

Data Exclusivity. Highly Detrimental to India's Farm Economy and Agrochemicals Export

Reasons for opposing
data exclusivity



Crop Care Federation of India

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- ✧ Unlike the global pharmaceutical market, the agrochemical market is dominated by generics. Around **90%** of the global agrochemicals market consists of generics. In fact, all the **10 top selling** agrochemicals in the world are generics.
- ✧ India is a leader in producing and supplying generic agrochemicals worldwide.
- ✧ Granting data exclusivity to post patent and old agrochemicals is detrimental to India's interests. It will only delay the launch of new generics by Indian companies and gradually erode their global competitiveness.

- ✳ **The 88th Report of the Parliamentary Standing Committee on Patents and Trademarks System in India (24th Oct 2008) stated:**

5.48: “... Since the consequences of Data Exclusivity are quite serious, the Committee strongly recommend that the Government should not fall prey to such demands of MNCs. The Government must thwart such attempts, being made at the behest of certain vested interests.”

- ✳ **In a press release dated 29th March 2011, Ministry of Commerce, Government of India asserted:**

*“..... **data exclusivity** is something beyond the provision of Article 39.3 of TRIPS Agreement grant of data exclusivity for pharmaceuticals and agrochemicals would have considerable impacts....”*

- ✳ **Second Committee Report appointed by Government of India on the direction of the High Court of Delhi in the case Nitto Denko Corp v. Union of India, in Feb 2015 stated:**

*“... the patent monopoly for **20 years** itself is considered too long to block genuine competition. In today’s world, technologies covered by inventions become obsolete too fast. Encouraging obsolete technologies and protecting them with longer patent term is not advisable.”*

- ✳ **The 36th Standing Parliamentary Committee on Agriculture, Animal Husbandry, and Food Processing in December 2021 stated:**

1.18. The Committee also believe that India has a very large and growing market of agrochemicals and with huge arable land, it will be able to attract introduction of new molecules from foreign as well as domestic companies even without provision for any Data Protection.

- ✳ **Neither the Insecticides Act 1968 nor the Pesticides Management Bill (draft) – 2017 and 2020 carries any provision for data exclusivity.**

Article 39.3 of the TRIPS Agreement.

- ✳ **Article 39.3 of the TRIPS Agreement – interpreted according to the ordinary meaning of the words used, does not mandate the granting of exclusive rights for regulatory data.**

“Use by the government to assess the efficacy and toxicity of a pharmaceutical or agrochemical product is not a commercial use subject to Article 39.3. Granting marketing approval to a second entrant, based on the second product’s similarity to a previously approved first product, is not a proscribed “use” under Article 39.3.”

~Prof. Carlos Correa, South Centre

“With regard to data submitted for approval of pharmaceutical and agrochemical products.....competent authorities may adopt measures to avoid unauthorized disclosure of secret data.....these authorities are not prevented from using...such data to assess subsequent applications by third parties for registration of similar products.”

~ UNCTAD

TRIPS Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights..... It does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party...”

“... developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS”.

Ref: Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRIH), WHO- 2006 See page 124 & 181

- ✳ **Negotiating history (1986-94) of the TRIPS Agreement shows that a minimum 5-year data exclusivity was proposed by the USA and European Community (EC). But this was opposed by India and others – finally not adopted.**
- ✳ **India signed the WTO TRIPS Agreement in 1995. Indian laws do not provide data exclusivity for pharmaceuticals and agrochemicals. This is legitimate and TRIPS compliant.**

- ✧ The primary objective of the Indian Patents Act, 1970 is the promotion of science and technology for the benefit of India's own social and economic development.
- ✧ Owning patents in India for new pesticide molecules but not commercializing them for the benefit of Indian agriculture should be considered as a planned abuse of the patent monopoly rights.
- ✧ **For every ten patents granted since 2010 to the western MNCs for new pesticide molecules, six have not been commercially introduced in India though they were promptly commercialized in other countries.**

Particulars	No. of agrochemicals
No. of agrochemicals (new molecules) patented in India between 2010-2022	62
No. of patented agrochemicals commercially launched in India between 2010-2022	27 (44%)
No. of patented agrochemicals commercially not launched in India between 2010-2022 though launched outside India.	35 (56%)

Data Source for analysis: Agribusiness by S&P Global and CIB&RC (Ministry of Agriculture)

- ✧ This abuse brazenly contravenes the mandatory requirements in **Section 83** of Indian Patents Act, 1970.
- ✧ The western MNCs who fail to commercialize all their patented molecules are the ones actively lobbying for “**data exclusivity**” to bring their old and off patent pesticide molecules to the Indian market.
- ✧ This would end up creating yet another market monopoly to the western MNCs, beyond the patent protection.

