



## ACFI Member Concerns

### Industry Issues of Concern PESTICIDES

#### I. **Non-Manufacturing Performance of Technical Indigenous Manufacture Registrants u/s 9 of the Insecticides Act 1968**

We wish to bring to your kind attention the non-manufacturing performance by registrants u/s 9 for Technical Indigenous Manufacture (TIM).

**ACFI Note prepared on some Pesticide Industry Issues of Concern to be taken up with DoC&PC, MoC&F, GOI.**

The recent decisions of the Registration Committee taken in its 371<sup>st</sup> & 375<sup>th</sup> RC meetings leading to proposed restrictions on the import quantity of pesticides imported in the country and recommended cancellation of Technical Import (TI) registrations of a company wherein the respective company is a dual registrant u/s 9 of the Act and is in possession of CRs i.e. TI & TIM.

We wish to draw your attention towards the fact that wherein there is an attempt to impose restrictions on import of pesticides against the mere notion that TIM registrant's actual produce or manufacture the product in the country. This needs to be

re-visited for the fact that there are pesticides which are registered for TIM u/s 9 of the Act., are actually not producing the same despite valid registrations.

To name a few molecules wherein the above statements have relevance, they are:

1. Carbendazim
2. Chlorothalonil
3. Ethepon
4. Gibberellic Acid
5. Paraquat dichloride

These pesticides are believed to be 100 percent imported and fulfilling the demands of the Indian Agricultural Community in absence of any manufacturing taking place in the country.

Therefore, we request the Dept. of Chemicals & Petrochemicals to kindly re-look into the above mentioned fact and consider grant of pending applications for the above mentioned and similar products for registration pending under TI versus TIM and allow the registrations of such pesticides as specified and amended from time to time for Technical import.

#### II. **Gazette Notification GSR 480 (E) dated 12 May 2017 and published on 17 May 2017**

We are putting below our concerns/objections to point no. 5 of the draft gazette notification referred to above along with advantages of open import in line with prevailing statutory and regulatory guidelines/Insecticides Act for your consideration, which states as:

*“(5) For any import of registered insecticides, permission for import of specified quantity, during a quarter or year shall be obtained in addition to the certificate of registration.”*

#### Concerns/Objections against Quota System:-

1. As given in Part XIII of The Constitution of India pertaining to Trade, Commerce and Intercourse within the Territory of India freedom of trade, commerce and intercourse throughout the territory of India shall be free subject to other provisions of this part. Parliament by law impose such restrictions on the freedom of trade, commerce or intercourse between one State and another or within any part of the territory as may be required in the public interest. There is no public interest involved in starting quota system for import of pesticides and also this will be in contravention of International agreements and treaties that India has signed. Therefore, the proposed quota system will be ultra-vires of The Constitution of India and also the International agreements and treaties.

2. A quota is a direct restriction on the total quantity of a product that may be imported during a specified period. Quotas restrict total supply which can lead to escalation of prices of the product due to limited availability in the event of limited supplies of indigenously manufactured product.

3. Limited supplies of the product have the potential of more availability of spurious products in the market leading to their adverse impact on the flora, fauna and abiotic factors.

4. Proposed amendment will promote RED-TAPISM and will lead to LICENSE RAJ with the potential of delays in issuance of license for import of the pesticide ultimately affecting timely supplies to farmers.

The use of pesticides are climate sensitive wherein the use of pesticides may be required. Further, pesticide use is seasonal & crop specific and dependent on the pest development scenario. Therefore, timely availability of technical grade pesticides or MUPs may be affected as the same is required further to be formulated in the country. Logistics too will be impacted and needs to be taken into account.

Sudden pest infestation may result in as a National Epidemic Pest Scenario and will require sudden and immediate rise in demand of a particular pesticide/s required for effective control measures.

5. A quota system has the potential to promote malpractices among some officials charged with the allocation of import licenses.

6. Competition increases number of players in the market leading to inbuilt mechanism in correction of pricing of a product. A quota system is much more restrictive as it restricts competition leading to abnormal profits for the companies leading to detrimental effects on Indian economy and undue increase in prices of pesticide products for the farmers and agriculture commodities for the consumers.

7. Fixing an Import Quota may lead to straining diplomatic relations with countries from where pesticides are being imported.

8. This may further impact the sourcing of raw materials required for manufacturing pesticides in the country as most of the raw materials are imported.

