LINDANE (048)

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EXPLANATION

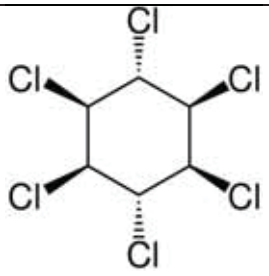
Lindane was first evaluated by the Joint Meeting in 1966 (T,R). It had been last re-evaluated within the periodic review programme in 2002 (T) and 2003 (R). The Meeting agreed that the definition of the residue for compliance with MRLs and for estimation of dietary intake should be: lindane, for both plant and animal commodities. The residue is fat-soluble.

Since lindane was currently listed in Annex A of the Stockholm Convention by which Parties must take measures to eliminate the production and use of such chemicals, and there was no information on existing national registrations for lindane uses, the 46th CCPR (2014) requested a periodic review in 2015 to convert the existing CXLs for sweet corn, cereals, eggs, pountry and meats into Codex EMRLs.

Lindane has no use for crop protection. According to the Stockholm Convention, as a specific exemption, it may be used as a human health pharmaceutical for control of head lice and scabies as second line treatment (decision SC-4/15 under the Stockholm Convention

Subsequently, monitoring data were submitted by EFSA for the period of 2009-2013, the GEMS Food programme (2000-2011) In addition, individual residue data were provided by the Netherlands, and summarized results from India and the USA.

IDENTITY

Common name	Lindane;(for material containing ≥99% gamma stereoisomer)
Chemical name	
IUPAC:	1α,2α,3β,4α,5α,6β-hexachlorocyclohexane (gamma stereoisomer)
CAS:	(1α,2α,3β,4α,5α,6β)-hexachlorocyclohexane (gamma stereoisomer)
Other names	Gamma-BHC; Gamma-HCH;
CAS number:	58-89-9 (for the gamma isomer)
CIPAC Code:	488
Molecular formula:	$C_6H_6Cl_6$
Molecular weight:	290.82984 g/mol
Structural formula:	

PHYSICAL AND CHEMICAL PROPERTIES

The physical and chemical properties, metabolism and environmental fate were evaluated by the 2003 JMPR as part of the periodic review programme.

METHODS OF RESIDUE ANALYSIS

Analytical methods

Lindane is typically analysed with multi residue procedures enabling detection of a large number of samples whose pesticide treatment history is usually unknown. In the screening procedure the emphasis is to detect residues which are around the legal limit; achieving the lowest detectable concentration is not of the primary goal.

No analytical methods were referenced in the submissions of monitoring data. The reported LOQ values varied to a large extent in case of individual commodities and among commodities. The reported ranges of LOQs, where available, are mentioned together with the results of monitoring data. If the LOQ exceeded the present CXL values, for the evaluation of data, the residues were taken as non-detected.

Similarly, no information was provided on the design of sampling programmes or on the size of samples collected. In view of the very large number of samples analysed, the potential deviation from the principles of random sampling or the size of samples do not affect the applicability of the data for estimation of EMRLs.

RESIDUES IN FOOD IN COMMERCE OR AT CONSUMPTION

Residue data derived from the European monitoring programmes

For the period of 2009-2013, the European Food Safety Authority (EFSA) provided approximately 25000 monitoring results on lindane residues in unprocessed food products reported by EU Member States, as well as Norway and Iceland for the products for which currently Codex has established CXLs. The tested products were obtained from more than 60 different countries. However, the majority of the results (approximately 24,000 samples) refer to samples originating from the reporting countries. More specifically, the samples originated from Germany (5,261), the United Kingdom (2,508), Ireland (2,180), Denmark (,1856), France (1,738), Spain (1,385), Romania (1,336) and Poland (1,049); for the remaining testing countries the number of samples analysed amounted to less than 1000. The data compilation includes data on all sampling strategies (surveillance data and data reflecting targeted sampling strategies).

It is noted that no specific results for straw and fodder (dry) of cereal grains are available in the EFSA pesticide monitoring database.

Barley

In total, 630 results on lindane in barley were submitted by 17 European reporting countries. The samples originated from 21 different countries. In none of the samples detectable residues at or above the LOQ were found (LOQ ranged from 0.002 mg/kg to 0.05 mg/kg).

