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17th April 2023

To

Dr. Rajiv Bahl

Director General

Indian Council of Medical Research (ICMR)

V. Ramalinga Swami Bhawan

Ansari Nagar

New Delhi – 110 029

Email: secy-dg@icmr.gov.in

Sir,

Sub: Your enquiry committee report dated 18th April 2019 to probe into the scientific misconduct complaint made by Crop Care Federation of India (CCFI).

Ref: 1. Research article titled *“Correlation of Pesticide Exposure from Dietary Intake and Bio-monitoring: The different sex and socio-economic study”* published by Dr. Sukesh Narayan Sinha *et al* in July 2018 issue of the Journal Ecotoxicology and Environmental Safety.

2. W.P.(C) 1380/2019 filed by Crop Care Federation of India and Delhi High Court final order dated 11th April 2023.

3. The copy of the Enquiry Committee Report dated 18th April 2019.



We must state at the outset that we are deeply concerned and disappointed with the Enquiry Committee Report which failed to studiously investigate into the complaint of serious research misconduct made by us concerning the published article under reference.

In all the government funded scientific research, the rigour, transparency and unaccountability are important. They help ensure that the research result is valid and reliable. The published study suffers from poor statistical design, incredible research data and measurement data errors.

This Enquiry Committee was formed in response to a complaint by Crop Care Federation of India (CCFI) in the year 2018. The Committee submitted their report on 18th April 2019. However, when we sought the same under Right to Information Act on 28th February 2019, you refused to give the same stating *"information cannot be disclosed as per Section 8.1 (d) of RTI Act, 2005"*.

When an Enquiry Committee is formed by a government funded institute upon a complaint from the public including NGO's, the report of the Committee should be immediately shared with the complainant – in this case CCFI – in accordance with the principles of natural justice.

Can you explain why you didn't do this for nearly four years since 2018? Why did you keep the Enquiry Committee Report in your own records from 2019 – 2023? **Why did you wait for the complainant (CCFI) to seek a court directive in 2023 to force you to share the so-called Enquiry Committee Report? We seek your explanation.**

ICMR's policy concerning research misconduct enquiries states *"Research misconduct, if suspected, needs to be investigated. An institution must investigate all allegations of misconduct as present or future participants' lives may be endangered if facts are not presented accurately. Such investigations must be done in a timely, fair, and transparent manner and the results should be made available in the public domain"*.



National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR, 2017 states *“the research should be conducted in a fair, honest, impartial, and transparent manner to guarantee accountability. Related records, data and notes should be retained for the required period for possible external scrutiny/audit.”*

Why did you ignore these important policy guidelines? **We seek your explanation.**

The Enquiry Committee Report claims that *“this research work is funded by Indian Council of Medical Research after due scrutiny by subject experts, New Delhi, and approved by the institutional scientific advisory committee. The methodology employed in the research work is validated and has sound statistical design. The inferences drawn are based on validated scientific protocols. The enquiry committee, found no evidence of any scientific misconduct, fabricated or falsification of data in the published work”.*

We have no hesitation in asserting that the Enquiry Committee Report is an eye wash aimed at keeping under the carpet the serious scientific misconduct brought out to your notice by us. The enquiry committee appointed by the public funded bodies can't be reduced to a mere formality. It must be meaningful.

We cite below certain fundamental flaws in the study published that your enquiry committee simply overlooked, probably under your covert instructions in order to keep the serious mistakes under the carpet.



Example 1: The mean values of pesticide residues were much higher than the range. (See table 5 in pg. no. 175 of the published article)

Age group	Sex	Organo Phosphorous Pesticide Metabolites	Range ($\mu\text{-mol L}^{-1}$)	Mean ($\mu\text{-mol L}^{-1}$)	Our Comments
6 -10	M	DMs	0.2-1.3	1.96	Mean is higher than upper limit of range. This is fundamentally flawed.
6-10	F	DMs	0.2-1.3	1.61	Mean is higher than upper limit of range. This is fundamentally flawed.
11-15	F	DMs	0.3-2.8	2.8	Mean is equal to upper limit of range. This is fundamentally flawed.
11-15	F	Des	2.6-3.1	2.3	Mean is less than lower limit of range. This is fundamentally flawed.
11-15	F	Des	2.6-3.1	1.4	Median is less than lower limit of range. This is fundamentally flawed.

How can the mean and median values be lower or higher than the range? Such egregious errors and fundamental flaws show the rot in the raw data (laboratory data). We accuse you of fabricating/falsifying the laboratory data. How could your Enquiry Committee conclude that *“the enquiry committee, found no evidence of any scientific misconduct, fabricated or falsification of data in the published work?”* **How did they fail to notice the glaring flaws? Please explain**

Example 2: Major error in grouping.

