

REASONED OPINION

Modification of the existing MRLs for oxadixyl in parsley, celery and leek ¹

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SUMMARY

The European Commission has been informed by Belgium that parsley, celery and leek originating from Belgium may contain levels of oxadixyl, a pesticide which is no longer authorised at EU level, exceeding the legal limit established in Regulation (EC) No 396/2005. According to the Belgian authorities, the unexpected presence of oxadixyl in these crops is due to the persistence of the active substance in soil.

A specific monitoring programme was initiated in Belgium. In total the analytical results of 3058 samples were forwarded to EFSA via the European Commission. In accordance with Article 43 of Regulation (EC) No 396/2005 EFSA was requested by the European Commission to provide a scientific opinion with a view of setting temporary MRLs for oxadixyl in parsley, celery and leek.

Article 16 of Regulation (EC) No 396/2005 provides that temporary MRLs may be set in exceptional cases based on monitoring data, in particular where pesticide residues may arise as a result of environmental or other contamination, provided that an EFSA opinion demonstrates that there are no unacceptable risks to consumers and animals. The temporary MRLs established according to this procedure shall be reassessed at least once every 10 years.

EFSA assessed the data made available by Belgium and the results of the EU monitoring programme reported to EFSA. Since the information reported in the Belgian evaluation report was very limited, EFSA took into account also other sources of information in the public domain.

The toxicological profile of oxadixyl was never assessed at EU level. Toxicological reference values for performing a long-term consumer risk assessment (Acceptable Daily Intake- ADI values) have been derived by several EU Member States and the US EPA in the framework of national pesticide authorisations. The ADI values ranged from 0.01 mg/kg bw/d (France) to 0.125 mg/kg bw/d (Belgium). Since the toxicological studies are not available to EFSA, EFSA decided to base the chronic risk assessment on the lowest ADI (i.e. 0.01 mg/kg bw/d). Lacking information on the acute toxicity and an ARfD value, EFSA is of the opinion that this ADI value is the most appropriate surrogate for assessing the short-term exposure regarding oxadixyl residues.

The submitted monitoring data demonstrated that in a low percentage of the samples of parsley, celery and leek the existing MRL of 0.01 mg/kg is exceeded (0.5% to 2.7% of the samples). Based on the results of the monitoring data EFSA concluded that in line with the current EU residue definition for enforcement, it would be necessary to raise the MRLs for the three crops to the following levels:

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0.3 mg/kg for parsley, 0.1 mg/kg for celery, 0.07 mg/kg for leek. These MRL proposals would encompass 95 percent of the contaminated samples expected on the market with a probability of 95%. However, the consumer safety has to be demonstrated first.

Sufficiently validated analytical methods for enforcing MRLs for oxadixyl on these crops are available.

There are some indications that oxadixyl related metabolites may occur in the crops grown on contaminated soil resulting from the plant and soil metabolism. The co-occurrence of metabolites and/or degradation products should therefore be further assessed, e.g. by examining the chromatograms carefully. Lacking information on metabolism in plants, soil degradation, and uptake of soil metabolites in crops, a definite residue definition for risk assessment cannot be proposed by EFSA. On a provisional basis the residue definition for consumer risk assessment is assumed to comprise only parent oxadixyl.

Because of the data gaps identified by EFSA, only a provisional consumer risk assessment focussing on the parent compound oxadixyl was performed using the EFSA Pesticide Residue Intake Model (PRIMo) rev. 2. The long-term consumer intake of oxadixyl accounted for 10.1% of the ADI. The crops under consideration contributed to a minor extent (max. 0.2% for leek and 0.03% for fresh herbs). The acute consumer exposure for leek accounted for 35.4% of the toxicological reference value; for celery and parsley an exposure of up to 5.7% and 2.1% of the toxicological reference value were calculated. Thus, the provisional consumer risk assessment performed for the parent compound oxadixyl did not indicate a potential consumer health risk.