Maize

In total, 642 results on lindane in maize were submitted by 15 reporting countries. The samples originated from 25 different countries. Detectable residues at or above the LOQ were found in none of the samples (LOQ ranged from 0.001 mg/kg to 0.1 mg/kg).

Oats

In total, 898 results on lindane in oats were submitted by 20 reporting countries. The samples originated from 26 different countries. None of the samples contained detectable residues at or above the LOQ (LOQ ranged from 0.001 mg/kg to 0.05 mg/kg).

Rye

In total, 1,658 results on lindane in rye were submitted by 21 reporting countries. The samples originated from 25 different countries. None of the samples contained detectable residues at or above the LOQ (LOQ ranged from 0.0004 mg/kg to 0.05 mg/kg).

Sorghum

In total, 36 results on lindane in sorghum were submitted by two reporting countries. The samples originated from three different countries. None of the samples contained detectable residues above the LOQ were found (LOQ ranged from 0.01 to 0.02 mg/kg).

Wheat

In total, 4942 results on lindane in wheat were submitted by 25 reporting countries. The samples originated from 45 different countries. In only one sample, originating from France, lindane was quantified above the LOQ (0.078 mg/kg). The LOQ values ranged from 0.001 mg/kg to 0.05 mg/kg.

Sweet corn (kernels)

In total, 424 results on lindane in sweet corn were submitted by 15 reporting countries. The samples originated from 27 different countries. None of the samples contained detectable residues at or above the LOQ (LOQ ranged from 0.002 to 0.02 mg/kg).

Milks

Altogether, 4,319 results of lindane residue data in milk of different species (cattle, sheep, goat and horses) were submitted by 25 reporting countries. The samples included only unprocessed, frozen and pasteurised milk. The samples originated from 28 different countries. The LOQ values ranged from 0.00004 to 0.001 mg/kg. It is noted that the results concerning 379 samples were reported on a fat basis. The detectable residues are summarized in Table 1.

Table 1 Lindane residues detected in milk samples.

Commodity	LOQ [mg/kg]	Expression of residues	Residue detected [mg/kg]
Cattle milk	0.00004	Whole product basis	0.00004, 0.00004,0.00004, 0.00008
	0.00005	Whole product basis	
	0.0001	Whole product basis	0.0001
		Fat basis	0.0006
Sheep milk	0.001	Whole product basis	0.002
Goat milk	0.0003	Whole product basis	0.0003
	0.0001	Whole product basis	0.0006

Meat (from mammals other than marine mammals)

Overall, 3,360 samples of meat and 2,657 samples of fat of mammals (swine, bovine, sheep, goat and equine) were analysed for lindane residues. These samples originated from 42 different countries and were tested by 27 EU countries. The LOQ values ranged from 0.0001 to 0.005 mg/kg. Overall, 40 samples contained measurable residues at or above the LOQ. For 2,957 meat samples the results were expressed on whole weight basis, which were converted to a fat basis by applying a default fat content of 20 % unless the actual fat content of the sample was reported. For 403 meat samples the results were expressed on a fat basis. It is noted that for 15 of the fat samples, where the results were reported on whole weight basis, a specific fat content was reported which was taken into account for the evaluation of the data.

Table 2 Lindane resides detected in animal meats

Commodity	LOQ [mg/kg]	Residues expressed	Residue detected [mg/kg]
Swine meat	0.0001	Wpb [a]	0.0002
	0.0005	Fat basis	0.0005, 0.0006, 0.0008, 0.001 (2), 0.002 (2), 0.003 (2)
	0.005	Fat basis	0.007, 0.009, 0.013, 0.015, 0.017
	0.001	Fat basis	0.001,0.001
	0.002	Wpb	0.002
Bovine meat	0.0005	Fat basis	0.0005, 0.0006, 0.0007,0.0008, 0.001, 0.002,0.003
	0.001	Fat basis	0.001 (3), 0.005
	0.002	Fat basis	0.0037
Sheet meat	0.001	Fat basis	0.001 (3)
Swine fat	0.005	Fat	0.007
Bovine fat	0.01	Fat	0.015
	0.005		0.006
Sheep fat	0.005		0.005, 0.006, 0.006, 0.009, 0.01, **0.53**

