Regulation of pesticides in India

Chandra Bhushan
Associate Director

Centre for Science and Environment

Concept of economic toxins

- Pesticides are ‘economic toxins’
- We use pesticides because we want to produce more food and hence nutrition
- But we also know that pesticides are poison – causes both acute and chronic health effects
- Therefore, use of pesticide is a ‘poison – nutrition’ tradeoff

Concept of economic toxins

- We can live with pesticides if this tradeoff is a prudent one - if the overall benefit of nutrition far exceeds the negative impact of poison
- We can live with pesticides if our laws, regulations and enforcements are geared towards ensuring this prudent tradeoff
- Currently in India, the regulatory regime for pesticide is failing to ensure prudent tradeoff.
- India suffers from double burden of pesticides – acute as well as chronic

Pesticide poisoning

- Endemic – intentional, unintentional and occupational
- Annually about 8,000-10,000 cases and 1,000 plus fatality – government data
- Government data misleading – far more poisoning cases than those reported or recorded or identified
- In AP, Govt. reported 200 odd cases from the entire state, whereas in Warangal alone more than thousand cases reported in government hospitals alone and hundreds died due to poisoning during the same period

Pesticide poisoning

- Estimates – highly variable – from million plus cases to few hundred thousand
- Death estimates between 25000 to 5000
- Accidental children poisoning now being more and more reported
- Reason – combination of socio-economic, practice and types of product used

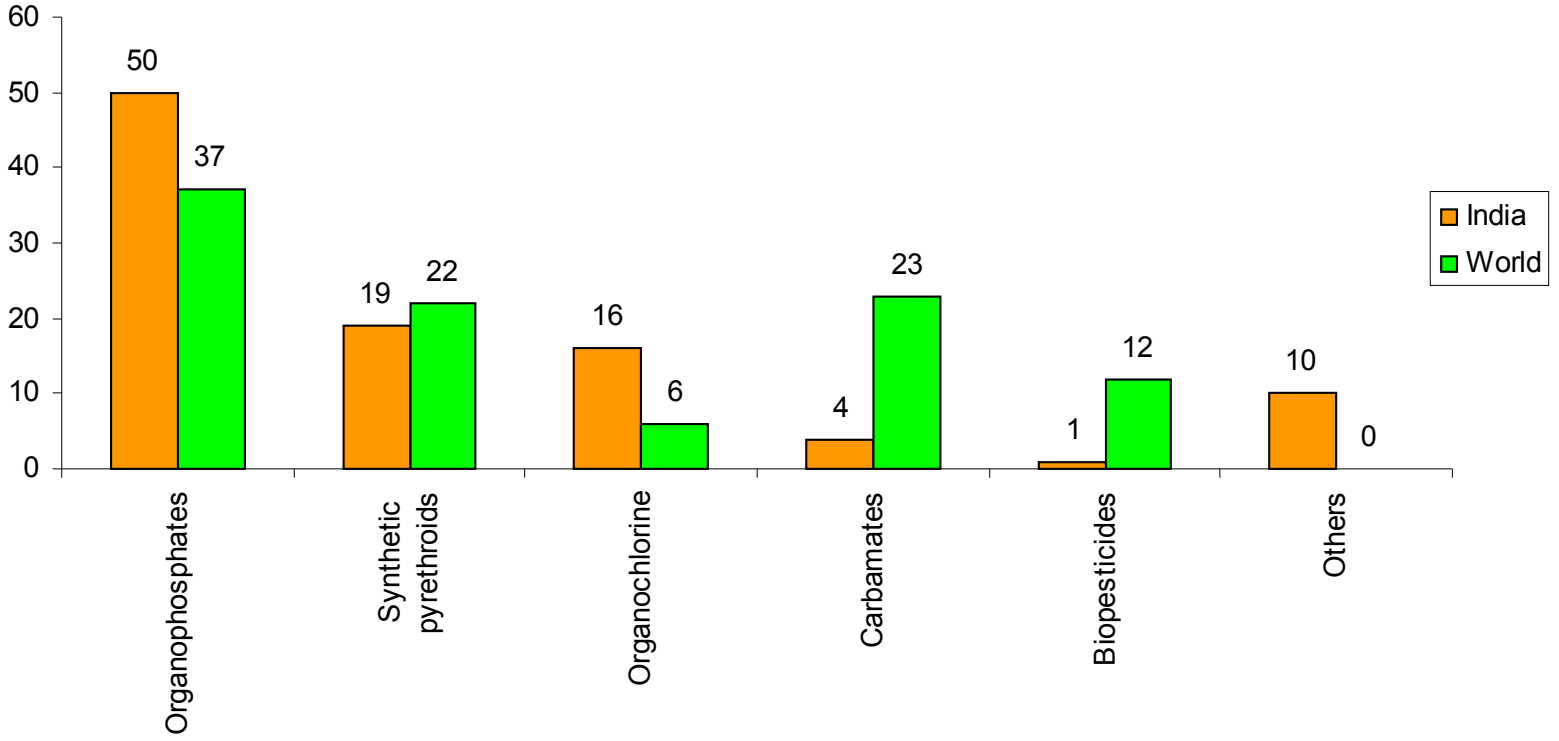
Pesticide poisoning

- Safety gears costly and also not suitable for tropical climate
- Practice – Poor to dangerous
- Barefoot and barehanded, wearing bare minimum cloth, leaking spray tank
- Mixing of concentrated chemicals and refilling spraying tanks (female+male) and spraying (male) - even tasting the mix
- Multiple pesticides used – mix and match - subsequent medical management difficult