The data in the table 4 (see page 175) carries two age groups of children

6 - 15 years

11 - 15 years



There is a fundamental error in this method of grouping. Where were the children age of 11, 12, 13, 14 and 15 years listed? In both the groups? This would change the sample size (N) unrealistically.

Yet you audaciously claim that the *“methodology employed in the research work is validated and has sound statistical design.”*

Can this be considered as sound statistical design? Who validated this at the ICMR?

Frankly, you will not find such fundamental statistical design flaws even in the project works of high school students. You must seriously introspect and improve your scientific capabilities. Remember, public money and resources can't be wasted on shoddy science at the ICMR.

Example 3: Non clarity on the sample size.

There is no clarity at all about the sample size (N) in the study. Is it 377 as narrated in the text and shown in the table 3? Or is it 197 as shown in the table 2 in page 173? Or is it 196/184 as shown in table 4 page 175? The sample size varies from one page to another. **The authors need to explain the inconsistency and disclose the correct sample size.**

Example 4: About injecting the samples into the instrument

In the published article the authors claim that *“samples (10 ml) were injected into the instrument using a Shimadzu auto sampler fitted with Hamilton 100 ml syringe”* (see section 2.5, page 172). This is not possible in any Ultra-Fast Liquid Chromatography (UFLC). Therefore, this is a false claim. **Did members of your Enquiry Committee attempt to check this?**



About your claim of intellectual property rights on raw data:

In pg. no. 2, point 5 of the Enquiry Committee Report states *“The published data is in public domain and no raw data or original chromatographs shall be provided to any private firm(s) by the institution as it is the intellectual property of the institution....”*

This is wrong. It is surprising that ICMR does not know the basics about the laws governing the IPR.

Please note the raw data and factual information cannot be protected under copy right law. While a compilation of data is copyrightable the underlying raw data is not. In this case, the raw data includes chromatograms too.

According to National Data Sharing and Accessibility Policy – 2012 of Government of India, **Data means** *a representation of information, numerical compilations and observations, documents, facts, maps, images, charts, tables and figures, concepts in digital and/or analogue form.*

National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, ICMR, 2017 in para 3.3.2 states that *“Once a researcher has published the results of an experiment, it is generally expected that all the information about that experiment, including the final data, should be freely available for other researchers to check and use. Data should be shared or placed in a public domain in a de identified/anonymized form, unless required otherwise, for which applicable permissions/re-consent should be sought unless obtained beforehand.”*

Why did you ignore this important policy guideline? Please explain.

About the responses given by the accused scientists

In pg. no. 3 of the Enquiry Committee Report it is stated that *“The enquiry committee after going through the response provided by Dr. S. N. Sinha,*



Scientist F, and Dr. J. Padmaja, Scientist F, unanimously concluded that there is no evidence of scientific misconduct or deceit, doctored, fabricated or falsified data in the published work”.

However, your Enquiry Committee Report does not carry a copy of their alleged responses provided to the Committee. Why? This is a serious omission. Remember, all the responses provided by the scientists and others who deposed before the Committee must form an integral part of the Enquiry Committee Report.

We hereby ask you to give us a copy of their statements.

Supreme Court’s observations relevant to this case

While upholding the dismissal of a bank manager for misappropriation of money, our Supreme Court observed on 5th Jan 2021 (SLP(C) No(s). 32067-32068 of 2018) that devotion, integrity, and honesty would remain sine quo non for those handling money in the bank. The same applies to scientists who misappropriate laboratory data through fabrication and falsification. Scientific misconduct is akin to corruption in the society. There should be zero tolerance.

About Honorable Delhi High Court order

Delhi High Court in their order dated 11th April 2023, expressly stated that *“The petitioner (CCFI) would be at liberty to challenge the report given by the respondents (ICMR) in accordance with law, if so necessitated”.*

Our demands:

1. Give us all the chromatograms and laboratory raw data of this impugned study.
2. Withdraw the published article and issue public apology for having misused public funds for a fabricated study.



3. Take strong disciplinary action against all those who committed the scientific fraud and those who helped suppressing the fraud.

In the year 2014, two CSIR scientists at IMTECH, Chandigarh were dismissed from their services for having indulged in data fabrication in a published study. There is no reason why the ICMR should not take similar action against all the scientists involved in this fabricated study.

We urge you to respond/act within next 10 days.

We are hopeful you not to force us to go to the HC once again to make you respect the scientific integrity.

We are sending this communication without prejudice to our other rights.

Thanking You,

Nirmala Pathrawal
Executive Director

Copy to : Dr. Mrs. Hemalatha, Director, National Institute of Nutrition, Tarnaka, Hyderabad- 500007. Email: dirnin_hyd@yahoo.co.in