ಗ್ರಾಮ್ಸ್ / Grams : "ಜಲರಕ್ಷ" "Jalaraksha"
ಫ್ಯಾಕ್ಸ್ / Fax : 080-25586231
ಈಮೇಲ್ / E-mail : kspcb@kar.nic.in

ದೂ: 25581383, 25589112, 25586520
ವೆಬ್‌ಸೈಟ್ / Website : http://kspcb.kar.nic.in

ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ
Karnataka State Pollution Control Board

"ಪರಿಸರ ಭವನ"
4 ಮತ್ತು 5ನೇ ಅಂತಸ್ತು, ನಂ. 49, ಚರ್ಚ್ ಸ್ಟ್ರೀಟ್,
ಬೆಂಗಳೂರು – 560 001, ಕರ್ನಾಟಕ, ಭಾರತ

"Parisara Bhavana"
4th & 5th Floor, # 49, Church Street,
Bangalore - 560 001, Karnataka, INDIA

No: KSPCB/50/CC/2008-09/ 926 Date:02- 07-08.

:MEMORANDUM:

3 JUL 2008

Sub: Guidelines for Biotech Companies and R & D in Bio- Technology.

Ref: 1. Discussions held during the 329th Technical Advisory Committee (TAC) meeting on 13-09-07.
2. This Office letter dtd: 20/12/07 to Prof. Smt. Shaila, Department of Biology & Cell Biology, Indian Institute of Science (IISc), Bangalore & Dr.Chanakya, Indian Institute of Science (IISc), Bangalore.
3. Note dated: 09-06-2008 from the Member Convener, Technical Advisory Committee.

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The Karnataka State Pollution Control Board is receiving several applications seeking 'Consent for Establishment & Expansion' (CFE) and 'Consent for Operation (CFO)' pertaining to Bio-technology projects. This has necessitated formulating guidelines, keeping in view the way such projects affect the surrounding environment after establishing/ operating in the proposed location. This would help 'Technical Advisory Committee' (TAC) to evaluate the proposals submitted by the Bio-technology projects.

As per the decision of the TAC in its 329th meeting held on 19-09-2007, Prof Smt Shaila, Department of Biology & Cell Biology, Indian Institute of Science (IISc), Bangalore & Dr.Chanakya, Indian Institute of Science (IISc), Bangalore were requested vide letter cited under ref(2) to formulate a draft guidelines. Accordingly, they had come up with the draft guidelines, for establishing Biotech companies, diagnostic, clinical research and contract R & D in Biotech and contract diagnostics/ validation related areas. The same was discussed by TAC members and other senior officers of the Board.

In view of the above, the guidelines for Biotech companies are herewith enclosed as **Annexure** and the same may be adopted with respect to the Biotech companies with immediate effect and until further orders.

MEMBER SECRETARY.

Encls: As above

Copy submitted to:

The Secretary, Department of Environment and Ecology for information

Copy to:

1. C.E.O for information.
2. SEO-2, SEO-3, SEO-4 for information.
3. EO- 17-Cat. Section, EO-CFE (Non EIA), EO-CFE (Construction Projects), EO-HWM, EO-Corporate Cell, EO-Help Desk, EO-CFO(SEO-2), EO-CFO (SEO-4), EO-T.G Halli, EO-Complaint Cell for information

4. The Chief Scientific Officer, Central Environmental Lab, KSPCB for information.
5. DEO- HWM section, DEO-CFO(SEO-2 section), DEO-Corporate Cell, DEO-CFO (SEO-4 section), DEO-CFE (Construction Projects) for information.
6. The Regional Officer, Regional Offices: Bangalore City-1, Bangalore City-2, Bangalore City-3, Bangalore North-1, Bangalore North-2, Bangalore South-1, Bangalore South-2, Bangalore East-1, Bangalore East-2, Peenya, Bangalore West, Mysore, Mandya, Chamarajnagar, Tumkur, Chitradurga, Davangere, Kolar, Shimoga, Dharwad, Belgaum, Bagalkot, Bijapur, Bellary, Raichur, Koppal, Bidar, Gulbarga, Udupi, Mangalore, Hassan Chikkmagalur, Karwar
7. The Chief Administrative Officer for information.
8. The Chief Accounts Officer for information.
9. The Legal Officer for information.
10. Master file.
11. Case file.
12. File No. 453.

ANNEXURE

Guidelines for Biotech companies, diagnostic, clinical research and contract R&D in biotech and contract diagnostics/validation related areas.

1. CFE application needs to have a copy of the GEAC clearance. Any company using microbiological or biological products or inputs needs to either obtain a certificate of acceptance from GEAC or certificate stating that the industrial/ commercial activity requested does not come under the purview of/is exempt from GEAC. A copy of the original application to GEAC and a copy of the response from GEAC to be enclosed in CFE. This is done to ensure that a competent body has judged that Rule for GM, etc. 1989 is properly applied.

2. Both the national level GEAC and the state level clearance needs to be obtained and documents pertaining to this need to be attached.