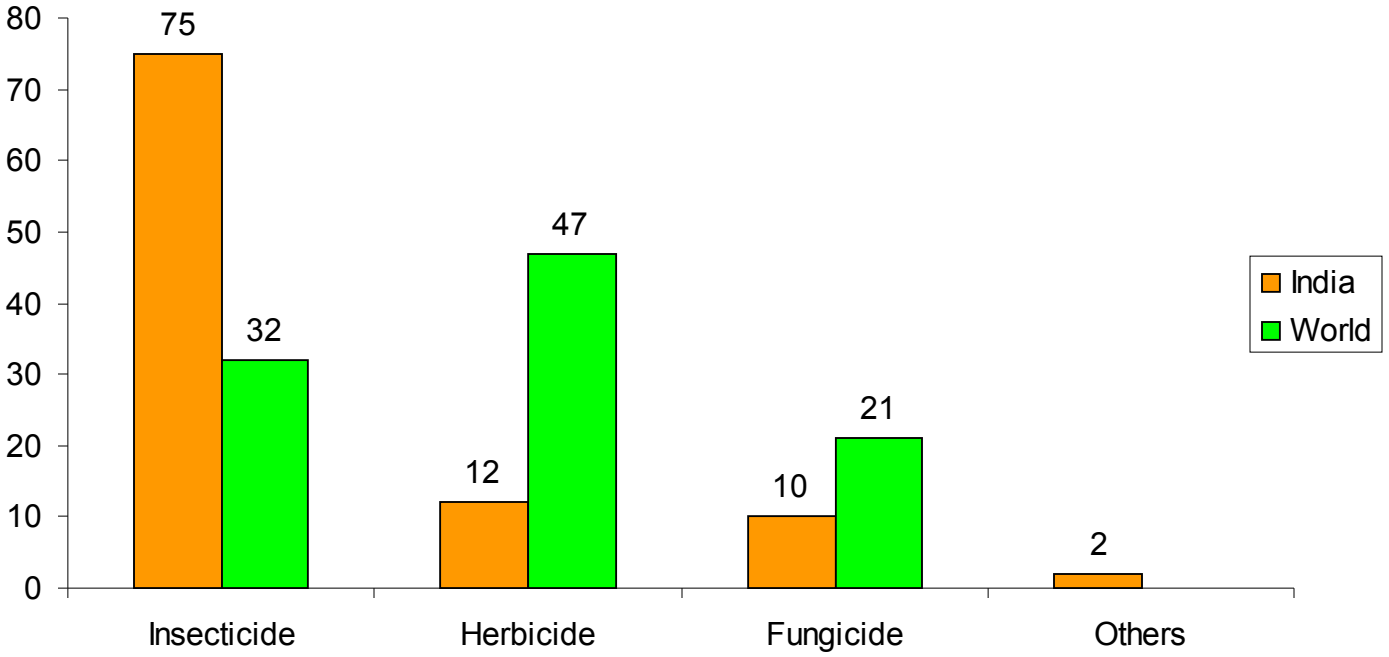
Pesticide poisoning

- Mild to severe poisoning not reported, no medical care – only life threatening severe cases bought to hospitals
- Introduction of class system - slightly higher paid pesticide sprayers (low-income marginal/ landless farmers)