[a:] Wpb: Whole product basis

Mammalian edible offal

In total, 680 results on lindane residues in mammalian edible offal of different species (swine, bovine, sheep, goat and equines) were submitted by 23 reporting countries. It is noted that for 71 samples the results were expressed on a fat basis. The samples originated from 25 different countries. The LOQ values ranged from 0.0001 to 0.02 mg/kg. All but four samples were free of detectable residues (residues below the LOQ). The only detectable residues were measured in one sample of sheep edible offal (0.018 mg/kg on fat basis) and in three samples of bovine liver (0.0008 mg/kg, 0.001 mg/kg, 0.002 mg/kg on fat basis).

Poultry meat

Overall, 1,760 samples of poultry (chicken, geese, duck, turkey, and Guinea fowl) meat and poultry fat were reported (700 samples of poultry fat and 1,060 samples of poultry meat). These samples originated from 32 countries and were taken in 23 countries. The LOQ values ranged from 0.00005 to 0.02 mg/kg. For 931 poultry meat samples the results were reported on whole product basis. Thus, the results had to be recalculated on a fat basis using a default fat content of 10 % unless the specific fat content of the sample was reported. The LOQ was 0.0005 when the following residues were detected on a fat basis: 0.0006 (2), 0.0007 (3), 0.0008, 0.0009, 0.001 (5), 0.002 (11), 0.004 (2). The residues measured on whole product basis were recalculated assuming 10% fat. They were: 0.001, 0.002 and 0.004 mg/kg.

Poultry offal

In total, 406 results of poultry offal were reported; 402 thereof concerned poultry liver. The results for 13 samples of poultry edible offal were reported on a fat basis; the specific fat content of the samples were also reported. The samples originated from 18 different countries and tested by 15 countries. The LOQ values ranged from 0.0005 to 0.01 mg/kg. Four samples of poultry liver were reported at or above the LOQ. They were on a fat basis: 0.0009, 0.001, 0.0045, 0.1 mg/kg

Eggs

Overall, 2,465 results of lindane in eggs of different species (chicken, duck and quail) were submitted by 26 reporting countries. The samples included only unprocessed, frozen and pasteurised eggs. These samples originated from 28 countries. For 261 samples the results were expressed on a fat basis. The detectable residues at or above the LOQ are summarized in Table 3. (LOQs ranged from 0.00008 to 0.05 mg/kg).

Table 3 Lindane resides detected in eggs

LOQ [mg/kg]	Residues expressed	Residue detected [mg/kg]
0.0001	Wpb[1]	0.0001 (4), 0.0002 (2)
0.0005	Wpb	0.01
0.001	Wpb	0.001
0.005	Wpb	0.006, 0.007,
0.01	Wpb	0.25, 0.30
0.0005	Fat basis	0.0005 (2), 0.0006, 0.0007 (2), 0.0008, 0.001(4), 0.002
0.001	Fat basis	0.001 (4), 0.002
0.005	Fat basis	0.006

Wpb: whole product basis

GEMS/Food data

The GEMS/Food data package contained 4,110 individual results collected during 2000-2011 in Australia, New Zealand, China HK SAR, Germany, Slovakia and Denmark.

The summary of relevant results is given in Table 4. In addition, the results of analysis of other commodities are given in Table 5.

Table 4 Summary of the results of analyses for lindane residues in eggs, milk and meat samples

	N	LOD mg/kg	LOQ mg/kg	Residues detected
Chicken eggs	163	0.003	0.007	0
Eggs and egg products NS	37	0.003	0.007	0
Eggs	**200**			0
Cattle milk	341	0.002	0.0035	0
Milks, NS	19	0.001	0.003	0
Goat milk	1	0.0014	0.0034	0
Milks	**361**			0
Chicken meat	7	0.0007	0.003	0.0034
Turkey meat	4	0.001	0.003	0
Poultry meat	4	0.0007	0.003	0
Poultry meat	**15**			1
Cattle meat	5	0.001	0.005	0
Swine meat	4	0.001	0.02	0
Mammalian meat NS	7	0.0003	0.001	0
Mammalian meats	**16**			0
Poultry fat	206	0.0007	0.002	0
Fats and oils NS	1054	0.0007	0.002	0
	1260			0