Before the open questions regarding the plant metabolism and soil degradation have been addressed satisfactorily, no final conclusion can be drawn regarding the nature and magnitude of oxadixyl related metabolites in crops grown on contaminated soils. Lacking supporting scientific data, at the moment a potential consumer exposure to oxadixyl related substances and a resulting consumer risk cannot be ruled out.

EFSA is of the opinion that before a risk management decision is taken to raise the existing MRLs for parsley, celery and leeks and to set temporary MRLs in Annex III of Regulation (EC) No. 396/2005 it has to be demonstrated

- that no oxadixyl related residues (plant or soil metabolites) are present in the crops under consideration or
- that the oxadixyl related plant and/or soil metabolites occurring in the crops under consideration are of no toxicological relevance or
- that the expected short-term and long-term exposure to oxadixyl related substances does not exceed the toxicological reference values for these substances.

EFSA also recommends that the residue situation in particular in leafy crops should be closely monitored by setting up specific programmes.

In addition, on suspect sites the presence of oxadixyl related residues in soil should be investigated. If relevant, the setting of risk management restrictions should be considered for contaminated soils, e.g. to set restrictions for the production of crops like leafy vegetables where a high transfer rate is expected.

KEY WORDS

Oxadixyl, parsley, celery, leek, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, phenylamide.

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BACKGROUND

Recently, in Belgium samples of parsley, celery and leek were found which contain residues of oxadixyl, a pesticide which is no longer authorised at EU level, exceeding the legally permitted residue concentration of 0.01* mg/kg. According to the Belgium authorities the unexpected presence of oxadixyl is due to the persistence of the active substance in soil treated in the past with this active substance. According to Belgium it is excluded that the MRL exceedances are resulting from illegal uses.

Belgian surveillance laboratories and private control organisations initiated a monitoring programme which confirmed the finding that in certain samples the current MRL is exceeded.

In view of modifying the existing MRLs for oxadixyl in parsley, celery and leek in accordance with Article 16 of Regulation (EC) No 396/2005, Belgium compiled an evaluation report which contained a summary of the results of the monitoring activities and a consumer risk assessment. This report was notified to the European Commission and on 15 November 2011, in accordance with Article 43 of the Regulation, a request was forwarded to EFSA.

The request was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-01181 and the following subject:

Oxadixyl- Request for a scientific opinion on the setting of temporary MRLs in parsley, celery and leek

Belgium proposed to raise the existing MRL for oxadixyl on parsley to 0.3 mg/kg and the MRLs for celery and leek to 0.1 mg/kg.

EFSA proceeded with the assessment of the application. Additional information was requested from Belgium regarding the behaviour of oxadixyl in soil, on the toxicological profile of oxadixyl and its relevant metabolites and analytical methods to be used for enforcement. On 6 January 2012 Belgium responded by providing some additional data (Belgium, 2012).

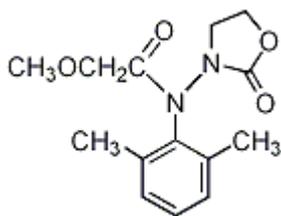
TERMS OF REFERENCE

In accordance with Article 43 of Regulation (EC) No 396/2005, EFSA shall provide a scientific opinion with a view of setting temporary MRLs for oxadixyl in parsley, celery and leek.

The European Commission considered this opinion should be issued by EFSA without consulting the scientific Panel as provided for in Article 44 of Regulation No 396/2005. The European Commission and EFSA agreed to provide the reasoned opinion by 31 January 2012.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Oxadixyl is the ISO common name for 2-methoxy-*N*-(2-oxo-1,3-oxazolidin-3-yl)aceto-2',6'-xylylidide (IUPAC). The chemical structure of the compound is herewith reported.