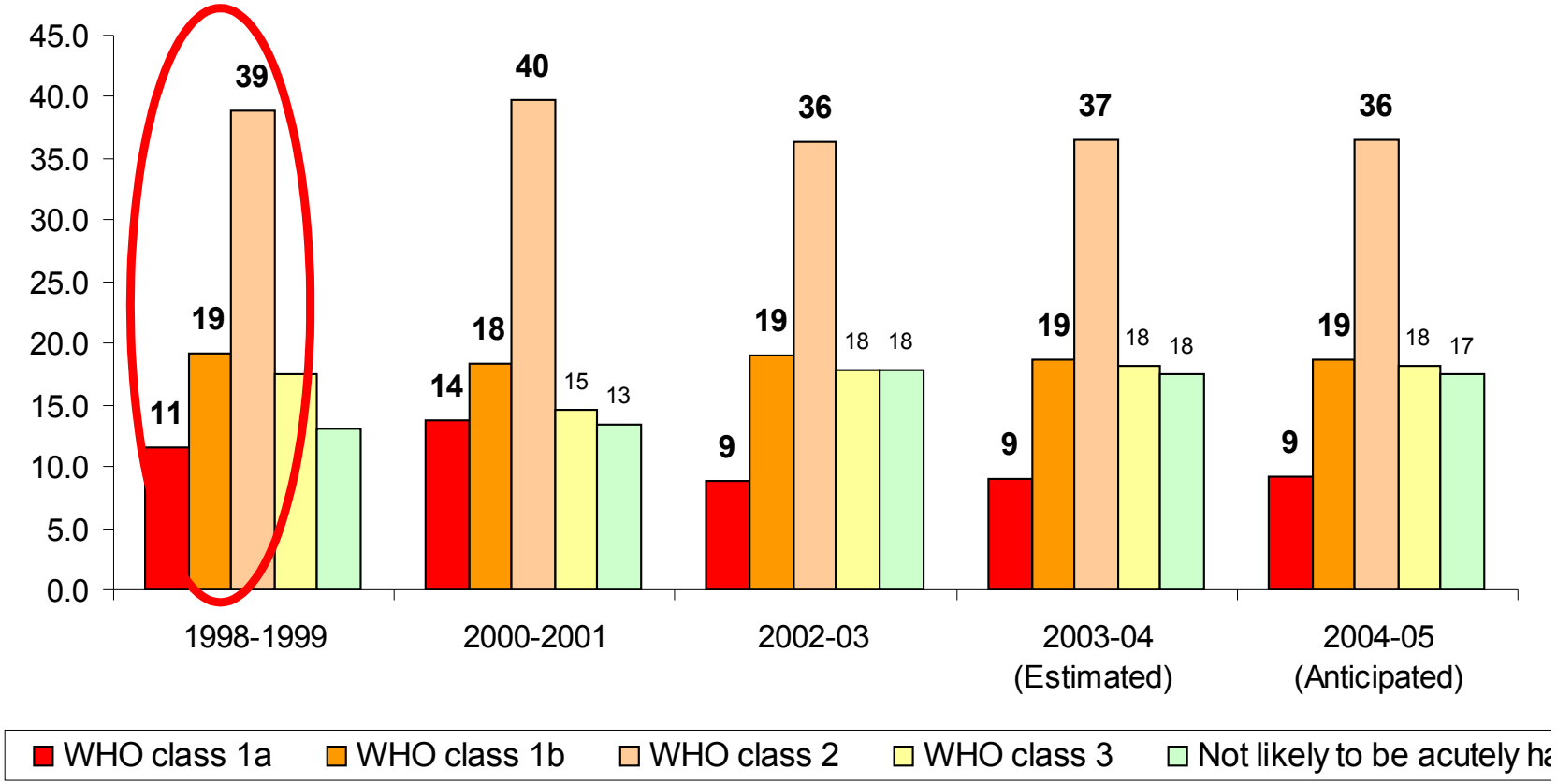
Pesticide use pattern - India



Pesticide use pattern - India



Class apart !

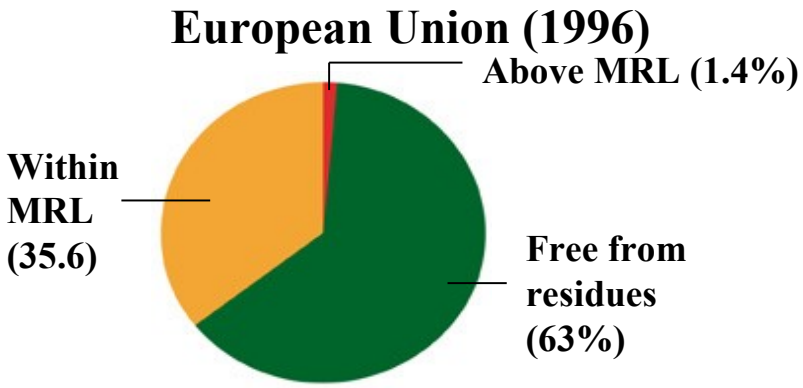


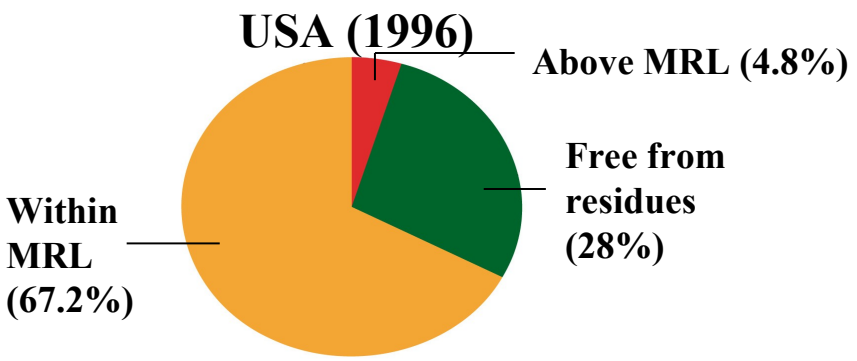
Two-thirds of the total pesticides consumed under WHO class I and II

