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COMBRO II PROJECT

Quality & Yield

Supporting smallholder farmers' decisions on top quality commercial products



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“we have decided to focus attention on the regulatory environment work messages from our partners AATF and the relevant National Regulatory Agencies..”

Dear Reader,

A word from the project leader

First let me start by noting that this issue of our newsletter is significantly delayed. We are working to ensure that you will receive the 12th issue on time. This last quarter has seen a great mix of project implementation as well as monitoring work going on. Importantly we have just gone through the project internal audit which gave us a chance to closely reflect on our work by objectives and milestones including the budget situation. In the coming weeks, we will be able to share some of the insights coming out of this exercise including the action plan. The internal audit, allowed us to make a thorough assessment of the level and quality of implementation across objectives versus available budget.

In this issue, we have decided to focus attention on the regulatory environment work messages from our partners AATF and the relevant National Regulatory Agencies. Excerpts from our policy briefs series have been included in this issue to highlight where we are in Kenya, Nigeria, and Ghana. In subsequent issues, we will also highlight the regulatory messages for Tanzania, Ethiopia and Uganda. It is worth mentioning that the project plans to put more emphasis on quality control of bio-fertilizers and bio-pesticides in the remaining time-period so as to complete it on budget.

The regulatory environment remains defined by common hurdles including multiple focal points, capacity limitations as well as awareness. However it is important to point out that the work of COMPROII project under objective 3 has yielded some good results in moving countries along the regulatory environment in Ghana, Kenya, Nigeria, and Tanzania. In the last quarter of 2015, the project will work closely with partners in Ethiopia and Uganda with the intention to yield similar results, and therefore ensure that none of the project country is left behind.

In the 12th issue that will be circulated shortly, the focus will be again on quality control specifically on laboratory and field testing of the products and the contrast analysis of the regulatory frameworks. Conversely, in the 13th issue that will be published before the end of this calendar year, the project will share with you the progress of the dissemination of high quality bio-fertilizers and the status of the awareness creation about this technologies. Allow me to conclude these remarks with a reminder that your feedback is very important to us to improve the quality and the content of the newsletter. Equally important, the project strongly invites all the project partners including graduate students to input into the newsletter issues to increase the visibility of your contribution to the project success. Needless to say that the project expects the newsletter readers to adopt or promote the high quality products recommended by COMPRO-II in their respective areas to increase crop yields and consequently contribute to the adoption of such technologies for food security and income generation. Looking forward to your constructive feedback.

On a sad note, as you may be aware and will read it in the following tribute, COMPRO-II has lost one member of the Steering Advisory Committee early this year (i.e. Prof Seth Danso); may his soul rest in peace.

Dr. Cargele Masso
COMPROII Project Leader

COMROII Team pays tribute to Prof. Seth Danso

COMPROII team will always cherish the insightful wisdom and scientific guidance that Prof. Seth Danso epitomized. The quality of input received by post graduate students on COMPROII project. His advice to PhD students for instance was summed in the statement “Ask yourself, what new knowledge is my research adding to in this area? If you do not have a clear answer to this, do not start your research”. Prof. Danso’s oversight role as a member of the Steering Advisory Committee of the COMPROII project, will be deeply missed.



Born 1944, Prof. Danso Akyea Kofi Seth was educated in Ghana where he obtained B.Sc. in agriculture from the University of Ghana in 1970, M.Sc. in 1972 and PhD in 1974. Formerly he was a research fellow in Colombia, Post-doctoral research fellow in Nigeria, Lecturer in Ghana, Second Officer FAO/IAEA then First Officer IAEA Austria, professor, Head of Department, Vice Dean and Director ECOLAB at University of Ghana. His research interests include: Plant nutrition, ecology and biodiversity, biotechnology, soil organic matter, land degradation, biological nitrogen fixation and use of bio-fertilizers in sustainable agriculture. He was a member of the International Society of Soil Science, Soil Science Society of America, American Society of Agronomy, Crop Science Society of America, American Society of microbiology, and Soil Science Society of Ghana. He was Chair of Geo-Environmental Science, Gold award and Fellow of Ghana Academy of Arts and Sciences and Ford Foundation Scholar, Fellow African Academy of sciences He has 120 Peer-reviewed publications.

