NIGERIA’S STATUS ON PESTICIDE REGISTRATION AND MAXIMUM RESIDUE LEVELS

By

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At

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INTRODUCTION

Overview

At the end of this presentation participants are expected to know:

✓ The law that govern pesticide Importation, Distribution and Uses in Nigeria
✓ The role of NAFDAC and other collaborating MDAs
✓ The Regulations crafted from the law
INTRODUCTION cont’d

✓ The efforts at regional Harmonization on pesticide registration
✓ MRLs and capacity of NAFDAC
✓ Dossier Requirement
✓ Challenges and the future plans
• Nigeria is a country in West Africa with a population of over 140 million (world’s 9th largest in terms of population).

• Nigeria has a total land area of about 923,700 sq.km and is bordered by Niger Republic, Republic of Benin, Chad and Cameroon.
INTRODUCTION cont’d

- A lot of movement of goods, man and animals across borders take place.
- The Federal Government of Nigeria has MDA, including Ministry of Health. National Agency for Food and Drug Administration and Control is a parastatal under the Ministry of Health.
- NAFDAC was established by Decree No 15 of 1993, now encapsulated in the NAFDAC Act, Cap N1 Laws of the Federation of Nigeria.
• The Drugs and Related products (Registration, etc) Act No. 19 of 1993 (as amended) specifies that: “No processed food, drug, drug product, cosmetic, medical device or water shall be manufactured, imported, exported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of this Decree or regulations made under it”.
Arising from the law, the Agency has put in place various Regulations, including the *Pesticides Registration Regulations* and the *Chemical and Chemical Products (control, monitoring) Regulations*. The latter is still in draft form, awaiting comments.
INTRODUCTION cont’d

- NAFDAC is aware of a draft pesticide legislation bill sent for inputs since 2003, by Agrochemicals Association of Nigeria. The draft bill provides for a Nigerian Pesticides Council for the country with clearly defined objectives.
INTRODUCTION cont’d

• The NAFDAC mandate as explained earlier includes the coordination of the evaluation of pesticides to ensure that safe and effective pesticides are available for use by the public.
INTRODUCTION cont’d

- Under the current administrative structure, the registration of pesticides and agrochemicals is handled by the Veterinary Drugs and Pesticides (VDP) Unit in the Registration and Regulatory Affairs Directorate of NAFDAC. There are also the Chemical Import Control (CIC) and Chemical Monitoring (CM) Units of the Narcotics and Controlled Substance (NCS) Directorate, responsible for control of agrochemicals and pesticides.
PESTICIDES REGISTRATION AND REGULATION

- NAFDAC has put in place a functional database which contains all registered regulated products in Nigeria, available at [www.nafdacregistry.net](http://www.nafdacregistry.net) As at August 2008, Nigeria had registered a total number of 354 pesticides and agrochemicals.
NAFDAC collaborates with stakeholders in the public and private sectors, e.g. Federal Ministry of Environment, Federal Ministry of Agriculture, Federal Ministry of Health and CropLife Nigeria (Plant Science Industry), in its efforts to reflect current developments in Agrochemical and Pesticides Regulation and Control in the appropriate legislations and guidelines.
PESTICIDES REGISTRATION AND REGULATION cont’d

- Nigeria strongly supports regional efforts to harmonize the registration of pesticides, e.g. participation in the Regulatory Officers meeting in Cotonou in 2000, the WHO 6th Global collaboration for development of pesticide for public health (GCDPP) meeting in Geneva, regional workshop for harmonization of pesticides regulations in the ECOWAS region, Permanent Inter-States Committee for Drought Control in the Sahel (CILLS) and West African Economic and Monetary Union (UEMOA) held on 26th April 2007 in Lome.
PESTICIDES REGISTRATION AND REGULATION cont’d

- Conclusions and recommendations of these regional collaborations clearly indicate the need for harmonization of registration and regulation of pesticides at regional levels.
- Nigeria supports the ECOWAS regional structure and procedures for pesticide registration through the West Africa Committee on Pesticide Registration (WACPR) already ratified by the ECOWAS Council of Ministers.
MAXIMUM PERMISSIBLE RESIDUE LEVELS

• Pesticide residues in Nigeria are analysed and monitored in an IAEA accredited dedicated laboratory at the NAFDAC central laboratory complex, Oshodi, Lagos. Current methods used for detection include the Quecher’s method, GC-ECD and GC-MS. We plan to purchase the new GC-MS-MS.