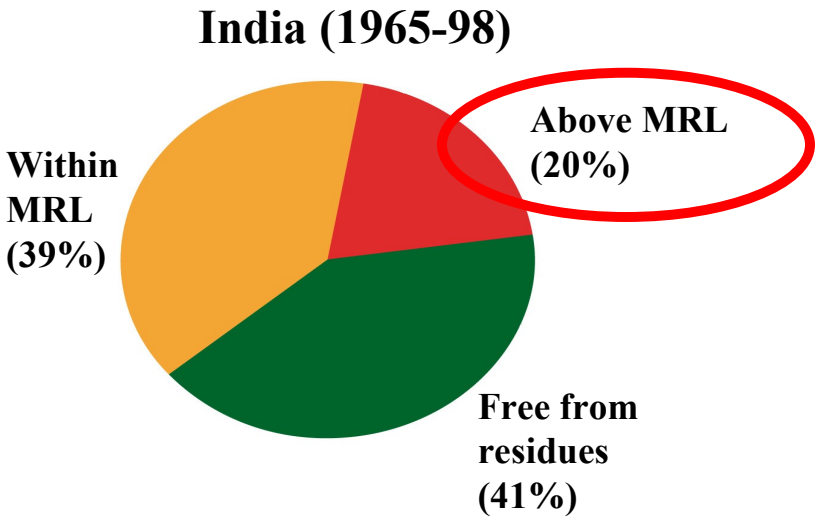
Pesticide poisoning

- Generally recognised now that *'farmer education'* alone not sufficient – changes in types of pesticides used required
- Though India attended and actively participated in FAO's Code of Conduct – it has told its parliamentarians that it need not follow the code - *to phase out WHO class Ia and Ib pesticides*

Pesticide contamination - Snapshot







Source:
G S Dhaliwal & Balwinder Singh, 2000: 208

Pesticide contamination - India

- **So-called systematic monitoring only started in late 1980s – AICRP on Pesticide Residue, primarily to develop 'GAP' and then to monitor residues in agricultural produce**
- **AICRPPR not meant for informing people about contamination – *India still does not have a system to do so*.**
- **Regulators have hardly monitored residues in food commodities.**
- **So institution that monitors doesn't informs or regulates – institution that is supposed to so doesn't monitors**

Pesticide contamination - India

- **Food commodities highly contaminated**

1999 AICRPPR Report

- Finds that 20% samples exceed MRLs (all commodities included)
- Finds fruits, vegetables and milk to be highly contaminated
- In states like UP and Kerala, more than 40% fruits and vegetable samples exceeded MRLs – finds monocrotophos, DDVP and Methyl Parathion as most prevalent – all 3 WHO class I pesticide
- Finds 78% milk samples exceeding HCH MRL and 43.4% exceeding DDT MRL

Pesticide contamination - India

- Finds high levels of DDT and HCH in baby milk powder – corroborating earlier ICMR study
- Says no standard for pesticides in baby food – *still no standards*

Brand No.	Himachal Pradesh		Hyderabad		Kerala HCH (mg/kg)	West Bengal HCH (mg/kg)	Bangalore HCH (mg/kg)
	HCH (mg/kg)	DDT (mg/kg)	HCH (mg/kg)	DDT (mg/kg)			
BRAND I	3.734	1.47	0.578	0.226	0.251	0.522	0.225
BRAND II	1.128	0.839	1.067	0.32	0.243	0.494	0.013
BRAND III	1.886	0.344	0.415	0.042	0.354	0.142	0.081
BRAND IV	2.863	0.468	0.458	0.021	0.241	0.694	0.071
BRAND V	3.031		0.389	0.054	0.168	0.279	0.026
Average pesticide Residues	2.5284	0.78025	0.5814	0.1326	0.2514	0.4262	0.0832
* Number of times higher than EU baby milk powder norms	252.8	78.0	58.1	13.3	25.1	42.6	8.3

Pesticide contamination - India

2001 AICRPPR Report

- Again finds high contamination levels in fruits and vegetables – 61% contaminated – 11.7% failed MRLs
- In milk says contamination still high – 15.2% failed HCH MRL and 7.7% failed DDT MRL. Finds new pesticide like Endosulfan, chlorpyrifos and chlorthalonil residues in milk. No standard for endosulfan in milk – *not yet*.

Pesticide contamination - India

Recent AICRPPR Reports

- Not available in public domain
- Says milk still a problem, about 15% exceeded MRLs
- Says fruits now fine – no problems – only one out of 317 samples failed MRLs
- Says vegetables still with slight problem – similar to developed world – only 5% exceeded MRLs
- However, monitoring done by independent institutions found far higher failure rate during same period, including CSE's.

Pesticide contamination-**Indians**

- Most bio-monitoring done for DDT and HCH (Lindane) – most finds far higher levels than those found in any other part of the world

Summary of ICMR 2001 Study

HUMAN FAT

- **DDT: 4.7–26.0 ppm**
- **Lindane: 0–16.85 ppm**

MOTHER'S MILK

- **DDT: 0–0.344 ppm**
- **Lindane: 0–0.38 ppm**

HUMAN BLOOD

- **DDT: 0.02–0.71 ppm**
- **Lindane: 0–0.49 ppm**

Pesticide contamination-**Indians**

- NIOH for the first time links health problems in Kerala with Endosulfan
- CSE Punjab Study
- Overall, pesticide contamination of Indian food and water widespread
- High body burden of pesticide in Indians
- Chronic health affect, most likely manifestation

Our regulatory framework

- Our problem starts with the institutional structure
- Ministry of Agriculture (MOA) regulates the manufacture, sale, import, export and use of pesticides through the 'Insecticide Act, 1968'.
- There is a clear conflict of interest in this arrangement. MOA, which is suppose to promote pesticides to increase food production, has also been assigned the task of regulate pesticides
- *Agricultural scientists are generally not health specialists* - this is very important because the health impact of pesticides are more invisible than visible.

