Statement on the dietary exposure assessment for the temporary maximum residue levels for chlordecone in certain products of animal origin

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission requested EFSA to carry out a consumer exposure assessment in relation to the maximum residue levels (MRLs) for chlordecone in products of animal origin recommended by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) in an assessment performed in 2018. The MRL proposals under assessment are lower than the current EU MRLs established under Regulation (EC) 396/2005. The dietary exposure calculations performed by EFSA demonstrated that the short-term and the long-term intake of chlordecone residues at the level of the proposed MRLs for animal products under assessment is not expected to exceed the toxicological reference values derived by the French authorities.

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Keywords: chlordecone, animal commodities, livestock, pesticide, MRL, exposure assessment

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1. Introduction and background information

Chlordecone is an organochlorine compound with insecticidal activity that has been widely used in French Antilles.

| Common name     | Chlordecone          |
|-----------------|----------------------|
| IUPAC           | perchloropentacyclo[5.3.0.02,6.03,9.04,8]decan-5-one |
| CAS             | 1,1a,3,3a,4,5,5a,SB,6-decachlorooctahydro-2H-1,3,4-(methanetiy1) cyclobuta[cd]pentalen-2-one |
| Other names     | Kepone, Merex        |
| CAS number      | 143-50-0             |
| CIPAC Code      | 297                  |
| Molecular formula | C10Cl10O           |
| Molecular weight | 490.633              |
| Structural formula | ![Structural formula](image) |

Chlordecone has been banned in 2004 for being used in plant protection products (Commission Regulation (EC) No 850/2004\(^1\)).

Chlordecone is listed in Annex A of the Stockholm Convention (decision SC-4/12). Due to its high persistence, chlordecone is still present in the environment, and leads to contamination of food produced in contaminated areas. It has a tendency to accumulate in the food chain, leading to residues in animal products.

The current EU maximum residue levels (MRLs) for chlordecone are established in Annex III of Regulation (EC) No 396/2005\(^2\). The residues are labelled in the MRL legislation as being fat soluble.

On 12 July 2019, the French competent authorities notified to the European Commission two emergency measures, which had been taken at national level pursuant to Article 53 of Regulation (EC) 178/2002.\(^3\) Following the opinions of the French Agency for Food, Environmental and Occupational Health and Safety (ANSES), France had fixed new national maximum residues levels (MRLs) for chlordecone in bovine, ovine, caprine, porcine and poultry matrices (Table 1) at lower values than the ones currently applicable under Regulation (EC) 396/2005 to ensure the protection of consumers of Guadeloupe and Martinique (ANSES, 2018b, 2019).

Table 1: Existing EU MRLs and new French MRL proposals for chlordecone in animal matrices

| Code number | Groups and examples of individual products to which the MRLs apply | Reg. (EC) No 839/2008 mg/kg | French MRL proposals derived by ANSES\(^{(a)}\) (mg/kg) |
|-------------|---------------------------------------------------------------|-----------------------------|---------------------------------|
| 1000000     | PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS               |                             |                                 |
| 1010000     | Commodities from                                             |                             |                                 |
| 1011000     | (a) Swine                                                     | 0.1                         | 0.02                            |
| 1011010     | Muscle                                                        | 0.1                         | 0.02                            |
| 1011020     | Fat                                                           | 0.1                         | 0.02                            |
| 1011030     | Liver                                                         | 0.1                         | 0.02                            |

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\(^1\) Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC. OJ L 158, 30.4.2004, p 7–49.
\(^2\) Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p 1–16.
\(^3\) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p 1–24.
Toxicological reference values were established by ANSES in a previous assessment (ANSES, 2018a), where ANSES proposed an acceptable daily intake (ADI) of 0.0005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.01 mg/kg bw. No toxicological reference values are established at European level.

2. Terms of reference as provided by the European Commission

On 17 October 2019, the European Food Safety Authority (EFSA) received a request from the European Commission⁴ to carry out a consumer exposure assessment in relation to the MRLs recommended by ANSES in the relevant opinions.