• The country does not set MRLs, but adopts the Codex limits and when necessary that of the importing country.
DOSSIER REQUIREMENTS FOR PESTICIDES REGISTRATION

• The Nigerian dossier requirement for pesticides registration has 10 sections. Sections 8 and 9 are relevant to the subject of this workshop. Section 8 deals with information on toxicology of the formulated product and ecotoxicology. Section 9 addresses information on bioefficacy trials.
DOSSIER REQUIREMENTS FOR PESTICIDES REGISTRATION cont’d

- The stated objectives of these sections are determinations of:
  - Bioefficacy
  - Phyto-toxicity
  - Residue levels in treated crops
- Information required in section 9 of the dossier include trial site, trial scientist/investigator, trial product and standard as well as timing/frequency of application.
DOSSIER REQUIREMENTS FOR PESTICIDES REGISTRATION cont’d

- It also includes trial results and residues at different levels i.e.
  - Metabolism in Plants
  - Residue decay curves in treated crops
  - Residue determination method
  - Pre-harvest intervals
  - Maximum Residue Level
  - Acceptable Daily Intake
## CURRENT CONCERNS

- Challenges we face in Nigeria include:
  - Pesticide mismanagement and handling by unlicensed retailers
  - Smuggling across our porous land borders, on every side of Nigeria
  - Non implementation of the harmonized registration documents and study protocols
  - Activities of other stakeholders including the Ministry of Agriculture and the Ministry of Environment where there are still conflicts of roles
  - Rejection of products known to exceed MRLs by importing countries e.g. Copper Sulphate in Cocoa. Cocoa is perhaps the most important export crop which is affected by MRL as set by the EU. Cocoa export is presently 350-400MT/per annum.
WAY FORWARD/RECOMMENDATION

1. Immediate adoption and implementation of harmonized guidelines for the registration of pesticides, harmonized protocol for Bioefficacy studies and harmonized residue study protocol. At the 60th ordinary session of the council of states of ECOWAS, held on May 17-18, 2008, a regulation on pesticide registration common to all ECOWAS member states was established and the West African Committee for Pesticide Registration (WACPR). Details of the implementation of the new committee as it affects registration of Crop Protection Products in Nigeria is being expected from ECOWAS.
Way Forward/Recommendation cont’d

2. On the issue of registration and withdrawal of registration certificates
NAFDAC seeks to work with current initiatives on MRLs. An example is the EU
legislation on pesticide residue (regulation 149/2008/EEC) which came into effect on
1st September 2008. This has been an important regulation affecting products
being exported from Nigeria. This has led to a review of the registration status of
products preserved with Endosulphan and Copper Sulphate e.g. Cocoa.
WAY FORWARD/RECOMMENDATION

cont’d

3. Effective Post Marketing Surveillance of registered pesticides is a huge task that we need assistance on capacity building.

4. Enlightenment of farmers on Good Agricultural Practices (GAP), NAFDAC and Ministry of Agriculture need assistance to build capacity.
### Glossary of Terms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>MRL:</td>
<td>Maximum Residue Limit</td>
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<tr>
<td>MDA:</td>
<td>Ministry, Department, Agency</td>
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<tr>
<td>FMOH:</td>
<td>Federal Ministry of Health</td>
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<tr>
<td>DG:</td>
<td>Director General</td>
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<tr>
<td>F&amp;A:</td>
<td>Finance and Accounts Directorate</td>
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<tr>
<td>A&amp;HR:</td>
<td>Administration and Human Resources</td>
</tr>
<tr>
<td>EID:</td>
<td>Establishment Inspection Directorate</td>
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<tr>
<td>LS:</td>
<td>Laboratory Services</td>
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<tr>
<td>PID:</td>
<td>Ports Inspection Directorate</td>
</tr>
<tr>
<td>R&amp;R:</td>
<td>Registration and Regulation Affairs</td>
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**Glossary of Terms cont’d**

- **NCS:** Narcotics and Controlled Substances
- **PRS:** Planning, Research and Statistics
- **ENF:** Enforcement Directorate
- **VDP:** Veterinary Drugs and Pesticides Division
- **CIC:** Chemical Import Control Division
- **CM:** Chemical Monitoring Division
- **HM:** Herbal Medicines Division
- **MD:** Medical Devices Division
- **DR:** Drug Registration Division
- **RA:** Regulatory Affairs Division
Glossary of Terms cont’d

- **FR:** Food Registration Division
- **DA:** Drug Abuse Division
- **NC:** Narcotics Control Division
- **LSZ:** Lagos Special Zone
- **SSZ:** South South Zone
- **SEZ:** South East Zone
- **SWZ:** South West Zone
- **ASZ:** Aba Special Zone
- **OSZ:** Onitsha Special Zone
- **NCZ:** North Central Zone
### Glossary of Terms cont’d

- **NEZ:** North East Zone  
- **NWZ:** North West Zone  
- **KSZ:** Kano Special Zone  
- **WHO:** World Health Organization  
- **GCDPP:** Global Collaboration for Development of Pesticide for Public health  
- **CILLS:** Permanent Inter-States Committee for Drought Control in the Sahel  
- **UEMOA:** West African Economic and Monetary Union
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<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tbody>
<tr>
<td>ECOWAS</td>
<td>Economic Community of West African States</td>
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<tr>
<td>WACPR</td>
<td>West Africa Committee on Pesticide Registration</td>
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<tr>
<td>GC-ECD</td>
<td>Gas Chromatography - Electron Capture Detector</td>
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<tr>
<td>GC-MS</td>
<td>Gas Chromatography – Mass Spectrometry</td>
</tr>
<tr>
<td>IAEA</td>
<td>International Atomic Energy Agency</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>GAP</td>
<td>Good Agricultural Practice</td>
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THANK YOU