Molecular weight: 278.3

Oxadixyl is a systemic fungicide with curative and protective action belonging to the group of phenylamide fungicides. It was first marketed in 1984 (BCPC, 2011). The mode of action is explained by a specific inhibition of ribosomal RNA polymerase in target fungi. It is used to control Peronosporales, such as downy mildews and phytophthora pest species in a wide range of crops.

Oxadixyl was scheduled for the evaluation in the framework of Directive 91/414/EEC in list 3. However, since no manufacturer submitted a dossier in support of a possible Annex I inclusion, a decision was taken not to include the substance in the positive list of active substances (Annex I) (Regulation (EC) No 2076/2002³). Authorisations for plant protection products containing oxadixyl had to be withdrawn by 25 July 2003 with a period of grace until 31 December 2003. An exception was made for an essential use of oxadixyl as a seed treatment on peas in Belgium for which the authorisation had to be withdrawn by 30 June 2007 with a period of grace until 31 December 2007.

The EU MRLs for oxadixyl are established in Annexes III of Regulation (EC) No 396/2005 (Appendix C). All MRLs are set at the limit of quantification (LOQ - 0.01* mg/kg for fruits, vegetables, pulses, cereals sugar plants and animal products; 0.02* mg/kg for oilseeds and oil fruit, tea, coffee, herbal infusions, cocoa, hops and spices) except for root and tuber vegetables and lettuce and other salad plants for which the MRLs are set at the level of 0.05 mg/kg and 0.1 mg/kg, respectively⁴. The specific MRLs for the two crop groups were requested by France in 2008 because persistent oxadixyl residues in soil were found to lead to residues above the LOQ.

Belgium is now requesting a modification of the existing MRLs for parsley, celery and leek because also in these crops oxadixyl residues exceeding the MRLs were found. Like the residues in lettuce and root and tuber vegetables, these residues are most likely resulting from a soil contamination due to former use of the pesticide. Details of the GAPs authorised in Belgium before the revocation of the authorisations in 2003 and 2007 are reported in Appendix A.

³ Commission Regulation (EC) No 2076/2002 of 20 November 2002. OJ L 319, 23.11.2002, p. 3-11.

⁴ In 2007, in the framework of setting temporary MRLs in Annex III of Regulation (EC) No 396/2005 EFSA was requested by the European Commission to perform a risk assessment screening for 290 pesticides regarding the proposed MRLs. One of the substances of this exercise was oxadixyl for which a MRLs of 0.1 mg/kg was proposed for leafy vegetables. The screening which focussed on the parent compound did not reveal a potential consumer risk. However, EFSA highlighted that the actual exposure might have been underestimated since metabolites were not considered (EFSA, 2007, 2008).

ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the Belgium (Belgium, 2011), summarising the results of the monitoring programme set up in Belgium. In addition, EFSA analysed the monitoring results submitted to EFSA in the framework of Art. 31 of Regulation (EC) No 396/2005 with regard to results reported for oxadixyl. As additional source of information, the data presented by international/EU organisations on the public domain regarding the active substance oxadixyl are used.

The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁵.

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

Belgium did not provide data on analytical methods to be used by enforcement laboratories for the determination of oxadixyl residues in plant commodities (Belgium, 2011).

Oxadixyl can be analysed with the multi-residue QuEChERS-method (CEN, 2008). The validation data presented in the database of EU Reference Laboratories (EURLs, former CRLs) demonstrate that the methods are suitable for enforcement practice. The validation data published on the website of the EURL (<http://www.crl-pesticides.eu>) are summarised in Table 1.1.