EFSA accepted the mandate and included it in the EFSA Register of Questions with the reference number EFSA-Q-2019-00665.

| Code number | Groups and examples of individual products to which the MRLs apply | Reg. (EC) No 839/2008 mg/kg | French MRL proposals derived by ANSES(a) (mg/kg) |
|-------------|----------------------------------------------------------|-----------------|---------------------------------|
| 1011040     | Kidney                                                   | 0.1             | 0.02                            |
| 1011050     | Edible offals (other than liver and kidney)              | 0.1             | 0.02                            |
| 1011990     | Other tissues (swine)                                    | 0.1             | 0.02                            |
| 1012000     | (b) Bovine                                               | 0.1             |                                 |
| 1012010     | Muscle                                                   | 0.1             | 0.02                            |
| 1012020     | Fat                                                      | 0.1             | 0.03                            |
| 1012030     | Liver                                                    | 0.1             | 0.02                            |
| 1012040     | Kidney                                                   | 0.1             | 0.02                            |
| 1012050     | Edible offals (other than liver and kidney)              | 0.1             | 0.02                            |
| 1012990     | Other tissues (bovine)                                   | 0.1             | 0.02                            |
| 1013000     | (c) Sheep                                                | 0.1             | 0.02                            |
| 1013010     | Muscle                                                   | 0.1             | 0.02                            |
| 1013020     | Fat                                                      | 0.1             | 0.02                            |
| 1013030     | Liver                                                    | 0.1             | 0.02                            |
| 1013040     | Kidney                                                   | 0.1             | 0.02                            |
| 1013050     | Edible offals (other than liver and kidney)              | 0.1             | 0.02                            |
| 1013990     | Other tissues (sheep)                                    | 0.1             | 0.02                            |
| 1014000     | (d) Goat                                                 | 0.1             | 0.02                            |
| 1014010     | Muscle                                                   | 0.1             | 0.02                            |
| 1014020     | Fat                                                      | 0.1             | 0.02                            |
| 1014030     | Liver                                                    | 0.1             | 0.02                            |
| 1014040     | Kidney                                                   | 0.1             | 0.02                            |
| 1014050     | Edible offals (other than liver and kidney)              | 0.1             | 0.02                            |
| 1014990     | Other tissues (goat)                                     | 0.1             | 0.02                            |
| 1016000     | (f) Poultry                                              | 0.2             | 0.02                            |
| 1016010     | Muscle                                                   | 0.2             | 0.02                            |
| 1016020     | Fat                                                      | 0.2             | 0.02                            |
| 1016030     | Liver                                                    | 0.2             | 0.02                            |
| 1016040     | Kidney                                                   | 0.2             | 0.02                            |
| 1016050     | Edible offals (other than liver and kidney)              | 0.2             | 0.02                            |
| 1016990     | Other tissues (poultry)                                  | 0.2             | 0.02                            |

(a): The values recommended by ANSES (2018b, 2019) were rounded according to the guidelines on the OECD MRL calculation.

Toxicological reference values were established by ANSES in a previous assessment (ANSES, 2018a), where ANSES proposed an acceptable daily intake (ADI) of 0.0005 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.01 mg/kg bw. No toxicological reference values are established at European level.

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⁴ “Request of a scientific opinion reviewing the temporary MRLs for chlordecone in certain animal products” ARES (2019) 6431000.
2.1. Interpretation of the Terms of Reference

As requested in the mandate, EFSA focussed in this statement on the dietary exposure assessment for the MRL proposals derived by ANSES for animal tissues, which are reported in Table 1. Considering the current risk management practice of extrapolating MRLs to other animal species, EFSA performed the dietary risk assessment also for food products (edible tissues) of equine and other farmed animals using the MRL proposal of 0.02 mg/kg.

EFSA used the toxicological reference values derived by ANSES (ANSES, 2018a). EFSA did not assess the toxicological reference values derived by the French authorities, as this was not requested in the mandate.

It was also clarified by the requestor that plant products should not be taken into account in the exposure calculations and that the mandate does not request EFSA to re-assess the scientific basis for the MRL proposals derived by ANSES.

3. Assessment

The consumer exposure assessment was performed using the revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). This dietary exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018, 2019). The exposure calculations were performed with the MRL proposals reported in Table 1. For bovine meat, the input values were calculated, assuming meat being a mixture of 20% fat and 80% muscle; hence the exposure calculations were performed with a chlordecone concentration of 0.022 mg/kg in meat.

3.1. Acute (short-term) exposure assessment

The estimated short-term exposure calculated for children accounted for up to 3% of the ARfD. The highest exposure was identified for poultry meat. For adults, the exposure was slightly lower (2% of the ARfD for poultry meat). More detailed results can be found in Appendix A. The acute exposure assessment reflects the assumption that a large portion of the food product under assessment containing residues at the proposed MRL is consumed by European consumers.

