CENTRE FOR SCIENCE AND ENVIRONMENT RECOMMENDATIONS

on the

FSSAI DRAFT REGULATIONS FOR INSECTICIDES AND ANTIBIOTICS

Centre for Science and Environment

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CSE COMMENTS AND SUGGESTIONS ON FSSAI DRAFT REGULATIONS FOR INSECTICIDES AND ANTIBIOTICS

The Food Safety and Standards Authority of India (FSSAI) had issued a notice in November 2015, calling for claims, suggestions, views, comments etc. from stakeholders on the draft amendment related to pharmacologically active substance prohibited for fish and fishery products; harmonization of insecticides, antibiotics and veterinary drugs residues; and fixation of MRLs for 17 insecticides. See *Annexure 3* for the FSSAI notice.

Key points—reflecting fundamental change required in the proposed draft

Maximum Residue Levels (MRLs) of an insecticide should be based on its Acceptable Daily Intake (ADIs): There should be no exception to this. All insecticides registered in India should have an ADI based on the Indian diet. MRLs should be revised if the exposure is greater than ADI or if an insecticide is approved for additional foods/crops.

Setting default tolerance limit would create a gap in insecticide regulations: The proposed default limit of 0.01 mg/kg allows for use of all insecticides irrespective of their status of registration, exposure etc., which should not be the case. It creates a gap in the pesticide regulation system. On one hand, it allows for all kinds of insecticides to be used against all kinds of foods/crops and defeats the purpose of the registration process. On the other hand, it bypasses the best practice of linking MRLs with ADIs. This could lead to an uncontrolled cumulative exposure of insecticides and should therefore not be adopted.

Limit of detection (LoD) should be used to discourage unlawful/unwanted presence of a chemical entity (insecticide/antibiotic): Limit of quantification (LoQ) helps establish certainty with a quantifiable number. In general, it is about three to four times higher than the LoD. Limit of detection on the other hand detects presence at a much lower level. It is a stringent and sufficient criterion to detect unlawful/unwanted presence of a chemical entity(ies) that is banned/not registered or is to be discouraged.

Regulations on antibiotics should aim to help control limit antibiotic resistance from animal use: In the proposed draft, 'IMPORTANCE' of antibiotics should also be factored in along with 'USE' of antibiotics. Presence of antibiotics that are considered critically important for humans should be regulated to discourage its use. LoD should be used to detect unwanted/unlawful presence of critical antibiotics.

CSE comments and suggestions on FSSAI notice

	RELEVANT SECTION	COMMENTS AND SUGGESTIONS	RATIONALE	REMARKS
PART 1: INSECTICIDES				
1.	**Insecticides which are registered under the Insecticides Act, 1968** (*Section 2.3.1 [1]*) (see *Figure 1, Annexure 1* for comments in process flowchart)	1. All registered insecticides (261) should have MRLs set. The proposed draft has MRLs for 197 insecticides. There are 64 insecticides registered under the Insecticides Act, 1968, but no MRLs are listed by the FSSAI. Of these, the European Union (EU) has MRLs for 21 and Codex has MRLs for five insecticides. The Food Safety and Standards Authority of India (FSSAI) should set MRLs for these insecticides (see *Table 1, Annexure 1*). Further, MRLs should be set for all registered pesticide-crop combinations (see *Table 2, Annexure 1*). 2. All MRLs for registered insecticides should be checked against ADIs. It should be aimed to be completed within a year. A CSE analysis of Theoretical Maximum Daily Intake (TMDI) of select insecticides suggests how existing MRLs exceeds ADI and highlights the importance of linking MRLs with ADIs (see *Table 3, Annexure 1*) i. In the case of 1) MRLs fixed under regulations and 2) MRLs not fixed under regulations and Codex MRL at Limit of Quantification (LoQ): • MRLs for pesticide–crop combinations should be checked against ADI. Only if exposure is in the acceptable range should MRL be accepted. Else, risk assessment should be performed based on which: ○ In case of 1): MRLs need to be adjusted or label claims to be deleted ○ In case of 2): MRLs need to be adjusted or label claims to be deleted or Codex MRLs at LoQ to be accepted (instead of directly opting to adopt Codex MRLs) ii. In case of MRLs not fixed under regulations and 1) Codex MRL above LoQ, but exposure not within acceptable range and, 2) no Codex MRLs and no monitoring data available: • Label claims should be deleted • There should be no default tolerance limit of 0.1 mg/kg. LoD should be used to detect presence • Besides, more clarity is required on proposed process of refinement for risk assessment. 3. Details on timelines, roles and responsibility of stakeholders to carry out the risk assessment and finalizing MRLs should be mentioned and shared in public domain.	• It is of paramount significance to have MRLs for all insecticides registered and in accordance with the crop-pest combinations. • MRLs based on ADI are the best practice. If required, MRLs should be readjusted. • Limit of detection is a stringent and sufficient criterion to detect unlawful/unwanted presence than LoQ. • Default tolerance limit would allow use of all pesticides and bypass the need to base MRLs on ADIs. • Updated information in public domain is most essential.	Modify as suggested

	RELEVANT SECTION	COMMENTS AND SUGGESTIONS	RATIONALE	REMARKS
2.	**Insecticides not registered under the Insecticides Act, 1968** ([*Section 2.3.1 [2]*]) (see *Figure 1, Annexure 1* for comments in process flowchart)	1. These insecticides should not be used, so LoD should be set in such cases to detect unwanted/unlawful presence. Details of testing methodology should also be provided. 2. Default tolerance limit of 0.01 mg/kg or LoD, whichever is lower should be set and allowed only for imports.	Insecticides not registered under the Act should not be allowed for use. The set default tolerance limit of 0.01 mg/kg will allow such use of those which are not registered/banned/withdrawn. It is important to set stringent criteria to detect presence of such insecticides.	Modify as suggested
3.	**Insecticides banned under the Insecticides Act, 1968** (*Section 2.3.1 [3]*) (see *Figure 1, Annexure 1* for comments in process flowchart)	1. These insecticides should not be used/detected, so LoD should be set in such cases. Details of testing methodology should also be provided. 2. Wherever such insecticides are detected, matter should be referred for further investigation. Extraneous Maximum Residue Levels (EMRLs) of 0.01 mg/kg should not be set.	Insecticides that are banned should not be detected as they are not allowed to be used. It is important to understand the cause of such presence. Necessary investigation is required to see if these insecticides are being used unlawfully or to know the reason for the entry of such insecticides. The proposed EMRL would create a gap for such illegal use or unwanted presence.	Modify as suggested
4.	**List of insecticides with MRLs in foods** ([*Section 2.3.2 [2]*])	1. MRLs should be set for individual food entity(ies) instead of broad food categories; specifically, limits for broad categories are higher than for individual food entity(ies) in Codex and/or EU (see *Table 4, Annexure 1* for a few examples). 2. Insecticides that are banned/withdrawn/restricted for use by the Central Insecticide Bureau and Registration Committee (CIBRC) should be accordingly excluded from the proposed FSSAI list (see *Table 5, Annexure 1* for examples).	• MRLs for broad food categories (instead of individual food entity(ies) could lead to: a. Higher limits for individual food entity(ies) b. Inclusion of food entity(ies) for which insecticides may not be tested or approved but which are part of the food category. • Only approved use of insecticides should be allowed.	Modify as suggested
5.	**List of insecticides banned as per the Insecticides Act, 1968** (*Section 2.3.2 [3]*)	1. The proposed FSSAI list of banned insecticides needs to be corrected and updated. It should mention all insecticides that are banned, withdrawn or restricted to be used by CIBRC (see *Table 6, Annexure 1*).	• Insecticides banned by CIBRC should be banned by FSSAI.	Modify as suggested

	RELEVANT SECTION	COMMENTS AND SUGGESTIONS	RATIONALE	REMARKS
PART 2: ANTIBIOTICS				
6.	**Drugs, pesticides and antimicrobials including antibiotics for veterinary use, registered under Drugs and Cosmetic Act (D&C Act), 1940** (*Section 2.3.3 A*), **List of antibiotics used both in humans and animals** (*Section 2.3.4, 4[1]*) AND **List of antibiotics exclusively used in animals** (*Section 2.3.4, 4[2]*) (see *Figure 1, Annexure 2* for comments in process flowchart)	1. The proposed standards should be based on a consolidated and complete list of antibiotics registered under D&C Act, including those approved by the Central Drug Standards Control Organization (CDSCO) and all state departments. Further, a periodically updated list should be in the public domain. i. As of now, the two current lists, i.e. 1) antibiotics used both in humans and animals and 2) antibiotics used exclusively in animals are largely based on a CDSCO- approved drug list for veterinary use. As there is no consolidated list with antibiotics additionally approved by state departments in the public domain, it is difficult to ascertain if antibiotics from these have been included. ii. Further, several antibiotics approved by CDSCO are not part of proposed draft. Cephalexin, tetracycline, sulphamethoxazole, neomycin, levofloxacin and amoxicillin are some examples (see *Table 1, Annexure 2*). iii. The list of antibiotics that are exclusively used in animals should be corrected and periodically updated. For example, • Colistin sulphate (mentioned in the list) apart from being extensively used in animals (for example, as a growth promoter in chickens) is now also used in humans as a last resort. • Further, it is difficult to ensure exclusive use of antibiotics in animals. The D&C Act for example does not recognize non-therapeutic use of antibiotics, thereby having no control over such use in animals. 2. Limit of detection should be set for antibiotics which belong to classes of critically important antimicrobials. A separate such list should be specified: i. The list could be based on the World Health Organization (WHO) list of critically important antimicrobials for human use[1] (see *Table 2, Annexure 2* for classes of critically important classes). ii. Limit of detection will monitor unlawful/unwanted presence as use of such antibiotics is to be discouraged in order to preserve them for human use. 3. Also, set LoD for antibiotics not recommended for use by Codex and/or banned in other countries on the basis of toxicity, such as chloramphenicol and furazolidone, which as of now are part of proposed draft. These should be specifically prohibited and such a list should be periodically updated.	• As standards are based and differ on 'USE' of antibiotics in animals and humans, it is important to have a complete and correct understanding of antibiotics registered with D&C Act for animal use across the Center and state drug-control departments in the country. • Standards for antibiotic residues have to be an integral part of a country-level plan to combat the growing threat of antibiotic resistance. Globally, specific focus has been put on preserve antibiotics considered critically important for human use. It is therefore important to discourage use of such antibiotics. • With high level of overlap in classes of antibiotics (including those that are critical) used in animals and humans, it is important to factor in into the standards, the 'IMPORTANCE' based on criticality to humans rather than only 'USE' of antibiotics. Since this involves classes and not individual antibiotics (as what is proposed), it further address the issue of cross resistance. For example, the rising cross resistance because of popular use of enrofloxacin (a fluoroquinolone) in chickens and ciprofloxacin in humans worldwide (including in India) led to a ban/restriction on enrofloxacin/ fluoroquinolones in animals in some countries (for example, the US, Denmark, Netherlands). • The Department of Animal Husbandry, Dairying and Fisheries (DADF) through its advisory of June 2014[2] and Dec 2014[3] does not allow use of antibiotic growth-promoters (which may include antibiotics from critically important classes) and promotes judicious use of antibiotics. Restriction on therapeutic use of critical antibiotics should be the next step through concerned drug department and animal husbandry department. In such a scenario, LoD is a monitoring tool that should be used to discourage use and detect unwanted/ unlawful presence.	Modify as suggested