Our legislation

- The ‘Insecticide Act, was enacted after a major poisoning case due to pesticide in Kerala in 1958, where over 100 people died – *this had an important implication on the design of the act*
- Act and Rules are primarily geared towards regulating the acute health effects of pesticides
- The focus on the chronic health effects is highly inadequate – result is poor scrutiny of pesticides from chronic toxicity point of view
- Terms like chronic toxicity or ADI is missing from the entire act

Section 9 (3B) – Provisional registration for 2 years

- New pesticide can be registered and used for two years without considering any health and safety consideration. No data is required for the following:
  - Neuro-toxicity
  - Teratogenicity
  - Effect on reproduction
  - Carcinogenicity
  - Metabolism
  - Mutagenicity
  - Health records of Industrial workers

Mix and Match Products

- **If farmers mix and match, pesticide formulators are not far behind. They produce and sell what is called as *'Combination Formulations (CBN)'*.**
- **In India, CBN can be registered without any mandatory chronic toxicity assessment. Manufacturers do not need to produce data on neurotoxicity, teratogenicity, carcinogenicity, mutagenicity etc.**

Standard setting

- Fixing of Acceptable Daily Intake (ADI) is not part of the registration process. Nor setting of MRLs on food commodities is part of the registration process.
- Prevention of Food Adulteration Act (PFA) – Ministry of Health (MOH) - monitors and regulates pesticide contamination in food commodities – sets maximum residue limits (MRL) of pesticides on food commodities
- **Problem is this** – till recently pesticides were registered for use by MOA, without MRL being set by MOH.

Registered without MRLs

- Till 2004, of the 181 pesticide registered, MRLs for only 71 were notified under the PFA.
- Even today, of the 194 pesticides registered, MRLs for only 121 have been notified under the PFA.
- But numbers are alone good enough – one has to see on how many commodities MRLs have been fixed.
- In India, pesticides are registered for use on 'Y' number of crops, but MRLs are set only for 'Y-X' number of crops.

Missing MRLs

- This is the snapshot of the current satus:
- Of all the pesticides allowed for paddy, MRLs for only 60% of the pesticides have been fixed
- Of all the pesticides allowed for Wheat, MRLs for one-fourth of the pesticides have not been fixed yet
- Of all the pesticides allowed for Mango, MRLs for half of the pesticides have not been fixed yet
- This list can go on------
- **MRL fixing in India is an administrative formality – not a regulatory tool**

How safe are the MRLs?

- MRLs can be considered as a safe threshold only when, the cumulative daily intake of pesticide of the population remains with the ADI.
- In other words, if the Theoretical Maximum Daily Intake of Pesticides (TMDI) - estimated on the basis of MRLs - remains within the ADIs
- Despite all the missing MRLs, CSE estimated the TMDI of eight most common pesticides used in India
- It did this estimation for a 60 kg adult and a 10 kg child.

How safe are the MRLs?

- Now, India's last dietary data was generated in early 1990s. So, CSE used FAO's food balance sheet for food intake data (reducing it by by 20% to account for losses).
- For the child however, it used the Indian Nutrition Profile, complied by NIN, Hyderabad

TMDI Calculations

Monocrothophos mayhem

Estimating exposure to this pesticide for a 60 kg adult (below), and a 10 kg child (below, right)

Food commodity	Indian MRL (mg/kg)	Diet (gm/day)	Pesticide intake (mg/day)	Distribution* (per cent)
Wheat	0.025	158	0.0040	2.6
Rice	0.025	209	0.0052	3.5
Cereals, other	0.025	77	0.0019	1.3
Pulses	0	29	0.0000	0.0
Potatoes	0.05	43	0.0022	1.4
Tomatoes	0.2	20	0.0040	2.7
Onions	0.1	15	0.0015	1.0
Vegetables, other	0.2	160	0.0321	21.2
Condiments and spices	0	5	0.0000	0.0
Oranges & citrus fruits	0.2	20	0.0038	2.5
Other fruits	1	92	0.0921	61.0
Meat and poultry	0.02	14	0.0003	0.1
Eggs	0.02	4	0.0001	0.1
Milk	0.02	179	0.0036	2.4
Sugar & sweeteners[1]	0	105	0.0000	0.0
Animal fats	0.02	6	0.0001	0.1
Vegetable oil & crops[2]	0	45	0.0000	0.0
Tea, cofee and cocoa	0	2	0.0000	0.0
Total pesticide intake			**0.1510**	
ADI			**0.0360**	
Per cent of ADI			**419**	

Food commodity	Indian MRL (mg/kg)	Diet (gm/day)	Pesticide intake (mg/day)	Distribution* (per cent)
Cereals	0.025	119	0.0030	9.8
Leafy vegetables	0.2	7	0.0013	4.4
Roots & tubers	0.05	38	0.0019	6.3
Other vegetables	0.2	16	0.0032	10.6
Fruits[3]	0.86	20	0.0175	57.6
Meat, Fish & egg[4]	0.012	10	0.0000	0
Milk & milk products	0.02	164	0.0033	10.8
Pulses	0	20	0.0000	0
Sugar & sweeteners	0	19	0.0000	0
Oil and fats	0.02	7	0.0001	0.5
Condiments & spices	0	4	0.0000	0
Total pesticide intake			**0.0305**	
ADI			**0.0060**	
Per cent of ADI			**508**	

Note: Monocrothophos JMPR ADI = 0.0006 mg/kg of body weight

*This means: the proportion of pesticide intake through different food items.