3.2. Chronic (long-term) exposure assessment

The results of the chronic exposure assessment are also reported in Appendix A. The highest total exposure resulting from all animal products under assessment accounted for a maximum of 19% of the ADI (Swedish general population).

Among the individual products, bovine meat was the main contributor in most of the diets (19% of the ADI), followed by swine meat (9% of the ADI) and poultry meat (6% of the ADI).

It should be highlighted that in accordance with internationally agreed methodologies, the calculation of the long-term exposure is usually performed with a median residue concentration expected in the food products consumed, while in the given case the calculations were performed with the MRL, which is considered as a very conservative approach leading to an overestimation of the exposure. However, in the current calculation the contribution of other products with chlordecone contamination (e.g. milk, eggs, plant products, fish) was not taken into account. Hence, the chronic exposure assessment is indicative only and risk managers need to be aware of these limitations when interpreting the results.

The exposure calculations using EFSA PRIMo model 3.1, together with the opinions issued by ANSES (ANSES, 2018a,b, 2019) are considered as supporting documents to this statement.

4. Conclusion

The dietary exposure calculations performed by EFSA demonstrated that the short-term and the long-term intake of chlordecone residues at the level of the proposed MRLs for animal products under assessment is not expected to exceed the toxicological reference values derived by the French authorities. It is highlighted that the chronic exposure assessment is considered indicative, since realistic estimates for the expected residue concentrations in all food products that may contribute to the overall dietary exposure of chlordecone are currently not available.
In accordance with the provisions of Article 16(1)(a) and Article 16(2) of Regulation (EC) No 396/2005 temporary MRLs for pesticide residues that are the result of environmental contamination such as chlordecone should be regularly reassessed, taking into account results from pesticide monitoring programmes, since contamination of food is expected to gradually decrease over time.

References

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Abbreviations

ADI acceptable daily intake
ANSES French Agency for Food, Environmental and Occupational Health and Safety
ARfD acute reference dose
bw body weight
CAS Chemical Abstract Service
CIPAC Collaborative International Pesticide Analytical Council
FAO Food and Agriculture Organization of the United Nations
IEDI international estimated daily intake
IESTI international estimated short-term intake
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LOQ limit of quantification
MRL maximum residue level
OECD Organisation for Economic Co-operation and Development
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RD residue definition
TMDI theoretical maximum daily intake
WHO World Health Organization
## Appendix A – Pesticide Residue Intake Model (PRIMo)

### Chlordecone (F)

#### LOQs (mg/kg) range from

| LOQ (mg/kg) | LOQ (mg/kg) |
|-------------|-------------|
| 0.05        | 0.05        |

#### Input values

| Details–acute risk assessment | Details–chronic risk assessment |
|-----------------------------|-------------------------------|

#### Supplementary results – assessment/children

| Source of ADI | Source of ARfD |
|---------------|----------------|
| ANSES         | ANSES          |

#### Year of evaluation

- EFSA PRIMo revision 3.1; 2019/03/19

### Normal modes

#### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

| Commodities | MDI Diet | Highest contributor to MDI diet | 2nd contributor to MDI diet |
|-------------|----------|---------------------------------|-----------------------------|
| Bovine: Muscle/meat | 19% 0.10 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Swine: Muscle/meat | 19% 0.10 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Poultry: Muscle/meat | 18% 0.09 | Bovine: Muscle/meat | Swine: Muscle/meat |
| Bovine: Muscle/meat | 15% 0.08 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Swine: Muscle/meat | 15% 0.08 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Poultry: Muscle/meat | 15% 0.08 | Bovine: Muscle/meat | Swine: Muscle/meat |
| Bovine: Muscle/meat | 14% 0.07 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Swine: Muscle/meat | 14% 0.07 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Poultry: Muscle/meat | 14% 0.07 | Bovine: Muscle/meat | Swine: Muscle/meat |
| Bovine: Muscle/meat | 13% 0.06 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Swine: Muscle/meat | 13% 0.06 | Bovine: Muscle/meat | Poultry: Muscle/meat |
| Poultry: Muscle/meat | 13% 0.06 | Bovine: Muscle/meat | Swine: Muscle/meat |