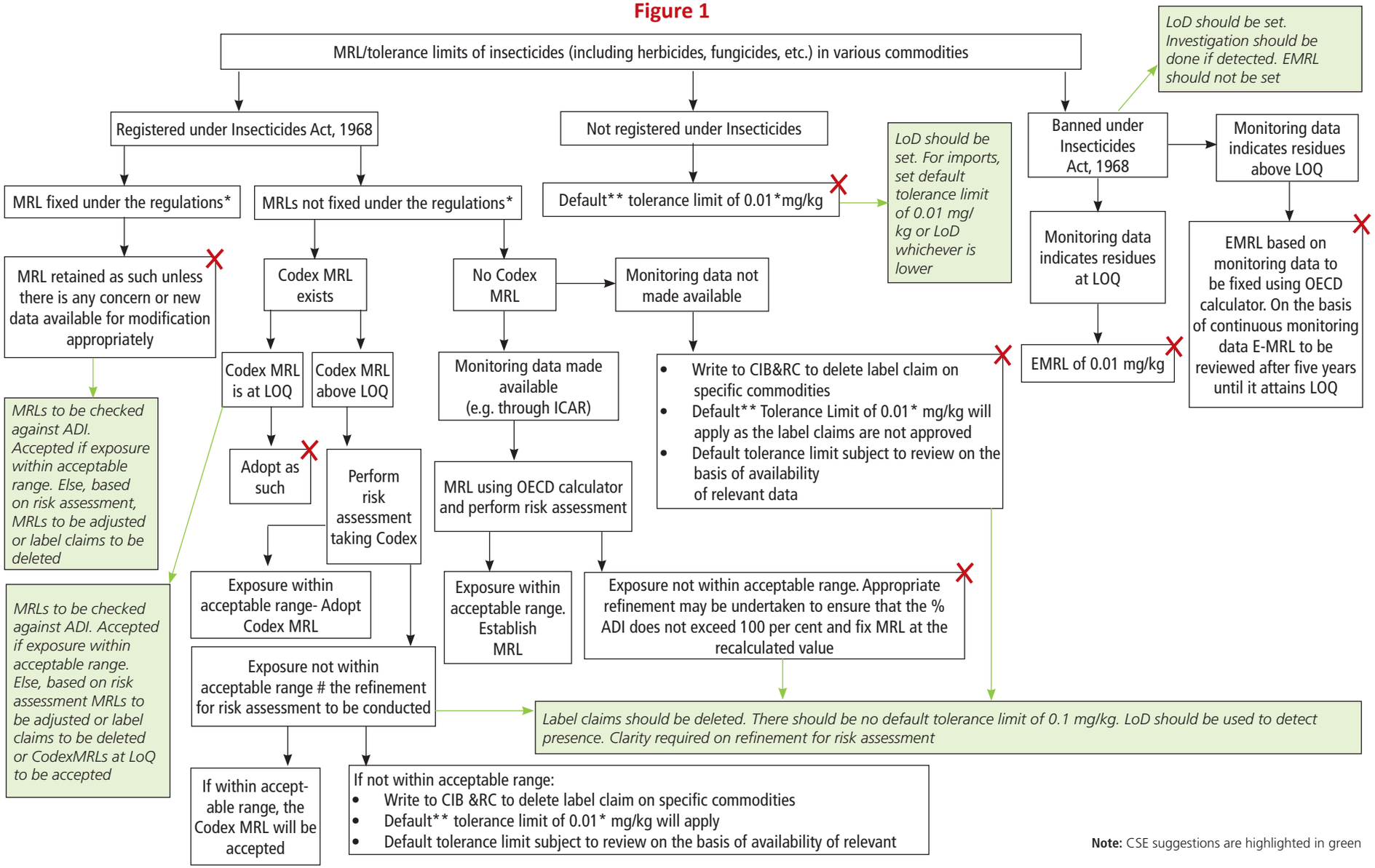
	RELEVANT SECTION	COMMENTS AND SUGGESTIONS	RATIONALE	REMARKS
7.	**Antibiotics which are not registered under D&C Act should be prohibited from use** (*Section 2.3.3 B*)	1. Level of detection should be set 1) In case of critically important antibiotics and 2) Antibiotics not recommended for use by Codex and/or banned in other countries on the basis of toxicity—such as carbadox—and are mentioned in proposed list. Also provide testing methodology details with LoD. 2. For other antibiotics, whichever is lower between LoD or default tolerance limits of 0.001 mg/kg should be set.	Use of antibiotics that are not registered, are critical for humans as well as not recommended due to toxicity should not be used.	Modify as suggested
8.	**List of prohibited antibiotics in seafood-processing units** (*as per Section 2.3.3 C [2]*)	1. Fluoroquinolones along with certain other anibiotics should be included in this list. These were part of the earlier list of prohibited antibiotics, which seem to have been modified (see *Table 3, Annexure 2*). 2. Level of detection should be set and used to monitor unlawful presence.	Critically important antibiotics should not be allowed to be used. In view of the growing threat of antibiotic resistance, there is limited merit in losing control of antibiotic use, particularly in processing units.	Modify as suggested
9.	**Tolerance limits for antibiotics in honey** (*as per Section 2.3.3 C [3]*)	1. As per the FSSAI advisory of 2011, no antibiotics are allowed to be present in honey.[4] Instead of setting the tolerance limit at LoQ, LoD should be set to detect unlawful/unwanted presence. 2. Further, a separate list should be specified for those not recommended by Codex to be used for toxicity, such as chloramphenicol and nitrofurans like furazolidone. As of now, these are part of the existing draft.	Antibiotic use in honey is to be discouraged through strict control. Further, there is a need to specify highly toxic antibiotics.	Modify as suggested

References:

1 WHO list of critically important antimicrobial for human use, 2011: http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf
2 DADF Advisory of June 2014: http://www.cdsco.nic.in/writereaddata/Meneka%20Sanjay%20Gandhi.pdf
3 DADF Advisory of Dec 2014: http://dahd.nic.in/dahd/WriteReadData/Advisory%20on%20use%20of%20antibiotics%20in%20food%20producing%20animals.pdf
4 FSSAI advisory on antibiotics in honey: http://www.fssai.gov.in/portals/0/pdf/Advisory%20honey_24sept2010.pdf

ANNEXURE 1—INSECTICIDES

Figure 1



Note: CSE suggestions are highlighted in green

Table 1: CIBRC registered insecticides for which MRLs are not set by FSSAI; however, Codex and/or EU have MRLs for few (highlighted)

Insecticide#	Insecticide#	Insecticide#	Insecticide#
Allethrin	Coumachlor	Lime sulphur	**Pyraclostrobin^ + epoxiconazole^**
Aluminium phosphide	Coumatetralyl	Magnesium phosphide plates	S-bioallethrin
Ampelomyces quisqualis	**Cyfluthrin*^**	**Metaldehyde^**	Sodium cyanide
Azadirachtin^ (neem products)	Cyphenothrin	*Metarhizium anisopliae*	Streptomycin + tetracycline
Bacillus sphaericus	**Dazomet^**	Methoxy ethyl mercury chloride (MEMC)	Sulphur
Bacillus thuringiensis var. galleriae	Dichloropropene and Dichloropropanemixure (DD mixture)	**Methyl bromide***	Temephos
Bacillus thuringiensis var. israelensis	D-trans allethrin	Metofluthrin	**Tetraconazole^**
Bacillus thuringiensis var. kurstaki	**Endosulfan*^**	Nuclear polyhyderosis virus of *Helicoverpa armigera*	Thiomethoxain
Barium carbonate	Ethiprole	Nuclear polyhyderosis virus of *Spodoptera litura*	**Thiopanate methyl + pyraclostrobin^**
Beauveria bassiana	Ethylene dichloride and carbon tetrachloride mixture (EDCT Mixture 3:1)	**Oxycarboxin^**	**Thiram^**
Bendiocarb	**Flufenoxuron^**	Prallethrin	**Topramizone^**
Bifenazate*^	**Flufenzine^**	**Propanil^**	Transfluthrin
Bromadiolone	Gibberellic acid	Propetamphos	*Trichoderma harzianum*
Carboxin^	**Imazamox^**	**Propoxur^**	*Trichoderma viride*
Chlorpyriphos methyl*^	Imiprothrin	*Pseudomonas fluorescens*	*Verticillium lecanii*
Clodinafop-propargyl + sodium acifluorfen	**Iprovalicarb^**	**Pymetrozin^**	Zinc phosphide

Note: The list is based on CIBRC list of registered insecticides as on 20.10.2015. # Insecticides include biocides, pesticides, fungicides etc.; *Insecticides (5) for which Codex has MRLs; ^Insecticides (21) for which EU has MRLs

Table 2: Discrepancies in the FSSAI proposed list of insecticide MRLs and their respective approved uses by CIBRC (some examples)

	Insecticide	Crops approved for by CIBRC	Food commodities for which MRLs are proposed
1	Beta cyfluthrin	Cotton	Okra, brinjal, cottonseed
2	Fenvalerate	Cauliflower, brinjal, okra, cotton	Cauliflower, brinjal, okra, cottonseed, cottonseed oil, meat and poultry, milk, red gram, Bengal gram, groundnut, cabbage, tomato
3	Dichlorvos	Paddy, wheat, soybean, castor, groundnut, mustard, sunflower, cucurbit, cashew	Foodgrains, milled food grains, soybean, fruits, vegetables, mustard seed/oil, groundnut seeds, groundnut oil, milk
4	Emamectin benzoate	Cotton, okra, cabbage, chilli, brinjal, red gram, chickpea, grapes	Cottonseed, cottonseed oil, okra, groundnut oil, milk

Note: As per CIBRC list titled 'Major uses of insecticides dated 31.08.2015'

Table 3: Theoretical Maximum Daily Intake (TMDI) as percentage of ADI (calculations for select insecticides based on JMPR ADIs)

Diet for TMDI calculation*			Dimethoate			Captan			Carbofuran		
	Adult (g/day)	Child (g/day)	*MRL (mg/kg)*	Adult intake (mg)	Child^ intake (mg)	*MRL (mg/kg)*	Adult Intake (mg)	Child^ intake (mg)	*MRL (mg/kg)*	Adult intake (mg)	Child^ intake (mg)
Cereal and millets	**375**	**60**									
Rice	173	28	***0.01***	0.00173	0.00028	***0.03***	0.00519	0.00084	***0.1***	0.0173	0.0028
Wheat	139	22							***0.03***	0.00417	0.00066
Others	63	30							***0.1***	0.0063	0.003
Pulses	75	30							***0.1***	0.0075	0.003
Milk and milk products	**300**	**515**	***0.05***	0.015	0.02575				***0.05***	0.015	0.02575
Roots and tubers	**200**	**50**	***2.0***	0.4	0.1	***15***	3	0.75	***0.1***	0.02	0.005
Potato	116	29									
Onion	62	15.5									
Others	22	5.5									
Green leafy vegetables	**100**	**50**	***2.0***	0.2	0.1	***15***	1.5	0.75	***0.1***	0.01	0.005
Cabbage	36	18									
Palak and others	64	32									
Other vegetables	**200**	**50**	***2.0***	0.4	0.1	***15***	3	0.75	***0.1***	0.02	0.005
Tomato	44	11									
Cauliflower	24	6									
Brinjal	34	8.5									

Okra	16	4									
Others	82	20.5									
Fruits	**100**	**100**	***2.0***	0.2	0.2	***15***	1.5	1.5	***0.1***	0.01	0.01
Mango	14	14									
Banana	56	56									
Apple	11	11									
Citrus	8	8									
Others	11	11									
Sugar	20	15									
Oils and fats	25	25	***0.01***	0.00025	0.00025				***0.1***	0.0025	0.0025
Tea leaves	3	0							***0.1***	0.0003	
TMDI*				**1.22**	**0.53**		**9.01**	**3.75**		**0.11**	**0.06**
JMPR ADI (mg/day): 60 kg adult**				0.12			6			0.06	
JMPR ADI (mg/day): 12.9 kg child					0.0258			1.29			0.0129
TMDI (as % ADI)				**1014.1**	**2039.8**		**150.1**	**290.8**		**188.4**	**486.1**

*Based on NIN guidelines and NSSO survey based proportions; **JMPR ADI in mg/kg BW for dimethoate is 0.002, captan is 0.1, carbofuran is 0.001; ^ Child of 1–3 years weighing about 12.9 kg. In some cases, assumptions taken while allocating MRLs.

Table 4: Broad categories of food having higher MRLs as proposed by FSSAI and the corresponding lower MRLs of individual food entity(ies) by CODEX (few examples)

	Name of insecticide	Commodity	FSSAI MRL (mg/kg)	CODEX MRL(mg/kg)
1	2,4-Dichlorophenoxy acetic acid	Fruits	2.0	0.1 (berries and other small fruits) 1 (citrus fruit) 0.01 (pome fruits) 0.05 (stone fruits)
2	Chlorpyriphos	Meat and poultry (carcass fat)	0.1	0.01 (poultry meat) 0.01 (poultry edible offal of)
3	Paraquat dichloride	Foodgrains	0.1	0.03 (maize) 0.05 (rice) 0.03 (sorghum)
4	Phorate	Meat and poultry	0.05	0.05 (poultry meat) 0.02 (edible offal)
5	Pyrethrins	Fruits and vegetables	1.0	0.05 (citrus fruits) 0.2 (dried fruits) 0.05 (fruiting vegetables, cucurbits) 0.05 (roots and tuber vegetables) 0.05 (tomato)

Table 5: Insecticides with restricted approved use by CIBRC, but have MRLs set otherwise (few examples)

	Insecticide (status at CIBRC)	FSSAI status
1	Diazinon (banned for agriculture)	MRLs for foodgrains and vegetables
2	Fenitrothion (banned in agriculture)	MRLs for foodgrains, milk, meat etc.
3	Fenthion (banned in agriculture)	MRLs for foodgrains, milk, meat etc.
4	Monocrotophos (banned for use on vegetables)	MRLs for carrot, turnip, etc.