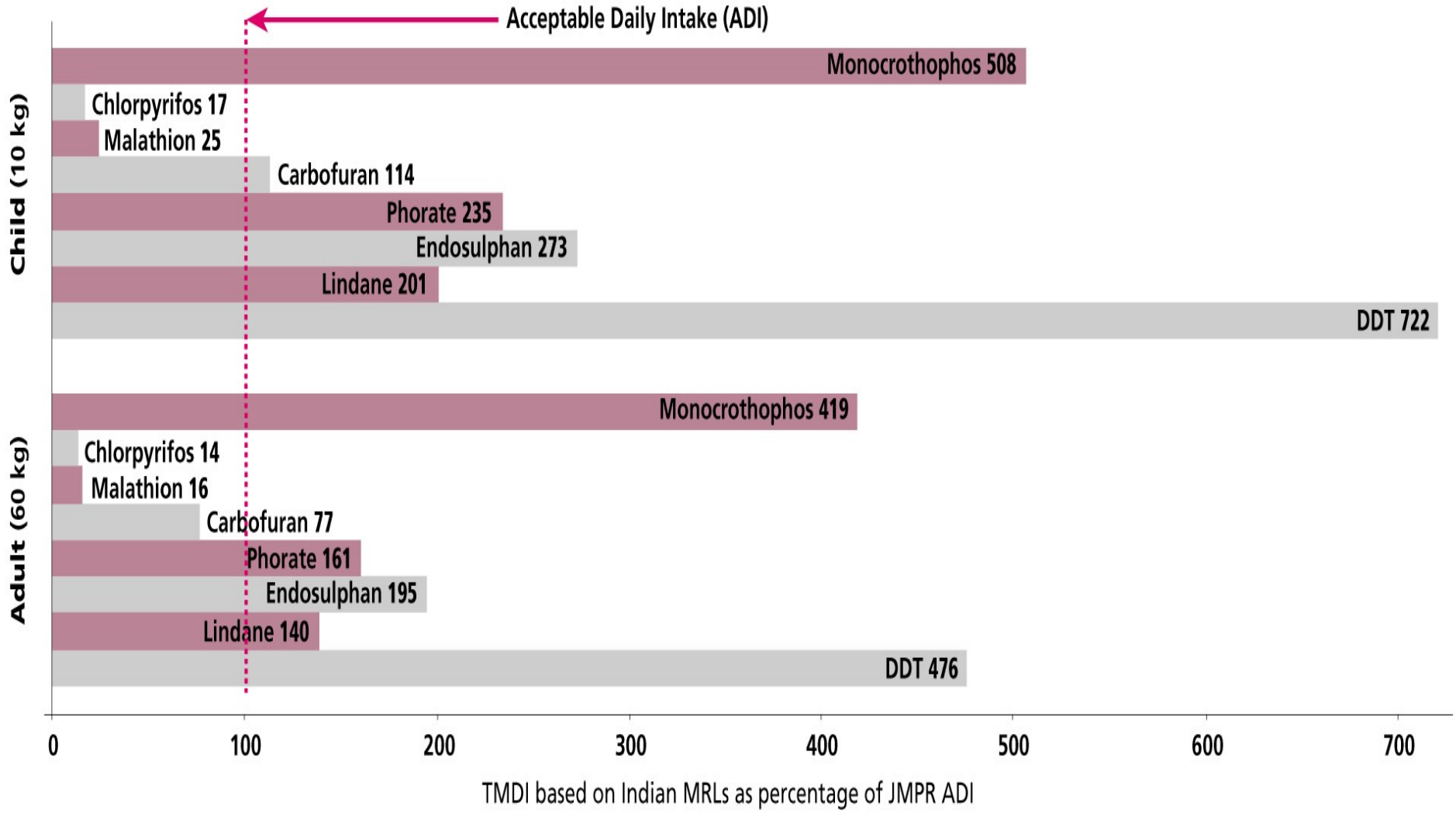
1 There is MRL for sugar beet, but none for sugarcane. Therefore MRL assumed as 0. This is an under-estimation.

2 There is MRL for cotton seed oil but data for consumption not available there for assuming MRL as 0. This is an under-estimation.

