Recent Updates on Agrochemical Regulation in Kenya and Morocco

Rajiv Paul, Ph.D.

Senior Regulatory Ecotoxicologist
Auxilife Scientific Services Pvt. Ltd.
A-503, Speciality Business Centre,
Balewadi Road, Balewadi,
Pune-411045
Maharashtra, India.

GPC Global Product Compliance

CHEMEXCIL

AUXILIFE your trusted partner in India

RRMA REGULATORY REPRESENTATIVES & MANAGERS ASSOCIATION

1

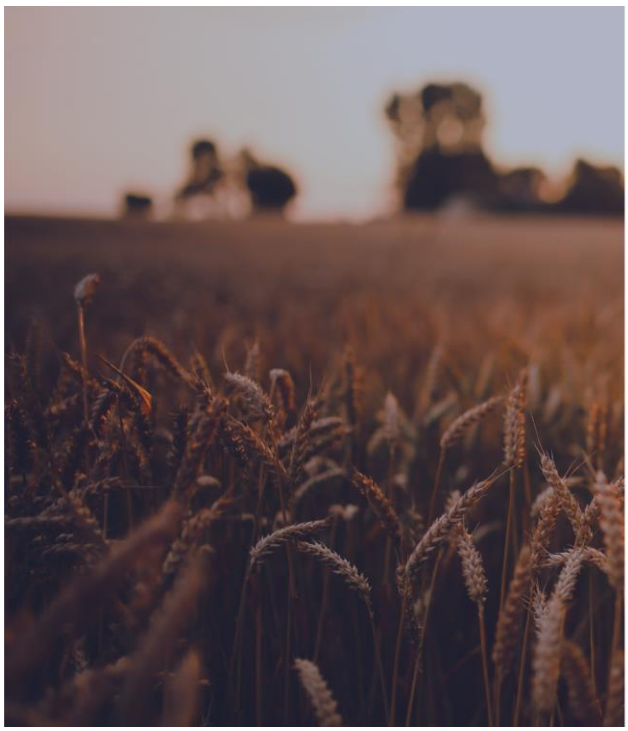


Table of contents

- Introduction
- Pesticides in Kenya & Morocco
- Regulatory Requirements
- Risk Assessments
- Challenges and Solutions

2

Abbreviations

- PCP: Pest Control Products
- PCPB: Pest Control Products Board
- ONSSA: Office National de Sécurité Sanitaire des Produits Alimentaires
- UIPP: Union des Industries de la Protection des Plantes
- KEPHIS: Kenya Plant Health Inspectorate Service
- AAK: The Agrochemicals Association of Kenya
- NEMA: National Environment Management Authority
- COR: Certificate of Registration
- FPEAK: Fresh Produce Exporters Association of Kenya
- AOEL: Acceptable Operator Exposure Level
- ADI: Acceptable Daily Intake
- ARfD : Acute Reference Dose

3

Introduction

- Pesticides or phytosanitary products are chemical substances that contribute to safeguarding the quality of agricultural production.
- Pesticides have undergone an important evolution and are diversified.
- Developing countries use about 20% of the pesticides in the world, and this use is increasing (WHO and UNEP, 1990).
- The world market for pesticides represents about 40 billion dollars. Europe: 27.7%; Africa: 4% (UIPP).
- The heavy use (industrial and domestic) of pesticides contributes to negative health, environmental and economic consequences.

4

Introduction

- Many pesticides are
  - toxic (acute/long term),
  - endocrine disrupters,
  - toxic to different wildlife species,
  - known to cause severe or irreversible adverse effects.
- Pesticides persist in the environment- a global threat to the entire ecological system
- Excessive use and misuse of pesticides causes:
  - contamination of soil and water sources,
  - loss of biodiversity,
  - destroying beneficial insect populations- natural enemies of pests
- Regulators are mostly concerned about health risks from pesticide residues, their effect on non-target organisms are hugely underestimated, especially in the African registration procedures.

5

KENYA

6

Pesticides in Kenya

Agriculture holds about 24% of Kenya's GDP with an estimated 75% of the population working in the sector either directly or indirectly.