Table 5 Summary of the results of analyses for lindane residues in fruits, vegetables, fish and seafood samples

	N	LOD mg/kg	LOQ mg/kg	Residues detected
Almonds	4	0.02	0.1	
Apple	12	0.001	0.005/0.1	
Avocado	7	0.02	0.1	
Banana	12	0.0001	0.01	

Dragon fruits	4	0.001	0.005	
Grapes	13	0.02	0.5	
Kiwi fruit	13	0.02	0.1	
Longan	4	0.001	0.005	
Mango	8	0.02	0.1	
Melons	4	0.1	0.5	
Nectarine	8	0.02	0.1	
Orange	12	0.02	0.1	
Papaya	4	0.0001	0.0005	
Peach	4	0.0001	0.0005	
Pear	4	0.0001	0.0005	
Pineapple	4	0.0001	0.0005	
Plum	4	0.0001	0.0005	
Pumelo/grapefruits	4	0.0001	0.0005	0.0028
Strawberries	8	0.02	0.1	
Watermelon	12	0.02	0.1	
Fruits	**145**			
Celery	8	0.002	0.1	
Cucumber	11	0.02	0.1	
Lettuce	13	0.02	0.1	
Mushrooms	8	0.02	0.1	
Onions	8	0.02	0.1	
Peppers sweet	8	0.02	0.1	
Persimmon	4	0.0001	0.0005	
Tomato	8	0.02	0.1	
Lambs lettuce	1	0.001	0.003	
Beans, dry	1	0.003	0.005	
Vegetables	**67**			
Cod	5	0.0004	0.002	
Eels	42	0.0003	0.001	
Herring	241	0.0001	0.0005	
Mackerel	36	0.0002	0.001	
Salmon	500	0.0001	0.0007	0.0019, 0.003, 0.0045, 0.0095
Sardines	7	0.1	0.4	
Fishes NS	1818	0.0002	0.0007	0.0028, 0.0029 (6), 0.0031, 0.0032 (6), 0.0033, 0.0036 (5), 0.0037 (2), .0038 (2), 0.004, 0.0042 (2), 0.0043 (2), 0.0045, 0.0051 (2), 0.0063 (4), 0.0083
Fish and sea food NS	119	0.0002	0.002	
Fish and sea food	**2768**			

Monitoring data from India

Monitoring data for lindane residues in cereals, eggs, poultry and meat obtained in India under "Monitoring of Pesticide Residues at National Level" during 2009-14 were reported in summarized form. They are shown in Tables 6 and 7.

Table 6 Summary results of monitoring lindane residues in cereals, meat and eggs in India

Year	Commodity	Number of samples	LOQ mg/kg	Detected residues [mg/kg]
2009-2014	Cereals (Rice & Wheat)	7650	0.01	0.01,0.02 (2), 0.04, 0.05, 0.06, 0.08, 0.16
	Meat & Eggs	2361	0.01	0

The Netherlands

Fifty seven positive results derived from monitoring programmes carried out between 2004–2013 were provided. The relevant commodities and the detectable residues found were: maize whole meal (0.003 mg/kg), maize grits (0.012 mg/kg), wheat wholegrain floor (0.003, 0.006 mg/kg). The total number of samples analysed were not reported.

United States

The Pesticide Data Program (PDP) is directed at raw agricultural products and various processed foods originated from domestic production and import. Although processed foods are also included, the emphasis is on the raw agricultural product, which is typically analysed as the unwashed, whole (unpeeled), raw commodity. In addition to monitoring foods for human consumption, FDA also samples and analyses domestic and imported animal feeds for pesticide residues (US FDA).

None of the 80,224 samples analysed between 2007–2012 contained detectable amounts of lindane in the commodities relevant to the present evaluation. Only 14 samples, comprising frozen potato, ginseng and ginseng products, chick pea, dried mushroom and panax root powder contained lindane residues in the range of 0.003 and 0.7 mg/kg.