Legal Frameworks limiting our capacity for regulation in Kenya

By: Kabole M , Tarus, D., Masso, C., Watiti, J.

Multiple Agencies in Regulation

Regulation of fertilizers in Kenya involves multiple agencies. The Fertilizers and Animal Foodstuffs Act, Cap 345, under The Ministry of Agriculture, Livestock and Fisheries (MOALF) State Department of Livestock was passed to regulate the importation, manufacture and sale of agricultural fertilizers and animal foodstuffs and substances of animal origin intended for the manufacture of such fertilizers and foodstuffs, and to provide for matters incidental to and connected with the foregoing. In this act, the term “fertilizer” is defined as any substance or mixture of substances which is intended or offered for improving or maintaining the growth of plants or the productivity of the soil, but does not include manure, compost, wood ash, gypsum or refuse when sold in its original condition and under the same name, nor does it include organic fertilizers, other than lime. This law has had its deficiencies in ensuring effective regulation of the fertiliser claimed products including biofertilisers.

Growing Interest

The use of biofertilisers has gained popularity as shown by the import requests received by Kenya Plant Health Inspectorate Service (KEPHIS), working under the Kenya Standing Technical Committee on Imports and Exports (KSTCIE). KEPHIS, as a secretariat to KSTCIE, facilitates the process of risk assessment before introduction of live organisms. These include live biological controls, bio- fertilizers, bio-stimulants, organic fertilizers, their products and other regulated articles. Once risk assessment is complete, products approved for introduction are referred to relevant research institutions for efficacy or registration. KSTCIE constitutes public, private agencies of which the public agencies include; Pest Control Products Board, Kenya Agriculture and Livestock Research Organisation, Kenya Wildlife Service(KWS), National Environmental Management Organisation (NEMA), National Museums of Kenya (NMK), Directorate of Veterinary Service-State Department of Agriculture, universities among others. This role is efficiently executed by KEPHIS mainly because of their mandate under the Plant Protection Act, CAP 324, but not without challenges.

What are the main challenges?

The legal mandate to regulate biofertilisers among the other mentioned products is not available. As a result, a streamlined structure to ensure consistency in regulating these products in matters quality and market place monitoring is not available. Because of this, KEPHIS has managed to invest a section of their resources towards regulation of these products but still has constraints especially with having a laboratory for testing the products` identity, quality, safety and efficacy.

Inadequate penalties to defaulters of the set interim measures have caused regulation of these products become a problem resulting in fake, substandard products in the market. This is despite the work done by Kenya Bureau of Standards in conjunction with KSTCIE

to develop and review the Biofertiliser and Organic fertilizer standards. These spell out the general requirements for a biofertiliser (labeling, packaging) as well as the specifications of different organism based biofertilisers.

Efforts by the Ministry of Agriculture, Livestock and Fisheries (MOALF) have been made with the development of the draft biofertiliser and soil conditioners bill remaining in draft since 2006.

Current Progress

Several measures to alleviate some of these challenges were proposed, and action taken by KEPHIS under KSTCIE. These among other, include the development of bio-fertilizer and related products interim measures which would be presented as registration guidelines. The registration guidelines stipulate the processes involved in importing, risk assessment, registering, distributing and monitoring of bio-fertilizer products. It however is silent on the penalties for non compliance since it is not legally supported.

Standard operating procedures (SOPS) for sampling, laboratory, greenhouse and field safety, quality and safety testing of bio-fertilizers have also been developed under the same support.

It is however important to realise that development of an interim structure would only last for a while. It is necessary to work in haste to develop a policy that would encompass all soil fertility products. A special emphasis to biofertilisers should be made as the products are sensitive to handle and varied in their effectiveness and safety.