As a resultant of restrictions imposed on finished product imports may lead to hike in costs involved for imports of raw materials and there availability meant for indigenous manufacture in the country, if the importing countries also desire to restrict exports of their raw materials to India. The consequences could prove detrimental and worth deliberating.

Whereas, advantages of Open Import in line with prevailing statutory and regulatory guidelines/Insecticides Act:-

1. DAC&FW has the mandate to look after the quality, pricing and availability of a product for the welfare of the farmer.
2. Open import encourages competition from abroad which leads to domestic manufacturers to improve their efficiencies to deal with the competition and also corrects the prices of the products.
3. Import prevents growth of domestic monopolies and consumers' exploitation due to competition from abroad.
4. Import introduces new products and improves farmer's welfare. Import has also made a tremendous contribution to the development of less developed countries like India in the nineteenth and twentieth centuries.
5. The life cycle of new chemistry's in India has shown that the market for recently off patent molecules typically starts out small and does not provide sufficient market size to justify large capital expenditure in production capacity. The importers traditionally have facilitated the availability of products from additional sources and broadened the market base in the country. Whilst, promoting the product through stewardship as a result of extensive fieldwork, eventually creating an attractive market where companies recognize an opportunity to invest in production capacity. Without this crucial interim step by importers many molecules would remain small niche molecules dominated only by the Multi Nationals or the 1<sup>st</sup> time registrants of the product in the country.
6. Import can help countries to access best technologies and products available in any part of the world.
7. While other developed economies move away from production of hazardous chemicals due to environmental concerns, India is trying to promote indigenous manufacture of such products.
8. Competitive pricing of pesticides due to imports of the product from any part of the world will help in realizing the dream of Hon'ble Prime Minister of India towards Doubling the Farmers' Income by the year 2020.

We request you to kindly consider our concerns as stated above while finalizing the said draft gazette notification.

**III. Clarification sought on 375RC MoM / Ref.: MoM 375RC Agenda No.3.1 ( Annexure-I S.No. 1 read with S.No. 2 )**

We appreciate the recent DAC&FW directive as per s.no 1 ( Annexure I - 375RC MoM ) and the Registration Committee's ( RC ) decision to encourage the GOI's initiative regarding the "Make in India" campaign. We welcome the RC's decision to withdraw the TI versus TIM guidelines, presumably u/s 9(3).

However, we do have a few concerns on the fate of the existing applications pending at the Sect. CIB&RC and are under scrutiny or may be awaiting initial scrutiny. Further, pendency period runs across 1-3 yrs in some cases within the initial scrutiny or post deficiency response.

We believe that, had the applications presently pending with the Sect. CIB&RC been scrutinized and approved within the stipulated time period as stated u/s 9 (3) of the Act, 1968, the scenario would have been different, and probably our concerns too on the recent RC decision.

This comes from the fact that our Members had complied diligently to the existing guidelines at that point of time, generated requisite data and submitted applications for registration accordingly. The fact that applications are applied after the relevant time period required for data generation ( i.e. 2-3 years ) remains a known fact. However, not usually considered by the Sect. CIB&RC as part of the total time required to apply for an application for registration of a pesticide.

At this point of time, we are not mentioning of our concern and fate of the ongoing data generation for molecules which were scheduled for submission under the recent erstwhile guidelines TI versus TM u/s 9(3) and the financial implications the applicants may suffer as a result of the recent 375RC MoM.

ACFI comments regarding Annexure I:Improvement/Harmonization of the Guidelines of Registration Committee keeping in view the “Make in India” Initiative of the Govt. of India.

S.No.	Directives from DAC&FW vide their letter No. 13035/64/2016-PP-I dated 05th April, 2017 and email dated 18.5.2017	RC decision for implementation
1	<p>No new application of Registration for Technical Import of already Registered Molecules under technical indigenous manufacturing category shall be entertained except Technical import from new source.</p> <p><i>ACFI: welcomes the decision of DAC&amp;FW, with an understanding that <u>the decision shall not impact the scrutiny &amp; approval of existing applications pending at the Regulatory Authority.</u> The decision will be applicable from the date of publishing of the MoM of the 375RC.</i></p>	<p>In view of the directive from DAC &amp; FW, the guidelines for <b>TI v/s TIM category</b> are withdrawn with immediate effect and no application under the categories shall be accepted in the CIB&amp;RC henceforth.</p> <p><i>ACFI: welcomes the decision of the RC, with an understanding that the decision shall not impact the scrutiny &amp; approval of existing applications pending at the Regulatory Authority. The decision will be applicable from the date of publishing of the MoM of the 375RC.</i></p> <p><i>In case, the RC decides not to process the pending applications further, reasonable opportunity &amp; guidance be provided on the fate of such applications.</i></p> <p>Further, RC decided that in line with the DAC &amp; FW directive, the guidelines for TI vs FIM* should also be withdrawn. However, in view of the fact that the matter is pending in the Hon'ble High Court of Gujarat, <b>an affidavit may be filed in the Hon'ble High Court of Gujarat with the request for withdrawal of the TI v/s FIM* category guidelines</b> with the concurrence of DAC &amp; FW.</p> <p>(FIM*: Formulation Indigenous Manufacture with out registering technical)</p> <p><i>ACFI: welcomes the decision of the RC, with an understanding that <u>the decision shall not impact the scrutiny &amp; approval of existing applications pending at the Regulatory Authority.</u> The decision will be applicable from the date of</i></p>

