples depicted non-compliance, the product has to be destroyed according to the draft regulation of Apiculture Resources Development and Protection Part 4Article 11, Sub Article 9which states "The inspector of the competent Authority shall have the power and duties to detain and seize any honey suspected or recognized as unfit for human consumption and take samples for analysis. It has to be destroyed if unfit for human consumption".
Concerning the detection of residues of substances which are unauthorised or illegal in Ethiopia, no action limits are applied.
Beeswax supplied to market also must not be adulterated with paraffin or other waxes, oils or animal fats. Any person that offers adulterated, altered and contaminated honey and beeswax with adulterants and hazardous substances will hold the responsibility for the risks.

2.11 Official sampling procedures in the field, including information on how samples are secured after collection (using flow charts) -(Dec 98/179/EC

The Ministry of Agriculture is the Competent Authority responsible for overseeing the sampling of honey at depots of honey and beeswax producers.
The Office of Pesticide Registration and Control under the PHRD of MoA has established procedures for inspection of pesticides at customs and the regional stores prior to their dispatch for use. The trained inspectors collect and document data including pesticide

specifications, classification, batch, supplier/manufacturer, expiry date and third party certification of QC tests.
Honey and Beeswax inspectors shall be designated officially by the Authority for taking, registering, preparing and organising the transport of the official control samples under appropriate conditions. The samples are directly sent by them to the test laboratory.
The honey and beeswax processors have to label the address of the beekeeper, the place of collection, the year, harvesting time of the products and other relevant data and information to trace the farm of origin.
Each sample will be placed in a clean, chemically inert container to protect the sample from contamination and from being damaged during transport. The container will be sealed in such a way that unauthorized opening is detectable. After taking precautions against leakage and spoilage the samples are sent to the selected test laboratory as soon as posible (latest within a week).
The collected samples are sealed with numbered tamper-proof tags. The official makes a manifest listing the tag numbers, the samples origin (country, state or town), its location of collection, date of sampling, and additional information useful to the analyst or to regulatory officials for follow-up action if necessary. If there is a departure from recommended sampling proedures, records accompanying the sample fully describes procedures actually followed.
To enhance traceability, the inspector records at least the following data for the sampling report related to details (modified from EU Decision 98/179/EC) in the sampling:

1. address of the competent authorities
2. name of the inspector or identification code
3. official code number of the sample
4. sampling date
5. name and address of the owner or the person in charge of the apiaries or the
    a. bee products
6. name and address of the apiary for origin of honey (when sampling on farm)
7. name or registration number of the beekeeper or the association
8. registration number of the apiary (if the beekeeper has more apiaries at
    a. different locations)
9. name of honeybee species and honeybee races
10. average production (honey and/or wax) in the year 2012
11. name of medicines etc. (if used)
12. date of administering (if used)
13. dose, concentration administered (if used)
14. means of harvest/primary extraction
15. means of storage of raw honey
16. means of transport to the honey processing unit
17. sample matrix
18. substance or substance groups (see annex IA, IB) for residue and contaminant examination
19. particular remarks

The sampling report and three copies are signed by the inspector and the owner or the officer responsible of the company, belonging to the EHBPEA.
The original of the sampling report remains at the competent authority, one copy is for the inspectors office, another copy remains at the office of the company, while the third copy is for EHBPEA.

2.12 Sampling time and sample quantity

In accordance with Proclamation 674/2010, Article 20: 'Any person who transports a container that has previously contained a pesticide shall ensure that the container is physically separated from and does not come into contact with any food, feedstuffs or animals. During transport a devoted vehicle is assigned in a field trip for sampling honey.

Samples will be taken at the end of the honey harvest season(s) by the official inspectors of the competent authority at district levels from randomly selected honey drums at different locations in the collection centers of outgrower cooperatives, or storerooms of the processors who are the exporters themselves (under EHBPEA membersship). Because of the fact, that bees collect the raw material for honey (nectar or honeydew) within an area of about 30 km², honey is an excellent substance for monitoring environmental contamination. Hence, honey sampling and testing are applied for overall monitoring, detecting of residues and/or illegal treatment from the identified collection sites and storerooms.

The minimum quantity of honey is fixed at 0.5 kg for each sample as advised by the designated laboratory.This quantity is enough to carry out all the analytical determinations to complete the screening and the confirmatory analyses, necessary for the residue monitoring plan. Each sample is still enough for second or third analysis in case that a test result is found doubtful. To enhance the traceability, the sampling has been done according to the EU requirements, unforeseen without notification of the stakeholders, and unexpected at any time (on no particular day of the week and at no fixed time of the year) at the descretion of the inspectors who operate on behalf of the competent authority.

2.13 Transport of the samples

The samples and the accompanying documents (manifest) were sent by TNT and handed over to the laboratory selected (Chemiphar Uganda (U) Ltd) by the competent authority for analysis.
The accompanying document, established by the competent authorities contains the following information:

1. address of the competent authority
2. name of the inspector or identification code
3. official code number of the sample
4. sampling date
5. name of honeybee species and honeybee races
6. sample matrix
7. substance or substance groups (see Annex IA, IB) for residue and
8. contaminant examination
9. particular remarks

Unlike the sampling report, the accompanying documents contain no information about the origin of the honeys. The samples are marked by an official code number to exclude any influence on the test results.
Control plans shall specify the suitable storage and transport conditions for each analyte/matrix combination to ensure analyte stability and sample integrity. In case of any non-compliance with the requirements of the control plan the laboratory has to inform the compentent authority without delay.
In agreement with the test laboratory, the MoA has fixed a turnaround time of maximum of four weeks for minimising the time between sampling and getting the test results. The time should be as short as possible to have a successful chance to trace a honey back to its producer in the case of non-compliant results with the residue monitoring plan.

2.14 Traceability to the farm of origin in case of non-compliant test results of honey

In the case of a non-compliant test results of honey, the official records made by the inspectors allows them to trace the sample back to the producer (see 2.11).

3. The Laboratory Network

Within July-Sept 2007, the Laboratory of the Quality and Standards Authority of Ethiopia received accreditation vs ISO 17025:2005 by the South African National Accreditation Service for conducting a few microbiology tests in foods and drinks. Towards accreditation, the Drug Product Quality Assesment of the FMHACA under the Ministryof Health has developed a Quality Manual to manage its operations. Training is conducted on QA/QC with the support of the UAIDand conducted by theUSP. More recently, the Ethiopian Conformity Assessment Enterprise (formerly QSAE) has several residue tests for pesticides in coffee. However, there is no accredited laboratory in Ethiopia with respect to testing the quality specifications and safety parameters (residues and contaminants) in foods and agricultural products. With regard to the level of competence of the National Reference Laboratories, as well as routine testing of Quality Assurance, or GLPs, EU Decision 98/179/EC has to be put in practice. Laboratory accreditation has to be in accordance with ISO/IEC 17025 and/or GLP.

3.1 The designated laboratory to carry out analyses for the RMP

The analysis of the samples has been carried out by Chemiphar (U) Ltd, the laboratory approved for official residue control by the competent authority. ChemipharUgandais an internationally recognised and accreditated laboratory, accredited by Belac, a Belgian accreditation body. The Laboratory has even specialised in testing for honey quality parameters, satisfies the EU legislation and is involved in routine residue contaminant control analysis.

Chemiphar (U) Ltd. Uganda
P.O. Box 25525 Kampala – Uganda
e-mail: chemiphar.uganda@chemiphar.com
URL: http:/www.chemiphar.com

Ethiopia submits its past and the current three RMPs for honey to the EU incorporating the residue test certificates produced by the laboratory of Chemiphar (U) Ltd.

3.2 Level of competence of the test laboratory

Chemiphar (U) Ltd. Ugandais accredited for testing food samples containing residues of veterinary drugs/antibiotics, including chloramphenicol, sulfonamides and pesticides as well as trace element levels of heavy metals.. Its accreditation status is in accordance with ISO/IEC 17025:2005 fullfils the EU requirements for testing residues and contaminants.
Chemiphar (U) Ltd. Ugandaproves its competence both, by participation in internationally recognised external quality control assessments through regular participation in proficiency testing schemes recognised or organised by national or community reference laboratories.