3. Siting of these companies /institutions including large diagnostics laboratories needs to be taken up .in 'stand alone' buildings without potential interference and proximity (vertical and horizontal) to other human intense activities such as those found in eateries, banks, shopping complexes and other personnel intensive businesses and industries etc.

   Notes- As most of these organizations can and have the potential to change their raw material inputs and nature and quantity of outputs and wastes, as well as this category is listed as red, siting practices should be adhered to.

4. Nature and list of activities /work flow to be taken up needs to be specified with a floor plan showing work /activity flow, material flow and wastes generation points (including wastewater) and potential fugitive emissions, measures taken to counter them.

   Notes- One should not distinguish or favour these organizations and be strict with industries alone. The same application of law needs to be done for this category also – This will facilitate assessment of environmental risks.

5. Separate collection of wastewater from biotech work – from sinks, wash basins and their collection, transport and disposal. This should have an estimate of waste and wastewater generated on a daily basis and a plan for the above including a written consent from a certified biological waste treatment facility. There is a need for total absence of wash basins, bath rooms and toilets connected to conventional sewage lines in the work area. It should contain the plan as well as a list of efforts taken up to ensure that wastes generated at these work spots are not mixed up with sewage /solid wastes in any way.

   Albeit their wastes being very small in quantity, it is difficult and improper to provide blanket permission for sewage based disposal even if contents are sterilized. The appropriate class of waste management will fall between biomedical and GM wastes. It may be good to apply the latter.

6. Biohazard accidents /spillage containment and management plan for each floor or activity such that accidents and spillages can be contained, managed, rendered safe and the hazard removed and detoxified if necessary. Plan should have a clear isolation zone and a list of personnel in-charge and how to access them in the event of such a hazard.

   Materials used may have long half lives or may be potentially dangerous even if denatured. Can be infective and cause potential hazard to laboratory personnel as well as to those exposed. This precaution is required because these organizations will not disclose or limit the source of biological material they are handling or obtain non-GM certification. This step is taken from an environmental perspective.

7. For contract research and diagnostics laboratories, the place of origin, the mode of shipment in, the final end-user and mode of return and shipment needs to be specified. It is better to know the flow and then determine potential risks to environment and humanity.

8. Biotech companies need to list all bio- hazardous materials that will be stocked and how its inventory will be regulated.

9. Local bio-safety committee needs to be formed and its clearance along with mention of committee composition (with signed documents) needs to be submitted.
   Organizations/ set ups that do not want to divulge the nature or materials used in research require an alternative and legally bound body that will certify qualities that determine environmental safety of the overall experimentation as well as risks. The IRB, IAEC, IBSC of the system [with full quorum] needs to clear the proposal and certify that they are aware and are qualified to say that there are no environmental risks from the research /diagnostic being tried. At a latter date these bodies may fill an appropriate form every time they review the ongoing project and send it to KSPCB. Because all BM/GM research will go through these above review bodies (that are legal) these bodies may certify the above and the overall process will be quick.

10. If we consider these Biotech activities as industrial activities, then they should produce conversion certificates for the land from residential to industrial purposes from competent authorities. This avoids many hassles of giving permissions in residential and human intense areas.

    The industries must prepare On-site and Offsite emergency plans as per provisions of the chemical emergency rules and get it approved by Dept. of Factories and Boilers and attach the approval with the application clearly indicating the activities, bio-safety levels and management plan. This is required to handle emergencies and should not be left to the fire department. This also tells us the risks faced and preparedness to fight it.

    Details of micro-biological or biological products stocked and used, their characterization in terms of type of product, quantity, virulence status, from where it is procured, how it is procured, how it is transported, in what containers, temperatures followed, type of the container, how long it is going to be observed,

mode of final disposal of the contents and container, agency consulted and contracted for disposal, details of handlers at different stages, their safety, their emergency measures, etc. These are normally asked for all chemicals and inputs shown by typical chemical industries. In the event of a hazard, the causes may be identified and risks quickly assessed to allow appropriate action.

11. Details of potential dangers expected in case of accidental contamination, extent of problem which may arise (magnitude), seriousness, how long it may persist, how the company is gong to tackle such situations i.e., preparedness to handle and to contain. Examples of such installations elsewhere by the company in other parts of the World and the measures taken there are to be cited.

12. Diagramatic process or work flow chart.

13. Details of personal protective equipments, safety measures including how the airborne contaminants are taken care within the work environment, awareness among various categories of persons deployed, procedures for periodical in-house monitoring for levels of contamination, safety certification indicating it is free from contamination including medical certification of the workers employed, procedures for maintaining log-book, etc

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Abbreviations:

CFE - Consent For Establishment.
GEAC - Genetic Engineering Approval Committee.
IRB - Institutional Review Board
IAEC - Institutional Animal Ethics Committee.
IBSC - Institutional Bio-Safety Committee.
BM - Biologically Modified.
GM - Genetically Modified.