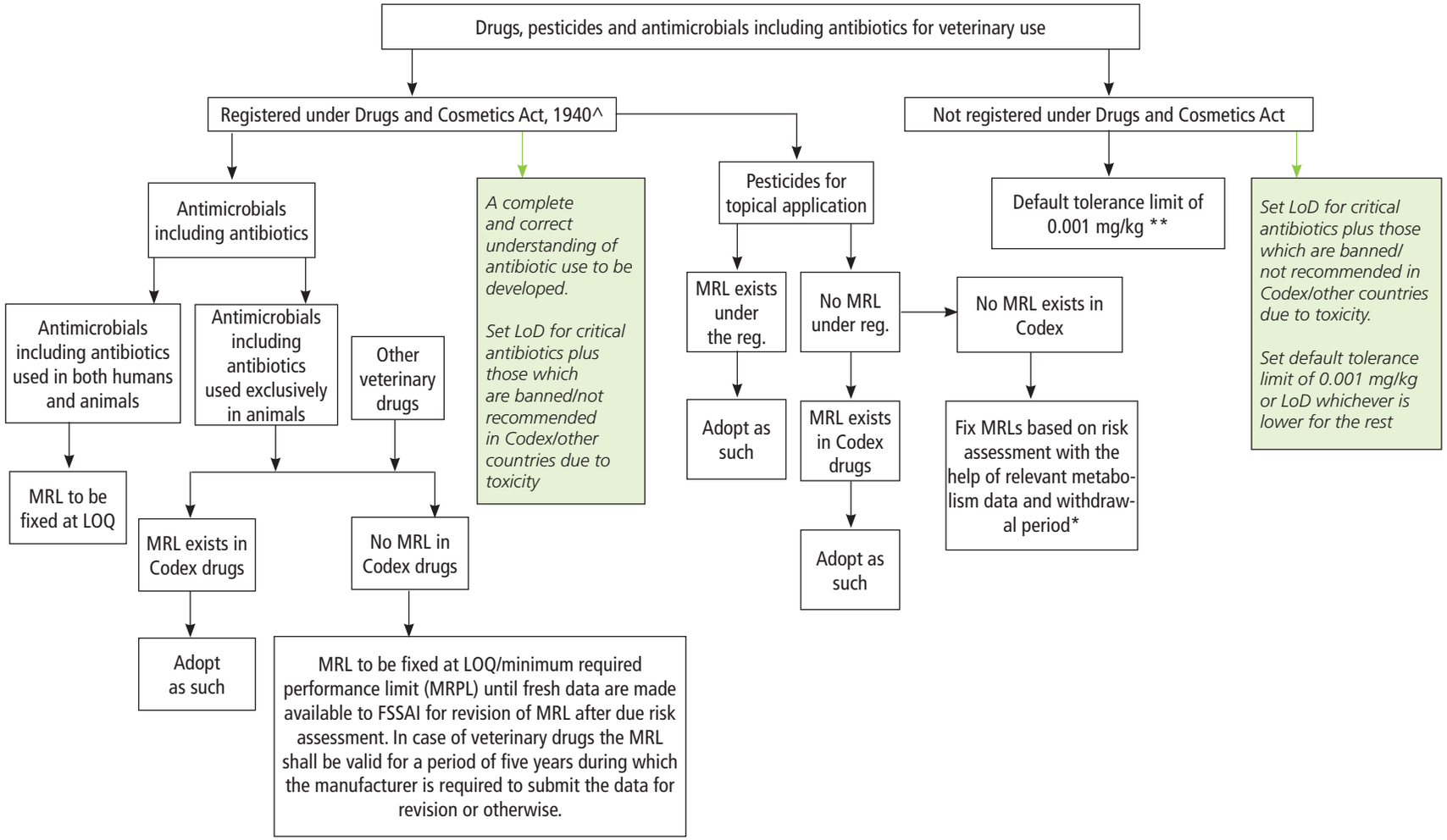
Note: based on CIBRC 'List of pesticides/ formulations banned in India as on 20.10.2015'

Table 6: Insecticides that should be considered for modification of FSSAI proposed list of banned insecticides

	Insecticides			
Pesticides banned for manufacture, import and use	1	Benzene hexachloride	12	Menazon
	2	Calcium cyanide	13	Metoxuron
	3	Chlorbenzilate	14	Nitrofen
	4	Chlorofenvinphos	15	Paraquat dimethyl sulphate
	5	Copper acetoarsenite	16	Pentachloro nitrobenzene (PCNB)
	6	Dibromochloropropane (DBCP)	17	Pentachlorophenol
	7	Endrin	18	Phenyl mercury acetate
	8	Ethyl mercury chloride	19	Sodium methane arsonate
	9	Ethyl parathion	20	Tetradifon
	10	Ethylene dibromide (EDB)	21	Toxaphene (camphechlor)
	11	Maleic hydrazide	22	Trichloro acetic acid (TCA)
Pesticide formulations banned for import, manufacture and use	23	Carbofuron 50% SP		
Pesticide/pesticide formulations banned for use but continued to manufacture for export	24	Nicotin sulfate		
Pesticides withdrawn	25	Dalapon		
	26	Nickel chloride		
	27	Paradichlorobenzene (PDCB)		
	28	Simazine		
	29	Warfarin		

ANNEXURE 2—ANTIBIOTICS

Figure 1



Note: CSE suggestions are highlighted in green

Table 1: Antibiotics approved by CDSCO but not included in the FSSAI lists

	Name of antibiotic		Name of antibiotic
1	Neomycin	8	Penicillin benzyl sodium
2	Benzylpenicillin	9	Tetracycline
3	Kanamycin	10	Levofloxacin
4	Ofloxacin	11	Cephalexin
5	Cefovecin	12	Sulphamethoxazole
6	Cefouroxime	13	Amoxicillin
7	Benzathine benzyl penicillin		

Table 2: List of critically important antibiotic classes for human use as per WHO

	Antibiotic class		Antibiotic class
1	Aminoglycosides	9	Macrolides and ketolides
2	Carbapenems and other penems	10	Monobactams
3	Cephalosporins (3rd and 4th generation)	11	Oxazolidinones
4	Cyclic esters	12	Penicillins (natural, aminopenicillins andantipseudomonal)
5	Fluoro- and other quinolones	13	Polymyxins
6	Glycopeptides	14	Rifamycins
7	Glycylcyclines	15	Drugs used solely to treat tuberculosis or other mycobacterial diseases
8	Lipopeptides		

Source: 'Critically Important Antimicrobials for Human Medicine', 3rd Revision, 2011, WHO

Table 3: Antibiotics excluded in the proposed list (but present in the earlier version) of prohibited substances in seafood industry

	Name of antibiotic		Name of antibiotic
1	Nitrofurans including nifuratel, nifuroxime and nifurprazine	4	Nalidixic acid
2	Neomycin	5	Fluoroquinolones
3	Sulfonamide drugs (except approved sulfadimethoxine, sulfabromomethazine and sulfaethoxypyridazine)		

ANNEXURE 3

Notice calling for claims, suggestions, views, comments etc from stakeholders within a period of 60 days on the draft amendment related to Pharmacologically active substance prohibited for fish and fishery products; Harmonization of Pesticides, Antibiotics and Veterinary Drugs Residues; Fixation of MRLs for 17 pesticides.

1. In the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011, in regulation 2.3 relating to "Residues", for sub-regulations 2.3.1 and 2.3.2, the following shall be substituted, namely :-

"2.3.1: Insecticide Residues on Agricultural Commodities and Resultant Processed Food

1. Insecticides which are Registered under Insecticides Act, 1968 (46 of 1968)

In case of recommended crops as per Insecticides Act, 1968 (46 of 1968), maximum residue limits (MRLs) fixed under the regulations shall be retained as such unless there is any concern or new data available for modification appropriately. If MRLs are not fixed under regulation, then it may be checked whether codex MRL for the same is available or not. If codex MRL is available and if the recommended codex MRL is at LOQ, it shall be adopted as such. If the recommended codex MRL is above LOQ, then risk assessment shall be carried out taking codex value. In such cases if the exposure is within acceptable range, codex MRL shall be adopted. If the exposure is not within acceptable range appropriate refinement of risk assessment may be conducted. After refinement, if the value is within acceptable range, then codex MRL may be adopted. If not, then Central Insecticides Board and Registration Committee (CIB&RC) shall be requested to delete appropriate label claims. In such cases default tolerance limit of 0.01*mg/kg shall apply which is subjected to review on the basis of availability of relevant data. If there is no codex MRL, then it may be checked whether monitoring data is available or not. If monitoring data is available MRL may be calculated using OECD calculator followed by risk assessment. If the exposure is within acceptable range, fix the MRL accordingly and if the exposure is not within the acceptable range, appropriate refinement may be undertaken to ensure that ADI is not exceeding 100% and fix the MRL at the recalculated value. If monitoring data is not available, CIB&RC shall be requested to delete label claim on specific commodities. Till that time default tolerance limit of 0.01*mg/kg** shall apply which is subjected to modification or amendment based on availability of data.

2. In cases where insecticides which are not registered under Insecticides Act, 1968 (46 of 1968), a default tolerance limit value of 0.01 mg./kg. shall apply.

3. In cases of insecticides which are banned under Insecticides Act, 1968 (46 of 1968), it is to be identified whether monitoring data indicates residues at LOQ or higher than that. In case the value is at LOQ, the extraneous maximum residue limit (EMRL) as 0.01 mg./kg. at LOQ shall be adopted. In case the value is above LOQ, an EMRL based on monitoring data shall be fixed using OECD calculator. It shall be reviewed after every 5 years and amendment shall be made accordingly till the figure comes to LOQ.

4. The details in form of flow chart as per Annexure I.

2.3.2: *Restriction on the use of insecticides*

(1) Subject to the provisions of regulation 2.3.2(2), no insecticides shall be used directly on articles of food:

Provided that nothing in this regulation shall apply to the fumigants which are registered and recommended for use as such on articles of food by the Registration Committee, constituted under section 5 of the Insecticides Act, 1968 (46 of 1968).

(2) The amount of insecticide mentioned in column (2) on the foods mentioned in column (3), shall not exceed the Maximum Residue Limits (MRL) prescribed in column (4) of the Table given below:

Sl. No. (1)	**Name of the Insecticide (2)**	**Food (3)**	**MRL in mg/kg (4)**
1.	2,4-Dichlorophenoxy Acetic Acid	Sugarcane	0.01
		Food grains	0.01
		Milled food grains	0.01
		Potato	0.2
		Milk	0.05
		Meat and Poultry	0.05
		Eggs	0.05 (shell free basis)
		Fruits	2.0
		Potato	0.2

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
2.	Acephate	Rice	0.07
		Safflower seed	2.0
		Cotton Seed	2.0
		Milk	0.02
		Meat & Meat Products	0.01*
	(a) Methamido-phos- metabolite of Acephate	Safflower seed	0.1
		Cotton Seed	0.1
3.	Acetamiprid	Chilli	0.01
		Rice	0.01
		Okra	0.1
		Cabbage	0.03
		Milk	0.02
		Meat & Meat Products	0.01*
		Cottonseed Oil	0.1
4.	Alachlor	Cotton Seed	0.05
		Groundnut	0.05
		Maize	0.1
		Soybeans	0.1
5.	Alphacypermethrin	Cottonseed Oil	0.05
		Pine Apple	0.5
6.	Alphanaphthyl Acetic Acid	Tomato	0.1
		Chilli	0.2
		Mango	0.05
		Cottonseed Oil	0.05
		Grapes	0.05
		Pineapple	0.5

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
7.	Ametroctradin	Grapes	0.05*
		Potato	0.05*
		Cucumber	0.3
8.	Aminopyralid	Milk	0.01*
9.	Anilophos	Rice	0.1
10.	Atrazine	Maize	Nil
		Sugarcane	0.25
11.	Aureofungin	Citrus	0.01**
12.	Azimsulfuron	Rice	0.02*
13.	Azoxystrobin	Grapes	0.5
		Tomato	1.0
		Mango	0.01
		Chilli	1.0
		Cucumber	0.05*
		Potato	0.05
		Milk	0.01
		Cumin	0.03*
		Maize	0.03*
		Wheat	0.03*
		Rice	0.03*
14.	Benfuracarb	Red Gram	0.05
		Rice	0.05
15.	Benomyl	Food grains	0.5
		Milled food grains	0.1
		Vegetables	0.5
		Mango	2.0

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Banana (whole)	1.0
		Other fruits	5.0
		Cotton seed	0.1
		Groundnut	0.1
		Sugar beet	0.1
		Dry fruits	0.1
		Vegetables	0.5
		Eggs	0.1 (shell free basis)
		Meat & Poultry	0.1 (carcass fat basis)
		Milk	0.1 (F)
16.	Bensulfuron Methyl	Rice	0.01
17.	Beta Cyfluthrin	Okra	0.01
		Brinjal	0.01
		Cottonseed	0.02
18.	Bifenthrin	Sugarcane	0.03
		Rice	0.05
		Apple	0.5
		Tea	0.05
		Cottonseed	0.05
		Milk	0.01
19.	Bispyribac Sodium	Rice	0.05
20.	Bitertanol	Wheat	0.05
		Groundnut	0.1
		Milk	0.05
		Meat & Meat Products	0.01*