All the results for setting up the national residue control plan are based on the use of validated analytical methods. The validation has been carried out concerning article 3 of Commission Decision 2002/657. The official samples have been taken pursuant to Directive 96/23 EC and have been analysed using methods that

- are documented in test instructions according to ISO 78-2 (6)
- comply with part 2 of the annex I to Commission Decision 2002/657/EC
- have been validated according to the procedures
- comply with the relevant MRPL to be established in accordance with Article 4

3.3 Level of competence of national laboratories for quality tests, residues and food contaminants

The laboratory of the Product Quality Assessment Directorate of the FMHACA is already working in the field of residue analysis and mainly specialised in the following fields (see Annex III A):

Pesticide residue analyses
Pesticide exposure tests
Veterinary drug residue analyses
Heavy metal analyses and trace element monitoring
Drug residue analysis (drugs and chemicals in animal body)
Microbiological assay of antibiotics
Occupational and environmental toxicity monitoring (pollutant analysis, exposure to hazardous chemicals including pesticides etc.)

TheTesting LaboratoryDirectorate (formerly under QSAE) of the newly established Ethiopian Conformity Assessment Enterprise (ECAE) is ISO 17025 accredited for microbiological testing in foods, drinks and agricultural products. It participated in past proficiency tests for heavy metals in water and recieves test samples for the quality control of bee products (see annex III B). Both the ECAE and the FMHACA laboratories are best equipped and are using UV-VIS-, Atomic Absorption-Spectrometer-, GC-, GC-MS, HPLC. In the case of theFMHACA Laboratory additional equipment HPTLC (High Performance Thin Layer Chromatography), LC-MS-techniques are used for analysis. The Testing Laboratory of the new ECAE and the MoA jointly use a modern Agilent GC-MS. Additionally, the MoA recently acquired and commissioned new GC-MS and GC equipment. Trained technical staff operate the GC-MS and GC systems starting from automatic extraction to analysis of pesticide residues in coffee - the major export product of Ethiopia. This is the first time that GC-MS and GC residue tests in coffee have been employed in Ethiopia. These tests are being conducted jointly by the residue experts from the ECAEand the MoA. Tests in other commodities including honey is a natural extension of this programme.

Both government reference laboratories in the fields, stated and recommended for testing quality parameters, residue, and contaminant levels in bee products (especially honey and beeswax) have ongoing programmes to improve their competence. Before getting accreditation they will be able to support the residue monitoring programme on the basis of three functions below.

- handling samples and interpretation of residue and quality test results from local and foreign accredited laboratories
- as centers for conducting training in test residue and quality test method validations
- test samples to be sent abroad for accredited testing may also be given in future to these two laboratories for testing for the sake of inter-comparisons.

After getting accreditation, the Product Quality Assessment Directorate of FMHACA and the Laboratories of the ECAE and MoA should be able to carry out the annual monitoring residue control in foods. For ensuring the test results, the laboratories have to participate regularly in internationally recognised external quality assessments to prove its competence.

The full addresses are as follows:
Product Quality Assessment Directorate
FMHACA
P. O. Box 5681, Addis Ababa, Ethiopia
Tel. +251 1776984, Fax +251 1 52 13 92
E-mail: *daca@ethionet.et*

Testing Laboratories Directorate
Ethiopian Conformity Assessment Enterprise
P. O. Box: 2310, Addis Ababa, Ethiopia

Tel: (251-11) 6 46 05 25, Fax: (251-11)6 46 08 80,
E-mail: qsae@ethionet.et

The other national laboratory which is currently upgrading its anlaytical capability is the Pesticide Chemistry Laboratory under the PHRD of the MoA shown in Annex III C. It has aquired new GC-MS and GC equipment and authomatic extractors for pestcide residue analysis. It has also organized continueous training for sample preparation and pesticide residue analysis.

4. The authorization and use of pharmacologically active and other substances in food producing animals

The national drug policy of Ethiopia gives priority to selection of drugs based on the country´s animals health problems, trained manpower, financial resources, infrastructure with full consideration of safety, efficacy, quality and cost.

4.1 The use of stilbens and thyrostats in food producing animals

The Food, Medicine, and Healthcare Administration and Control Authority (FMHACA) of Ethiopia has set up a "*List of Drugs for Ethiopia (LIDE)",* where all registered drugs are listed. The list consists of international non-proprietary (generic) names of drugs that can be imported or locally produced and it is also the basis of drug registration. The development of such a national drug list is an ongoing process. When the pharmaceutical industry introduces new medicines, they will be critically evaluated in terms of, *inter alia*, their potential to improve safety and efficacy, better patient compliance and other drug qualities.
In the actual list neither stilbenes nor thyrostats are listed. The national legal basis for prohibition of all these substances in Ethiopia is fixed in proclamation No 661/2009; part three, "drug registration and control". This is in agreement with Article 11.1 of Directive 96/23/EC.

4.2 The use of hormones and beta-agonists for growth promotion in food producing animals

Similar to stilbenes and thyrostats, the use of hormones and beta-agonists for growth promotion in food producing animals is strictly forbidden. Although there are some hormonal preparations registered in Ethiopia, its use is only in endocrine disorders. Development and growth stimulation of bee colonies can not be stimulated by using any chemicals, neither by hormones nor by beta-agonists. Therefore there is no risk at all to have any residue problems in bee products caused by that group of substances. The national legal basis for prohibition of these substances in Ethiopia is also fixed in Proclamation No 661/2009 -Part Four "Administration and Control of Medicines', which covers registration (Article 13).

4.3 The use of substances included in Annex IV to Council Regulation (EEC) No 2377/90

The FMHACA which replaced the Ethiopian Drug Adminstration and Control Authority, DACA, is the competent authority for controlling and allowing the import of human drugs and had tranistory role in regulating veterinary drugs (Currently shifted to the MoA as per the 728/2011 proclamation). This authority has a national drug policy which gives priority to selection of drugs based on the country's animals health problems, trained manpower, financial resources, infrastructure with full consideration of safety, efficacy, quality and cost.

The "Guidelines for Registration of Veterinary Drugs"developed by the FMHACA ensure the safety, efficacy and quality through evaluation and registration of veterinary products, which are to be imported or locally produced before they offered for use in the country. (http://www.daca.gov.et/Documents/NEGARIT%20GAZETA.pdf
After a veterinary product is registered, its registration is valid for five years only. It is, therefore, mandatory for manufacturers to apply for re-registration by submitting the required documents before the due date.
For the registration of new veterinary drugs and/or drugs for re-registration after 5 years, a lot of requirements have to be fullfilled. Special different application forms to be set up for providing all kind of information concerning the drugs (therapeutic use, strength, dosage form, specification, quality control process, active constituents, pharmacological category etc.) to make things more transparent. The Competent Authority has also published a list for Ethiopia where all registered veterinary drugs can be found in http://www.daca.gov.et/Documents/lvd4.pdf
The development of such a national drug list is an ongoing process. Hence, the list will be subjected to continuous deletion and addition; as the pharmaceutical industry introduces new medicines, they will be critically evaluated in terms of, *interalia*, their potential to improve safety and efficacy, better patient compliance and other drug qualities.
There are some more other guidelines in the Amharic language like "Guideline for Licensing and Certification of Importers and Wholesalers", August 2002 and **"Requirements Licensing of Drug Retailers"**, August 2002. All guidelines and certifications have the purpose to ensure the safety, quality and efficacy of pharmaceutical products that are produced within or imported into the country.
The certificate to be submitted to the competent authority for the registration of manufacturers of veteriary drug products (both raw material and finished products) should be the WHO type certificate of pharmaceutical products issued by the National Competent Authority communicated in the "WHO Certificate Scheme on the quality of pharmaceutical products moving in the International Commerce".
The Certificate of Good Manufacturing Practice (GMP) and Product Certificate to be submitted for registration of manufacturers of medical supplies must be indicated in the "Guideline on the Requirement for the Registration of Medical Device".
When checking the list of registered veterinary drugs for Ethiopia, antibacterial substances like chloramphenicol or nitrofurans (nitrofurazone) which are included in annex IV to Council Regulation (EEC) No 2377/90 can be also found.
However, due to the fact that no serious bee diseases like American foul brood, European foul brood, sac brood etc. can be found in Ethiopia, these substances are not allowed and absolutely not used and are therefore not present in bee products like honey or beeswax.
Nevertheless, problems with unauthorised use of chloramphenicol and nitrofurans have occurred world-wide. To be sure that there are no problems with honey, this substances (belonging to group A6) have been also included in the Ethiopian Residue Monitoring Plan for honey (see 2.4.2).
In addition to these substances belonging to group A6 many other antibiotics are not registered and not listed as veterinary drugs that may be used in Ethiopia. In respect of honey and beeswax there is no problem at all that these substances may cause any problems, because there are no bee diseases in the country that make it necessary to use any of these veterinary substances.