		<p><i>publishing of the MoM of the 375RC.</i>  <i>In case, the RC decides not to process the pending applications further, reasonable opportunity &amp; guidance be provided on the fate of such applications in accordance to any interim decision of the Hon'ble HC of Gujarat on the matter or final decision of the Hon'ble Court whichever is earlier .</i></p>
02	<p>As per the decision of 371st RC the applications under process in the Secretariat of CIB&amp;RC for import category, where the technical of the pesticide has been registered for indigenous manufacture shall not be processed.</p> <p><i>ACFI: believes, that if implemented as a blanket decision not to approve import applications wherever Indigenous manufacturing is approved in the country, may lead to specific violation of the IA 1968 along with International obligations to which India is a signatory.</i></p>	<p>In view of the directive from DAC &amp; FW, the applications under the TI v/s TIM category shall not be processed.  RC also directed Secretariat to prepare a list of such applications under this category and place to the RC in its next meeting  RC further decided that the applications under TI vs FIM* guideline shall also not to be processed and a list of files may be put up to RC in its next meeting.</p> <p><i>ACFI: welcomes the decision of the RC, with an understanding that <u>the decision shall not impact the scrutiny &amp; approval of existing applications pending at the Regulatory Authority.</u> The decision will be applicable from the date of publishing of the MoM of the 375RC.</i>  <i>In case, the RC decides not to process the pending applications further, reasonable opportunity &amp; guidance be provided on the fate of such applications.</i></p>

#### IV. Clarification sought on 375RC MoM/Ref.: MoM 375RC Agenda No.3.1( Annexure-I S.No. 3-6 )

We do have a serious concerns over the DAC&FW Directive and subsequent RC decision at s.no 3-6 ( Annexure I - 375RC MoM ) as stated over the regulators move to restrict and control import quantity of pesticides in the country. For reasons as stated:

1. A decision which may lead to severe diplomatic relations. It may also lead to exporting countries to either further restrict exports to India and also lead to controlled export of raw materials which are usually imported from the same country source or so
2. Restriction of imports does not justify and environmental concerns or impact on health of the citizens of our country
3. Since the products are technical of the product are not only required to be formulated either at the importers end for indigenous manufacture of its approved formulations, or formulated by other SME/MSME sector companies formulating the pesticides and making the same available across the country. The whole chain of supply is affected and Plant Protection in Indian Agriculture is expected to be impacted

4. What happens in case of National Exigency? As was witnessed in the case of Cotton Mealy Bug infestation, wherein shortage of pesticides was observed and the Importers walked in to fill in the supply chain and availability of formulated pesticides for timely control.
5. Quality concerns with respect to import consignments are anyway being adhered and complied with as directed by DAC&FW

Therefore, we fail to understand the need to regulate import consignment quantity as stated above s.no. 2. The total technical imported is anyway being used for indigenous manufacturing by the importers themselves or other 9(4) registrants which may qualify as SMEs or MSMEs category of industry giving rise and contributing to the GOI 'Make in India' campaign.

ACFI comments regarding Annexure I:Improvement/Harmonization of the Guidelines of Registration Committee keeping in view the "Make in India" Initiative of the Govt. of India.