APPRAISAL

Lindane was first evaluated by the Joint Meeting in 1966 (T, R). It had been last re-evaluated within the periodic review programme in 2002 (T) and 2003 (R). The Meeting established an ADI of 0-0.005 mg/kg bw and ARfD of 0.06 mg/kg bw. The Meeting agreed that the definition of the residue for compliance with MRLs and for estimation of dietary intake should be: lindane for both plant and animal commodities. The residue is fat-soluble.

Since lindane is currently listed in Annex A of the Stockholm Convention by which Parties must take measures to eliminate the production and use of the chemical, and there was no information on existing national registrations for lindane uses, the Forty-sixth Session of the CCPR (2014) requested a periodic review in 2015 to convert the CXLs into Codex EMRLs.

Monitoring data were submitted by the European Food Safety Authority (EFSA) for the period of 2009-2013 and from the GEMS/Food programme (2000-2011) to the Meeting. In addition, individual residue studies were provided by the Netherlands in processed maize and wheat, and summarized results from India and the USA.

Methods of residue analysis

Lindane can be recovered using numerous multi residue procedures. The sensitivity of the detection depends on the extraction and cleanup procedures, and the instrumentation available for qualitative and quantitative determination. No information was provided on the methods of analyses of samples for which lindane residues were reported. However, in the screening procedures, the objective is to detect residues which are around the legal limit, and to achieve the lowest concentration is not the primary goal. The reported LOQ values varied significantly in cases of individual commodities and among different commodities. The median reported LOQ values reported by EFSA and GEMS/Food were: cereal grains (0.01 mg/kg), mammalian and poultry meat (0.001 mg/kg), mammalian and poultry edible offal (0.001 mg/kg), milks (0.0004 mg/kg) and eggs (0.001 mg/kg). The Meeting assumed that these values can be realistically achieved applying current instrumental detection techniques and they were taken into consideration in estimation of EMRL values. If the LOQ exceeded the present CXL values, the reported <LOQ values were considered as non-detected.

Residues reported from monitoring programmes

The EFSA submitted the results of analyses of about 25,000 individual samples relevant to the present evaluation. The results originated from 60 different countries with the majority (96%) from the EU Member States, Iceland and Norway. In addition the Netherlands reported detected residues in some samples.

The GEMS/Food data package contained 4,110 individual results collected in Australia, New-Zealand, China HK SAR, Germany, Slovakia and Denmark. The data package included several commodities for which no CXL had been established. When sufficient numbers of results were available, these data were also considered for estimation of EMRLs.

India provided the summarized results of analyses of 7,650 cereal grain samples, including rice and wheat, and 2,361 meat and egg samples.

The summary results of the US FDA Pesticide Data Programme (2007-2012) were provided, which included over 80,000 residue measurements obtained from a large variety of commodities. None of the samples analysed between 2007 and 2012 contained lindane residues above the LOQ in the commodities relevant to the present evaluation.

The above data sets including the results of analyses of large numbers of samples did not indicate differences among geographical regions; therefore it was assumed that they provide information on the lindane concentration resulting from environmental contamination present around the world. Consequently, they were considered together for estimating EMRLs. According to previous practice of the JMPR, EMRLs should cover a minimum of 99 percentile of the relevant residue data population with a 99% probability (FAO Manual sub-chapter 6.11.2). To meet this criterion a

minimum of 459 valid results are required. For covering 99.9 percent of the likely residues present with 99 percent probability, 4,603 results would be needed.

Sweet corn

None of the 424 samples, reported by EFSA originating from 27 different countries, contained detectable lindane residues.

Using the mature maize residue data (642) as supporting evidence, the Meeting concluded that the database is sufficient to recommend an EMRL of 0.01 mg/kg for sweet corn kernels.

The Meeting withdraws its previous recommendation of 0.01(*) mg/kg.