5. General information on authorisation of veterinary medicinal products

A new regulation for establishing a Supervising Authority for implementing, administering and controlling veterinary drug and animal feed is on drafting by the competent authority under the MoA.

The established Supervising Authority conducts authorisation and marketing of veterinary medicinal products and feed additives when the draft is endorsed by the Council of Ministers. Adopting the former DACA guidelines, it updates the list of veterinary drugs for

Ethiopia and conducts surveillance of registration and use. The following guidelines are followed:

- "set standards of quality, safety and efficacy of drugs and ensure their observance;
- set standards of competence for organizations to be involved in drug trade;
- prepare list of drugs for the country, structure the drug in the list into different categories, revise the list whenever necessary;
- formulate policy governing the sector; prepare draft legislation and present it for approval of the government;
- create favourable conditions for the promotion and expansion of drug trade and shall encourage and provide support to those who are involved in the trade;
- control the quality of raw materials and packing materials used for the production of drugs;
- monitor domestic or foreign new scientific achievements in the drug sector
- in order to adapt them to the country´s condition thereby promoting and strengthening the sector;
- prepare standards of safety, efficacy and quality of traditional medicines; and shall evaluate laboratory and clinical tests in order to ensure the safety, efficacy and quality of traditional medicine; it shall issue in order to use traditional medicine in the health service;
- serve as Drug Information Center and control drug information to be distributed to professionals in the public; it shall also disseminate current and unbiased information;
- make follow-up on domestic and foreign new scientific achievements on drugsector and shall put maximum effort of their implementation so as to promote and expand the sector;
- issue license for conducting clinical trial; monitor the process; evaluate the results and authorize the use of the result in such a way that it benefits the country;
- identify ingredients that caused death or ill health due to dry poisoning and forward possible remedies by conducting investigation on sample ingredients;
- organize a quality control laboratory needed to carry out its duty;
- collect a service fee;
- own property, enter into contracts, sue and be sued in its own name;
- perform other lawful activities as may be necessary for the attainment of its objetive".

Veterinary medicinal products that are not authorized in Ethiopia are not allowed to be imported and used. The measures in place for monitoring and/or preventing illegal imports have to be carried out by inspectors, assigned by the Authority. The Authority may delegate part of its powers and duties to regional legal bodies to the extent and whenever it deemed necessary for the efficient performances of its activities. One of the main functions for the competent authority is inspection as stipulated in Article 5, (Sub-article 2 a, d and g), which, accordingly empowers inspectors to:

- enter and inspect, during working hours, the establishments of food and medicine importers, exporters, producers, distribution, transporters and controllable health-related institutions;
- investigate and, if necessary, retain a photocopy of records, documents, prescriptions and the like pertaining to drugs;
- take samples of foods and drugs produced locally or imported as evidence; in accordance with the sampling procedures that shall be formulated by the Authority;
- subject to quality control of foods and drugs that are adulterated, spoiled, counterfeit, contaminated or those suspected to be dangerous to the public, he shall be authorized to order the quarantine of such items until the results of the laboratory are known;
- to inpect the disposal of foods and drugs when they expire or when they are deemed to be unfit for use in accordance with this Proclamation.

Concerning drug registration, its control and standard of quality, the following has been fixed:

- "No drug, wether produced locally or imported, shall be put into use unless it is duly registered by the Competent Authority;
- The registration shall be effected in accordance with regulations to be issued for the implementation of this proclamation;
- A registration certificate which remains valid for five years shall be granted for a drug registered pursuant to article 16 of this proclamation;
- The certificate shall show whether the drug is a prescription-drug or non-prescription drug; and also the level of health institution or drug retail outlet where it shall be available;
- Any registered drug shall be presented for re-registration at least 120 days prior to the end of the validity date of the registration certificate;
- The authority shall issue detailed guidelines regarding the documents that should accompany an application for re-registration;
- The authority shall assure the quality of drugs as per its own pharmacopoeia of other countries which are recognized by it;
- No drug, raw material or packing material which fails to comply with its quality specifications shall be put into use;
- The authority shall carry out post marketing surveillance in order to ensure the safety, efficacy and quality of drugs that are put into use;
- The FMHACA shall have the power to ban the use, or to revoke the registration, of a drug that was put into use when, later on, it is proved to be ineffective or its risks outweighs its benefit".

Summary.

i. Antibiotics are NOT applied for use in treating honey bees. The National Formulary data for Vet-drugs set by DACA (pp. 1-70) is still valid and describes presciption drugs for various animals and does not include honeybees. The formulary covers antimicrobials like suplha drugs, chloroamphenicol and nitrofurans for treatment of specified pests and food-producing animals: Group A6 substances (cloroamphenicol, nitrofurans, nitrofurazone) are not registered in Ethiopia which means that they are not imported. List of Drugs and Formularies(Accessed 15 Mar 2010)

ii. Off-label applications of any veterinary and human medicinal products are not allowed in Ethiopia.

- Bee diseeases like American and European Fouldbrood are not detected in the country.
- Importation of bees and used apiculture and honey production. equipment/ tools from abroad are prohibited as national preventive measures.

5.1 Human safety assessments

The Food and Medicine and Healthcare Administration Authority, FMHACA, has adopted the guideline for the registration of veterinary drugs (which was controlled by the former Drug Administration and Control Authority (DACA) of Ethiopia with the objective of providing applicants with information concerning documentation to be submitted for registration of veterinary products.
http://www.daca.gov.et/Documents/Guidevetregi.pdf
Note: *Currently an Authority is being established under the MoA to register and control Veterinary Drugs and Animal Feeds.*
To be able to market a veterinary medicinal product in Ethiopia, authorisation must be obtained to produce or import from abroad. The applicants are required to submit a marketing authorisation dossier to the Competent Authority. The dossier is then the subject of a scientific assessment which verifies the quality of the veterinary medicinal product, its

safety to the user, the consumer, the environment and the target animal, and its efficacy. This assessment is based on the criteria in the annex to Directive 2001/82 EC and on a number of European guidelines. On the basis of different EU Directives and former DACA guidelines and data as well as numerous types of application forms which are adopted to make the application easier and more transparent. The application dossier comprises five main parts:

- Administrative
- Quality
- Toxicology
- Residues
- Efficacy

The requirements for the registration of new veterinary drugs are also including different clinical and pharmacological tests carried out prior to authorisation being granted for veterinary medicines. The tests are mainly based on

- **Pre-clinical studies**
  - animal pharmacology
    (pharmacodynamics, pharmacokinetics, toxicological data and other studies)
  - toxicological data
    (acute toxicity, long term toxicity, reproduction and teratology, effects on parturition, fertility and general reproductive performance, teratology studies, embryotoxicity teratogenicity, prenatal and postnatal studies, carcinogenicity, mutagen city, other studies)
    -microbiology (in vitro studies, sensitivity disk interpretation and validation studies, in vivo studies)

- **Report on drug trials on target animals**
  - clinical pharmacology (pharmacodynamics, pharmacokinetics)
  - pharmacodynamics
  - pharmacokinetics
  - combinations
  - bioavailability report

The report covers summary, objective, subjects, materials, study design, chemical analysis, result, subjects, discussion and conclusion)

- **Clinical trials**
  - pivotal studies
  - non-pivotal studies
  - special clinical trials (determination of the withdrawal period of drugs)
  - combinations of different drugs (combined preparations)

All these human safety assessment tests and studies mentioned before are carried out prior to authorization is granted for veterinary medicines. The tests are absolutely necessary for the registration of veterinary drugs in Ethiopia. The tests have to be done according to European standards. The certificate to be submitted for registration of Veterinary Drug Products should be the WHO type certificate of pharmaceutical products, issued by the competent authority.

The Certificate of Good Manufacturing Practice (GMP) and the Product Certificate has to be submitted to the Competent Authority for the registration of manufacturers of medical supplies and has to be indicated in the "Guidelines on the Requirement for the Registration of Medical Device". All these human safety assessment tests and studies had been fixed in the former Drug Administration and Control Proclamation No. 176/1999. Proclamation 661/2009 has more provisions for residues and safety, and the new Competent Authority, FMHACA, is empowered to "set and impement standards of quality, safety and efficacy of vet-drugs and ensure their observance".