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Tea	0.05*
		Apple	0.4
21.	Buprofezin	Cottonseed Oil	0.01
		Chilli	0.01
		Mango	0.01
		Grapes	0.01
		Okra	0.01*
		Rice	0.05
		Milk	0.01
22.	Butachlor	Rice	0.05
23.	Captan	Rice	0.3
		Fruit & Vegetables	15
24.	Carbaryl	Sesamum	0.05
		Fish	0.2
		Food grains	1.5
		Milled food grains	Nil
		Okra and leafy vegetables	10
		Potato	0.2
		Other vegetables	5.0
		Cottonseed (whole)	1.0
		Maize cob (kernels)	1.0
		Rice	2.5
		Maize	0.5
		Chilli	5.0
		Mango	0.01**
		Sugarcane	0.01**
		Citrus (Orange)	0.01**

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Grapes	0.01**
		Milk	0.05
25.	Carbendazim	Food grains	0.5
		Milled food grains	0.1
		Vegetables	0.5
		Mango	2.0
		Banana (whole)	1.0
		Other fruits	5.0
		Cotton seed	0.1
		Groundnut	0.1
		Sugar beet	0.1
		Dry fruits	0.1
		Eggs	0.1(shell free basis)
		Meat & Poultry	0.1(Carcass fat basis)
		Milk	0.1 (F)
		Potato	0.01*
		Tea	0.01*
26.	Carbofuran (sum of 3-hydroxy carbofuran expressed as carbofuran))	Food grains	0.1
		Milled food grains	0.03
		Fruit & Vegetables	0.1
		Oil seeds	0.1
		Sugarcane	0.1
		Meat & Poultry	0.1 (carcass fat basis)
		Milk	0.05 (F)
		Pea	0.01**

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Tea	0.01**
27.	Carbosulfan	Chilli	2.0
		Rice	0.2
28.	Carfentazone Ethyl	Wheat	0.01
28 (a)	Carfentrazone ethyl plus Carfentrazone ethyl cholro propionic acid	Rice	0.1*
		Tea	0.02*
29.	Carpropamid	Rice	1.0
30.	Cartap Hydrochloride	Rice	0.5
31.	Chlorantraniliprole	Bengal Gram	0.03*
		Black Gram	0.03*
		Bitter Gourd	0.03*
		Okra	0.3
		Soybean	0.03*
		Pigeon pea	0.03*
		Tomato	0.03*
		Chilli	0.03*
		Brinjal	0.03*
		Rice	0.03
		Cabbage	0.03
		Sugarcane	0.03
		Cotton	0.03
		Milk	0.05
		Meat & Meat Products	0.01*
32.	Chlorfenapyr	Chilli	0.05
		Cabbage	0.05
33.	Chlorfluazuron	Cabbage	0.1*

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Cottonseed	0.01*
34.	Chlorimuron ethyl	Rice	0.01
		Soybean seed	0.01
		Wheat	0.05
35.	Chlormequat Chloride (CCC)	Potato	0.1
		Brinjal	0.1
		Grape	1.0
		Cotton Seed	1.0
36.	Chlorothalonil	Groundnut	0.1
		Potato	0.1
		Milk	0.07
		Meat & Meat Products	0.01*
37.	Chlorpropham	Potato	30
38.	Chlorpyriphos	Beans	0.01**
		Gram	0.01**
		Black Gram	0.01**
		Coconut	0.01**
		Tea	0.01**
		Groundnut	0.01**
		Food grains	0.05
		Milled food grains	0.01
		Fruits	0.5
		Potatoes and Onions	0.01
		Cauliflower and Cabbage	0.01
		Other vegetables	0.2
		Meat and Poultry	0.1

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		(carcass fat)	
		Milk	0.01(F)
		Cotton seed	0.05
		Cottonseed oil (crude)	0.03
		Carbonated Water	0.01
39.	Chlothianidin (Chlothianidin and its metabolites Thiazolymethylguanidine (TMG), Thiazolymethylurea (TZMU), Methylnitroguanidine (MNG) TMG)	Sugarcane	0.2*
		Cottonseed	0.02
		Cottonseed Oil	0.02
		Rice	0.02
		Tea	0.02*
		Milk	0.02
		Meat & Meat Products	0.01*
40.	Chromafenozide	Rice	0.03*
41.	Cinmethylene	Rice	0.05
42.	Clodinafop-propargyl	Soybean	0.05*
		Wheat	0.1
43.	Clomazone	Rice	0.01
		Soybean seed	0.01
		Soybean seed oil	0.01
44.	Copper Hydroxide	Rice	0.1*
		Potato	0.1*
		Grapes	0.1*
45.	Copper Oxychloride(determined as copper)	Fruit	20
		Potato	1.0
		Other vegetables	20
		Areca nut	0.01**

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Cardamom	0.01**
		Coconut	0.01**
		Coffee	0.01**
		Pepper	0.01**
46.	Copper Sulphate	Coffee	0.01**
		Cardamom	0.01**
		Citrus	0.01**
		Coconut	0.01**
		Guava	0.01**
		Papaya	0.01**
		Pea	0.01
47.	Cuprous Oxide	Paddy	0.01**
		Potato	0.01**
		Areca nut	0.01**
		Chilli	0.01**
		Citrus	0.01**
		Coffee	0.01**
		Grapes	0.01**
48.	Cyantranilipole	Grapes	0.01
		Pomegranate seed	0.01
		Pomegranate Juice	0.01
		Cabbage	0.01
		Chilli	0.05
		Tomato	0.03
		Gherkin	0.01
49.	Cyazofamid	Potato	0.02*
		Tomato	0.01*
		Grapes	1.0

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
50.	Cyhalofop-butyl	Rice	0.5
51.	Cymoxanil	Tomato	0.01*
		Potato	0.01
		Grapes	0.1
52.	Cypermethrin (sum of isomers) (Fat soluble residue)	Rice	0.01
		Cottonseed Oil	0.01
		Wheat grains	0.05
		Milled wheat grains	0.01
		Brinjal	0.2
		Cabbage	2.0
		Okra	0.2
		Oil seeds except groundnut	0.2
		Meat and Poultry	0.2 (carcass fat basis)
		Milk	0.01 (F)
	(a) Alpha Cypermethrin	Cottonseed Oil	0.05
53.	Deltamethrin (Decamethrin)	Chilli	0.05
		Red gram	0.01
		Mango	0.01
		Tea	2.0
		Okra	0.05
		Tomato	0.05
		Brinjal	0.3
		Groundnut	0.01*
		Cottonseed	0.1
		Food grains	0.5
		Milled Food grains	0.2

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Rice	0.05
		Milk	0.05
		Meat & Meat Products	0.5
54.	Diafenthiuron	Cardamom	0.5
		Brinjal	1.0
		Chilli green	0.05
		Chilli red	0.05
		Cottonseed Oil	1.0
		Cabbage	1.0
55.	Diazinon	Food grains	0.05
		Milled food grains	Nil
		Vegetables	0.5
56.	Dichlorvos (DDVP) (content of di- chloroacetaldehyde (D.C.A.) be reported where possible)	Food grains	1.0
		Milled food grains	0.25
		Vegetables	0.15
		Fruits	0.1
		Soybean	0.01**
		Milk	0.01
		Groundnut seeds	0.05
		Groundnut Oil	0.2
		Mustard seed/ Oil	0.01
57.	Diclofop-Methyl	Wheat	0.1
58.	Diclosulum	Soybean	0.05*
59.	Dicofol	Fruits and Vegetables	5.0
		Tea (dry manufactured)	5.0
		Chilli	1.0

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Sorghum	0.01**
60.	Difenoconazole	Chilli	0.01
		Rice	0.01
		Pomegranate	0.01*
		Milk	0.01
		Meat & Meat Products	0.01*
		Apple	0.01
		Grapes	0.01*
		Maize	0.01*
		Wheat	0.01*
		Tomato	0.2
61.	Diflubenzuron	Cottonseed	0.2
		Tea	0.01**
62.	Dimethoate (residue to be determined as dimethoate and expressed as dimethoate)	Mustard	0.01
		Fruits and Vegetables	2.0
		Chilli	0.5
		Paddy	0.01**
		Pepper	0.01**
		Milk	0.05
		Meat & Meat Products	0.05
63.	Dimethomorph	Grapes	0.05
		Potato	0.05
		Cucumber	0.2
64.	Dinocap	Mango	0.1
65.	Dinotefuron	Rice	0.03*

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Cottonseed Oil	0.05*
		Milk	0.1
66.	Dithianon	Apple	0.1
67.	Dithiocarbamates(the residue tolerance limit are determined and expressed as mg/CS2/kg and refer separately to the residues arising from any or each group of dithiocarbamates)	Chilli	0.2
		Dry chilli	2.0
		Food Grains	0.2
		Milled food grains	0.05
		Potato	0.1
	(a) Dimethyl dithiocarbamates residue resulting from the use of ferbam or ziram, and	Tomato	3.0
	(b) Ethylene bis-dithiocarbamates resulting from the use of mancozeb, maneb or zineb (including zineb derived from nabam plus zinc sulphate)	Cherries	1.0
		Other fruits	3.0
	(c) Mancozeb	Chilli	1.0
		Cauliflower	0.02
		Groundnut	0.01
		Cumin	0.5
		Black Pepper	2.0
		Mustard seed	0.1
		Gherkin	0.1*
		Tea	0.05*
		Onion	4.0
		Milk	0.05
		Meat & Meat Products	0.1
	(d) metiram as CS_2	Green chilli	0.05*

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Dry chilli	0.5
		Grapes	0.1*
		Potato	0.05*
		Tomato	5.0
		Groundnut seed	0.1
		Groundnut seed oil	0.1
		Milk	0.05
		Onion	0.05*
	(e) Zineb as CS_2	Brinjal	0.01**
		Turmeric	2.0
		Tea	0.1*
68.	Diuron	Sugarcane	0.02
		Cottonseed	1.0
		Banana	0.1
		Maize	0.5
		Citrus (Sweet Orange)	1.0
		Grapes	1.0
69.	Dodine	Apple	5.0
70.	Edifenphos	Rice	0.02
		Rice bran	1.0
		Eggs	0.01(shell free basis)
		Meat and poultry	0.02 (carcass fat basis)
		Milk	0.01(F)
71.	Emamectin Benzoate	Cottonseed	0.02
		Cottonseed oil	0.02
		Okra	0.05

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Groundnut oil	0.05
		Milk	0.01*
72.	Epoxyconazole	Ground nut oil	0.05*
		Groundnut cake	0.05*
73.	Ethephon	Pomegranate	0.05
		Pine Apple	2.0
		Coffee	0.1
		Tomato	2.0
		Mango	2.0
74.	Ethion(Residues to be determined as ethion and its oxygen analogue and expressed as ethion)	Gram	0.01
		Pigeon Pea	0.01
		Soybean Seed	0.01
		Tea (dry manufactured)	5.0
		Cucumber and Squash	0.5
		Other Vegetables	1.0
		Cotton seed	0.5
		Milk	0.5 (F)
		Meat and Poultry	0.2 (carcass fat basis)
		Eggs	0.2 (shell free basis)
		Dry fruits	0.1 (shell free basis)
		Food grains	0.03
		Milled food grains	0.01
		Peaches	1.0
		Other fruits	2.0

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
75.	Ethofenprox (Etofenprox)	Rice	0.01
		Milk	0.02
		Meat & Meat Products	0.01*
76.	Ethoxysulfuron	Rice	0.01
77.	Etoxazole	Brinjal	0.2
		Tea	0.01*
78.	Famoxadone	Grapes	0.05
		Potato	0.05
		Tomato	0.01*
79.	Fenamidone	Potato	0.01
		Grapes	0.05
		Gherkin	0.2
80.	Fenarimol	Apple	5.0
81.	Fenazaquin	Apple	0.2
		Chilli (green)	0.5
		Okra	0.01
		Brinjal	0.01
		Tomato	0.01
		Tea	3.0
82.	Fenitrothion	Food grains	0.02
		Milled food grains	0.01
		Milk	0.05 (F)
		Meat	0.03
		Fruits	0.5
		Vegetables	0.3
83.	Fenobucarb (BPMC)	Rice	0.01

