



# INDIAN DRUG MANUFACTURERS' ASSOCIATION

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## INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

April 16, 2015

**Shri Shashi Shekhar, IAS,**

Special Secretary to the Government of India &  
Chairman - Central Pollution Control Board,  
East Arjun Nagar,  
Delhi - 110 032

Respected sir,

**Sub: DIRECTIONS UNDER SECTION 18(1)(B) OF THE WATER (PREVENTION & CONTROL OF POLLUTION) ACT, 1974 AND THE AIR (PREVENTION & CONTROL OF POLLUTION) ACT, 1981 IN THE MATTER OF POLLUTION CONTROL IN 17 CATEGORY OF HIGHLY POLLUTING INDUSTRIES, CETPS AND COMMON HAZARDOUS WASTE & BIOMEDICAL WASTE INCINERATORS REGARDING SELF-MONITORING OF COMPLIANCE - CPCB letter no. B-29016/04/06/pci-1/ to 5401, dated February 05, 2014**

**Ref.: Your regional office letter No. 105/PCB/RO-II/RCP/MDK/2015-6417 dated 16-03-2015-reg.**

We write with reference to the above subject matter and directions being issued by you. We are in complete agreement with the submission made by the Bulk Drug Manufacturers' Association (BDMA) dated 31-3-2015.

We also refer to our submission dated 25 February 2015 to the Hon'ble Minister State (Independent Charge) for Environment, Forest & Climate Change (copy enclosed) requesting for proactive action from the Government to mitigate the high effluent treatment cost in Bulk Drug production of SMEs. As requested in our submission we reiterate our appeal that there is an urgent need to revisit and revise the environmental laws as they are very stringent and almost in line with those applicable to the large Chemical Industries. We recommend that the laws should be modified taking into account the smaller tonnage of APIs as compared to the huge volumes of Chemical Industry and also the extent to which the API pollutes the environment.

Our further concern is the Environment Ministry putting restriction on:

a. Increasing the production

b. Adding the product

c. Restricting the manufacturer to manufacture their existing product on job work basis with other companies who are also having effluent treatment facility & the permission from the State Pollution Board.

We emphasise that the pollution authorities should be more concerned with the total pollution coming out of a given facility and see whether it is within the prescribed limit, not so much about what is being manufactured. Because in most cases such "job work" products are made on a temporary basis and should be differentiated from the regular products a facility manufactures and has approval for. To keep operations viable, one has to make sure a plant is continuously occupied on a daily basis and it is just not feasible (for the job work giver and performer) if every time, one has to wait till the pollution authorities give the green signal. The pollution authorities need to work with the industry to come up with a sort of agreement where a particular facility can declare that they have added the product but the total effluent from their system is not going beyond the limit assigned to them.

We further submit to you the following:

1. We appreciate the intention of self-monitoring, but submit to you that it is not possible for each and every industry including small and medium scale units to provide the online monitoring systems for air emissions and liquid effluents discharged.
2. Each online monitoring instrument costs around Rs 40 lakhs to 50 lacs, which works out to around Rs. 80 lakhs to 100 lacs (for Gas and liquid emissions) for a unit with single process emissions stack.
3. In a chemical process industry technically each processing block will have independent stacks based on the nature of gaseous emissions and safety considerations. That means a single process block can have multiple stacks. It is an elaborate exercise to provide online monitoring for each stack involving substantial investment. It may be also noted that in a factory premises there can be multiple processing blocks.
4. Instead of directing all industries to install online instruments, it would be more reasonable to direct big complexes like petrochemicals, refineries, fertilizer units, smelters, cement plants and units with large turnover to provide the same. In addition common incinerators and CETPs may also be directed to provide online instruments.

5. As regards the other industries, they should be allowed to continue with the present compliance of monitoring once in a month through an independent agency.

6. As regards, the Pharmaceutical industry there are no gaseous emission parameters to be monitored as per the CPCB circular No. B-29016/04/06/PCI-1/5401 dated February 05, 2014. In case of the liquid effluents most of the industries send effluents to CETPs and the samples are collected regularly and analyzed to see that they comply to the CETP inlet standards. This data is also used to work out the treatment charges to be paid by the industry.

7. The effluents analysis data is regularly submitted to concerned State Pollution Control Boards. As this is almost a continuous self monitoring the Pharma, Bulk drug units and other industries sending effluents to CETPs may be exempted from the online monitoring of discharged effluents.

8. It may be also noted that the discharge point of effluents of industries is CETP outlet for all industries which send their effluents to CETP.

It is also pertinent to bring to your notice the document released by CPCB dated 07-11-2014 titled "Guidelines for Online continuous monitoring system for Effluents". Please refer to item 3.9 Limitations of Online analysers "(Pages 10,11) which is reproduced below:

#### "3.9 Limitations of On-Line Analysers

In spite of the inherent advantages of on-line sensors/monitors, their wide application is still limited due to the following reasons:

- On-line monitoring suffers from more problems than laboratory-based methods because to date, the majority of on-line monitoring technologies developed are direct adaptations of traditional, laboratory-based analytical methods which were not originally designed for field applications. Instead they are required to operate in extreme and variable measurement environments. Consequently, these methods require frequent calibration and maintenance.
- In addition the analysers are often influenced from cross responses due to matrix variations between the standards and samples analysed, as the measurement conditions are not controlled.
- Changes in sample matrix affect on-line analysers making it difficult to obtain continuous, reliable measurement in the field.
- There are also significant economic and logistic costs associated with maintaining remote equipment, as it is difficult for operators to detect problems such as sensor fouling.

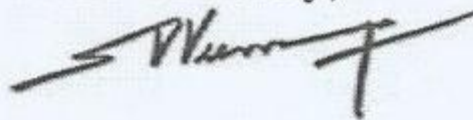
- The problems associated with conventional on-line analysers are due to the fact that univariate linear calibration models derived from Gauss's theory of least squares are employed to determine unknown concentrations. Therefore, the samples and standards must be measured with equal care, under the same measurement conditions, to obtain reproducible and accurate results. Since such consistent measurement conditions are rarely present in the field this affects the operating conditions required for reliable performance and causes a high degree of unreliability in the results from online instrumentation.
- Due to this reason the users/regulatory authorities need to frequently validate their online results with laboratory based methods.
- The cost associated with maintenance of these conventional instruments has also greatly limited their wide spread application.

NOTE: The industry must take full preview of available technologies while product selection and above referred limitations have to be curtailed."

We also here by submit to you, that, as per the CPCB document page 26, for Chromium and Arsenic measurements, Experience in Indian Conditions is not available.

Based on the above submissions, we hereby request you to exempt the industry from installation of online monitoring facilities till specific clarifications are given by CPCB with respect to the differences within their own published guidelines and directions issued by them. For the same we had already made a representation to the Central Pollution Control Board.

Yours sincerely,



S. V. Veerramani  
President

Encl: as above