Cereal grains

Individual residue analyses are available from European countries for barley (630), maize (642) oat (898), rye (1,658), sorghum (36), and wheat (4,942). Quantified residues were reported by France in wheat (0.078 mg/kg), and The Netherlands in whole maize flour (0.003 mg/kg), maize grits (0.012 mg/kg), and whole wheat flour (0.003 and 0.006 mg/kg). Of a total of 8,806 raw cereal grain samples, only one wheat sample (0.078 mg/kg) and one maize grit sample (0.012 mg/kg) contained residues above the current CXL of 0.01 mg/kg (0.022%). Based on this result it can be stated that at least 99.8% of the expectable residues are below the current CXL with a 99% probability. This conclusion is supported by the large number of results reported by India and USA.

The Meeting recommended an EMRL of 0.01 mg/kg for cereal grains.

The Meeting withdraws its previous recommendations of 0.01 (*) mg/kg for maximum residue levels in barley, maize, oats, rye, sorghum and wheat.

Straw and fodder of cereal grains

Based on the results reported by the 2003 JMPR (Pesticide Residues in Food - 2003 Evaluations Part I P583, pp 177) indicating similar, generally non-detected, residues in wheat grains, hay and straw, supported by the summarized US FDA data package, the Meeting concluded that residues above 0.01 mg/kg are unlikely to occur in straw and fodder, dry, from environmental contamination.

The Meeting recommended an EMRL of 0.01 mg/kg for straw and fodder of cereal grains.

The Meeting withdraws its previous recommendation of 0.01 (*) mg/kg.

Meat (from mammals other than marine mammals)

Overall, 3,360 samples of meat and 2,657 samples of fat of mammals (pig, cattle, sheep, goat and horse) were analysed for lindane residues. These samples, reported by EFSA, originated from 42 different countries. Overall, 40 samples contained residues at or above the LOQ. However, only one sheep fat sample contained residue (0.53 mg/kg) above the current CXL of 0.1 mg/kg (0.016%). The next two highest values were in swine meat (fat) 0.017 mg/kg and 0.015 in beef fat.

Sixteen mammalian meat samples reported from the GEMS/Food database contained non-detected residues

The Meeting concluded that the residue level reported is much lower than that which was reported at the time of the estimation of the current CXL of 0.1 mg/kg.

The Meeting recommended an EMRL of 0.01 mg/kg (fat) for meat (from mammals other than marine mammals)

The Meeting withdraws its previous recommendation of 0.1 mg/kg (fat).

Edible offal (mammalian)

Overall, 680 samples of mammalian edible offal of different species (pig, cattle, sheep, goat and horse) were analysed for lindane residues. These samples originated from 25 different countries.

Four samples contained residues but none of them exceeded the current CXL of 0.01 mg/kg. Three cattle liver samples contained residues (0.0008 mg/kg, 0.001 mg/kg, 0.002 mg/kg on a fat basis), and one sheep edible offal (0.018 mg/kg on a fat basis). The residues expressed on a whole product basis would be about 20 times lower.

The Meeting concluded that there was sufficient information to recommend an EMRL of 0.001 mg/kg for edible offal (mammalian).

The Meeting withdraws its previous recommendation of 0.01 (*) mg/kg.

Milks

Altogether 4,319 lindane residues in unprocessed, frozen and pasteurised milk samples of different species (cattle, sheep, goat and horses) were reported by EFSA. Overall, detected residues were ≥ LOQ (0.00004 (3), 0.00008, 0.0001, 0.0003, 0.0006 and 0.002 mg/kg on a whole product basis and 0.0006 mg/kg on a fat basis. None of them exceeded the current CXL.

Cattle (341) and goat (1) samples obtained from GEMS/Food database contained non-detected residues (< 0.002 mg/kg).

Based on the extensive data base, the Meeting recommended an EMRL of 0.001 mg/kg for milks.

The Meeting withdraws its previous recommendation of 0.01 (*) mg/kg.

Poultry meat

Overall, 700 samples of poultry fat and 1,060 samples of poultry meat (chicken, geese, duck, turkey, and Guinea fowl) were derived from 32 countries. The LOQ was 0.0005 when the following residues [mg/kg] were detected on a fat basis: 0.0006 (2), 0.0007 (3), 0.0008, 0.0009, 0.001 (5), 0.002 (11), 0.004 (2). The residues measured on a whole product basis were recalculated assuming 10% fat. The values were: 0.001, 0.002 and 0.004 mg/kg.