5.2 Establishment of drug withdrawal periods

The possible presence of residues in products of animal origin or in the environment requires a rigorous assessment of the study of these products and control of their manufacture, marketing and use. The regulations governing veterinary medicines and the requirements as to quality and manufacture are practically identical. For veterinary medicinal products, additional provisions have been introduced to ensure the safety of food stuffs of animal origin and of the environment.
In the case of veterinary medicinal products intended for food producing animals, the Competent Authority of Ethiopia has set, where necessary, a minimum withdrawal period with which the holder of the treated animal must comply. This withdrawal period corresponds to the period during which the foods produced by the treated animal may not be sold for human consumption. The withdrawal period is the required time between the last administration of the veterinary medicinal product to the animal under normal conditions of use and the production of foodstuffs from such animal, in order to guarantee that such foodstuffs do not contain residues in excess of the maximum limits established pursuant to Regulation No. 2377/90 (EC), which means that for Ethiopia it is based on the maximum residue limits (MRLs), set at Community level for each substance.

The List of Veterinary Drugs for Ethiopia includes Group A6 chemicals:

- Chloramphenicol
- Nitrofurazone
- Metronidazole
- Furaltadon,
- Furazolidone

(http://www.daca.gov.et/Documents/lvd4.pdf)

However, none of these in Group A6 are registered/imported. Even if imported in future Chloroamphenicol, for example, may be used to treat cats, dogs, horses and pigs which, except the latter, they are not food-producing animals in Ethiopia. Even pigs are not widspread farm animals and are raised only around the city of Addis Ababa. Withdrawal periods prior to slaughter are clearly specified for food producing animals.

5.3 Off-label use of veterinary medicine

The FMHACA has a transitory regulatory responsibility (until a Supervising Authority is established for the new Proclamation of Veterinary Drugs and Animals Feeds and regulations enter into force) on the basis of the existing regulations relating to marketing and control of veterinary medicinal products and feed additives.
Concerning drug registration, control and standard of quality, the following has been fixed:

- According to all sub-articles of Article 14 of Proclamation 661/2009, no drug, raw material or packing material which fails to comply with its quality specifications shall be put into use
- The authority shall carry out post marketing surveillance in order to ensure the safety, efficacy and quality of drugs that are put into use;
- The authority shall have the power to ban the use, or to revoke theregistration, of a drug that was put into use when, later on, it is proved to be ineffective or its risks outweighs its benefit".

This means, that off- label use of any veterinary and human medicinal products is not allowed in Ethiopia. Additionally, the new draft of the MoA regulation for veterinary medicines and feedstuffs states clearly states it is an offence to feed to any animal, or buy, possess or supply for the purpose of feeding to any animal, any feedingstuff containing a veterinary medicinal product or specified feed additive unless:
(a) the veterinary medicinal product or specified feed additive is authorised for that species of animal and for the purpose for which it is used, or,

(b) in the case of a veterinary medicinal product, it was prescribed for that animal.

5.4 Import and distribution of drugs and veterinary medicinal products

For the import, export, manufacture or distribution of any veterinary drugs, a licence from FMHACA is required. This responsibility will be transferred to a new Veterinary Medicines and Feed Control Authority under the MoA. The action of the government is absolutely justifiable since the latter administers and controls veterinary services.
Today import and wholesale of drugs in Ethiopia are done by the public sector, private sector, NGO's and international organizations.
The Pharmaceutical Administration and Supply Service (PASS) of the Ministry of Health and the Pharmaceutical and Medical Supply Import and Wholesale Share Company known as PHARMID (semi-governmental organization) are responsible for import and distribution of all drugs to the public sector. PHARMID has eight wholesale distribution branches in Ethiopia (2 in Addis Ababa and 6 in different regions). Public procurement is done through international and local tenders as well as by direct purchasing or negotiation. It is limited to the "*List of Drugs for Ethiopia"* (LIDE). Guideline on drug donation is prepared in the local language. The supply of veterinary medicinal drugs is based on the issue of a prescription paper which must state, in particular, the names of the medicines selected, their dosage, their method of administration and the withdrawal period, if applicable (see annex II).
http://www.daca.gov.et/Documents/Guidprescription2.pdf

Procurement of all drugs in the private sector is done by direct order to manufacturers abroad and it is also limited to the "*List of Drugs for Ethiopia* (LIDE).
The drug retail activity is done by the public sector, private sector, city councils, and the Red Cross Society of Ethiopia. This sub-sector has also shown significant growth in number of outlets during the last decade and half.

5.4.1 Distribution channel for veterinary drugs in Ethiopia

FMHACA⇒ (permission, prescription system, physically inspection of local and abroad companies, maintenance of the approved list of
⇓ importing companies)
Importers ⇒ (NGO´s, Government …)
⇓
Warehouses ⇒ (PHARMID, PASS)
⇓
Regions ⇒ (Stock keepers)
⇓
Retailers ⇒ (veterinary pharmacies)
⇓
Farmers ⇒ (public)

This responsibility will be transferred to the would be Supervising Authority of the MoA for controlling and administrating veterinary drugs and animal feeds as per the Proclamation 728/2011.

Annex IA
List of pesticides, veterinary drugs and heavy metals to be determined in honey in accordance with 96/23/EC

B1 Antibacterial substances, including sulphonomides, quinolones				
Compounds Type	**Material: Honey Method: HPLC**	**Detection level**	**Level of action**	**Results**
Sulphaguanidine	as above	10 ppb	50 ppb	
Sulphanilamide	as above	10 ppb	50 ppb	
Suplphacetamide	as above	10 ppb	50 ppb	
Sulphadiazine	as above	10 ppb	50 ppb	
Sulphthdiazole	as above	10 ppb	50 ppb	
Sulphapyridine	as above	10 ppb	50 ppb	
Sulphamerazine	as above	10 ppb	50 ppb	
Sulphamether	as above	10 ppb	50 ppb	
Sulphadimidine	as above	10 ppb	50 ppb	
Sulphamethoxypyridazine	as above	20 ppb	50 ppb	
Oxytetracycline	as above	10 ppb	50 ppb	

Annex IA contd.

Group B2c – Pyrethroids and carbamates			
Compounds Class	**Compounds Type**	**Compounds Brand Name**	**Material: Honey Method: Gas Chromatography**
Pyrethroids	Cypermethrin		
	α-Cypermethrin		
	Deltamethrin		
	Fluvalinate*	Apistan	
	Flumethrin*	Bayvarol	
	Permethrin		

Cypermethrin, α-Cypermethrin (and deltacypermethrin) and Deltamethrin *are the only ones registered for use in Ethiopia.*

(i) These twoare substances not considered to pose any risk of residue contamination in Ethiopian honey and they are not as well registered and imported for use in Ethiopia. These residues mostly occur in honey as residues if treatments of hives for infestations of varroa mite species. (ii) Varroa mites have NOT been detected so far in Ethiopia. (ii) 95 % Beekeeping in Ethiopia is traditional fixed comb hives occupied by wild swarms of bees. (iv) It is not feasible to administer bee medicines using this type of hive.

Annex IA contd.

Group B 3a Organochlorine compounds* including PCBs			**Material: Honey Method: Gas Chromatography**
Organochlorine compounds*	*Endosulfan**		as above
	Endrin		as above
	Hexachlorobenzene		as above
	HCH (3 isomers)		as above
	Heptachlor		as above
	Heptachlor epoxide		as above
	Quintozene		as above
	Tecnazene		as above
	Vinclozolin		as above
PCB's	PCB Congener 28		as above
	PCB Congener 52		as above
	PCB Congener 101		as above
	PCB Congener 118		as above
	PCB Congener 138		as above
	PCB Congener 153		as above
	PCB Congener 180		as above

***Endosulfan* is the only one registered for use in Ethiopia)**

Annex IA contd.

Group B3b Organophosphorus compounds			
Compounds Class	**Compounds Type**	**Compounds Brand Name**	**Material: Honey Method: Gas Chromatography**
Organophosphorous	Bromophos		as above
	Bromophos-ethyl		as above
	Chlorfenvinphos		as above
	Chlorpyrifos		as above
	Chlorpyrifos-methyl		as above
	Diazinon		as above
	Dichlorvos		as above
	Dimethoate		as above
	Ethion		as above
	Ethoprophos		as above
	Etrimfos		as above
	Fenitrophion		as above
	Heptenophos		as above
	Malathion		as above
	Methacrifos		as above
	Methidathion		as above
	Mevinphos		as above
	Parathion		as above
	Parathion methyl		as above
	Phosphamidon		as above
	Pirimphos methyl		as above
	Triazophos		as above

Annex IA contd.