Being an agricultural economy, Kenya's demand for pesticides is relatively high and steadily increasing.

Kenya: **Pest Control Products Board (PCPB)** under **Pest Control Products Act**, Cap 346, Laws of Kenya of 1982

7

Regulatory Requirements- Kenya

- Important Mandate of PCPB- "Assessing the safety, efficacy, quality, merit and economic value of PCP with a view to approving them, if found suitable in local situation".
- All applications for consideration of approval of PCP must be accompanied by submission of risk assessment reports (2019/2021- Risk assessment workshops).
- Applicants will be required to provide detailed human (occupational and dietary) and environmental (Bees) risk assessment reports for all applications of new products and label extensions to ensure any PCP do not pose unacceptable risks (July 2021).

8

Regulatory Requirements- Kenya

Risk assessment report

- During submission of summary dossier for new products.
- Upon completion of efficacy trials for label extension. Following conclusion of the local experimental efficacy trials.

Applicants need to provide the summary of risk assessment:

- Quality of the data referenced for hazard assessment (e.g., Experimental design and quality of the critical study or studies).
- Kenya Good Agricultural Practice (GAP) Table for efficacy and residue.
- Operator/Worker/Consumer exposure models and local risk assessment.
- Bee exposure model and the local situation.
- The input and output page of the exposure should be attached.
- Brief discussion of conclusion arising from the model's output.
- Discussion on the proposed realistic pesticide risk management.