S.No.	Directives from DAC&FW vide their letter No. 13035/64/2016-PP-I dated 05th April, 2017 and email dated 18.5.2017	RC decision for implementation	ACFI Comments
3	<p>Import of Insecticides (Pesticides) shall be permitted on submission of three years authentic import data by the holder of registration.</p> <p><i>ACFI: believe that this is a violation of the Act 1968 by definition itself. This may be in contravention to the current Industrial Policy since the abolition with DGTD and or the existing DGFT ( Ministry of Commerce ) which is responsible for Import&amp; Export Policy of the country.</i></p>	<p>RC deliberated the DAC &amp; FW directives for their implementation point of view and decided as under:</p> <p>a. Import of any pesticides in to the country shall be allowed on the basis of a valid registration certificate and a specific quantity permission issued by the Secretariat of CIB &amp; RC with the approval of RC.</p> <p>b. The specific Quantity permission shall only be applicable for import of pesticides which are already</p>	<p><i>Imports and supply of such chemicals was regulated for 50% local distribution prior to the country's 1998 Industrial Policy. Nowadays, subsequent Import registrants are anyway supplying 100% for local formulation giving rise to the SME &amp; MSME sector.</i></p> <p><i>Therefore, we fail to understand the need to regulate import consignment quantity. The total technical imported is anyway being used for indigenous manufacturing by the importers themselves or other 9(4) registrants which may qualify as SMEs or MSMEs category of industry</i></p>

registered for indigenous manufacture in the country.

*If it is truly about Make in India campaign of the GOI, it may be suggestive that the RC should also gather stats for the registrants having applied under (4) TIM (AR) versus TI under extremely lenient relaxed guidelines. It may also like to actually investigate actually how many of the registered products under TIM category u/s 9 are actually manufactured in India and whether the quantity being manufactured in the country is sufficient to cater to the need of plant protection.*

c. A list of such pesticides shall be prepared by Secretariat of CIB&RC and shall be presented to the RC in its next meeting.

*It may also be worth mentioning and for the RC to deliberate on the availability locally available raw materials and other inert ingredients required to manufacture TIM or FIM in the country. We understand most of the above are anyway being imported.*

d. Secretariat of CIB&RC shall issue a Public Notice in this regard containing details as enumerated at 3, 4, 5 & 6 in the policy directives from DAC&FW.

*Refer comments as mentioned in 3(b).*

e. A communication shall be sent to Custom Authority, Department of Revenue, Ministry of Finance, GOI, in this regard for allowing import of any insecticide with a quantity import permission along

*Since these Directives are a matter of Policy. Has the Central Insecticides Board ( CIB ) been consulted on the issue as required u/s 4 sub section*

with valid certificate of registration from the approved source. This process may be implemented with effect from 01.10.2017.

f. An additional condition to be incorporated in the certificate of registration that **“no import can be made on the basis of this certificate of registration without quantity import permit from the Department, henceforth.** A Public Notice shall also be hoisted on the website of CIB&RC for applicability of this condition for already issued certificates of registration for import of technical/formulation.

g. A separate unit is to be created with additional manpower in the Secretariat of CIB&RC for effective implementation of the policy and timely issuance of quantity import permission to the importers.

RC further directed that Secretariat shall develop an SOP with format of application to be submitted for seeking specific import permission for import of pesticides / insecticides, requirement of supporting documents if any, procedure for processing such applications and format for specific quantity permission etc.

*(1) read with sub section (2) and u/s 36(1) pertaining to the functioning of the CIB ?*

*This may be in contravention to the current Industrial Policy since the abolition with DGTD and or the existing DGFT ( Ministry of Commerce ) which is responsible for Import& Export Policy of the country.*

*This is in direct contravention and violation of the Monopolies and Restrictive Trade Practices Act 1969 and Competition Act, 2002.*

*Refer comments 3(b-f) Will this contain of SRFs/RAs or APPOs? In case of the former, legality and in case of the latter experience will be an issue.*

*We shall await the SOP and respond accordingly.*



			<i>Further, it is worth mentioning that this decision has come post a Draft Gazette issued by DAC&amp;FW dated May 12<sup>th</sup> published May 17, 2017.</i>
4	The import of Insecticides (Pesticides) shall be restricted to 75% of the average of three years of import from the date of application filed by the registrant.		<i>Justification and modality of the same to be compared with current capacity and availability under manufacture read with our comments at 3( a-f).</i>
5	In case the Certificate of Registration of molecule of any registrant is less than three years old, import of pesticides shall be restricted to 75% on the basis of data provided by the registrant for such period.		<i>In cases, where TI may not have occurred, in such cases CRs may be withdrawn to clear the clutter of registrants on record.</i>
6	In case of new registration of any molecule, import shall be allowed on quarterly basis.		<i>Refer comments 3( a-f)</i>

**V. Clarification sought on 375RC MoM/ MoM 375RC Agenda No.3.1( Annexure-I S.No. 9 )**

We do have a serious concern related to the decision at s.no 9 ( Annexure I - 375RC MoM ) to force surrender a CR under a specific category i.e. import in cases wherein a registrant is in possession of separate CRs granted for import & indigenous manufacture.