B3c - Chemical elements			
Compounds Class	**Compounds Type**	**Compounds Brand Name**	**Material: Honey Method: Atomic Absorption**
Chemical Elements	Lead		as above
	Cadmium		as above
	Arsenic		as above
	Zinc		as above
	Mercury		as above

Annex IB

Annex IC
Active list of veterinary dugs registered for use in Ethiopia[16]since 2002 and those listed by the EU for the Residue Monitoring Plan

Active list Vet drugs Registered in Ethiopia (see official list[17])	EU-listed vet drugs for RMP, 96/23/EC

Summary of RMP for Ethiopian Honey: detection level, level of action and sampling for laboratory testing of Groups

A6, B1, B2c, B3a, B3b, B3c under 96/23/EC Will be annexed

Compound Class	Generic Name	DACA Reg. Date	Compound Class	Generic Name
TETRACYLINES	Oxytetracycline	19/11/03	TETRACYLINES	Oxytetracycline Chlorotetracycline Doxycycline Tetracycline
ANTIBIOTICS			ANTIBIOTICS	
	Benzylpenicillin Procaine+ Neomycine sulphate	17/06/2005		Chloramphenicol Streptomycin
SULPHA DRUGS	Sulphadimidine sodium	07/06/2005	SULPHA DRUGS	Sulphadimidine Sulphaguanidine Suplphacetamide Sulphadiazine Sulphthdiazole Sulphapyridine Sulphamerazine Sulphamether Sulphanilamide Sulphamethoxypyridazine
OTHERS	Multivitamin and mineral Albendazole	06/04/2005 27/01/2002		

[16] DACA, Registered Veterinary Drugs from 2002-2007

	Amprolium	05/03/2005	
	Diminazene Aceturate+ Phenazone	26/12/2004	
	Fenbendazole	07/12/2004	
	Levamisole	31/01/2005	
	Oxyclozanide +Tetramisole	16/03/2005	
	Tetramisole	03/12/2003	
	Tetramisole + Oxyclozanide	09/11/2004	
	Tryclabendazole	11/05/2005	

Annex I D
Partial List of Pesticides registered for use in Ethiopia (March,2012) and common to those listed under 96/23/EC, the *italics* indicate the pesticides common to both

Pesticides Registered in Ethiopia			Pesticides listed under 96/23/EC Common names
#	Common names (no of formulations/brand name)	Ethiopian list by 96/23/EC	
	ORGANOPHOSPHORUS		**ORGANOPHOSPHORUS GROUP B3b**
1.	*Dimethoate*	B3b	*Dimethoate*
2.	*Diazinon* (2)	B3b	*Diazinon*
3.	*Malathion (*3)	B3b	*Malathion*
4.	*Pirimiphos-Methyl*	B3b	*Pirimphos methyl*
5.	*Chlorpyrifos*	B3b	*Chlorpyrifos*
6.	*Ethoprophos*	B3b	Ethoprophos
7.	*Methidathion*	B3b	Methidathion
8.	Chlorpyrifos-Ethyl		Chlorpyrifos-methyl
9.	Diclorfop—Ethyl		Bromophos-ethyl
10.	Fenitrothion (3)		Etrimfos
11.	Fenthion		Dichlorvos
12.	Glyphostate (5)		Ethion
13.	Pirimiphos-Ethyl		
14.	Trichlorfon		Fenitrophion
15.	Profenofos (2)		Heptenophos
16.	Glyphosate		Methacrifos
17.	Glyphosate + Terbuthylazine		
18.	Monocrotophos		Mevinphos
17.	Pirimiphos-methyl		Parathion
.	Paraquat		Parathion methyl
			Phosphamidon
			Triazophos
			Chlorfenvinphos
	ORGANOCHLORINES		**ORGANOCHLORINES, GROUP B3a**
19.	*Endosulfan*	B3a	*Endosulfan*
	Dicofol	B3a	Dicofol
			Aldrin

			DDT & Isomers
			Dichlofluanid
	CARBAMATES and PYRETHROIDS		Captan
20.	*a-Cypermethrin (2)*	B2c	Hexachlorobenzene
21.	*Cypermethrin* (2)	B2c	Dieldrin
22.	*Deltamethrin* (4)	B2c	Endrin
23.	Bifenthrin		HCH (3 isomers)
24.	Cyfluthrin		Heptachlor
25.	Cyfluthrin		Heptachlor epoxide
26.	Delta-Cypermethrin		Tecnazene
27.	Cyhalothrin Lambda		Vinclozolin
28.	Flurasulam + Flumetsulam		Quintozene
29.	D-Phenothrin		
30.	Tetramethrin		
31.	Fenoproprathrin		
32.	Lambda-Cyhalothrin (2)		
33.	Furathiocarb		**CARBAMATES and PYRETHROIDS B2c**
34.	Tetramethrin = neopnamin 0.20%+ pynamin forte = D -allethrin 0.250% + sumithrin = d-phenothrin 0.120%		*Cypermethrin*
35.	Decarbofuran		*a-Cypermethrin*
36.	Carbaryl		*Deltamethrin*
37.	Carbosulfan		Flumethrin
38.	Carbosulfan (8)		Permethrin
			Fluvalinate
	OTHERS		
39.	2,4-D		
40.	Alachlor + atrazine		
41.	Alachlor		
42.	Alkylarylpolyglycol		
43.	Aluminium phosphide		
44.	Ametryne + atrazine		
45.	Amitraz		
46.	Atrazine		
47.	Benomyl		
48.	Bifenthrin		
49.	Brodifacoum		
50.	Bromadiolone		
51.	Bromopropylate		
52.	Bromoxynil + ioxynil + mecoprop		
53.	Buprimate		
54.	Chlorothalonil		
55.	Cladinafop-propargyl		
56.	Copper-hydroxide		
57.	Cymoxinil + copper oxychloride		
58.	Dicamba + mecoprop		
59.	Diclofop-methyl		
60.	D-phenothrin 0.05% + Teramethrin 0.25%		
61.	Fenopropathrin		
62.	Fenoxaprop-p-ethyl		
63.	Fenthion		

64.	Fipronil		
65.	Flocoumafen		
66.	Flucythrinate		
67.	Flurasulam 75 G/L + flumetsulam 100 G/L SC		
68.	Fluroxypyr + MCPA		
69.	Fluzifop-p-butyl		
70.	Hexazinone		
71.	Imidacloprid		
72.	Iprodione		
73.	Kresoxim-methyl		
74.	Mecoprop		
75.	Mepiquat chloride		
76.	Metelaxyl		
77.	Metolachlor + Atrazine		
78.	Monocrotofos		
79.	Neem		
80.	Novaluron		
81.	Oxydemethon-methyl		
82.	Pendimethalin		
83.	Phenoxaprop-p-ethyl		
84.	Prometryn + metolachlor		
85.	Propamocarb hydrochloride		
86.	Propiconazole		
87.	s-metolachlor		
88.	Spinosad		
89.	Spiromesifen		
90.	Sulfur		
91.	Tebuconazole		
92.	Terbuthylazine + glyphostate		
93.	Thiacloprid		
94.	Thiamethoxam 20% + metalaxyl - 20% + difenoconazole 2%		
95.	Thiamethoxam 35% FS		
96.	Thiram 80% WP		
97.	Triadimefon		
98.	Tribenuron methyl		
99.	Trichlorofon 95%		
100	White oil		
101	(Xdf 6.25 g/l + 2,4-d 300 g/l) suspo-emulsion (s.e)		
102	Zinc phosphide 80% Techical		

Annex IE
Production of Pesticide Formulations at Adamitulu

This is the only enterprise in the country that processes pesticide formulations. The plant is located near Zeway, 170 Km from south of Addis Ababa. The formulations which are in the form of liquid, dust and as a wettable products are limited to six insecticides and one herbicide 2,4-D. The imported pesticides to be formulated in the company are registered by the competent authority. The list of pesticides registered and imported by the public company are listed below:

Pesticide	Uses
Deltamethrin 25 gm/lt	For the control of mealy cabbage aphids on cabbage
Deltamethrin 25 gm/lt	For the control of maize stock borer (Buseolla fusca) on maize.
Malathion	For the control of maize Weevil (*Sitophilus zeamays*) on stored maize
Malathion	For the cotrol of sweet potato butterfly (*Acraea acerata*) on sweet potato
Endosulfan	For the control of African bollworm (*Helicoverpa armigera*) on cotton
Dimethoate	1. For the control of Aphids on field pea 2. For the control of Russian Wheat Aphid (Diuraphis Noxia) on barley
Fenithrothion	For the control of sweet potato butterfly (*Acraea acerata*) on sweet potato
Diazinon	-For the control of termite damage in hot pepper
Diazinon	For the control of maize stalk borer (*Busseola fusca*) and sweet potato butterfly (*Acraea acerate*) on maize and sweet potato respecitviely.
2,4-D dimethylamine salt	For the control of broad leaved weeds on Tef.