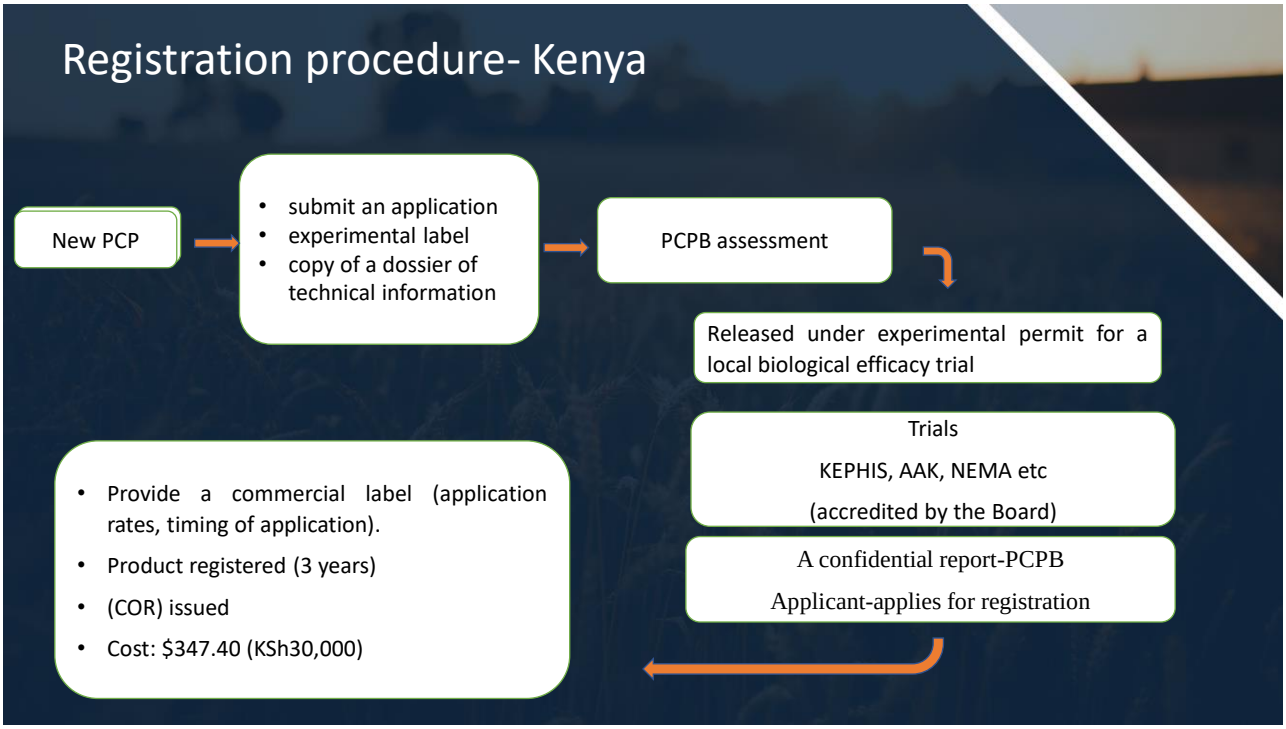
9

Regulatory Requirements- Kenya

- During the registration process,
  - Purity and the efficacy of the product is tested (YES)
  - Data on human health and environmental health (NO)
- The Pest Control Products Act does not even state environmental and/or human health as a possible concern during the registration process.
- The assumptions on which a pesticide is registered in Europe is different in Kenya which may lead to higher exposure risk for farmers, consumers and the environment.
- A significant gap between the common conditions of use in Kenya and the prescribed instructions on the label, it leads to:
  - high human and environmental exposures and
  - consequently, to risks exceeding estimated levels based on the assumption that label instructions are followed.

10

Registration procedure- Kenya



11

Regulatory Requirements- Kenya

Registrations and Licencing

PCPB controls the importation of pesticides through various registrations and licensing:

- **Agency licensing- pesticides manufacturers outside Kenya (validity, 1 year)**
- **Product registration- pesticide products imported to Kenya (validity 3 years)**
- **Premise licensing- premises handling pesticides (validity, 1 year)**
- **Import permit**
- **Import Standardization Mark (ISM)**
- **Environmental protection**

12

Regulatory Requirements- Kenya

Agrochemical stakeholders' self-regulation in Kenya

- Develop industry standards and code of practice, Kenya GAP-
  - owned by the Fresh Produce Exporters Association of Kenya (FPEAK) and it targets horticulture farmers in Kenya
  - safe to eat for the consumer, ensuring conservation of the environment/health and safety of those doing the production
  - to promote and ensure the implementation of socially and environmentally sound production and marketing practices of their fresh produce.
  - Kenya-GAP is for both local and international markets
  - Other international standards that promote good agricultural practices such as GLOBAL-GAP

13

Risk Assessment- Kenya

GAP table for efficacy

- Applicant/ Active ingredient/ Formulation/concentration
- Crop/situation
- Pest/group/type
- Application/rate/time/interval/PHI

Gap table for residue

- Applicant/ Active ingredient / Formulation/concentration
- Country/use/formulation details
- Application/rate/time/interval/PHI
- Results/MRL

14

Risk assessment- Kenya

Operator exposure modelling and local risk assessment

- EFSA calculator (2015) (NEW VERSION, approved on 30 November 2021- supersedes the previous output, Not in implementation (EU Commission)
  - 1. Agricultural Operator Exposure Model (AOEM)-mixing, loading and spraying of liquid pesticides
  - 2. The US Pesticide Handler Exposure Database (PHED)- application of granules
- CropLife OPEX Tool

Data Required:

- Acceptable Operator Exposure Level (AOEL) (EFSA Calculator),
- No Observed Adverse Effect Level (NOAEL) (CropLife OPEX Tool)
- Crop type/Type of application and application equipment
- Type of pesticide formulation
- Maximum application rate (kg of a.i. per ha)
- (in some cases) Volume application rate (L of spray solution per ha)
- (if available) Dermal absorption factor
- Type of personal protective equipment available/required

❑ AOEL<100% (Risk considered acceptable)

15

Risk Assessment- Kenya

Worker exposure modelling and local risk assessment

- EFSA calculator (2015) (NEW VERSION, approved on 30 November 2021- supersedes the previous output, Not in implementation (EU Commission)
- The US-EPA **ExpoSAC model**

Data required

- Acceptable Operator Exposure Level (AOEL) (EFSA Calculator)
- Crop type
- Type of application and application equipment.
- Maximum application rate (kg of a.i. per ha).
- (If available) dermal absorption factor.
- (If available) pesticide-specific dislodgeable foliar residue
- Type of personal protective equipment available/required
- AOEL<100% (Risk considered acceptable)