Way Forward

With the efforts by KSTCIE to implement the guidelines to improve regulation of bio-fertilisers, it is important for the relevant arms of government to join hands and develop fertiliser related policy(ies). This should be advised by baseline study of the current challenges and the existing interim measure experiences so as to come up with a comprehensive policy that promotes good practices. Interventions by COMPRO II to support harmonisation of these regulations and policies across its partner countries (Kenya, Uganda, Tanzania, Ethiopia, Nigeria and Ghana) have also been felt.

In the meantime, awareness will need to be enhanced on the registration guidelines so that all stakeholders support its implementation. Equally important, accreditation/ approval of laboratories for quality, safety and efficacy testing of biofertilisers should be enhanced to support provision of safe, efficacious products to the Kenyan Market.

The role of NAFDAC

The Federal government of Nigeria established National Agency for Food and Drug Administration and Control (NAFDAC) by Decree 15 of 1993 as amended by Decree 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria 2004 with the mandate to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (known as Regulated Products).



NAFDAC Headquarters in the Federal Capital Territory, ABUJA, Nigeria.

The mission is to safeguard public health by ensuring that only the right quality food, drugs and other regulated products are manufactured, imported, exported, distributed, advertised, sold and used in Nigeria. NAFDAC's core values are to:

- Ensure availability of efficacious, safe and good quality NAFDAC regulated products.
- Maintain reference laboratories of international standard.
- Promote an effective and efficient well motivated and disciplined workforce.

In line with the mandate and vision of the Agency, the management obtained approval to restructure the Agency into Thirteen (13) from the previous Nine (9) Directorates to improve efficiency which brought about the establishment of Veterinary Medicine and Allied Product Directorate.

In carrying out our mandate, the Agency shall have the following functions amongst others:

1. Conduct appropriate test and ensure compliance with standard specification.
2. Compile standard specifications and guidelines for production, importation, exportation, distribution and sale of regulated products.
3. Undertake appropriate investigation into the production premises and raw materials for regulated products.
4. Pronounce on the quality and safety of Regulated Products after appropriate analysis.
5. Control exportation and issue quality certification of Regulated Products intended for export purposes.
6. Undertake registration of regulated products.
7. Monitor advertisement of regulated products.

8. Establish and maintain relevant laboratories or other institutions in strategic areas of Nigeria.
9. Undertake and co-ordinate research programmes on the Storage, Adulteration Distribution and Rational use of regulated products.

The establishment of the Veterinary Medicine and Allied Products Directorate is to:-

- Provide science based advice on the quality, safety and efficacy of agricultural inputs.
- Develop and promote standards, regulations and guidelines in consultation with other Government Agencies and Stakeholders on pesticides and agricultural inputs.
- Monitor the distribution, sale and use of pesticides and agricultural inputs.
- Supervise the conduct of field trials for pesticides and agricultural inputs and evaluate the data.
- Inspect and monitor production premises for pesticides and agricultural inputs

The essence of regulation and control is to ensure that only quality regulated products that are safe, efficacious and wholesome reach the market and ultimately the consuming public. This is achieved through various processes of the Agency including product registration, inspection of production facilities, laboratory evaluation, post marketing surveillance and enforcement activities.



Source: A retailer in an agrochemical outlet in the Northern Region of Nigeria

In 2012, AATF invited NAFDAC along with representatives from other Regulatory authority in Africa to a Bio-pesticide registration guidance document draft review Workshop and in line with international practice, a committee was set up to review the pesticide registration regulation.