- ✱ Under our Patents Act, a failure to commercialize the patent is unacceptable and actionable. Section 83 of our Patents Act carries several obligations to achieve this. They include:

Understanding Section 83	What it requires?
83 (a)	<i>Patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;</i>
83 (b)	<i>[Patents] are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;</i>
83 (c)	<i>The protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users ...;</i>
83 (f)	<i>“that the patent rights is not abused by the patentee.... the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology;</i>
83 (g)	<i>Patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.</i>

- ✱ Section 84(1)(c) of the Patents Act allows grant of **compulsory licence** if a patented invention has “**not been worked**” (i.e. not commercially launched) in India.

The bad experience with data exclusivity.

- ✧ Between 2007–2017, a “*de facto* data exclusivity” was in force thanks to the Ministry of Agriculture’s executive order no 17-2/2006-PPI dated 30th October 2007 and F.No.17-2/2006-PPI dated 18th February 2008. This “*de facto* data exclusivity” was subsequently set aside by a court order.
- ✧ During this “*de facto* data exclusivity” period, many old agrochemicals were introduced in India, including those banned in other countries.

Examples of the agrochemicals registered as new and innovative in India	Year of global launch (a.i)	Year of introduction in India
Ametryn 80% WG	1962	2015
Bentazone 480 g/l SL	1968	2016
Buprimate 26.7% w/w EC	1975	2017
Diffubenzuron 2% Gr.	1975	2008
Tetraconazole 3.8% EC	1988	2010

- ✧ **Evidently, India became a dumping ground for old pesticides.**
- ✧ All these agrochemicals were mostly imported, simply repacked in India and sold to farmers at an exorbitant price exploiting the monopoly. For example, **Halosulfuron Methyl 75%** (a 25 years old, post-patent herbicide) was imported at ~ **Rs 12,000/kg** repacked and sold to Indian farmers at ~ over **Rs 40,000/kg**.
- ✧ Old Information/data that entered public domain long ago were produced in India as “undisclosed information” to claim data exclusivity.

De facto data exclusivity era witnessed spike in import of agrochemicals

Particulars	Period	Growth in agrochemical import
Data Exclusivity Era	2007-2017	547%
After removal of Data Exclusivity	2017-2024	17%

Source: WTO-ITC (Accessed on 25th November 2025)

Note: Removal of data exclusivity led to domestic production which resulted in decline in imports.

- ✧ The *de facto* data exclusivity era ended up with a significant jump in imports and huge outflow of foreign exchange.
- ✧ This considerably impacted domestic manufacture, investments and employment generation.

There is no evidence to show that absence of data exclusivity hampers introduction of new agrochemicals in India.

- ✧ **The “perception” that grant of data exclusivity alone achieves introduction of new molecules is a myth.**
- ✧ **Absence of data exclusivity has not hampered introduction of new agrochemicals in India.** In the last two years, as many as **36 new pesticide** molecules were registered in India - **@ 1.5 new molecule per month**. This is a record high, and it is higher than the registrations in countries that have granted data exclusivity such as Brazil, Malaysia, Thailand etc.
- ✧ India ranks second largest in agricultural production (**\$ 640 bn**). India has the largest gross area under crop cultivation (**219 mn ha**) in the world. This, on its own, attracts agrochemical companies to increasingly register their new products in India. There is no need for any sops such as data exclusivity.
- ✧ Data exclusivity can confer market exclusivity beyond patent period. The effect of this could be most egregious in India that has a robust, off patent-generic industry that is export intensive.
- ✧ Data exclusivity, if granted in India, other countries which rely on India's supply will also suffer. It will considerably erode our export competitiveness.
- ✧ Indian agriculture is predominantly of small farmers. **Availability, accessibility, and affordability** of new agrochemicals are critical factors that directly influence the farms' productivity, profitability, and overall livelihood of the small farmers. Experience shows that Data exclusivity failed to ensure this.
- ✧ Data exclusivity would hinder the ability of local manufacturers to produce affordable generic versions for the domestic and international markets. This would in turn weaken the **“Atmanirbhar Bharat”** and **“Make in India”** initiatives of the government.
- ✧ Allowing data exclusivity would create a strong monopoly beyond patents, delay introduction of generics, raise prices and hurt the farm economy and agrochemical exports.