One chicken meat (fat) sample of the 15 poultry meat samples obtained from GEMS/Food database contained residues of 0.0034 mg/kg lindane. None of the samples contained residues above the current CXL. The results indicate that 99.5% of the samples would unlikely contain residues above 0.004 mg/kg (fat) in 99.9% of the cases.

Based on the data available the Meeting concluded that 0.005 mg/kg residue level would sufficiently cover the residues carried over from environmental contamination, and recommended it as the EMRL for poultry meat (on fat basis).

The Meeting withdraws its previous recommendation of 0.05 mg/kg.

Poultry, edible offal of

In total, 406 results of poultry offal were reported by EFSA of which 402 were poultry liver. Four samples contained detected residues. They were on a fat basis: 0.0009, 0.001, 0.0045, 0.1 mg/kg. The residues expressed on a whole product basis would be at least 20 times lower.

Based on the 406 residue dataset, it can be assumed that 99% of the sampled lot would contain less than 0.01 mg/kg lindane residues with at least 98% probability.

Based on the available data the Meeting recommended an EMRL of 0.005 mg/kg for poultry, edible offal.

The Meeting withdraws its previous recommendation of 0.01 (*) mg/kg.

Eggs

Altogether 2,665 residue determinations were conducted in eggs on a whole product or fat basis as reported by EFSA and obtained from the GEMS Food database. The samples originated from more

than 26 countries. Of the 2,665 samples only 2 (0.075%) contained residues (0.25 and 0.3 mg/kg) above the current CXL.

Based on the available data the Meeting recommended an EMR of 0.001 mg/kg for eggs.

The Meeting withdraws its previous recommendation of 0.01 mg/kg.

Fish and diadromous fish

Lindane residues were reported from the GEMS/Food data base. Residues were detected in 41 of 2,649 samples. They were in rank order: 0.0019, 0.0028, 0.0029 (6), 0.003, 0.0031, 0.0032 (6), 0.0033, 0.0036 (5), 0.0037 (2), 0.0038 (2), 0.004, 0.0042 (2), 0.0043 (2), 0.0045 (2), 0.0051 (2), 0.0063 (4), 0.0083 and 0.0095 mg/kg.

The Meeting considered that the residues in fish are a suitable indicator of environmental contamination. The Meeting concluded that the residue data on fish derived from the GEMS/Food database would provide sufficient basis (99.8% of residues with 99.5% probability) for estimation of likely maximum residue levels of lindane in fish.

Based on the data available the Meeting recommended an EMRL of 0.01 mg/kg for fish and diadromous fish.

RECOMMENDATION

The Meeting noted that there are no authorised uses of lindane for crop protection and withdraws its previous recommendations for maximum residue levels and recommends the following extraneous residue levels for use as EMRLs.

Definition of residue is unchanged.

Definition of reside for compliance with EMRLs and for estimation of dietary intake: lindane.

The residue is fat soluble.

		Estimated residue levels mg/kg			Recommendation [a]	
CCN	Commodity	EMRL [b]	*Median*	*Highest*	New	Previous
GC 0640	Barley				W	0.01*
GC 0051	Cereal grains, except rice	0.01	*0.005*	*0.005*		
WD 0120	Diadromous fish	0.01	*0.0036*	*0.0095*		
MO 0105	Edible offal (mammalian)	0.001	*0.00002*	*0.0002*	W	0.01*
PE 0112	Eggs	0.001	*0.0007*	*0.002*	W	0.01*
GC 0645	Maize				W	0.01*
WS 0125	Marine fish	0.01	*0.0036*	*0.0095*		
MM 0095	Meat (from mammals other than marine mammals)	0.01 (F)	*0.00007 (0.0005)*	*0.0005 (0.006)*	W	0.1
ML 0106	Milks	0.001	*0.00003*		W	0.01*
GC 0647	Oats				W	0.01*
PM 0110	Poultry meat	0.005 (F)	*0.0006 (0.0008)*	*0.001 (0.016)*	W	0.05
PO 0111	Poultry, edible offal of	0.005	*0.00008*	*0.0002*	W	0.01*
GC 0650	Rye				W	0.01*
GC 0651	Sorghum				W	0.01*
AS 0161	Straw and fodder of cereal grains	0.01			W	0.01*
VO 1275	Sweet corn (kernels)	0.01	*0.005*	*0.005*	W	0.01*
GC 0655	Wheat				W	0.01*

[a] Lindane was recently classified as 2A (Probable carcinogen) by IARC. Since lindane is listed in annex A of the Stockholm convention and should be eliminated from production and use no toxicological re-evaluation is requested.