Recommendation of the said committee was to review the current pesticide regulation to capture Bio-pesticide and Bio-fertilizer. In 2012, facilitation came from COMPRO II Project on the establishment and institutionalization of Regulatory framework on Bio-pesticide and Bio-fertilizer in NAFDAC. A fallout of which brought about the development of the under listed draft regulations:-

- Bio-pesticide Registration Regulation
- Bio-pesticide Labeling Regulation
- Bio-pesticide Advertisement Regulation
- Bio-fertilizer Registration Regulation
- Bio-fertilizer Labeling Regulation
- Bio-fertilizer Advertisement Regulation
- Fertilizer Registration Regulation
- Fertilizer Labeling Regulation
- Fertilizer Advertisement Regulation

The process of establishment and Institutionalization of regulatory framework will follow a process as stated below:-

Constitution of Committee to draft document ⇒ Review by Standard Regulation Committee
⇒ Review by Stakeholders ⇒ Review by Legal ⇒ Governing council for ratification ⇒
Ministry of Justice to gazette.

CURRENT EFFORTS

- Grassroots sensitization and advocacy visits to decision makers and opinion leaders as well as organize consultative meetings and workshops with different stakeholders across Nigeria.
- Develop and review documents on Quality control for Bio-pesticide and Bio-fertilizer.
- Development and Verification of Standard Operating Procedure (SOP) for Quality Control of (Rhizobium, Trichoderma, Arbuscular Mycorrhizal, Pseudomonas, Azotobacter, Bacillus spp and Azospirillum) Bio-fertilizer.
- Development of draft regulations for Bio-pesticide and Bio-fertilizer for Registration, Labeling and Advertisement.
- Development and implementation of registration guidelines for indigenous and foreign Bio-pesticide and Bio-fertilizer.
- Training of inspectors and technicians from NAFDAC and IAR on Bio-pesticide and Bio-fertilizer inspection and sampling.
- Identify independent laboratories collaboration in other geopolitical zones of the country.

WAY FORWARD

- Conduct awareness campaigns for stakeholders and dealers of Bio-pesticide and Bio-fertilizer on the new regulations and guidelines to ensure only registered, quality and safe products are in the market
- Sustain awareness campaign for the general public on the safe handling, storage and the implication of buying unregistered Bio-pesticide and Bio-fertilizer across the six geo-political zones of the country.
- Bio-pesticide and Bio-fertilizer Regulations final gazette by the ministry of Justice.
- Sustain capacity building for inspectors and technicians on the handling and sampling of Bio-pesticide and Bio-fertilizer.
- Establishment of a designated laboratory for quality control of Bio-pesticide and Bio-fertilizer in NAFDAC.

Bio-fertilizer Regulation in Ghana: Capacity Limitations to Effective Enforcement

Authors: Mensah A., Tarus D., Masso C., Watiti J.

The main objective of involving the private sector in the Ghanaian input supply system under the Economic Recovery Program in the late 1980's was seen as an alternative to injecting efficiency in the supply chain. This as was envisaged, would lead to improved productivity and profitability of the crop sub-sector. Timely and efficient delivery of quality farm inputs such as fertilizers and pesticides at affordable and competitive prices. The liberalization however brought with it challenges of maintaining quality and problem of short weight of fertilizers. At present, fertilizer regulation is governed under the Plants and Fertilizer Act, 2010 (ACT 803) which was enacted on the 4th of June, 2010 by Parliament. The Act 803 comprises of three (3) technical parts;

1. Plant Protection
2. Seeds
3. Fertilizer Control

For regulatory purposes, Part III of the Act 803 makes provisions for the following among others;

- Establishment of the Pesticide and Fertilizer Regulatory Division.
- Registration of importers, manufacturers and distributors.
- Fertilizer inspection and analysis.
- Development of fertilizer regulations
- Fertilizer register (database on fertilizer in Ghana)

Fertilizer regulations have been adopted by parliament and have now been published, likewise to the fertilizer Inspection and Fertilizer Analysis Manuals. With the assistance of COMPRO II Project, the registration guidelines for bio-fertilizers have been developed, approved, and are now being finalized for publication, distribution and implemented by PPRSD.