This decision Restricts a Registrant from:

1. Freedom of registrant to conduct business
2. Freedom of a registrant to conduct a commercially viable business
3. Freedom of a registrant to invest in a commercial legally compliant activity as per existing legislations of the Country
4. Freedom of right to operate and conduct business

ACFI comments regarding Annexure I:Improvement/Harmonization of the Guidelines of Registration Committee keeping in view the "Make in India" Initiative of the Govt. of India.

S.No.	Directives from DAC&FW vide their letter No. 13035/64/2016-PP-I dated 05th April,	RC decision for implementation	
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	2017 and email dated 18.5.2017		
9	<p>No Certificate of Registration shall be issued to any company for import, if the applicant possesses the Certificate of Registration of that product under indigenous manufacturing category. In case where registrant has registration certificate of indigenous manufacturing and import category the certificate of registration of import category shall be withdrawn.</p> <p><i>ACFI: The IA 1968 does not restrict any one from holding multiple category CRs issued separately for import or manufacture. Further, freedom to import or indigenously manufacture is the basic right of a registrant holder and a commercial decision of the latter. However, if any registrant desires to withdraw a CR issued for TI or TIM should be voluntarily and not forced upon to surrender a particular CR issued u/s 9 for Import or TIM category</i></p> <p><i>As stated above regarding the commercial viability of either import or indigenous manufacture, the decision to do so lies solely with the registrant. Therefore, the registrant reserves the right to utilize either CRs at per own discretion and should not be forced upon to surrender a specific CR i.e. either for import or indigenous manufacture Legality related to specific surrender, not involving health or environmental concerns as per the provisions as specified in various sections of the Act. is a major concern.</i></p>	<p>No Certificate of Registration shall be issued to any company for import, if the applicant possesses the Certificate of Registration of that product under indigenous manufacture category. An affidavit to be obtained from the applicant in this regard.</p> <p>In cases where registrant has registration certificate of indigenous manufacturing and import category both, the certificate of registration of import category shall be withdrawn. Secretariat of CIB&amp;RC shall write to</p>	<p><i>The IA 1968 does not restrict any one from holding multiple category CRs issued separately for import or manufacture. Further, freedom to import or indigenously manufacture is the basic right of a registrant holder and a commercial decision of the latter. However, if any registrant desires to withdraw a CR issued for TI or TIM should be voluntarily and not forced upon to surrender a particular CR issued u/s 9 for Import or TIM category</i></p> <p><i>As stated above regarding the commercial viability of either import or indigenous manufacture, the decision to do so lies solely with the registrant. Therefore, the registrant reserves the right to utilize either CRs at per own discretion and should not be forced upon to surrender a specific CR i.e. either for import or indigenous manufacture Legality related to specific surrender, not involving health or environmental concerns as per the provisions as specified in various sections of the Act. is a major concern.</i></p> <p><i>As stated above.</i></p> <p><i>How can the RC withdraw a CR u/s 28 be clubbed with Section 9(1)?</i></p>

		<p>DAC&amp;FW to issue a Gazette Notification in this regard to cancel such certificates of registration <b>under section 28 read with section 9 (1)</b> of the Insecticides Act, 1968.</p> <p>No request for transfer of such certificate of registration shall be considered with immediate effect. The necessary amendment in the relevant endorsement guidelines/checklist may be made and uploaded on the website.</p>	<p><i>A CR is understood to be withdrawn only u/s 28 which may be read along with section 26 or 27 individually or combined together or to that matter the provisions laid down u/s 29</i></p> <p><i>It construed to be a Violation of Competition Act, 2002</i></p>
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**VI. Clarification sought on 375RC MoM/Ref.: MoM 375RC Agenda No.3.1( Annexure-I S.No. 10 )**

We do have a serious concern related to the decision at s.no 10 ( Annexure I - 375RC MoM ) which overlook safety adherence towards indigenous manufacture of pesticides primarily toxic in nature.