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
84.	Fenoxaprop-p-ethyl	Cottonseed	0.02
		Black gram	0.01
		Rice	0.02*
		Wheat	0.02
		Soybean seed	0.02
		Onion	0.05*
85.	Fenpropathrin	Brinjal	0.2
		Okra	0.5
		Chilli	0.2
		Tea(green/black)	1.0
		Rice	0.03*
		Cottonseed oil	0.05
		Milk	0.1
		Meat & Meat Products	0.02
86.	Fenpyroximate	Chilli	1.0
		Tea (green)	2.0
		Coconut Water	0.02
		Tea(Black)	0.2
87.	Fenthion(sum of fenthion, its oxygen analogue and their sulphoxides and sulphones expressed as Fenthion)	Food grains	0.1
		Milled food grains	0.03
		Onion	0.1
		Potato	0.05
		Beans	0.1
		Peas	0.5
		Tomato	0.5
		Other vegetables	1.0

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Musk melon	2.0
		Meat and Poultry	2.0 (carcass fat basis)
		Milk	0.05 (F)
88.	Fenvalerate (Fat soluble residue)	Cauliflower	2.0
		Brinjal	2.0
		Okra	2.0
		Cottonseed	0.2
		Cottonseed Oil	0.1
		Meat and Poultry	1.0 (carcass fat basis)
		Milk	0.01 (F)
		Red Gram	0.01**
		Bengal Gram	0.01**
		Groundnut	0.01**
		Cabbage	0.01**
		Tomato	0.01**
89.	Fipronil	Cottonseed Oil	0.01
		Rice	0.01
		Chilli	0.01
		Sugarcane	0.01
		Cabbage	0.01
		Grapes	0.01*
		Milk	0.02
		Meat & Meat Products	0.01
90.	Flonicamid	Rice	0.05*
		Cottonseed Oil	0.02*

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
91.	Fluazifop-p-butyl	Soybean	0.05
		Cotton seed Oil	0.01*
		Groundnut	0.01*
92.	Flubendiamide	Brinjal	0.1
		Bengal Gram	0.1
		Cottonseed Oil	0.1
		Rice	0.1
		Cabbage	0.05
		Tomato	0.07
		Pigeon pea	0.05
		Black gram	0.03
		Chilli	0.02
		Milk	0.1
93.	Fluchloralin	Cottonseed	0.05
		Soybean	0.05
		Rice	0.01**
		Onion	0.01**
		Okra	0.01**
		Groundnut	0.01**
		Wheat	0.01**
		Potato	0.01**
		Brinjal	0.01**
		Cabbage	0.01**
		Black Gram	0.01**
94.	Flufenacet	Rice	0.05
95.	Flusilazole	Rice	0.01
		Chili	0.01

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Milk	0.05
		Meat & Meat Products	0.2
		Groundnut	0.05*
96.	Fluvalinate	Cottonseed Oil	0.05
		Tea	0.01
97.	Forchlorfenuron	Grapes	0.01
98.	Fosetyl-Al	Grapes	10
		Cardamom	0.2
99.	Glufosinate Ammonium	Cottonseed Oil	0.05*
		Tea	0.01
		Milk	0.01*
100.	Glyphosate	Tea	1.0
		Rice	0.01
		Meat & Meat Products	0.05
101.	Halosulfuron methyl	Sugarcane	0.03*
102.	Hexaconazole	Mango	0.02
		Rice	0.02
		Ground nut seed	0.02
		Tea(black)	0.02
		Grapes	0.1
		Chilli	0.5
		Potato	0.02
		Soybean	0.02
		Apple	0.1
103.	Hexazinone	Sugarcane	0.02

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
104.	Hexythiazox	Tea	1.0
		Chilli (green)	0.01
		Dried Chilli	0.01
		Apple	0.3
105.	Hydrogen Cyanamide	Grapes	0.01
106.	Iodosulfuron Methyl Sodium	Wheat	0.01
107.	Imazethapyr	Soybean	0.01*
		Soybean oil	0.1
		Groundnut oil	0.1
108.	Imidacloprid	Citrus (Acid Lime)	0.5
		Groundnut Seed	0.05
		Mango	0.05
		Sugarcane	0.1
		Okra	2.0
		Sunflower Seed	0.5
		Chilli	0.3
		Grapes	0.05
		Tomato	1.0
		Cucumber	0.2
		Cottonseed Oil	0.05
		Rice	0.05
		Brinjal	0.01
		Milk	0.1
		Meat & Meat Products	0.02
109.	Indoxacarb	Tomato	0.05
		Chilli	0.01
		Pigeon pea	0.1

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Chick Pea	0.05
		Rice	0.05
		Soybean	0.05*
		Cottonseed	0.1
		Cottonseed Oil	0.1
		Cabbage	0.1
		Milk	0.1
		Meat & Meat Products	0.01
110.	Iprobenfos (Kitazin)	Rice	0.2
111.	Iprodione	Rape seed	0.5
		Mustard seed	0.5
		Rice	10
		Tomato	5.0
		Grapes	10
112.	Isoprothiolane	Rice	0.1
113.	Isoproturon	Wheat	0.1
114.	Kasugamycin	Rice	0.05
		Tomato	0.05
115.	Kresoxim Methyl	Milk	0.01
		Meat & Meat Products	0.05
116.	Lambdacyhalothrin	Brinjal	0.2
		Tomato	0.1
		Rice	0.01
		Okra	2.0
		Red Gram	0.01
		Bengal Gram	0.01

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Chilli Green	0.05
		Chilli Red	0.01
		Groundnut seed	0.01
		Onion	0.01
		Soybean	0.01
		Mango	0.02
		Grapes	0.05
		Cottonseed Oil	0.05
117.	Linuron	Pea	0.05
		Potato	0.01**
118.	Lufenuron	Cauliflower	0.1
		Pigeon pea	0.1
		Cottonseed	0.01
		Black Gram	0.02*
		Chilli	0.05
		Cabbage	0.3
		Pigeon pea	0.01
119.	Malathion (Malathion to be determined and expressed as combined residues of malathion and malaoxon)	Food grains	4.0
		Milled food grains	1.0
		Fruits	4.0
		Vegetables	3.0
		Dried fruits	8.0
		Carbonated Water	0.01
120.	Mandipropamid	Grapes	0.05*
		Tomato	0.05*
		Potato	0.05*
121.	Mepiquat Chloride	Potato	0.1
		Cottonseed	0.5

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Cottonseed Oil	0.5
122.	Mesosulfuron Methyl	Wheat	0.01
123.	Metaflumizone	Cabbage	0.05
124.	Metalaxyl	Pearl Millet (Bajra)	0.05
		Maize	0.05
		Sorghum	0.05
125.	Metalaxyl-M	Potato	0.01
		Grapes	0.05
		Black pepper	0.5
		Mustard Seed	0.01
		Chilli	0.02
126.	Methabenzthiazuron	Wheat	0.5
127.	Methomyl	Tomato	0.05
		Pigeon pea seeds	0.05
		Chilli	0.05
		Groundnut seed	0.05
		Grapes	0.05
		Soybean	0.01*
		Cottonseed	0.1
		Milk	0.01*
		Meat & Meat Products	0.02
128.	Methyl Chlorophenoxy Acetic Acid (MCPA)	Rice	0.05
		Wheat	0.05
		Milk	0.01*
129.	Methyl Parathion (combined residues of methyl parathion and	Rice	0.01
		Black Gram	0.01

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
	its oxygen analogue to be determined and expressed as methyl parathion)	Cottonseed oil	0.01
		Mustard seed/oil	0.01
130.	Metolachlor	Soybean Oil	0.05
		Milk	0.01*
131.	Metribuzin	Tomato	0.05*
		Sugarcane	0.01*
		Potato	0.05*
		Soybean Oil	0.1
		Wheat	0.03
132.	Metsulfuron Methyl	Rice	0.01
		Wheat	0.1
		Sugarcane	0.02
133.	Milbemectin	Chilli green	0.01
		Chilli red	0.01
134.	Monocrotophos	Food grains	0.03
		Milled Food grains	0.01
		Citrus fruits	0.2
		Other fruits	1.0
		Carrot, Turnip, Potatoes and Sugar beet	0.05
		Onion and Peas	0.1
		Other Vegetables	0.2
		Cottonseed	0.1
		Cottonseed Oil (raw)	0.05
		Meat and Poultry	0.02
		Milk	0.02
		Eggs	0.02 (shell free

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
			basis)
		Coffee (Raw beans)	0.1
		Chilli	0.2
		Cardamom	0.5
		Green Gram	0.01**
		Pigeon Pea	0.01**
		Coconut	0.01**
135.	Myclobutanil	Apple	0.01
		Chilli	0.2
		Groundnut seed	0.1
		Grapes	1.0
136.	Novaluron	Chili	0.01
		Chickpea	0.01
		Cottonseed	0.01
		Cottonseed Oil	0.01
		Tomato	0.01
		Cabbage	0.01
137.	Orthosulfamuron	Paddy	0.1
138.	Oxadiargyl	Mustard Seed	0.05
		Onion	0.1
		Cumin	0.01
		Rice	0.1
139.	Oxadiazon	Rice	0.03
		Onion	0.01**
140.	Oxydemeton-Methyl	Cottonseed oil	0.01
		Chilli	2.0
		Dry chilli	20
		Mustard oil	0.01

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Food grains	0.02
		Milk	0.01
		Meat & Meat Products	0.01*
141.	Oxyfluorfen	Rice	0.05
		Groundnut Oil	0.05
		Mentha	0.01
		Tea	0.2
		Potato	0.01
		Onion	0.05
142.	Paclobutrazol	Mango	0.01
143.	Paraquat dichloride (Determined as Paraquatcations)	Food grains	0.1
		Milled food grains	0.03
		Potato	0.2
		Other vegetables	0.05
		Cottonseed	0.2
		Cottonseed oil (edible refined)	0.05
		Milk (whole)	0.01
		Fruits	0.05
		Tea	0.05
		Coffee	0.01**
144.	Penconazole	Grapes	0.2
		Black gram seed	0.02
		Mango	0.05
		Apple	0.02
		Milk	0.01
		Meat & Meat	0.05

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Products	
145.	Pencycuron	Rice	0.01
146.	Pendimethalin	Wheat	0.05
		Rice	0.05
		Soybean Oil	0.05
		Cottonseed Oil	0.05
		Chilli	0.05*
		Ground nut	0.01**
		Onion	0.01**
147.	Penoxuslum	Rice	0.1*
148.	Permethrin	Cucumber	0.5
		Cottonseed	0.5
		Soybean	0.05
		Sunflower Seed	1.0
149.	Phenthoate	Food grains	0.05
		Milled food grains	0.01
		Oilseeds	0.03
		Edible oils	0.01
		Eggs	0.05 (shell free basis)
		Meat & Poultry	0.05 (carcass fat basis)
		Milk	0.01 (F)
		Gram	0.01**
150.	Phorate (sum of Phorate, its oxygen analogue and their sulphoxides and sulphones, expressed as phorate)	Milled food grains	0.01
		Tomato	0.1
		Fruits	0.05
		Oil seeds	0.05

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Sugarcane	0.05
		Eggs	0.05 (shell free basis)
		Meat & Poultry	0.05 (carcass fat basis)
		Milk	0.05 (F)
		Green gram	0.01*
		Cottonseed Oil	0.01*
151.	Phosalone	Pears	2.0
		Citrus fruits	1.0
		Other fruits	5.0
		Potato	0.1
		Other vegetables	1.0
		Rapeseed/Mustard Oil (crude)	0.05
152.	Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	Food grains	0.05
		Milled food grains	Nil
		Fruits and Vegetables	0.2
153.	Picoxystrobin	Rice	0.05*
		Grapes	0.05*
154.	Pinoxaden	Wheat	0.02
155.	Pretilachlor	Rice	0.05
156.	Pirimiphos-methyl	Rice	0.5
		Food grains except Rice	5.0
		Milled food grains except rice	1.0
		Eggs	0.05 (shell free basis)

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Meat & Poultry	0.05 (carcass fat basis)
		Milk	0.05 (F)
157.	Profenofos	Cottonseed oil	0.05
		Soybean	0.01*
		Meat & Meat Products	0.05
158.	Prohexadione calcium	Apple	0.01*
159.	Propaquizafop	Black gram	0.01
		Soybean	0.01
		Onion	0.01*
160.	Propargite	Brinjal	2.0
		Chilli	2.0
		Apple	2.0
		Tea	10
161.	Propiconazole	Tea	0.1
		Groundnut seed	0.1
		Rice	0.05
		Soybean seed	0.01
		Wheat	0.05
		Milk	0.01
		Meat & Meat Products	0.01
162.	Propineb	Rice	0.05
		Tomato	1.0
		Apple	1.0
		Pomegranate	0.5
		Potato	0.5

