

AGRO-CHEMICALS

Overhaul of regulations called for

Uttam Gupta

According to a statement by the Union Agriculture Minister in Parliament, nearly 10-30 per cent of crop production — valued at about Rs 1,50,000 crore a year — is lost due to the ravages of the pests, weeds and disease. Reducing this loss would contribute to increasing agricultural productivity.

A variety of crop protection products (pesticides) are available to deal with these problems. However, the number of pesticide molecules registered in India is only 194 as against 755 in the US, 600 in Europe, 495 in Pakistan and 432 in Vietnam.

Our farmers can have access to a wider choice of crop protection (CP) solutions. However, for this to happen, first, we need to generate awareness about their potential benefits. Second, we need a regulatory system that enables their early introduction. Third, delivery of quality products to farmers must be ensured.

REGULATION

As regards second, under the Indian regulatory system, an applicant seeking market approval for a new CP product has to conduct studies locally spanning 3-4 years to test its safety and efficacy. This involves investment running into millions of rupees.

Besides, global studies are done over a much longer time horizon of 8-10 years in areas such as chemistry, toxicology, bio-efficacy, manufacturing processes, etc, involving investment of close to \$200 million.

This too is a must for getting registration. The Registration Committee takes 18-24 months in completing scrutiny of dossiers/applications and another 18-24 months is taken by Ministry of Health in setting the MRL (maximum residue limits) before the approval is granted.

'ME-TOO' TOO EASY

There is a provision under the Insecticides Act (1968) that permits "me-too" registration by subsequent applicants — without having to submit any data — immediately after grant of first registration! This leaves hardly any incentive for R&D companies to bring new molecules to Indian shores.

For nearly 200 CP molecules registered in India, there are a whop-



Farmers need to have access to a wider choice of crop protection solutions. — H. Satish

ping around 20,000 registrations in the "me-too" category. Such registrants are not aware of the safety profiles of reverse engineered products and their use can often lead to loss of crop and even damage to environment.

If, "me-too" applicants can get registration virtually for a song (registration fee that is nominal), getting a manufacturing licence is not difficult either. Under the Insecticides Act (1968), States are authorised to issue the manufacturing licence. The licences are given indiscriminately and the State licensing officer does not even conduct basic checks. At present, of the 1,250 manufacturing units in the country, nearly 1,200 units do not have bare minimum manufacturing facilities and infrastructure!

Under Rule 28 of Insecticide Rules (1971), the State pesticides inspector is required to inspect every manufacturing unit, under his jurisdiction, at least twice in a year. However, during the last three years (2004-05 to 2006-07), no such inspection was done!

Proper sampling and analysis are key to ensuring quality CP products. In this regard, information gathered under RTI (right to information) shows that 84 per cent of samples

were collected only from 50 companies of repute! From the remaining 1,200, only 16 per cent samples were taken.

The infrastructure for testing and analysis of samples is in a shambles. None of the laboratories at the State and regional level (there are 50 in all) has got accreditation status. To cap it, inefficiency and corruption rules the roost. In plain words, this means their test reports cannot be trusted.

PROBLEMS GALORE

The gaping holes in the Insecticides Act (1968) on the one hand and weak enforcement of the law by the State authorities on the other provides a fertile ground for proliferation of the sales of spurious and sub-standard CP products.

In a total domestic sale of about Rs 4,000 crore, spurious and sub-standard CP products account for about Rs 1,000 crore. The problem is recognised at the highest level in the State echelons and the Centre, yet, there is little action on the ground to combat it!

The society's psyche is such that it does not normally differentiate between a genuine manufacturer and a dubious/fly-by-night operator!

This not only plays havoc with the

fortunes of the farmers and the nation, it also brings a bad name to the CP industry.

To summarise, the current CP scene in India looks as under:

Awareness about what CP technology can do to Indian Agriculture by way of increasing crop yield is missing. A meagre 20 per cent of cultivated area is under CP umbrella;

Farmer's choice of new CP molecules is restricted.

For molecules already in use, they are unable to tap full potential due to improper/excessive use (thanks to lack of stewardship by 'me-too' suppliers);

R&D-based companies have no incentive to bring new products primarily due to lack of data protection. For the same reason, there is no incentive for setting up R&D facilities in India;

Sale of spurious/sub-standard products is rampant even as enforcement authorities have an indifferent attitude towards quality assurance;

The dubious/fly-by-night operators bring bad name to the entire CP industry, which faces the wrath of NGOs. This vitiates the atmosphere and hampers scientific use of CP products.

The following steps need to be implemented to get the best from CP

technology for the benefit of farmers and Indian agriculture:

WHAT CAN BE DONE

The Government and industry should launch an awareness campaign — in public/private partnership mode — about the benefits of CP technology.

The extension machinery of the States needs to be resurrected to tell farmers about safe and judicious use of CP products.

To enable early launch of new CP molecules, data submitted by original registrant must be protected by not allowing 'me-too' registration for a fixed period starting from date of registration in India.

This period of exclusivity will not only enable the first registrant to recover cost incurred on the expensive studies done for seeking registration but also do stewardship to enable farmers get optimum results.

The system of scrutinising applications needs to be streamlined to reduce delays in granting approvals.

All existing units must be checked for existence of basic manufacturing facilities and quality control and licences cancelled in delinquent cases. (Following a similar exercise in the pharmaceutical sector, nearly 2,000 units not having the required facilities were wound up.) No new licenses should be granted unless these basics are in place.

The sampling/testing/analysis infrastructure needs to be overhauled within a specified time frame. The sampling should cover all units with special focus on dubious operators. The law enforcers viz., pesticides inspectors, sample analyst etc should be held accountable for what they do.

The Customs and State enforcement authorities must collaborate to rein in unauthorised import of CP products from unapproved sources which will help substantially in controlling sale of spurious/sub-standard products.

The above issues need to be addressed in the Pesticides Management Bill (PMB) 2008, which, as per reports, is expected to be taken up for consideration by Parliament shortly.

(The author is Resident Director, CropLife India, New Delhi. The views expressed are personal.)