**Conclusion:**

The estimated long-term dietary intake (TMDI/IEDI/NEDI) was below the ADI. The long-term intake of residues of Chlordecone (F) is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for children

| IESTI         | No. of commodities for which ARfD/ADI is exceeded (IESTI): |
|---------------|-----------------------------------------------------------|
| ARfD/ADI     | Highest % of ARfD/ADI                                      |
| Commodity     | MRL/input (mg/kg)                                          |
| Exposure      | (µg/kg bw)                                                 |
|---------------|-----------------------------------------------------------|
| 3%            | Poultry: Muscle/meat                                       |
|               | 0.02/0.02                                                 |
|               | 0.34                                                      |
| 2%            | Swine: Muscle/meat                                         |
|               | 0.02/0.02                                                 |
|               | 0.24                                                      |
| 2%            | Bovine: Liver                                             |
|               | 0.02/0.02                                                 |
|               | 0.16                                                      |
| 1%            | Bovine: Edible offals                                      |
|               | 0.02/0.02                                                 |
|               | 0.15                                                      |
| 1%            | Other farmed animals:                                     |
|               | 0.02/0.02                                                 |
|               | 0.14                                                      |
| 1%            | Sheep: Muscle/meat                                         |
|               | 0.02/0.02                                                 |
|               | 0.11                                                      |
| 0.6%          | Bovine: Kidney                                            |
|               | 0.02/0.02                                                 |
|               | 0.08                                                      |
| 0.6%          | Swine: Edible offals                                       |
|               | 0.02/0.02                                                 |
|               | 0.06                                                      |
| 0.3%          | Swine: Fat tissue                                          |
|               | 0.02/0.02                                                 |
|               | 0.03                                                      |
| 0.2%          | Swine: Kidney                                              |
|               | 0.02/0.02                                                 |
|               | 0.02                                                      |
| 0.02%         | Poultry: Fat tissue                                       |
|               | 0.02/0.02                                                 |
|               | 0.00                                                      |

### Results for adults

| IESTI         | No. of commodities for which ARfD/ADI is exceeded (IESTI): |
|---------------|-----------------------------------------------------------|
| ARfD/ADI     | Highest % of ARfD/ADI                                      |
| Commodity     | MRL/input (mg/kg)                                          |
| Exposure      | (µg/kg bw)                                                 |
|---------------|-----------------------------------------------------------|
| 2%            | Poultry: Muscle/meat                                       |
|               | 0.02/0.02                                                 |
|               | 0.23                                                      |
| 1%            | Bovine: Muscle/meat                                        |
|               | 0.02/0.02                                                 |
|               | 0.13                                                      |
| 1%            | Other farmed animals:                                     |
|               | 0.02/0.02                                                 |
|               | 0.11                                                      |
| 0.9%          | Sheep: Muscle/meat                                         |
|               | 0.02/0.02                                                 |
|               | 0.09                                                      |
| 0.8%          | Bovine: Edible offals                                      |
|               | 0.02/0.02                                                 |
|               | 0.08                                                      |
| 0.7%          | Bovine: Edible offals (other)                             |
|               | 0.02/0.02                                                 |
|               | 0.07                                                      |
| 0.6%          | Swine: Edible offals                                       |
|               | 0.02/0.02                                                 |
|               | 0.06                                                      |
| 0.5%          | Swine: Edible offals (other)                              |
|               | 0.02/0.02                                                 |
|               | 0.05                                                      |
| 0.4%          | Swine: Kidney                                              |
|               | 0.02/0.02                                                 |
|               | 0.04                                                      |
| 0.4%          | Bovine: Kidney                                            |
|               | 0.02/0.02                                                 |
|               | 0.04                                                      |
| 0.4%          | Bovine: Other products                                    |
|               | 0.02/0.02                                                 |
|               | 0.04                                                      |
| 0.3%          | Goats: Muscle/meat                                         |
|               | 0.02/0.02                                                 |
|               | 0.03                                                      |
| 0.3%          | Bovine: Fat tissue                                         |
|               | 0.03/0.03                                                 |
|               | 0.03                                                      |
| 0.3%          | Swine: Liver                                               |
|               | 0.02/0.02                                                 |
|               | 0.03                                                      |
| 0.3%          | Poultry: Kidney                                            |
|               | 0.02/0.02                                                 |
|               | 0.03                                                      |
| 0.1%          | Sheep: Edible offals                                       |
|               | 0.02/0.02                                                 |
|               | 0.01                                                      |
| 0.06%         | Poultry: Fat tissue                                       |
|               | 0.02/0.02                                                 |
|               | 0.01                                                      |
| 0.02%         | Sheep: Kidney                                              |
|               | 0.02/0.02                                                 |
|               | 0.00                                                      |