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Green Chilli	2.0
		Grapes	0.5
163.	Pyraclostrobin	Grapes	0.05*
		Potato	0.05*
		Tomato	0.01
		Green chilli	0.05*
		Dry chilli	0.5
		Soybean	0.02*
		Cotton	0.02*
		Milk	0.03
		Onion	0.05*
		Groundnut oil	0.05*
		Ground nut cake	0.05*
164.	Pyrazosulfuron ethyl	Rice	0.01
165.	Pyrethrins (pyrethrum) (sum of pyrethrins I & II and other structurally related insecticide Ingredients of pyrethrum)	Food grains	Nil
		Milled food grains	Nil
		Fruits and Vegetables	1.0
166.	Pyridalyl	Cottonseed Oil	0.02
		Cabbage	0.02
		Okra	0.02
		Chilli	0.02
167.	Pyriproxyfen	Cottonseed	0.03*
		Cottonseed Oil	0.03*
		Brinjal	0.02
		Okra	0.03
		Chilli green	0.02
		Chilli red	0.02

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
168.	Pyrithiolac Sodium	Cottonseed Oil	0.02
169.	Pymetrozine	Rice	0.01*
170.	Quinalphos	Cauliflower	0.1
		Citrus	0.05
		Bengal Gram	0.05
		Cottonseed Oil	0.05
		Mustard seed oil	0.1
		Soybean	0.05
		Groundnut oil	0.3
		Rice	0.01
		Pigeon pea	0.01
		Cardamom	0.01
		Tea	0.01
		Fish	0.01
		Chilli	0.2
		Maize	0.01**
		Potato	0.01**
		Black Pepper	0.01**
171.	Quizalofop ethyl	Cottonseed	0.1
		Soybean seed	0.05
		Onion	0.01*
		Groundnut	0.1
		Black Gram	0.01*
172.	Quizalofop-P-tefuryl	Soybean Seed	0.02
		Cotton seed/ oil	0.05*
173.	Sirmate	Wheat	0.01
		Potato	0.01**

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Peanut	0.01**
174.	Sodium Aceflourofen	Soybean	0.05*
175.	Spinosad	Cottonseed oil	0.02
		Cabbage	0.02
		Cauliflower	0.02
		Red gram	0.01
		Chilli	0.01
		Meat & Meat Products	0.2
176.	Spiromesifen	Tomato	0.3
		Cotton	0.01*
		Apple	0.01
		Brinjal	0.5
		Chilli	0.1
		Tea (green & black)	1.0
		Okra	0.03
177.	Sulfosulfuron	Wheat	0.02
178.	Tebuconazole	Rice	0.05
		Green chilli	0.2
		Groundnut seed	0.05
		Groundnut oil	0.05
		Wheat	0.05
		Milk	0.01
		Tomato	2.0
		Meat & Meat Products	0.05
		Onion	0.5
179.	Thiacloprid	Cottonseed	0.05

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Cottonseed Oil	0.05
		Rice	0.01
		Brinjal	0.3
		Tea	5.0
		Soybean seed	0.03*
		Apple	0.05*
		Milk	0.05
		Meat & Meat Products	0.02
		Chilli (green)	0.02
		Chilli (red)	0.02
180.	Thifluzamide	Rice	0.05
181.	Thiodicarb	Cabbage	0.02
		Brinjal	0.05
		Red Gram	0.05
		Black Gram	0.03
		Chilli	0.01
		Cottonseed oil	0.02
		Meat & Meat Products	0.02
182.	Thiamethoxam	Rice	0.02
		Okra	0.5
		Cottonseed Oil	0.01
		Brinjal	0.3
		Tomato	0.01
		Wheat	0.01
		Tea	0.01
		Mango	0.01

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Potato	0.01
		Mustard seed	0.01
		Cumin	0.01
		Acid Lime	0.02
		Milk	0.05
		Meat & Meat Products	0.01
183.	Thiometon(Residues determined as thiometon its sulfoxide and sulphone expressed as thiometon)	Food grains	0.03
		Milled food grains	0.01
		Fruits	0.5
		Potato, Carrots and Sugar beets	0.05
		Other vegetables	0.5
184.	Thiophanate-Methyl	Apple	5.0
		Papaya	7.0
		Bottle gourd	0.01**
		Milk	0.05
		Wheat	0.03*
		Bottle gourd	0.4
		Pigeon pea	0.03*
		Cucumber	0.2
		Grapes	**3**
185.	Tolfenpyrad	Cabbage	0.01*
		Okra	0.7
186.	Trichlorfon	Food grains	0.05
		Milled food grains	0.01
		Sugar beet	0.05
		Fruits &	0.1

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Vegetables	
		Oil seeds	0.1
		Edible oil (Refined)	0.05
		Meat & Poultry	0.1
		Milk	0.05
187.	Triacontanol	Milk	0.01
188.	Triadimefon	Wheat	0.5
		Pea	0.1
		Grapes	2.0
		Milk	0.01
		Meat & Meat Products	0.01
		Chilli	0.4
		Coffee	0.01*
		Mango	0.03*
		Soybean	0.02*
189.	Trifloxystrobin and its metabolites (carboxylic acid-CGA321113)	Tomato	1.0
190.	Triallate	Wheat	0.05
191.	Triasulfuron	Wheat	0.01*
192.	Triazophos	Chilli	0.2
		Rice	0.05
		Cottonseed oil	0.1
		Soybean oil	0.05
193.	Tricyclazole	Rice	3.0
194.	Tridemorph	Wheat	0.1

Sl. No. (1)	Name of the Insecticide (2)	Food (3)	MRL in mg/kg (4)
		Grapes	0.5
		Mango	0.05
195.	Trifluralin	Wheat	0.05
196.	Validamycin	Rice	0.01
197.	Flupicolide	Grapes	0.02*
198.	Tembotrione	Maize	0.02*

* MRL fixed at LOQ

** Insecticides are registered under the Insecticide Act, 1968 (46 of 1968) but label claim for the said commodity are not fixed hence MRL fixed at LOQ

F: MRL Calculation on Fat Basis

Note: All these MRL/tolerance limit values are provisional for a period of five years and not fixed on the basis of actual data in the Indian context. They may be reviewed after five years or as and when the relevant scientific data is made available to FSSAI, whichever is earlier.

(3) The following insecticides mentioned in column (2) against the specified food in column (3) are banned as per the Insecticides Act, 1968 (46 of 1968).

Sl. No. (1)	Name of Insecticide (2)	Food (3)
1.	Aldicarb (sum of Aldicarb its sulphoxideand sulphone, expressed as Aldicarb)	Potato
2.	Aldrin, dieldrin (the limits apply to aldrin and dieldrin singly or in any combination and are expressed as dieldrin)	Food grains
		Milled Food grains
		Milk and Milk products
		Fruits and Vegetables
		Meat
		Eggs
3.	Chlordane (residue to be measured as cis plus trans chlordane)	Food grains
		Milled food grains
		Milk and milk products

Sl. No. (1)	Name of Insecticide (2)	Food (3)
		Vegetables
		Fruits
		Sugar beet
4.	D.D.T (The limits apply to D.D.T., D.D.D. and D.D.E. singly or in any combination)	Milk & milk products
		Fruits & vegetables including potato, meat, poultry & fish
		Eggs
5.	D.D.T. (singly)	Carbonated Water
6.	D.D.D. (singly)	Carbonated Water
7.	D.D.E. (singly)	Carbonated Water
8.	Dieldrin	Food grains
		Milled Food grains
		Milk and Milk products
		Fruits and Vegetables
		Meat
		Eggs
9.	Heptachlor (combined residues of heptachlor and its epoxide to be determined and expressed as Heptachlor)	Food grains
		Milled food grains
		Milk and Milk Products
		Vegetables
10.	Lindane Gamma-HCH) Gamma (γ) Isomer (Known as Lindane)	Food grains except rice
		Milled food grains
		Rice grain Unpolished
		Rice grain polished
		Milk
		Milk products
		Milk products
		Fruits and vegetable
		Fish
		Eggs
		Meat and poultry
		Carbonated Water
11.	Endosulfan	Sorghum
		Gram
		Fruits & Vegetables

Sl. No. (1)	Name of Insecticide (2)	Food (3)
		Cottonseed
		Cottonseed Oil
		Bengal Gram
		Pigeon Pea
		Fish
		Groundnut oil
		Paddy
		Tea
		Chilli
		Cardamom
12.	Endosulfan A	Carbonated Water
13.	Endosulfan B	Carbonated Water
14.	Endosulfan- Sulphate	Carbonated Water
15.	Methomyl 12.5% L &Methomyl 24% formulation	Cotton seed
16.	Phosphamidon 85% SL Phosphamidon residues (expressed as the sum of phosphamidon and its desethyl derivative)	Food grains
		Milled food grains
		Fruits and Vegetables
17.	Captafol 80% Powder	Tomato
18.	Ferbam (a) Dimethyl dithiocarbamates residue resulting from the use of ferbam or ziram	Tomatoes
19.	Formothion (Determined as dinethoate and its oxygen Analogue and expressed as dimethoate except incase of citrus fruits where it is to be determined as formothion)	Citrus fruits
		Other fruits
		Vegetable
		Pepper ,Tomatoes
20.	Simazine	Maize
		Sugarcane.

2.3.3: *Drugs, Pesticides and Antimicrobials Including Antibiotics for Veterinary Use*

A. Drugs, Pesticides and Antimicrobials including Antibiotics for Veterinary Use, registered under Drugs and Cosmetic Act, 1940 (23 of 1940)

1. Antimicrobials Including Antibiotics -

(i) Used in both humans and animals:

The MRL/ tolerance limit shall be fixed at LOQ for this category.

(ii) Exclusively used in animals:

In case of antimicrobials, including antibiotics which are exclusively used for animals, codex MRLs/ tolerance limit may be adopted wherever available. The cases for which codex MRLs are not available, MRL to be fixed at LOQ/minimum required performance limit (MRPL) until the fresh data are made available to FSSAI for revision of MRLs, after due risk assessment. In the said case the MRL shall be valid for a period of 5 years during which the manufacturer is required to submit the data for revision or otherwise the same shall continue.

2. Other Veterinary Drugs -

For all other veterinary drugs, codex MRLs/ tolerance limit may be adopted wherever available. For veterinary drugs for which codex MRLs are not available, MRL to be fixed at LOQ/MRPL till the fresh data is made available to FSSAI for revision of MRLs after due risk assessment. The MRLs fixed now shall be valid for a period of 5 years during which the manufacturer is required to submit the data for revision or otherwise the same shall continue.

3. Pesticides used for topical application -

For all pesticides used for topical application, the regulations/codex MRLs/tolerance limit may be adopted wherever available. If no regulations/codex MRLs/tolerance limits are available, risk assessment based on the metabolism data and withdrawal period shall be done; which is to be considered in conjunction with its MRL/tolerance limit, if any, as pesticide; to find out the residues left in the tissues/ milk/ eggs as well as the crops in which it is allowed to be used. Thereafter, appropriate MRLs/ tolerance limits may be fixed.

B. Drugs, Pesticides and Antimicrobials including Antibiotics for Veterinary Use, not registered under Drugs and Cosmetics Act, 1940(23 of 1940)

Drugs, pesticides and antimicrobials including antibiotics for veterinary use which are not registered under Drugs and Cosmetic Act, 1940 for use in India, shall have a default tolerance limit of 0.001 mg/kg. Since this category includes import tolerances, in case of any objection from the exporting country, the relevant data shall be asked from the exporting country for review and, if appropriate, necessary upward revision of the tolerance limit can be made.

C. Wherever the MRL/tolerance limits are fixed without any data, it should be prefixed with “T” (Temporary).

Note: All the MRL/tolerance limit values are provisional for a period of five years. They may be reviewed after five years or as and when the relevant scientific data is made available to FSSAI, whichever is earlier.

The details are in form of flow chart as per Annexure II.