Source: MoA, List of Registered Pesticides, Sep 2012.

The other major formulation inputs are solvents, emulsifiers and carriers. The plant has been in preparation to expand its formulation for 2,4-D and three other pesticides. The products are sold to the MoH, MoA, Regional Offices of Health and Agriculture as well as to private investors.
The Adamitulu enterprise has its own quality control laboratory including an HPLC equipment. According to the company QC tests are made in accordance with the parameters specified by the WHO and FAO. This includes determination of active ingredients, density and particle size.

Annex II. Veterinary Prescription Paper

Ser.No,__000000
Card No._____

Name and level of Health Institution_____
Address Region_____ Town_____Tel_____P.O.Box_____

.....

Veterinary Prescription Paper

Ser.No,__000000

Name and Level of Health Institution_____
Address: Region_____Town_____Tel_____P.O.Box____
Owner's Name_____
Address Region____ Town____ Woreda____Keble___locality__
Animal Type_____Age_____Sex_____ Status_____
ID No._____ CardNo._____
Diagnosis(ICD Code No.)_____

Treatment given(name, strength ,dosage form, dosage and quantity of drug)	Price of Each item	
	Birr	Cent

Refill _____Withdrawal period_____

Prescriber's
Name_____
Qualification_____
_____
Registration No._____
Signature_____
Date_____

Dispenser's
_____
_____
_____
_____

Annex III A: Drug Quality Control and Toxicology Laboratory

Status	Government laboratory, DACA, Ministry of Health
Objectives	To ensure the safety of foods and quality, safety and efficacy of drugs, medical supplies, cosmetics and their raw and packaging materials through laboratory-base quality testing before and after marketing
Accreditation status Divisions	Has prepared Quality Manaual and SOPs, training on auditing and ISO 17 i. Physico-chemical Laboratory division ii. Toxicology Laboratory Division iii. Microbiology Laboratory Division
Accreditation in Process:	Quality manual, SOPs, work, instructions prepared
Manpower:	Each equipment has trained analyst; qualified maintenance staff
Staffing	Total 30; 60% technical staff (pharmacists, chemists, biologists, ,
Training	Locally and abroad *-training programme is part of accreditation process - recent one was US sponsored training by USP staff*
Testing Services	Microbiological assay of antibiotics Pesticide residue analyses Pesticide exposure tests, veterinary drug residue analyses Heavy metals analyses and trace elements monitoring Drug residue analysis (drugs and chemicals in animal body) Occupational and environmental toxicity monitoring (exposure to hazardous chemicals, pollutant analysis) *Most testing equipment, with a notable exception of LC-MS, are operation Has aquired 5 new HPLC eqiupment.*
Handling of Samples	Has documented procedure for sample handling from reception, labeling, to analysis and analysis report
Equipment	1 GC-MS 10 HPLC, 1 LC-MS, 1 HPTLC 2 UV-Vis Spectrophotometers 1 Atomic Absorption Spectrophotometer (Flame and Graphite Furnace)
Problems and shortcomings	i. Shortage of trained staff ii. Lacs maintainace engineers and technicians iii. Lacks chemicals including (certified) reference materials for QC works iv. Lacks equipment accessories

Annex III B: The Chemical Testing Laborator; Conformity Assessment Organization (formerly Quality and Standards Authority of Ethiopia)

Status	Government laboratory, under the Conformity Assessment Organizationsince Feb 2 It is the official laboratory that issues certificates of analyses for products from clie
Objectives	To undertake the analyses of chemicals, food and agricultural products from clients
Accreditation	Accredited for Metrology (mass and temperature) and microbiology tests in foods a water *Note: the laboratory has training programmes; has done most of the basic documentation; suceesfully participated in international proficiency testing programmes for heavey metals in water*
Training	Locally and abroad, mainly in South Africa
Products tested	Quality parameters including for honey and beeswax; honey and beeswax samples analyzed; Heavy metals in water; microbiological testing for food and agricultural products, pesticide residues tests in coffee with GC-MS
Equipment	HPLC, GC, Atomic Absorption Spectrophotometer, a GC-MS with a reference library of over a million compounds. The GC-MS is now functional for testing pesticide residues in Coffee. Note: *Both GC and GC-MS are very powerful tools for pesticide residue analyses*
Problems and shortcoming	i. Shortage of trained staff due to high attrition rate ii. Lack of maintainance engineers and technicians iii. Lack of chemicals including (certified) reference materials for QC works iv. Lack of equipment accessories

Annex III C: Pesticide Chemistry Laboratory, Addis Ababa

Status	Government laboratory under the Animal and Plant Health Regulatory Directorate of MoA. It is the official laboratory that issues certificates of analyses before a new pesticide registration is approved for use in Ethiopia. Pesticide residue analyst employed to manage GC-MS laboratory and train young technical staff
Objectives	To support the registration and control of pesticides; ii. To conduct tests for pesticide formulations and pesticide residues.
Accreditation	None
Manpower	6 professionals with degrees (2 PhD, 1 MSc Chemists)) and 1 technician at diploma level
Equipment	GC, HPLC for pesticide residue testing; purchased 1 GC-MS and 1 GC toenhance analytical capability
Pesticides tested	includes endosulphan, DDT, organophosphates, carbamates.
Problems and shortcomings	i. There are no maintenance engineers and technicians. Some of the equipment are not functional ; ii. The laboratory staff are involved in field work for the implementation of the Pesticide Disposal Project The laboratory is not in a position to validate methodsforf pesticide residues in a crop; no participations in interlaboratory comparisons/proficiency testing programmes iii. It is not accredited vs ISO/IEC 17025, which among others, requires training, and documentation at all levels including quality manual and standard operating procedures (SOPs) prior to implementation

Annex IV: Ethiopian Standard Specifications for beehives, honey, beeswax

1. ES 1202:2005 Specifications -Honey
2. Beeswax ES 1203:2005 Specifications -Beeswax
3. Hives ES 1204:2005 Specifications -Hives

Annex V: List of Apiculture Stakeholder Institutions and Companies

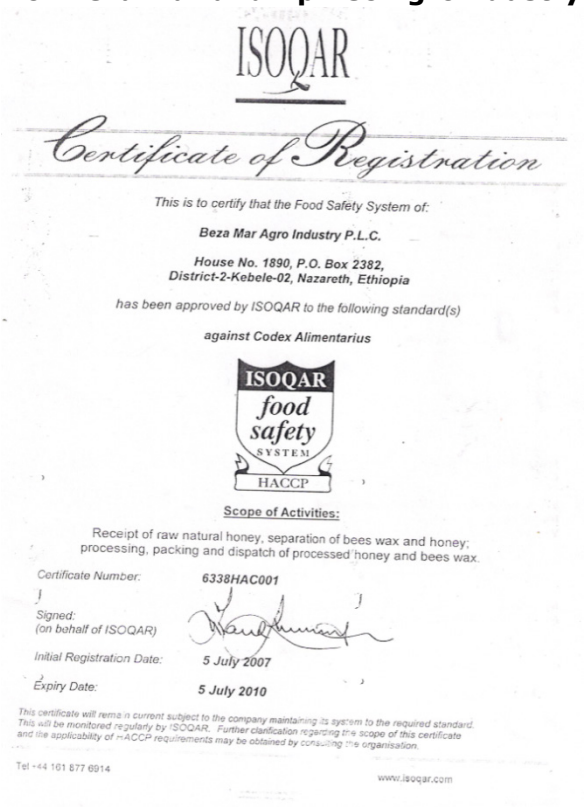
Government Institutions			
	Institution	**Address**	**Function/Responsibility**
	Animal Health Regulatory Directorate APHRD (MoA)	P.O.Box: 62347 Addis Ababa, Ethiopia bsiraw1@yahoo.com moa@ethionet.et	Controls animal health (SPS measures); registers pesticides, CA for follow-up and clearance of the RMP, registration and control of pesticides, animal feed
	Livestock & Feed Resources Development Directorate	P.O.Box: 62347 Addis Ababa, Ethiopia	Promotes apiculture development in addition to other livestock, fishery and feed resources development
	Ambo Plant Protection Research Center	Ethiopian Institute of Agricultural Research* Tel. 011 2362036 Fax 011 2362206	Pesticide management and integrated pest management research
	Testing Laboratory Directorate, Conformity AssessmentEnterprise	P. O. Box: 2310, Addis Ababa Tel: 251-11 6 46 05 25 Fax: (251-11)6 46 08 80, qsae@ethionet.et	Testing foods, water, and industrial products, pesticide residues in crops
	Ethiopian Standards and Technology Agency	P. O. Box: 2310, Addis Ababa Tel: (251-11)6 46 05 25 Fax: 251-11 6 46 08 80, qsae@ethionet.et http://www.qsae.org	Issuing national standards; for Foods and agro-products including for Honey and beeswax quality specifications and tests
	Product Quality Assessment Directorate, (FMHACA)	Addis Ababa, Ethiopia Tel 1-776984 Fax 1 52 13 92 daca@ethionet.et	Testing foods, drugs and toxic substances in formulations and as residues, Tests for Honey for Quality Parameters
	Food, Medicine, and Healthcare Administration and Control Authority, (FMHACA)	P. O. Box 5681 Addis Ababa, Ethiopia Tel: 00251 – 11 - 5524122 Fax.: 00251 – 11 - 5521392 daca@ethionet.et	Register and control foods, medicines, and health care services
	Food Science &	P.O.Box: 1242, Addis Ababa	Research:

	Nutrition Research Department, EHNRI	Tel: 011-2-756310; Fax: 011-2-757722/754744 ehnri@ethionet.et	Nutritional assessment, and food safety
	Holeta Bee Research Center/Laboratory	P. O. Box 22 Holeta, Ethiopia hbrc@ethionet.et	Bee research and apiary manangement training
	Ministry of Trade	Box 704 Addis Ababa, Ethiopia Tel: 251-1-513-990 Fax: 251-1-515-411	Encourages and supports agroprocessing for export
	Ministry of Health	P.O.Box 1234, Addis Ababa Ethiopia Tel 251 1 517011 Fax: 251 1 519366 moh@ethionet.et	CA for food safety; safety and efficacy of medicides
	Pesticide Laboratory; Animal Health Regulatory Directorate	P. O. Box 623476 Addis Ababa Ethiopia Tel +251 (11) 6 512734; Fax +251 (11) 6 646386 MoA@ethionet.et	Pesticide formulation and residue analysis
	National Animal Health Diagnostic and Diseases Investigation Center	Ministry of Agriculture Tel. +251113380894 Fax +251113380220 MoA@ethionet.org	Animal Diseases Diagnosis & Investigations, microbial testing
	EHBPEA member companies		
	APINEC Agro Industry Plc.	P.O.Box 27535 Code 1000 Addis Ababa, Ethiopia Project site : Bonga, Keffa Zone apinec@ethionet.et	Apiary, honey and beeswax refining and export
	Beza Mar Agro Industry PLC	Box 42787, Addis Ababa,Ethiopia bezamar@ethionet.et	Apiary, honey and beeswax refining and export
	BWAP Plc.	P. O. Box, 781 Code 1250 Addis Ababa, Ethiopia bwap@ethionet.et	Beeswax refining and export
	CENTURY General Trading PLC	P.O. Box 448 Code 1110, Addis Ababa, Ethiopia century@ethionet.et info@centurypromotion.com	Honey processing and export
	Harmony Agro Industry	bedrusultan@yahoo.com	Honey & beeswax production& processing
	Tutu and Family PLC	P.O.Box 781, Code 1250, Addis Ababa, Ethiopia; Tel 011 6 45 71 80 Tutu.honey@ethionet.et	Honey and beeswax refining and export
	RC Trade	P.O.Box 12767, Addis Ababa, Ethiopia Tel. 0116 511657 retrade@rctrade.com	Honey export

	COMEL Plc	P.O.Box 38, Tel. 0344 405888, Mekele, Ethiopia compelpvtltdco@yahoo.com	Honey beeswax processing and export
	DIMMAHoney Processing Plc.	P.O.Box 1360 Tel. 0344 402608, Mekele, Ethiopia dimma@ethionet.et;solg2008@yahoo.com	Honey and beeswax refining and export
	Yirgu Food Packer	Tel. 251-911222177, Addis Ababa, Ethiopia datamerkato@yahoo.com	Honey processing and export
	Rahi Honey Processing Enterprise	Tel 251 011-5-507204 rahihoneyplc@yahoo.com	Honey Processing Center in Adama, Leased apiary site in Kaffa Zone
	Wollella Livestock Products Cooperative	P. O. Box 626 Adama, Ethiopia 251-911238197	Honey processing for local market
	Zembaba Bee Products Development & Marketing Cooperative Union	Bahr Dar, Amhara Region zbeecoop@ethionet.et	Apicultural Development/Marketing
	Guraghe Zone Development Association	gzdass@yahoo.com	Honey and beeswax production
	Golla Bee Products plc	gollabee@ethionet.et	Beeswax extraction & refining
	Dawit Kidane	Dawitkidane2003@yahoo.com	Honey processing
	Tseday Mar	broyew@yagoo.com	Honey processing
	Meseret Mekuria	mekurialilly@yahoo.com	Honey processing
	Non-members to the EHBPEA		
	Ghion Beeswax Processing Enterprise	P.O. Box 22669, Addis Ababa, Ethiopia Tel 251-11 2-752237 Fax 251-11 2-755211	Beeswax refining and export
	Hora Sole Trading		Beeswax refining and export
	Omar and Awad Boabed	P.O. Box 1245., Addis Ababa, Ethiopia Tel 251-11-562579/80 Fax 251-11-560394	Beeswax refining and export
	Packford International	P.O.Box 2355, Addis Abab, Ethiopia, Tel 251-11-6635651; Fax 251-11-6635650	Beeswax refining and export
	NGOs and Dev. Organisations		
	Ethiopian Apiculture Board	P. O. Box 623476; 251-911-674692 Addis Ababa Ethiopia; 251-911-674692	Suport in apiculture development, marketing and lobbying with Govt bodies
	Ethopian Beekeepers Association	P. O. Box 623476 Addis Ababa Ethiopia; Tel 251-911-674692	Professional Assocatin for the advancement of beekeeping
	FARM Africa	P.O.Box 55, Bonga Ethiopia, Tel.+251-(0)47-5550154; P.O.Box 5746, Addis Ababa, Tel 251 011	NGO, Honey value chain cooperatives development and

		1553415, Fax 251 011 1552143	training
	GIZ	GIZOfficeEthiopia, Kazanchis , KirkosSubcity, Woreda 18 AddisAbaba, Telephone: +251-11-518020 Fax: +251-11-540764 Email:giz-aethiopien@giz.de	Funds for conducting training of farmers and extension staff; allocate credit for the purchase of beekeeping items such as modern hives
	IrishDevelopment Cooperation	P.O.Box 9585, Addis Ababa, Tel.+251-011-4665050, Fax:+251-011-4665013, http://www.dci.gov.ie	NGO, Training in Honey value chain
	SNV	Box 40675, Addis Ababa, Etiopía, Tel 251 (0)11 645389, Fax 251 (0)11 4 654388, snv@ethionet.et, www.business-ethiopia.com	NGO, supports the EAB for preparing the Residue Monitoring Plan, finances ASPIRE (HVC Scale-Up)
	SOS Sahel Ethiopia	P.O.Box 3262, Addis Ababa Tel.+251-011-4160279/4167583, Fax: +251-011-4160288 sos.sahel@ethionet.et, http://www.sahel.org.uk	NGO, Honey value chain cooperatives development and training
	ACDI/VOCA	Marathon Bldg, Megenagna P.O.B. 548 Code 1110 Addis Ababa T 11 6 620685 M 930 012727 vadams@acdivocaeth.org	USAID Contractor - Implements AMDe as part of the AGP including HVC promotion; provides grants to EAB for sector development

Annex VI
Certificates of Quality Management ISO 9001, HACCP for Beza Mar and Organic Certifications and for Beza Mar and Apinec Agroindustry



ISOQAR

Certificate of Registration

This is to certify that the Food Safety System of:

Beza Mar Agro Industry P.L.C.