India registers more agrochemicals than countries that enforce data exclusivity.

Country	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total in 12years
Thailand	2	3	0	1	2	0	3	1	6	6	2	1	27
Brazil	2	5	2	1	5	2	3	5	7	8	11	2	53
Taiwan	4	3	11	11	0	6	1	1	1	6	6	5	55
Malaysia	4	5	3	10	3	4	4	4	8	7	7	3	62
India	4	9	10	12	5	11	2	9	8	13	12	25	120

Source: Registration Authorities in the above countries

- ✧ The numbers speak. **India leads in new pesticide registrations in the Global South Countries** such as Thailand, Brazil, Taiwan, and Malaysia **that offer data exclusivity lag behind.**
- ✧ There is no truth in the propaganda that data exclusivity alone can fetch more registrations.
- ✧ Pertinently, **out of the 25 agrochemicals registered in India in 2024, 14 (60%)** are by MNCs.

India's global leadership in export of generic agrochemicals.

- ✧ India is now the **3rd largest exporter** of agrochemicals in the world, up from **5th** position a decade ago, ahead of **France** and **Germany**.

Rank	2013		2024	
	Country	Agrochemical Export Value (\$ bn)	Country	Agrochemical Export Value (\$ bn)
1	Germany	4.1	China	9.0
2	USA	3.9	USA	4.8
3	France	3.8	India	4.2
4	China	3.7	Germany	3.6
5	India	2.1	France	3.5
	Global Export	33	Global Export	43

Data Source: WTO-ITC (Accessed on 24th November 2025)

- ✧ Rate of growth of export from India is much higher than the growth rate of global export.
- ✧ **India is all set to soon become the second largest, overtaking the USA.**
- ✧ Indian Government shall ideally introduce policies that further facilitate manufacture and export of generic agrochemicals.
- ✧ Introducing data exclusivity would be retrograde counter to **“Atmanirbhar Bharat”** by potentially hindering global supply chain integration.

Conclusion. Dangers of data exclusivity

- ✳ India's experience with "*de facto* data exclusivity" regime was disastrous. It only helped importers to make windfall profits. For a brief period (2007-2017) India became a dumping ground for old agrochemicals.
- ✳ Agrochemicals banned in other countries were also introduced in India availing data exclusivity linked monopoly.
- ✳ The import of agrochemical spiked **547%** between 2007 and 2017.
- ✳ Evidence shows that developing countries that had granted "data exclusivity" ended up losing the domestic industry to imports. Data exclusivity slowly erodes the economic sovereignty.
- ✳ In India, experience shows that "data exclusivity" failed to foster innovation. It proved data exclusivity linked monopoly could easily be hijacked in an exclusionary manner leading to market abuse and anti-competitive practices.
- ✳ On one hand, many patents granted in India to MNCs for new and innovative agrochemical molecules are "**not worked**", (i.e., not launched) in India, and on the other hand, these companies and their associates demand "data exclusivity". This demand is anti-farmer, unethical, untenable, unacceptable, and strongly objectionable.

Final words

India has resisted data exclusivity since TRIPS Agreement for decades, in all the trade negotiations.

Data exclusivity would allow foreign forces to exploit Indian farmers – in the absence of generic competition.

Data exclusivity is a weapon in the hands of vested interests to weaken India's export intensive generic agrochemical industry.



THANK YOU



Crop Care Federation of India

Crop Care Federation of India (CCFI) is an apex trade association for Indian agrochemical industry. The CCFI members account for around 70% of India's agrochemical export. India is the third largest exporter of agrochemicals. Indian agrochemicals are sold in over 150 countries across the world. Over the last five years, India earned a trade surplus of **\$16 bn** from agrochemicals export.

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