2.3.4: *Antibiotic and other Pharmacologically Active Substances*

(1) The amount of antibiotic mentioned in column (2), on the sea foods including shrimps, prawns or any other variety of fish and fishery products, shall not exceed the tolerance limit prescribed in column (3) of the table given below:—

TABLE

Sl. No.	Name of Antibiotics	Tolerance limit mg/kg (ppm)
1.	Tetracycline	0.1
2.	Oxytetracycline	0.1
3.	Trimethoprim	0.05
4.	Oxolinic acid	0.3

(2) The use of any of the following antibiotics and other Pharmacologically Active Substances shall be prohibited in any unit processing sea foods including shrimps, prawns or any other variety of fish and fishery products —

1. Nitrofurans including

   i. Furaltadone
   ii. Furazolidone
   iii. Nitrofurnatoin
   iv. Nitrofurazone

2. Chloramphenicol
3. Sulphamethoxazole
4. *Aristolochia* spp and preparations thereof
5. Chloroform
6. Chloropromazine
7. Colchicine
8. Dapsone
9. Dimetridazole
10. Metronidazole
11. Ronidazole
12. Ipronidazole and other nitromidazoles
13. Clenbuterol

14. Diethylstibestrol (DES)

15. Glycopeptides

16. Stilbenes and other steroids

17. Crystal Violet

18. Malachite Green

(3) The limit of antibiotics mentioned in column (2), in honey on the basis of Limit of Quantification, shall not exceed the tolerance limit prescribed in column (3) when determined by the LC-MS/MS method in the table given below:-

Sl. No.	Name of Antibiotics	Tolerance Limit (microgram/kg)
1.	Chloramphenicol	0.3*
2.	Nitrofurans and its metabolites	0.5* either individually or collectively
3.	Sulphonamides and its metabolites	5.0* either individual or collectively
4.	Streptomycin	5.0*
5.	Tetracycline	5.0*
	(a) Oxytetracycline	5.0*
	(b) Chlortetracycline	5.0*
6.	Ampicillin	5.0*
7.	Enrofloxacin	5.0*
8.	Ciprofloxacin	5.0*
9.	Erythromycin	5.0*
10.	Tylosin	5.0*
	* Limit of Quantification on the basis of LC-MS/MS method.	

(4) The limit of antibiotics mentioned in column (2), for the tissues mentioned in column (3), shall not exceed the tolerance limit prescribed in column (4) of the tables given below:-

1. Antibiotics (Used Both in Humans & Animals)

S. No.	Name	Food	Tolerance limit (mg/Kg)
1.	Ampicillin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
2.	Cloxacillin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
3.	Chloramphenicol	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
4.	Dihydrostreptomycin Sulphate – (Dihydrostreptomycin)/ Streptomycin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
5.	Chlortetracyline Hydrochloride	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
6.	Erythromycin Thiocyanate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
7.	Flumequine	• All edible animal tissue • Fats derived	0.01

S. No.	Name	Food	Tolerance limit (mg/Kg)
		from animal tissues • Milk	
8.	Furazolidone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
9.	Lincomycin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
10.	Oxytetracycline	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
11.	Salinomycicin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
12.	Spectinomycin Hydrochloride (Spectinomycin)	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
13.	Sulphadiazine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
14.	Sulphathiazole Sodium	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

S. No.	Name	Food	Tolerance limit (mg/Kg)
15.	Trimethoprim	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
16.	Cloxacillin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
17.	Dicloxacillin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
18.	Sulfadiazine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
19.	Sulfanilamide	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
20.	Sulfaguanidine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
21.	Zinc Bacitracin (minimum 60IU/mg dried substance)	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

2. Antibiotics (Exclusive use in Animals)

S.No	Name	Food	Tolerance limit (mg/Kg)
1.	Amprolium Hydrochloride	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
2.	Apramycin Sulphate	**Cattle**	
		Kidney	0.01
		Sheep	
		Kidney	0.01
3.	Carbadox	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
4.	Ceftiofur Sodium (Ceftiofur)	**Cattle**	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
		Milk	0.1
		Pig	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
5.	CeftiofurHCl (Ceftiofur)	**Cattle**	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
		Milk	0.1
		Pig	
		Muscle	1
		Liver	2
		Kidney	6
		Fat	2
6.	Cephapirine Benzathine interauterine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

S.No	Name	Food	Tolerance limit (mg/Kg)
7.	Clopidol	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
8.	Cloxacillin Benzathine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
9.	Colistin Sulphate	**Cattle**	
		Fat	0.15
		Muscle	0.15
		Kidney	0.2
		Liver	0.05
		Milk	0.15
		Pig	
		Muscle	0.15
		Fat	0.15
		Liver	0.15
		Kidney	0.2
		Sheep	
		Liver	0.15
		Milk	0.05
		Muscle	0.15
		Kidney	0.2
		Fat	0.15
		Goat	
		Kidney	0.2
		Muscle	0.15
		Liver	0.15
		Fat	0.15
		Rabbit	
		Fat	0.15
		Muscle	0.15
		Liver	0.15
		Kidney	0.2
		Chicken	
		Kidney	0.2
		Liver	0.15
		Eggs	0.3
		Fat	0.15

S.No	Name	Food	Tolerance limit (mg/Kg)
		Turkey	
		Muscle	0.15
		Liver	0.15
		Kidney	0.2
		Fat	0.15
10.	Danofloxacin	**Cattle**	
		Muscle	0.2
		Liver	0.4
		Kidney	0.4
		Fat	0.1
		Pig	
		Muscle	0.1
		Liver	0.05
		Kidney	0.2
		Fat	0.1
		Chicken	
		Muscle	0.2
		Liver	0.4
		Kidney	0.4
		Fat	0.1
11.	Enrofloxacin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
12.	Ethopabate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
13.	Flavophospholipol (Flavomycin)	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
14.	Monensin Sodium (Monensin)	**Cattle**	
		Muscle	0.01
		Liver	0.1

S.No	Name	Food	Tolerance limit (mg/Kg)
		Kidney	0.01
		Fat	0.1
		Milk	0.002
		Sheep	
		Muscle	0.01
		Liver	0.02
		Kidney	0.01
		Fat	0.1
		Goat	
		Muscle	0.01
		Liver	0.02
		Kidney	0.01
		Fat	0.1
		Chicken	
		Muscle	0.01
		Liver	0.01
		Kidney	0.01
		Fat	0.1
		Turkey	
		Muscle	0.01
		Liver	0.01
		Kidney	0.01
		Fat	0.1
		Quail	
		Liver	0.01
		Kidney	0.01
		Muscle	0.01
		Fat	0.1
15.	Moxidectin	**Cattle**	
		Muscle[1]	0.02
		Liver	0.1
		Kidney	0.05
		Fat	0.5
		Sheep	
		Muscle	0.05
		Liver	0.1
		Kidney	0.05
		Fat	0.5
16.	Sulphaquinoxaline	• All edible animal tissue • Fats derived from animal tissues	0.01

S.No	Name	Food	Tolerance limit (mg/Kg)
		• Milk	
17.	Sulfadimidine Sodium	**Cattle**	
		Milk	0.02
		Not specified	
		Muscle	0.1
		Fat	0.1
		Kidney	0.1
		Liver	0.1
18.	Tilmicosin	**Cattle**	
		Muscle	0.1
		Liver	1
		Kidney	0.3
		Fat	0.1
		Pig	
		Muscle	0.1
		Liver	1.5
		Kidney	1
		Fat	0.1
		Sheep	
		Liver	1
		Kidney	0.3
		Fat	0.1
		Chicken	
		Liver	2.4
		Kidney	0.6
		Muscle	0.15
		Fat/Skin	0.1
		Turkey	
		Liver	1.4
		Kidney	1.2
		Muscle	0.1
		Fat	0.25
19.	Tylosin	**Cattle**	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Pig	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1

S.No	Name	Food	Tolerance limit (mg/Kg)
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Chicken	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat/Skin	0.1
		Eggs	0.3
20.	Tyvalosin Tartrate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
21.	Virginiamycin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

3. Other Veterinary Drugs

S.No.	Name	Tissue	MRL (mg/Kg)
1.	Acepromazine Maleate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
2.	Albendazole	**Species Not Specified**	
		Muscle	0.1
		Liver	5
		Kidney	5
		Fat	0.1
		Milk	0.1

S.No.	Name	Tissue	MRL (mg/Kg)
3.	Amitraz	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
4.	Aspirin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
5.	Buqarvaquone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
6.	Buserelin Acetate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
7.	Butafosfane	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
8.	Butalex	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
9.	Butaphosphan	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
10.	Calcium Borogluconate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
11.	Calcium Magnesium Borogluconate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
12.	carboprost tromethamine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
13.	Cefquinone Sulphate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
14.	Chloral hydrate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
15.	Claprostenol sodium	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
16.	Closprostenol Sodium	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
17.	Closantel	**Cattle**	
		Muscle	1
		Liver	1
		Kidney	3
		Fat	3
		Sheep	
		Muscle	1.5
		Liver	1.5
		Kidney	5
		Fat	2
18.	Clenbutrol Hydrochloride (Broncopulmin powder)	**Cattle**	
		Muscle	0.0002
		Milk	0.00005
		Liver	0.0006
		Kidney	0.0006
		Fat	0.0002
		Horse	
		Muscle	0.0002
		Fat	0.0002
		Liver	0.0006
		Kidney	0.0006
19.	Diethylcarbamazine	• All edible	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		animal tissue • Fats derived from animal tissues • Milk	
20.	Dimetridazole	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
21.	Dinitolmide	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
22.	Doramectone	**Cattle**	
		Muscle	0.01
		Liver	0.1
		Kidney	0.03
		Fat	0.15
		Milk	0.015
		Pig	
		Muscle	0.01
		Liver	0.1
		Kidney	0.03
		Fat	0.15
23.	Dexcloprostenolum	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
24.	Flunixin Meglumine	• All edible animal tissue • Fats derived from animal tissues	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		• Milk	
25.	Halofuginone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
26.	Haloxon	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
27.	Ivermectin	**Cattle**	
		Milk	0.01
		Liver	0.1
		Fat	0.04
		Pig	
		Liver	0.015
		Fat	0.02
		Sheep	
		Liver	0.015
		Fat	0.02
28.	Kaolin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
29.	Ketamine hydrochloride	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
30.	Levamisole Hydrochloride (Levamisole)	**Cattle**	
		Muscle	0.01
		Liver	0.1

S.No.	Name	Tissue	MRL (mg/Kg)
		Kidney	0.01
		Fat	0.01
		Pig	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Sheep	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
		Poultry	
		Muscle	0.01
		Liver	0.1
		Kidney	0.01
		Fat	0.01
31.	Lithium Antimony Thiomalate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
32.	Luprostiol	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
33.	Madramicin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
34.	Magnesium Hypophosphite	• All edible animal tissue • Fats derived from animal tissues	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		• Milk	
35.	Mastijet Flarte	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
36.	Meloxicam	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
37.	Mepyramine	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
38.	Methyl Hydroxybenzoate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
39.	Nandrolone Laurate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
40.	Niclosamide	• All edible animal tissue • Fats derived from animal tissues	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		• Milk	
41.	Nimesulide	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
42.	Nitroscanate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
43.	Nitroxynil	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
44.	Oxybendazole	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
45.	Oxfendazole	Group MRLs for the sum of fenbendazole, oxfendazole and oxfendazole sulfone (as oxfendazole sulfone equivalents)	
		Cattle	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1
		Milk	0.1
		Pig	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1

S.No.	Name	Tissue	MRL (mg/Kg)
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1
		Milk	0.1
		Goat	
		Muscle	0.1
		Liver	0.5
		Kidney	0.1
		Fat	0.1
46.	Oxyclozanide	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
47.	Parbendazole	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
48.	Pentobarbitone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
49.	Praziquantel	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
50.	Pregnant Mare Serum Gonadotrophin	• All edible animal tissue	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		• Fats derived from animal tissues • Milk	
51.	Proligestone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
52.	Promazine Hydrochloride	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
53.	Propofol	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
54.	Prosolvin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
55.	Rafoxanide	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
56.	Ronidazole	• All edible animal tissue	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		• Fats derived from animal tissues • Milk	
57.	Semduramycin Sodium	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
58.	Sulpha Chloropyrazine Sodium	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
59.	Sulphaquinoxaline	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
60.	Suramin	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
61.	Thiabendazole[2]	**Cattle**	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	0.1 mg/l
		Pig	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1

S.No.	Name	Tissue	MRL (mg/Kg)
		Fat	0.1
		Sheep	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Goat	
		Muscle	0.1
		Liver	0.1
		Kidney	0.1
		Fat	0.1
		Milk	0.1 mg/l
62.	Tiamulin Hydrogen Fumarate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
63.	Totrazuril	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
64.	Tylvalosin tartrate	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
65.	Triclabendazole	**Cattle**	
		Muscle	0.25
		Liver	0.85
		Kidney	0.4
		Fat/Skin	0.1
		Sheep	
		Muscle	0.2
		Liver	0.3
		Kidney	0.2
		Fat/Skin	0.1

S.No.	Name	Tissue	MRL (mg/Kg)
66.	Xylazine HCl	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
67.	Clorsulon	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
68.	Diminazene Diaceturate (Diminazene)	**Cattle**	
		Muscle	0.5
		Liver	12
		Kidney	6
		Milk	0.15 mg/l
69.	Hydrocortisone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
70.	Phenazone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
71.	Praziquantel	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
72.	Quinapyramine sulphate	• All edible animal tissue	0.01

S.No.	Name	Tissue	MRL (mg/Kg)
		• Fats derived from animal tissues • Milk	
73.	Cefphactril Sodium	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
74.	Chlorpyridazine Sod.	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
75.	Coligen	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
76.	Doramectone	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01
77.	Tiaprost Trometamoal	• All edible animal tissue • Fats derived from animal tissues • Milk	0.01