16

Risk Assessment- Kenya

Dietary/Consumer Risk assessment

- To determine whether the pesticide residues in agricultural commodities (and drinking water) do not pose an unacceptable risk to consumers
- To assess whether the residue level expected to occur in commodities does not lead to unacceptable consumer risk
- The **toxicological reference values** used in dietary risk assessment are the Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD).
- Maximum Residue Limit (MRL), Supervised Trials Median Residue (STMR), Highest Residue (HR), processing factors (if applicable)

17

Risk Assessment- Kenya

Dietary/Consumer Risk assessment

❑ **Chronic dietary risks**

- Calculation of the National Theoretical Maximum Daily Intake (NTMDI)- MRL as worst residue estimate
- NTMDI < ADI, No consumer risk; no further dietary risk assessment is needed.
- NTMDI > ADI, Refined by calculating a National Estimated Daily Intake (NEDI).
- The NEDI calculation uses Supervised Trials Median Residues (STMRs) instead of MRLs, as a more realistic residue estimate.
- NEDI < ADI, consumer risk is generally considered acceptable.

❑ **Acute dietary risks**

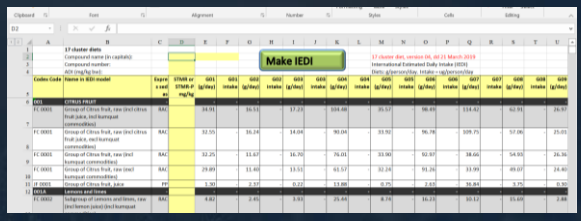
- Calculation of the National Estimated Short-Term Intake (NESTI), which uses the Highest Residue (HR) from supervised trials
- NESTI < ARfD, the acute dietary risk is considered acceptable.

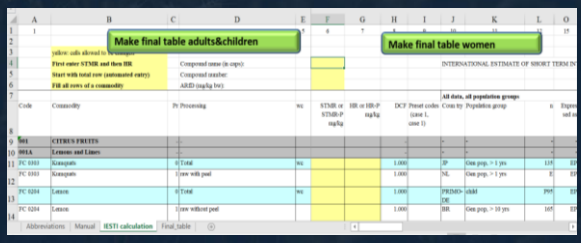
18

Risk Assessment- Kenya

Dietary/Consumer Risk assessment

- WHO, dietary exposure assessment of chemical in food, introduced by Global Environment Monitoring System (GEMS)
- IESTI calculation model
- IEDI calculation model





19

Risk Assessment- Kenya

Honeybee risk assessment

- Tiered approach
- Tier 1: A Conservative screen that separates pesticides that are not expected to present a risk from those pesticides that may.
- Higher tiers: Refine the estimates or measures of potential exposure, effects, and the resulting characterization of risk.
- Models
  - EPPO/OEPP (2003) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145.
  - The European Food Safety Authority (EFSA) published in 2013.
  - In addition, an Excel spreadsheet ("Bee tool") is available to facilitate the calculations of the assessments.
- Low LD_{50}/NOEL ➔ high impact and VICEVERSA

20

Risk Assessment- Kenya

- Crop attractiveness to bees: Yes /No
  - not attractive to bees ➔ no exposure likely
- Mode of application:
  - Some modes of application (e.g. dusting, aerial application, drilling treated seed that produces dust) ➔ **high exposure risk**
  - Some modes of application (e.g. seed/soil treatment with non-systemic pesticide; brushing) ➔ low exposure risk (unless soil nesting bees)
- Dose rate (kg a.i./ha)
  - High dose rate ➔ high exposure/impact risk and VICEVERSA

21

MOROCCO

22

Pesticides in Morocco

Morocco is an agricultural country, and agriculture is the backbone of the Moroccan socio-economic fabric.

The continuous increase of the area cultivated under modern and solidary agriculture (Morocco favours agro-ecological conditions) calls for the use of pesticides.