ACFI concerns are as stated:

5. Whether GOI is likely to formulate specific SOPs for Importers to shift towards investing in developing manufacturing capacity within the country of origin
6. Implementing FAO Chemical equivalence achieved through 5 batch analysis under GLP for indigenous manufacturers u/s 9 (3), wherein keeping TIM u/s 9(4) out of any such compliance
7. Exempting indigenous manufacturers from the adhering to the FAO Chemical equivalence achieved through 5 batch analysis under GLP for a period two years

As mentioned in s.no. 2&3, we believe the regulator is willing to oversee the fact that establishing chemical equivalence by subsequent registrants not only assures safety to the environment and public in general while manufacturing or use of such products as intended to do so. Lenient regulatory norms to facilitate under the GOI 'Make in India' campaign is welcome but not at the cost of any environmental impact or to human health concerns.

We also wish to share our concern on lending lenient manufacturing SOPs, wherein in a practical scenario and looking into the current available infrastructure and capacity to be involved in indigenous manufacture of chemicals of toxic nature raises a fear factor amongst us.

We feel it appropriate to mention at this point of time the fact that wherein many countries around the globe have restricted or banned manufacturing facilities of such pesticides due to environmental and health concerns, India is looking towards manufacturing of such hazardous products in nature on its soil. It may also be noteworthy and a pity to mention that the GOI is encouraging indigenous manufacture of such pesticides that may be at the verge of phasing out in rest of the world.

As we seek parity amongst implementing of regulatory norms as stated above, we look forward to your advice on the concerns and clarifications sought at the earliest possible

ACFI comments regarding Annexure I:Improvement/Harmonization of the Guidelines of Registration Committee keeping in view the “Make in India” Initiative of the Govt. of India.

S.No.	Directives from DAC&FW vide their letter No. 13035/64/2016-PP-I dated 05th April, 2017 and email dated 18.5.2017	RC decision for implementation	ACFI Comments
10	<p>The RC decision under <b>Sr. No. 3 sub-para a, b, c &amp; d annexure – VII of 371st RC</b> meeting minutes in relation to promote the indigenous manufacturing of pesticides are approved.</p> <p>The above mentioned reads as: S.No. 3. To improve local manufacturing facilities and guidelines shall be relaxed in favour of local manufacturers</p> <p><b><i>ACFI: Does the GOI propose to formulate an SOP and Policy to specifically facilitate &amp; encourage importers to establish manufacturing facilities in India while addressing the commercial viability of establishing the same.</i></b></p> <p>The existing guidelines relevant to grant of registration for Indigenous Manufacture of pesticides under various categories have to be simplified. The committee decided as under:</p> <p>a. The following studies-Acute oral (Mice), Acute inhalation (Rat), Primary skin irritation, Irritation to mucous membrane in case of TIM category u/s 9(3) shall not be required where chemical equivalence is established ( <b>5 Batch GLP Analysis as per FAO or existing norms complied by manufacturers for attaining overseas registrations</b> ), henceforth except in case of first registrant of the molecule.</p> <p><b><i>ACFI: Welcomes the decision of DAC&amp;FW to implement chemical equivalence under FAO norms involving 5 Batch Analysis conducted under GLP.</i></b></p> <p>b. Ames test (First tier) shall</p>	<p>The relevant guidelines may be updated as per the decision of DAC &amp; FW and uploaded on the website.</p>	<p><b>Same as stated under column no. 2 referring to DAC&amp;FW Directive</b></p>

replace all toxicology data requirement in case of TIM category u/s 9(4).

***ACFI: Welcomes the above said decision of DAC&FW***

- c. All the studies non-adhering to GLP principles conducted by GLP accredited laboratory shall be accepted henceforth for all categories of applications of Indigenous category.

***ACFI: This section is deemed to be in contravention to norms as stated by DAC&FW under 3 (a&b). Chemical equivalence as stated above under 3(a) is the sole basis for data waivers and in our opinion should not be diluted, while keeping on stake the impact on our environmental and risking human health of our country's population as a whole.***

- d. Toxicology studies conducted by Non-GLP laboratories shall also be accepted for two years from the date of approval these minutes to encourage indigenous manufacturing and ease out in the process of registration of TIM/FIM category.

***ACFI: Refer comments placed in s.no. 3(c). Further, why not such an extended time line also made available for TI or FI approvals for Additional New Sources may be worth deliberating further along with the industry.***

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**Date of preparation: 31.07.17 ( 1330 hrs )**

**Subject: FICCI Feedback on Pesticide Industry Issues**

**Status: Final**