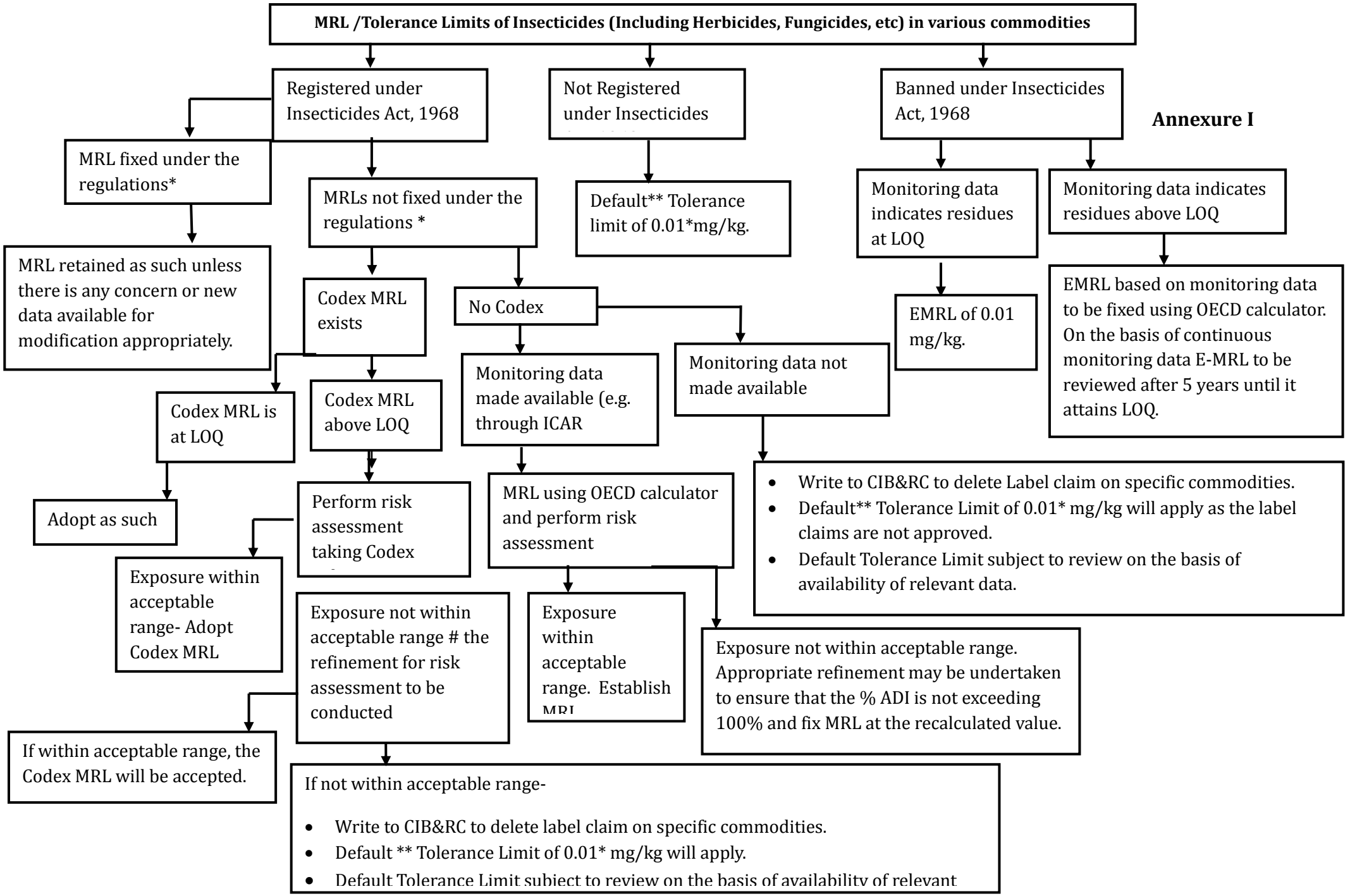
Explanation. - For the purpose of this regulation:

(a) the expression “insecticide” shall have the meaning assigned to it in the Insecticide Act, 1968 (46 of 1968);

(b) Name of the insecticides (includes herbicides, fungicides, pesticides etc.) as per the Insecticides Act, 1968 (46 of 1968) and the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011;

(c) The insecticides which are neither registered in India under Insecticides Act, 1968 nor recommended for use on a food shall have a tolerance limit of 0.01* mg/kg.”

Annexure I


MRL /Tolerance Limits of Insecticides (Including Herbicides, Fungicides, etc) in various commodities
Registered under Insecticides Act, 1968
Not Registered under Insecticides
Banned under Insecticides Act, 1968
MRL fixed under the regulations*
MRLs not fixed under the regulations *
Default** Tolerance limit of 0.01*mg/kg.
Monitoring data indicates residues at LOQ
Monitoring data indicates residues above LOQ
MRL retained as such unless there is any concern or new data available for modification appropriately.
Codex MRL exists
No Codex
EMRL of 0.01 mg/kg.
EMRL based on monitoring data to be fixed using OECD calculator. On the basis of continuous monitoring data E-MRL to be reviewed after 5 years until it attains LOQ.
Codex MRL is at LOQ
Codex MRL above LOQ
Monitoring data made available (e.g. through ICAR
Monitoring data not made available
Adopt as such
Perform risk assessment taking Codex
MRL using OECD calculator and perform risk assessment
Write to CIB&RC to delete Label claim on specific commodities.
Default** Tolerance Limit of 0.01* mg/kg will apply as the label claims are not approved.
Default Tolerance Limit subject to review on the basis of availability of relevant data.
Exposure within acceptable range- Adopt Codex MRL
Exposure not within acceptable range # the refinement for risk assessment to be conducted
Exposure within acceptable range. Establish MRL
Exposure not within acceptable range. Appropriate refinement may be undertaken to ensure that the % ADI is not exceeding 100% and fix MRL at the recalculated value.
If within acceptable range, the Codex MRL will be accepted.
If not within acceptable range-
Write to CIB&RC to delete label claim on specific commodities.
Default ** Tolerance Limit of 0.01* mg/kg will apply.
Default Tolerance Limit subject to review on the basis of availability of relevant

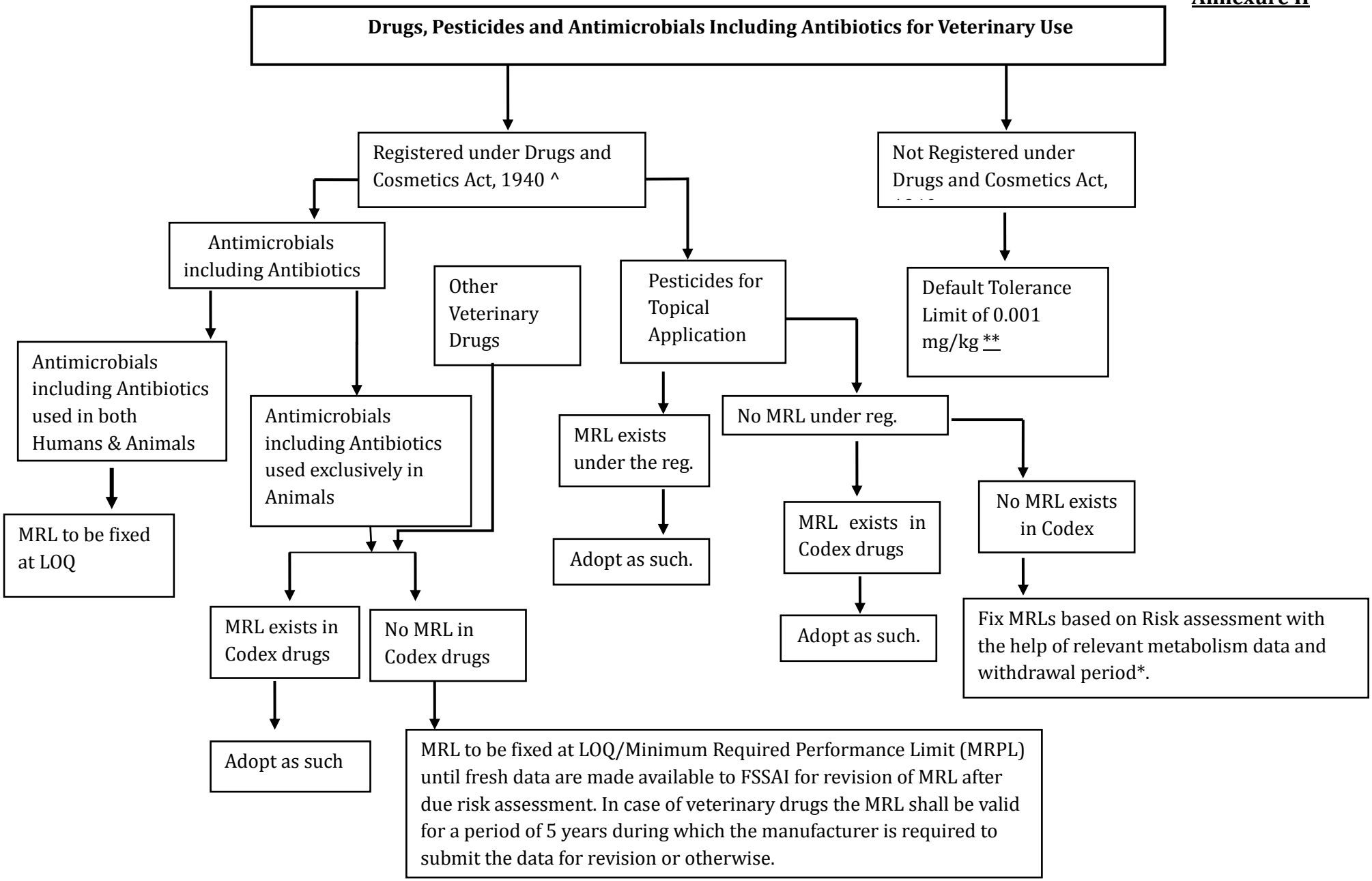
***** Subject to review based on new data made available or after five years whichever is earlier

#Where the exposure calculated for risk assessment is not within the acceptable range the due process of refinement in risk assessment shall be made. In spite of this exercise, if the calculated exposure exceeds the acceptable range, then the CIB&RC shall be requested to delete appropriate label claims.

^ The MRL/tolerance limit wherever fixed on the basis of monitoring data a review of identified pesticide Vs. Crops shall be undertaken w.r.t extent and quantum of use including toxicological profile of pesticide. In case the use is nil to negligible in nature the same MRL/ Tolerance limit need to be continued otherwise appropriate efforts will be made to undertake the GAP study.

** Since this category includes import tolerance, in case of any objection from the exporting country, the relevant data shall be asked from the exporting country for review and, if appropriate, necessary upward revision of tolerance limit can be made. All these MRL/tolerance limit values are provisional for a period of five years and not fixed on the basis of actual data in the Indian context. They may be reviewed after five years or as and when the relevant scientific data is made available to FSSAI, whichever is earlier.

Annexure II


Drugs, Pesticides and Antimicrobials Including Antibiotics for Veterinary Use
Registered under Drugs and Cosmetics Act, 1940 ^
Not Registered under Drugs and Cosmetics Act,
Antimicrobials including Antibiotics
Other Veterinary Drugs
Pesticides for Topical Application
Default Tolerance Limit of 0.001 mg/kg **
Antimicrobials including Antibiotics used in both Humans & Animals
Antimicrobials including Antibiotics used exclusively in Animals
MRL exists under the reg.
No MRL under reg.
MRL to be fixed at LOQ
Adopt as such.
MRL exists in Codex drugs
No MRL exists in Codex
MRL exists in Codex drugs
No MRL in Codex drugs
Adopt as such.
Fix MRLs based on Risk assessment with the help of relevant metabolism data and withdrawal period*.
Adopt as such
MRL to be fixed at LOQ/Minimum Required Performance Limit (MRPL) until fresh data are made available to FSSAI for revision of MRL after due risk assessment. In case of veterinary drugs the MRL shall be valid for a period of 5 years during which the manufacturer is required to submit the data for revision or otherwise.

^ All these MRL/ Tolerance limit values are provisional for a period of five years and not fixed on the basis of actual data in the Indian context. They may be reviewed after 5 years or as and when the relevant scientific data is made available to FSSAI, whichever is earlier.

* to be considered in conjunction with its MRL as pesticide

** Since this category includes IMPORT TOLERANCE, in case of any objection from the exporting country, the relevant data shall be asked from the exporting country for review and, if appropriate, necessary upward revision of Tolerance limit can be made. All these MRL/ Tolerance limit values are provisional for a period of five years and not fixed on the basis of actual data in the Indian context. They may be reviewed after 5 years or as and when the relevant scientific data is made available to FSSAI, whichever is earlier."

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