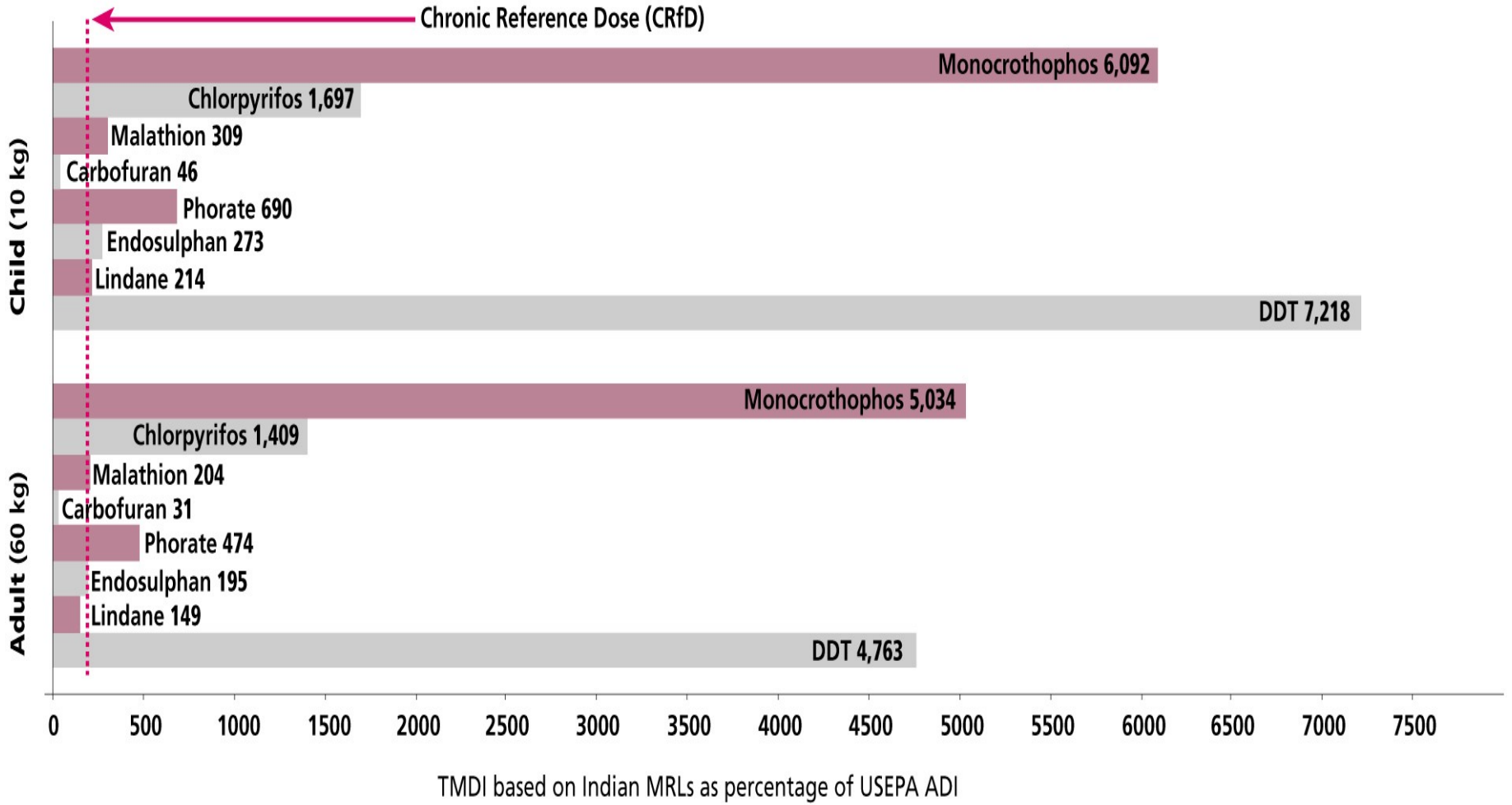
3 Consumption data for fruits not available separately. MRL for fruits is weighted MRL of citrus fruits and other fruits using consumption pattern as per FAO 2001 FBS.

4 Separate consumption data not available. MRL for meat, fish and egg is weighted MRL, using consumption pattern as per FAO 2001 FBS. This is an under-estimation.

Indian ‘prudent tradeoff’- TMDI vs. JMPR ADI



Indian ‘prudent tradeoff’- TMDI vs. UDEPA CRfD



ADI: India using pesticides with high chronic toxicity

Name of pesticide	Production 1998-99 to 2004-05 (last 5 years) (tonnes)	JMPR - ADI (WHO/FAO) (mg/kg bw)	YEAR OF REVIEW	US-EPA CRfd (mg/kg bw)	YEAR OF REVIEW
Monocrotophos	42000	0.0006	1995	0.00005	1986
Chlorpyriphos	29500	0.01	1999	0.0001	1999
Endosulphan	27100	0.006	1998	0.006	1993
Malathion	23500	0.3	1997	0.024	2000
Cypermethrin	23500	0.05	1996	0.01	1996
Acephate	20900	0.01	2002	0.0012	2000
Phorate	20200	0.0005	1996	0.00017	1999
D.D.T.	18300	0.005 (Conditional)	1983	0.0005	1994
Dichlorovos--D.D.V.P.	13700	0.004	1993	0.00017	1998
Ethion	11600	0.002	1990	0.0005	1999

But does CSE's estimations reflect the ground realities?

- CSE's estimations are not really over estimates - because few detailed total diet study done in India got very similar results.

Kanpur Total Diet Study

- Done by Department of Soil Science and Agricultural Chemistry, C S Azad University of Agriculture and Technology and Published in Dec 2002
- Collected samples of food normally eaten from in and around Kanpur, and analysed them for residues of organochlorine pesticides

Result of Kanpur Study

- The daily HCH intake in average vegetarian diet exceeded ADI by 110 per cent. In average non-vegetarian diet, this pesticide's intake exceeded ADI by 118 per cent;
- The daily Aldrin intake in average vegetarian diet exceeded ADI by 442 per cent; in average non-vegetarian diet, by 1,500 per cent;
- The daily Dieldrin intake in average vegetarian diet exceeded ADI by 514 per cent; in average non- vegetarian diet, by as much as 6000 per cent.