[b] Extraneous Maximum Residue Limit (EMRL) is the maximum concentration of a pesticide residue arising from environmental sources due to former agricultural uses, not from the use of the pesticide directly or indirectly on the food or feed.

Estimation of dietary intake

Cereal grains

The median LOQ value reported for barley, maize, oats, rye, sorghum and wheat is 0.01 mg/kg. For dietary intake calculations the 2003 JMPR estimated an STMR and HR of 0.005 mg/kg based on the results of supervised trials. As the estimated EMRL is at the same level as the previous CXL value, the Meeting concluded that the best estimates of the STMR and HR for these commodities and sweet corn are those recommended by the 2003 JMPR.

Animal commodities

Based on animal feeding studies taking into account the expected residue levels in feed commodities deriving from the use of lindane, the 2003 JMPR recommended HR and STMR values for muscle (0.005 mg/kg and 0.0007 mg/kg), fat (0.06 mg/kg and 0.005 mg/kg) edible offal (0.002 mg/kg and 0.0002 mg/kg) from mammals other than marine mammals, and STMR of 0.0003 mg/kg for milks.

Based on the monitoring data, the current residue level in mammalian meat and poultry meat is 10 times lower; the Meeting applied the 10 times lower factor in the corresponding commodities, compared with those estimated by the 2003 JMPR.

The Meeting estimated highest and median residue values for muscle (0.0005 mg/kg and 0.00007 mg/kg), fat (0.006 mg/kg and 0.0005 mg/kg) edible offal (0.0002 mg/kg and 0.00002 mg/kg) from mammals other than marine mammals, and a median residue of 0.00003 mg/kg for milks.

The 2003 Meeting recommended HR and STMR values for poultry meat (0.001 mg/kg and 0.0006 mg/kg), poultry fat (0.016mg/kg and 0.008 mg/kg), eggs (0.002 mg/kg and 0.0007 mg/kg) and edible offal (0.001 mg/kg and 0.0004 mg/kg).

For poultry meat and edible offal the residue levels are about 5–10 times lower, respectively, than those estimated in 2003.

The Meeting estimated highest and median residue values for poultry meat (0.0001 mg/kg and 0.00006 mg/kg), poultry fat (0.0016 mg/kg and 0.0008 mg/kg), poultry edible offal (0.0002 mg/kg and 0.00008 mg/kg) and eggs (0.0002 mg/kg and 0.00007 mg/kg

The fish consumption data was provided by the GEMS/Food database. The long-term intake is 0.43 g/kg bw and the short-term intake (97.5^{th} percentile of 1,043 consumption days) is 10 g/kg bw. The short-term intake was calculated with the highest residue observed in fish (0.0095 mg/kg) and the long term intake was calculated with the median of LOQ values (0.0036 mg/kg) reported for analyses of fish samples.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of lindane were calculated for the 17 GEMS/Food cluster diets using STMRs estimated by the Meeting. The results are shown in Annex 3 to the 2015 Report.

The ADI is 0–0.005 mg/kg bw and the calculated IEDIs were 0–1% of the maximum ADI. The fish consumption contributes to < 0.001% of the max ADI. The Meeting concluded that the long-term intake of residues of lindane from the environmental contamination of commodities considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The ARfD is 0.06 mg/kg bw. The short-term intake calculated using the HR and STMR values estimated by the Meeting were 0% of the ARfD for children and the general population. The fish consumption contributes to 0.016% of the ARfD. The Meeting concluded that the short-term intake of residues of lindane from the environmental contamination of commodities considered by the JMPR is

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