House No. 1890, P.O. Box 2382,
District-2-Kebele-02, Nazareth, Ethiopia

has been approved by ISOQAR to the following standard(s)

against Codex Alimentarius

ISOQAR food safety SYSTEM HACCP

Scope of Activities:

Receipt of raw natural honey, separation of bees wax and honey; processing, packing and dispatch of processed honey and bees wax.

Certificate Number: **6338HAC001**

Signed:
(on behalf of ISOQAR)

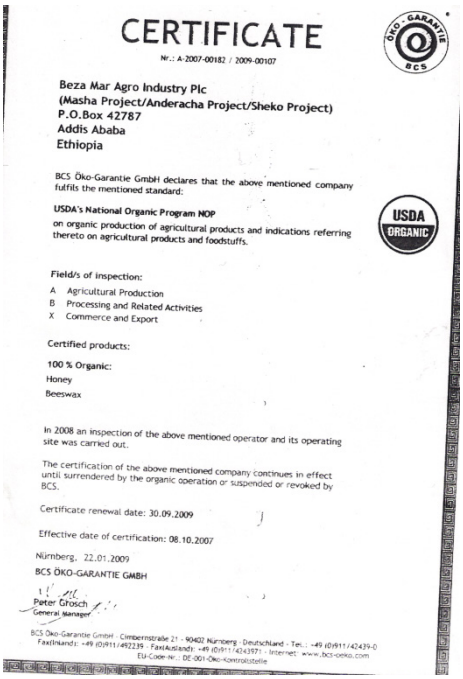
Initial Registration Date: **5 July 2007**

Expiry Date: **5 July 2010**

This certificate will remain current subject to the company maintaining its system to the required standard. This will be monitored regularly by ISOQAR. Further clarification regarding the scope of this certificate and the applicability of HACCP requirements may be obtained by consulting the organisation.

Tel +44 161 877 6914

www.isoqar.com



CERTIFICATE

Nr.: A-2007-00182 / 2009-00107

ÖKO-GARANTIE BCS

Beza Mar Agro Industry Plc
(Masha Project/Anderacha Project/Sheko Project)
P.O.Box 42787
Addis Ababa
Ethiopia

BCS Öko-Garantie GmbH declares that the above mentioned company fulfils the mentioned standard:

USDA's National Organic Program NOP
on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs.

USDA ORGANIC

Field/s of inspection:

A Agricultural Production
B Processing and Related Activities
X Commerce and Export

Certified products:

100 % Organic:
Honey
Beeswax

In 2008 an inspection of the above mentioned operator and its operating site was carried out.

The certification of the above mentioned company continues in effect until surrendered by the organic operation or suspended or revoked by BCS.

Certificate renewal date: 30.09.2009

Effective date of certification: 08.10.2007

Nürnberg, 22.01.2009

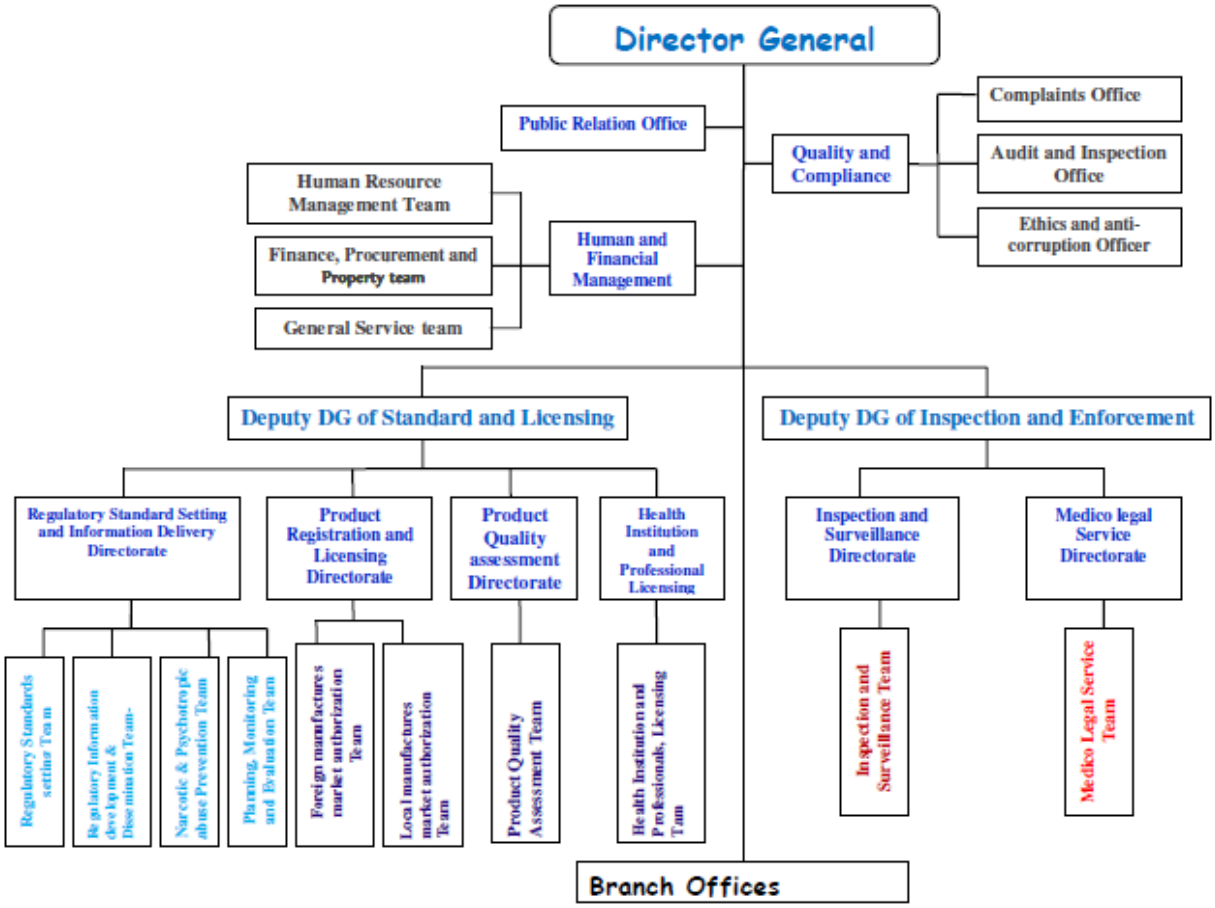
BCS ÖKO-GARANTIE GMBH

Peter Grosch
General Manager

BCS Öko-Garantie GmbH · Cimbernstraße 21 · 90402 Nürnberg · Deutschland · Tel.: +49 (0)911/42439-0
Fax(Inland): +49 (0)911/492139 · Fax(Ausland): +49 (0)911/4243971 · Internet: www.bcs-oeko.com
EU-Code-Nr.: DE-001-Öko-Kontrollstelle

Annex VII

Organogram II: The structure of the the Food, Medicine, and Healthcare Administration and Control Authority, FMHACA



Annex VIII
Sample Codes for the Residue Monitoring Plan-2013for the Ethiopian Honey according to EU Decision 97/747/EC

Total Production for the RMP 2013: 810 tons
Designated Laboratory: CHEMIPHAR (U) PLC

Summary of Sampling by substance Groups B1 and B2c, B3 (a, b, c) and A6

Total No. of Samples	**27**
No of Test Groups	**30**
	Number of Samples
Tests for B1 and B2c	7+8 (50%)
Tests for B3 a, b, c	12 (40%)
Tests for A6	3 (10%)
	30

Sample Codes:

Sample No Code	Substance Group Tests byEU Decision 97/747/EC
Code 6 A	
1	B3 a,b,c
2	A6
3	B3 a,b,c
4	B1
5	B2c
Code 6 B	
1	B1
2	B2 c
3	B3 a,b,c
4	B3 a, b, c
5	B2c
6	B1
7	A6
Code 6 C	
1	B3 a, b, c
2	A6 , B2c
3	B1 , B3 a,b,c
4	B3 a,b,c
Code 6 D	
1	B1, B2c
2	B3 a,b,c
3	B1
4	B3 a,b,c
Code 6 E	
1	B2c
2	B3 a,b,c
Code 6 F	
1	B2c
2	B3 a,b,c
3	B1

4	B3 a,b,c
5	B2c

Total 27 samples

B1	-	7
B2c	-	8
B3 a,b,c	-	12
A6	-	3
Total		30 test groups

Annex IX
Residue Test Certificates Reported by the Laboratory of Chemiphar (U) Ltd
Will be Enclosed After Having the Test Result, no. of pages ____