**F.No. 26-14/2024-CIR-I**
भारत सरकार/**Government of India**
कृषि एवं किसान कल्याण मंत्रालय/**Ministry of Agriculture & Farmers Welfare**
कृषि एवं किसान कल्याण विभाग/**Department of Agriculture & Farmers Welfare**
वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय
**DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE**
केंद्रीय कीटनाशी बोर्ड ए वम पंजीकरण समिति
**Central Insecticides Board and Registration Committee**
एन. एच. 4, फरीदाबाद (हरियाणा)-121001
**N.H. IV, FARIDABAD (HARYANA)-121001**
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Dated: June, 2024

## PUBLIC NOTICE

**Subject: Minor changes in the formulation-regarding.**

Reference is invited to the decision taken by the RC at agenda item no. 3.1 in its 456th RC meeting held on 30.05.2024 under the heading "Minor change in the formulation", which is reproduced as under:

"The Registration Committee (RC) from time to time has been deliberating on the issues pertaining to Minor Change in formulations and such issues have been attended on case-to case basis due to the wide spectrum of technicalities possible within the scope of Minor changes.
While deliberating the agenda, RC explicitly focused and deliberated on the need o f improving the quality of existing formulations with respect to its safety and efficacy as a matter of prime concern.

In view of the need for a comprehensive framework on the Minor Change in the formulations RC deliberated on various aspects related to it and decided to invite comments on the guidance document as Annexed at 3.1.1. A Public Notice may be issued for the same inviting comments giving 60 days' time to the stake holders."

2. In view of above decision, all stakeholders are requested to submit their comments to Secretary, Central Insecticides Board & Registration Committee through email at cibsecy@nic.in within 60 days from the date of issue of this public notice.

3. This has the approval of Secretary (CIB&RC).

Encl.: As above.

**Signed by Govind Ram**
**Date: 22-06-2024 10:16:04**
(Govind Ram)
Senior Administrative Officer

Copy to:
1. All Registered Pesticide Associations.
2. Chairman, Registration Committee.
3. PPS to Additional Commissioner (PP), DA&FW, Krishi Bhawan, New Delhi.

4. PPS to PPA, Dte. Of PPQ&S, NH-IV, Faridabad.
5. PPS to Secretary (CIB&RC), NH-IV, Faridabad.
6. IT Cell, HQ, Faridabad for uploading the same on the website.

**Annexure-3.1.1.**

From time to time some of the pertinent issues with respect to minor change in formulations have been identified by the RC, but not limited to regarding the usage of: hazardous solvents, adjuvants, PFOA and PFOA related compounds, dyes, fragrance, carcinogenic chemicals, chemicals under Annexure A (Elimination) of Stockholm convention; shape and/or change of shape; alternative safe replacements in place of any chemicals of concern, dyes, perfumes, antifoaming agents, and/or adjuvants etc.; and any more issues to be identified on further detailed review.

RC is appreciative of the fact that minor changes in formulations can arise due to a number of factors both regulatory and non-regulatory, such as inclusion/exclusion of chemicals in restricted/banned/concern list of regulatory authorities, reports indicating concern/adverse classifications by national/international research institutions of repute, studies indicating new/previously unknown effects with respect to a known chemical, availability or non-availability of chemicals for manufacturing, import/export restrictions, international treaties and agreements and such.

RC is also appreciative of the fact that the ambit of minor changes in formulations shall be applicable only for existing registrants for their own already registered products, and data of the same registrant shall be used for applications claiming minor change. Considering the wide spectrum of technicalities possible within the scope of minor changes focussed on either improving the quality of existing formulations with respect to its safety and efficacy or bringing a variation in the existing formulation with less or no safety concern a guidance document with indicative best practices for consideration of minor change is placed.

**Guidance document with indicative best practices for consideration of minor change**

The following notes should be considered as to the reasons but not limited to these only, which are not favourable to the cause of minor change in formulations:

- a change would alter the product's acute toxicity category or physical/chemical characteristics such that label modifications become necessary; or

- a change would affect the product's efficacy such that supporting data become necessary.

The following notes should be considered as to the reasons but not limited to these only, which are favorable to the cause of minor change in formulations:

- no problems with respect to packaging, registered/approved uses, doses etc. are expected due to the physical, chemical and technical characteristics;

- efficacy is not impaired in an unacceptable way;

- phytotoxicity is not increased so as to cause problems in comparison to the old formulation;

- there are no objections to the new formulation from a toxicological point of view;

- there are no objections to the new formulation from an ecotoxicological point of view, including the protection of honeybees if applicable, and

- restrictions and directions for use do not change.

(1) Addition, deletion, or substitution of one or more colorants in a formulation:

- the total percentage of changed colorant will be reviewed on case to case basis;
- the colorant has the appropriate exemption from the requirement of a tolerance if the product is registered for food use; and
- the product is not intended for use as a seed treatment or rodenticide.

(2) Addition, deletion, or substitution of one or more fragrances in a formulation:

- the total percentage of changed, added or deleted fragrance will be reviewed on case to case basis;
- information on the composition of the fragrance has been provided to the Secretariat by the registrant;
- the fragrance has been determined to be acceptable for such use by the Secretariat at the proposed concentration or the component(s) of the fragrance;
- the fragrance components are exempt from the requirement of a tolerance if the product is registered for food use; and
- the product is not intended for use in baits or repellents.

(3) Addition, deletion, or substitution/reduction/enhancement in percentage of one or more inert ingredients (other than fragrances or dyes) in a formulation:

- the concentration of active ingredient does not change;
- the change does not invalidate any product specific data submitted in support of the initial registration that causes additional data to be required;
- the identity of proposed substitute inert ingredient is known by the registrant;
- the inert ingredient is exempt from the requirement of a tolerance if the product is registered for food use;
- any change involves inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant, binder, antifoaming agent, preservative etc.); and
- the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.