

## **Editorial**

### **Crop Group based MRLs of Pesticides : A Science-based Approach to Regularize their Off-label Use**

The pest pressure in the form of insects, diseases, or weeds in a minor crop or a minor use of pesticides in a major crop is often overlooked or virtually disregarded amidst the scientific and regulatory fraternity. However, the “minor use” has been recognised as a national as well as international challenge as far as the trade is concerned. It has warranted the need for a scientific dialogue on minor crops, which is highly crucial considering India’s export of many such crops (e.g., spices, cumin, coriander, curry leaf, cashew, etc.) to various countries around the world and to ensure biosafety. Therefore, an urgent deliberation on policy implementation for crop group-based label expansion on minor crops is very much required.

Commercial agriculture has gained popularity in recent years, catering to domestic consumption as well as exports to other countries. Shifts from traditionally grown, less remunerative crops to more remunerative crops have occurred post green revolution, due to the favourable government policies, viz., liberalisation of trade and providing market access to agricultural produce; market infrastructure development; higher profitability; resilience and stability in production; and certain price-related supports. The availability of varied Agro climates has also led to crop diversification and the consequent evolution of regional niches. For example, there are several crops on which a particular plant protection chemical finds its use. The overall market potential of pesticides on such crops, however, does not justify the expenses for bio-efficacy, and residue data generation. Thus, the fixation of MRLs of any pesticide on such high-value, low-volume crops like spices and speciality crops that are cultivated in relatively smaller geographies does not provide adequate returns to the industry. Such crops, in the Indian context, are generally referred to as the commodities that require very low agri-inputs for cultivation. Nonetheless, their nutritional, aromatic and culinary attributes besides, dietary values and importance in international trade, and the national economy of a country through its export. Out of 339 pesticides registered in India till today, their labelled use is restricted to less than 80 out of 554 crops (<15%) grown in the country. The remaining 474 crops that are deemed to be minor crops, including most of the horticultural, plantation, oilseeds, pulses etc. experience use of pesticides that are not registered. The absence of label claims for spices, fruits, leafy vegetables, etc. leave farmers with fewer or limited pest management options. In addition, they also bear the risk of rejection in international trade on account of off-label use of the pesticide and the absence of country specific MRLs.

In general, once the pesticides get registered for use on major high-volume crops, their off-label use on minor/speciality crops having similar insect/ disease/ weed profiles becomes a common practice. The farmers in India remain mostly ignorant and unaware about the policies and significance of label claims. They are liable to use any pesticides that are available in the country, irrespective of their registration for use on specific crops, major or minor, so long they provide efficient control of pests and diseases. Use of such pesticides without having MRL and registration on a crop constitute an off-label use. The off-label use of pesticides is not only unique to India but occurs worldwide. The industry finds it uneconomical to register the pesticides on minor crops where their sale does not provide an edge over the cost involved in its registration. Off-label use of pesticides for crop protection is thus a necessary evil world over. With this ill-practice, it is the consumers and the nation at large, who suffer huge losses in terms of compromised biosafety and trade restrictions by the importing countries. In addition, it not only tarnishes the brand value of a reputed industry but also the image of the country causing huge losses to the national exchequer. To promote and encourage applicants (chemical manufacturers/ registrants) to register pesticides for minor uses, a number of industrialized countries incentivise addition of minor uses to the product labels. These include provision for data protection, reduced data requirements, data waivers, fast-track approvals, international data acceptance or registrations, etc.

The presence of pests and residues of unregistered pesticides invited 36 alerts from EU and 41 import refusals from USA on Fresh fruits and vegetables during the three years period ending 2016. Besides, the increased use of SPS based MRL standards by the developed countries has led to reduced market access of Indian products.

The residues of the commonly non-approved pesticides included acephate, acetamiprid, profenofos, methamidophos, imidacloprid, triazophos, cypermethrin, thiamethoxam, fenpropathrin, metalaxyl etc.

Crop grouping and extrapolation of stringent MRLs of pesticides developed on a representative crop across all the members in the group is a rational approach for the harmonization of concerns arising from off-label use on minor crops. This is also in compliance with the risk assessment and biosafety of consumers and backed by scientific logic and reasonings. Crop groups and development of group MRLs for a group of crops is practised as minor use programme in USA, Canada, EU and developed countries for more than 35-40 years. The criteria for legitimisation of off-label use of pesticides through extrapolation of MRL of pesticides on a crop which is representative of all other crops within the same group/sub-groups is also supported by Codex Committee on Pesticide Residues (CCPR).

The minor crops, which could be important with respect to domestic consumption and international trade, do not get due attention as there is no commercial interest in the investments involved (return on investment for the industry). Each label claim for a crop protection chemical costs industry, approximately INR 10–10.5 million (per crop), coupled with the substantial time taken to register these products. Keeping these factors in view, some of the prudent approaches could be to identify minor crops and a well-defined minor use programme within the ambit of Indian regulatory framework, followed by mechanisms to incentivize and facilitate registrations for minor uses. Besides, crops having lower national MRLs could be considered for harmonisation with Codex MRLs, if set at a higher level to minimise the trade restrictions. In Amrit Kaal, India envisages to become one of the top economies of the world and aspires to increase its trade of horticultural commodities from <1% to at least 10% to qualify as one of the third largest economies of the world. This is possible only through generation of Group MRL's (presently MRLs are generated individually for each crop) based upon extrapolation of MRL on the crop identified as the representative of a group of crops.

The crop(s) that represent the group as a whole in the worst-case scenario are those that can hold onto and conserve the highest possible levels of pesticide residues, which are then submitted to a risk assessment for biosafety. Cucumber, for instance, is the representative crop of the cucurbit vegetable family, which includes all other vegetables that are peeled and cooked before consumption thus, subjecting the pesticide residue to degradation. If, for example, a SOP is to be developed for the management of powdery mildew and the member happens to be bitter melon, then the SOP for bio-efficacy needs to be tested on bitter melon; concurrently, the pesticide residue following the same SOP needs to be determined on the representative crop cucurbit that is frequently consumed raw without peeling. It is imperative that if the pesticide residue on cucumber remains within the limits of toxicity, then its MRL can be safely extrapolated to every member of the group. As per the Codex classification 554 crops are clustered under 29 groups and 75 sub-groups with representative crops for each group and subgroup. Regulatory provisions require MRL on each crop which becomes unaffordable for the industries since the cost of registration does not commensurate with volume of its sale on minor/specialty crops. Thus, group MRL of a pesticide developed based upon its residues on representative crop and their adoption for all the members of the group/subgroup can provide a suitable approach for legitimising the off-label use of pesticides. The data generated for the minor use of pesticides, however, needs adequate incentivization in the interest of safeguarding our trade of agricultural commodities, national prosperity and human and environmental biosafety.

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