Office National de Sécurité Sanitaire des Produits Alimentaires (ONSSA), Law No. 42-95 on Plant Protection Products

23

Regulatory Requirements- Morocco

Pesticides for Agricultural Use:

- 1. Antiseptics and anticryptogamics- protection of vegetative cultures and materials;
- 2. Herbicides;
- 3. Defense products against vertebrates and invertebrates, nuisance to crops and agricultural products;
- 4. Vegetable defense products against bacterial and viral attacks
- 5. Products used in agriculture and destined for the fight against animal or vegetarian vectors of human or animal diseases,
- 6. The products intended for the cleaning and antiparasitic treatment of the premises, materials, vehicles, locations and dependencies used:
- 7. Substances that act on the physiology of plants (hormones of fertilization, fruit clearing, conservation products, inhibitors of germination);
- 8. The adjuvants are sold alone or mixed and are intended to improve the conditions of use of products

24

Regulatory Requirements- Morocco

The requests for homologation of pesticide products: defined in Article 1 of the law No. 42-95 , must be addressed, for each product. Each request must include:

1- **A form (triplicate):**

name of the declarant,

the address,

the social reason,

the name of the product

composition in active materials

uses to be specified.

2- **A dossier (triplicate):**

identification,

physicochemical characteristics,

methods of analysis,

efficiency

innocence of the product.

25

Regulatory Requirements- Morocco

- **Information of authorisations in other countries**
- **Toxicology**
  - Acute Oral Toxicity
  - Acute Dermal Toxicity
  - Acute Inhalation Toxicity
  - Skin Irritation
  - Eye Irritation
  - Skin Sensitisation
- Metabolism, Residues and Consumer exposure
  - Setted MRLs

26

Regulatory Requirements- Morocco

- Fate and behaviour in the environment
  - **Rate of degradation in soil**
  - **Mobility in soil**
- Ecotoxicology
  - **Birds**
  - **Mammals**
  - **Aquatic Organisms**
  - **Bees**

27

Risk Assessment- Morocco

Operator, Workers and Residents/Bystander exposure

- EFSA GD Exposure Calculator (AOEM) [Version: 30/03/2015]
- NEW VERSION, approved on 30 November 2021- supersedes the previous output
- Not in implementation (EU Commission)

Data Required:

- Acceptable Operator Exposure Level (AOEL) (EFSA Calculator),
- Crop type
- Type of application and application equipment
- Type of pesticide formulation
- Maximum application rate (kg of a.i. per ha)
- (in some cases) Volume application rate (L of spray solution per ha)
- (if available) Dermal absorption factor
- Type of personal protective equipment available/required

❑ % of AOEL <100 (**No Risk**)

28

Risk Assessment- Morocco

Combined Exposure

- For product with multiple (more than one) active substances
- Calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.
- Individual Hazard Quotients (HQ) are calculated, dividing the individual exposure levels by the respective systemic AOEL.
- The Hazard Index (HI) is the sum of the individual HQs.

29

Risk Assessment- Morocco

Metabolism, Residues and Consumer Exposure

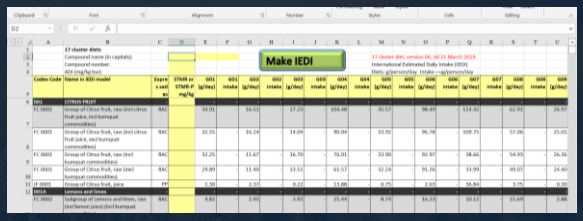
- Joint Order of the Minister of Agriculture and Maritime Fisheries and the Minister of Health No. 156-14 of the 15 Rabia I 1435 (17 January 2014) fixing the maximum limits of residues in or on primary products and food products.
- **Maximum limit of residues of a phytosanitary product (MRLs):**
  - The maximum concentration of residues of a plant protection product approved or authorized in accordance with the relevant legislation and regulations, present in or on primary products or food products;
- - Limit of determination**:**
  - the lowest concentration of residues that can be measured and recorded by regular monitoring of the level of residues, using recognized analytical methods.