AICRPPR Total Diet Study

- Details not available, but following results were published.
- 75 per cent of 264 vegetarian diet samples were found to contain residues of different pesticides. The presence of DDT and HCH were reported from most part of the country. Also, 11 per cent diets contained residues of pesticides above their ADI values.
- Similarly, 72 per cent of 243 non-vegetarian diet samples were found to be contaminated mainly with DDT, HCH, Endosulfan, Chlorpyrifos; 15 per cent of which were above ADI values

How safe are the MRLs?

- Even with all the missing MRLs, the TMDI values are very high, indicating that MRLs were never set in the country using ADI – **now we know that this was the case**
- This means that all the data on contamination levels shown before – **meeting or not meeting MRLs** – does not makes any sense now because the MRL itself is not set correctly
- Even if all our food commodities meet the existing MRLs, there is no guarantee of safety – as the sum total exposure exceeds ADI by a wide margin

How safe are the MRLs?

- The fact is that, MRLs in the country was indeed being set to fulfill legal formalities - simply because, though we had enacted the law, we had not setup the machinery to implement the law.
- Even today that is the status.
- Unless we have a viable plan and system to regulate pesticide levels in food commodities – all these standards make no sense

Our regulatory challenges

- Considering the highly fragmented nature of our landholdings, wherein only 1.6% holdings are more than 10 hectares (ha) in size and about 60% are less than 1% in size, how do we really monitor and implement the pesticide standards?
- We know that waiting period is not followed; we know that industry and pesticide dealers give wrong advice and supply wrong pesticides to farmers; we know that fruits and vegetables are treated just before marketing – But what are we doing about it?
- The one place where we can actually regulate, processed food, we have no standards in place to monitor? Industry doesn't wants it to happen and the government is supporting it.

Our regulatory system

- The most critical stage to reduce the impact of pesticide on the population is at the registration stage itself.
- But we fail at that stage.
- RC notifies that it has ‘restricted’ the use of Lindane, Methyl Parathion, Methyl Bromide, Sodium Cyanide. It says that it has banned the use of Monocrotophos on vegetables.
- But does it really have a system in place to implement these ‘restrictions’? The answer is no.

Our regulatory system

- RC does not have a system in place to actually review the registered pesticides regularly.
- Countries learning to determine "comparative risk assessment" of new products, before being registered. It favours lower risk products.
- Already being done in Sweden and part of wider EU policy approach on chemicals.
- New product can be registered only if its acute and chronic toxicity is less than existing pesticides. Can we do this?

Regulation costs money?

- More chemicals we register, higher the cost of regulation;
- In USA, managing pesticide risks cost 7.4 per cent of gross pesticide sale between 1971-95.
- The greater the registered/in use pesticide, the more the costs of surveillance, residue analysis, enforcement etc. Can we afford this cost? Who will pay?
- Cannot say that we are poor to enforce health-regulations once we have allowed use of substance.

We will have to rework our systems

- We will have to completely rework our existing regulatory mechanism for registering and using pesticides – FAO's International Code of Conduct on distribution and use of pesticide is a good starting point – **the minimum we must do**
- We will have to revise our standards to make sure ADI is not exceeded
- Then we have to make sure that the standards are enforced. Information is made available to the public and the entire process is transparent

What do we do then?

- **Slowly, world is moving beyond finding linkages between pesticides and disease they cause. It is no more important.**
- **It is understood that these toxins will have implications, even if we cannot prove it by scientific means.**
- **What is more important is to know how much and how many of these chemicals are trespassing human bodies.**
- **The new idea in regulation is to use biomonitoring studies to regulate chemicals.**
- **Can we introduce it in India?**

Stopping the treadmill

- **1939: DDT discovered. Paul Muller awarded Nobel Prize.**
- **1972: DDT found to be persistent. Bioaccumulative. Banned in US.**
- **Industry introduces alternatives calling it safe and less persistent: Methoxychlor and dicofol – relatively close to DDT. Endosulfan – with sulfur in structure.**
- **But found to be persistent - and problematic. They too are restricted/ banned in many countries**
- **Organophosphates introduced.**
- **Discovered in 1930s – used as nerve gas. Higher toxicity. Reduce the ability of enzyme cholinesterase to regulate signals between neurons**

Treadmill..costly

- **1990s: concern for children health grows. Scientists find that OPs not as low persistent as told by industry. Residues found in food, water and body fluids. Organophosphates indicted for childhood developmental problems.**
- **Review of organophosphates begins.**
- **USEPA introduces “common mechanism of toxicity” – cumulative toxic effects. Also cumulative risk assessment. Revised all RfDs for many OPs.**
- **Many like Monocrotophos banned**

No liability – only profits

- Commercial interests in new products and substitutes. Politics of science and data.
- Inventors get incentives through IPRs.
- Inventors of products that are found to have adverse impacts should also be penalised – strict liability on each product.
- Will force companies to do careful assessment and may be create incentives for environment-friendly products.
- **Need a global product assessment and liability convention.**

What we need….

- Safe and wise use policy for pesticides
- Scientific standard setting – include ADI
- Harmonization between registration and MRLs
- Re-registration to consider new scientific data in to decision making
- Comparative risk assessment methodology before we introduce new pesticides
- Transparency and accountability in registration
- Better surveillance and enforcement – Not only for food but also for body burden
- Public disclosure of monitoring data and use of data for regulation – ban problematic pesticide
- Global product assessment and liability convention