Current Progress

As mentioned above, the frameworks for the regulation of biofertilizers in Ghana are in place. This includes the policy, law, registration guidelines for biofertilizers, standard operating procedures and Plant Protection and Regulatory Service Directorate (PPRSD) to enforce these provisions. The registration guidelines lays down the processes involved in registering imported/locally manufactured biofertilizers, risk assessment, distributing and monitoring of those products.

Standard operating procedures (SOPS) for sampling, laboratory, greenhouse and field safety, quality and safety testing of biofertilizers have also been developed under the same support, and are now being validated by Kwame Nkrumah University of Science and Technology.

It is however important to realise that current policy on fertilizer does not adequately cover critical aspects of biofertilizers, and therefore the need to develop a policy that would adequately place special emphasis on biofertilizers.

Current Challenges

There is inadequacy of testing equipment for biofertilizers both at the reference lab and at PPRSD headquarters. Therefore there is need to seek financial resources to enable these labs obtain all the necessary equipment needed to carry out biofertilizer tests as recommended. Lack of proper equipment compromises the quality of results and subsequently the integrity of the entire system.

There is insufficient personal at PPRSD with the requisite skills and expertise on biofertilizers. Thus, the need to build internal capacity, through training of current staff (by attaching them to experienced bio-fertilizer experts/researchers), and hiring new ones with the required skills.

There is needed to increase financial allocations to PPRSD to enable it carry out efficient market surveillance and quality control for biofertilizers. These resources will be used in purchasing testing equipment, facilitating staff movement and carrying out lab/efficacy tests.

At the moment, the approved reference lab is only one. This lab is mostly overwhelmed with work thereby causing delays in obtaining results. This greatly impacts on the registration timelines. Furthermore, the distance between PPRSD and the reference lab (KNUST) is significantly prohibitive, thereby creating practical inconvenience in operations (transporting samples and making visits to the lab).

Way Forward

With the efforts by PPRSD to implement the registration guidelines for biofertilizers, it is important that the relevant arms of government should join hands in developing bio-fertilizer policies. This should be advised by a baseline study of the current challenges and the existing measure experiences so as to come up with a comprehensive policy that promotes good practices. Interventions by COMPRO II to support harmonisation of these regulations and policies across its partner countries are also highly appreciated.

It is important to create awareness/sensitization of stakeholders (farmers, industry players, researchers, policy makers and inspectors/enforcers) on these regulatory advances, particularly on the registration guidelines in order to obtain maximum cooperation and support in their implementation. In this regards, there is need for PPRSD to carry out a biofertilizer market survey to determine the number of biofertilizers in the market both registered and unregistered and the results of which can be used in the stakeholder sensitization, and also, appropriate legal action taken to ensure that only registered/ approved products are in the market.

GHANA

PPRSD in conjunction with Ghana bureau of standards to facilitate accreditation/ approval of laboratories for quality, safety and efficacy testing of biofertilisers should be enhanced to support provision of safe, efficacious products to the Ghanaian Market. As such, more research institutions and labs should be identified, audited, their capacity built and accredited appropriately to enable them provide efficient and reliable biofertilizer testing and validation. There is a need to work with the accredited/appointed labs in contractual terms to minimize delays and unnecessary delays in obtaining results.

PPRSD to create space (plots) for demonstrations and trialling of approved biofertilizers, and involve farmers in order to building their capacity towards responsible and sustainable use of biofertilizers. The involvement of farmers in demonstrations will increase their know-how on biofertilizers matters including their impact on the soils/environment (bio-remediation and sustainability). There is need for PPRSD to increase the capacity for its staff to be able to effectively deal with bio-fertilizer enforcement in the market. This can be achieved through training and hiring of qualified biofertilizer analysts and agronomists.

'Quality & Yield' is the newsletter of the COMPRO II project. It is a quarterly publication that highlights key activities and experiences of the project. 'Quality & Yield' is produced and Designed by CABI. We welcome short and medium length articles by project partners. Send your comments and articles to C.Masso@cgiar.org and J.Watiti@cabi.org
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