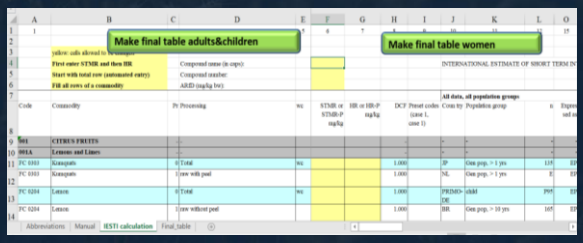
30

Risk assessment- Morocco

Dietary/Consumer Risk assessment

- WHO, dietary exposure assessment of chemical in food, introduced by Global Environment Monitoring System (GEMS)
- IESTI calculation model
- IEDI calculation model





31

Risk Assessment- Morocco

Effects on bees

- Oral/contact LD_{50}

Exposure

- Either through direct over-spray, or by contact with residues on plants whilst bees are foraging for food.
- In order to consider an extreme worst-case scenario, the maximum application rate is required to derive the hazard quotients.

Hazard quotients for bees

- Hazard quotients (products)
  - Exposure (Q_{HO}/ Q_{HC})
- HQ < 50; low risk to bees in the field.
- Reference: EPPO/OEPP (2003) Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10(2)). Bulletin OEPP/EPPO Bulletin 33: 141-145.

32

Risk Assessment- Morocco

Introduction and spread of *Xylella fastidiosa*

- Assessment of the risks
- As part of phytosanitary monitoring against *Xylella fastidiosa*
- First outbreaks in Italy (Puglia) in October 2013
- > Epidemiological data and scientific research
- Objective: To undertake a concerted expertise on the risk introduction and dissemination of *Xylella fastidiosa* through:
  - Assessment of the risk of introduction of this bacterium via imports of plants and plant products
  - Assessment of the risk of establishment and spread of *Xylella fastidiosa* on national territory,
- This study will make it possible to make recommendations that can further improve the response system to the threat of *Xylella fastidiosa*
- Bacterium is present in many countries, in particular, the American continent: Mexico, USA, Canada, Costa Rica, Argentina, Brazil, Paraguay, Venezuela.

33

Challenges and Solutions

Problem

- Often, pesticides are registered without adapting test results to local conditions (e.g. different species, climatic conditions and diet) and are taken from European or US MRLs. As for MRLs whose calculations are based on the diet of citizens, one needs to take into consideration that the African diet consists of much more maize than European diets.
- As for the effect of neonicotinoids, most toxicity tests are done with the European honeybee. No results are available on the effect on local bees (like stingless bees). This means we don't know what impact these neonicotinoids have on local pollinator populations.

Solution

- Adaptation of MRL's according to the African diet.
- Additional toxicity test should be performed with local species (fish, bees etc.) if needed.
- Increase in capacity amongst regulators, to conducting risk assessments for pesticide registration or review of existing registrations.

34

Challenges and Solutions

Problem

- 32-38% of the registered pesticides in Kenya and Morocco are withdrawn from the European market, partly because of the toxicity, persistence or lack of data (following the Precautionary Principle).
- Many registered pesticides cause chronic health effects and show very high toxicity towards the environment.

Solution

- Finding alternatives to these highly toxic pesticides.
- Crop protection methods in other countries with similar agronomic conditions that have cancelled the use of certain pesticides.
- Implementing taxes or import tariffs for highly hazardous pesticides- less expensive and less toxic pesticides more attractive to the farmer.
- Restrictions:
  - type of users (e.g. only certified users who have received training),
  - areas of use (e.g. not close to water bodies),
  - time of use (e.g. only in the evenings),
  - type of use (e.g. only as seed dressing or as stem injection)
  - or type of crop (only for specified crop/pest combinations under strictly controlled circumstances).

35

Regulatory Summaries

- Importer/exporter/manufacturer are to adhere to the licensing and regulations.
- Risk assessment is a new bee and important hurdle in African registration procedure.
- Following the mandates, models and tools are the prime requirements.
- Auxilife can assist in assessing the risk assessments in all the areas for the regulatory submission in both Kenya and Morocco.

36


Thank you for your attention!
GPC
Global Product Compliance
CHEMEXCIL
AUXILIFE
your trusted partner in India
RRMA
REGULATORY REPRESENTATIVES & MANAGERS ASSOCIATION

37