Table 1-1. Validation data for oxadixyl methods reported on the EURL website

| Chr ¹⁾ | Matrix Type | Spiking levels (mg/kg) | | Recoveries | | | No of Labs |
|-------------------|--------------------------------|------------------------|-------|------------|----------------------|-----|------------|
| | | Min. | Max. | Mean (%) | CV ²⁾ (%) | n | |
| GC | Acidic | 0.01 | 0.5 | 97 | 18.3 | 56 | 4 |
| GC | Dry (cereals, dry pulses) | 0.1 | 0.1 | 98 | | 1 | 1 |
| GC | Dry (spices, herbs, tea) | 0.05 | 0.25 | 80 | 14.2 | 4 | 1 |
| GC | Fatty, dry (oil seeds, nuts) | 0.05 | 0.25 | 81 | 3.1 | 4 | 1 |
| GC | Sugar containing | 0.1 | 0.5 | 95 | 8.5 | 6 | 2 |
| GC | Water containing | 0.01 | 1 | 97 | 14 | 172 | 6 |
| GC | Water containing, extract rich | 0.05 | 0.05 | 105 | 4 | 2 | 1 |
| LC | Acidic | 0.01 | 0.3 | 95 | 11.4 | 100 | 6 |
| LC | Dry (cereals, dry pulses) | 0.01 | 0.2 | 98 | 7.3 | 45 | 4 |
| LC | Fatty (oils) | 0.01 | 0.125 | 98 | 5.9 | 31 | 3 |
| LC | Fatty, wet (oily fruits) | 0.04 | 0.04 | 112 | | 1 | 1 |
| LC | Other | 0.025 | 0.04 | 74 | 8.5 | 2 | 2 |
| LC | Sugar containing | 0.01 | 0.1 | 98 | 8.2 | 45 | 4 |
| LC | Water containing | 0.01 | 0.3 | 93 | 13.6 | 187 | 7 |
| LC | Water containing, extract rich | 0.025 | 0.04 | 82 | 11.7 | 2 | 2 |

¹⁾ Chr: chromatographic system

²⁾ CV: coefficient of variation

⁵ Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

Since the commodities under consideration belong to the group of high water content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing MRLs for oxadixyl on parsley, celery and leek are available.

1.2. Methods for enforcement of residues in food of animal origin

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since parsley, celery and leek are normally not used as animal feed.

2. Mammalian toxicology

No EU evaluation of the toxicological properties of oxadixyl has been performed since no manufacturer supported the EU peer review in the framework of Directive 91/414/EEC by providing a dossier.

In Belgium, in the framework of the national authorisation of plant protection products containing oxadixyl, an ADI of 0.125 mg/kg body weight /day was established in 1985 by the Belgium High Council of Health, based on a NOAEL of 12.5 mg/kg of a 2-year rat study, applying a safety factor of 100.

The ADI derived by the French pesticide registration authorities in 1984 is significantly lower (0.01 mg/kg body weight/day). Details of the studies on which the ADI is based on are not available to EFSA.

The US EPA provides a document on its website which summarises the chemical information and toxicological studies for oxadixyl available in 1992 (EPA, 1992). US EPA derived a reference dose of 0.11 mg/kg bw/day based on the 2 year rat feeding study (NOEL of 10.9 mg/kg bw) using an uncertainty factor of 100.

The German Federal Institute for Risk Assessment (BfR) assessed oxadixyl in 1996 and concluded on an ADI of 0.05 mg/kg (BfR, 2002). No further information is available to EFSA on this assessment.

In Table 2-1 the toxicological reference values derived by the different bodies are summarised.

Table 2-1: Overview of the toxicological reference values

| | Source | Year | Value | Study relied upon | Safety factor |
|----------|--------|------|--------------------------|-------------------|---------------|
| Oxadixyl | | | | | |
| ADI | BE | 1985 | 0.125 mg/kg bw/d | 2 yr rat | 100 |
| ADI | FR | 1984 | 0.01 mg/kg bw/d | No information | |
| ADI | US EPA | 1992 | 0.11 mg/kg bw/d | 2 yr rat | 100 |
| ADI | BfR | 1996 | 0.05 mg/kg bw/d | No information | |
| ARfD | | | No assessments available | | |

The abovementioned toxicological evaluations of oxadixyl took place between 1984 and 1996. The setting of ARfD values was included in routine authorisation procedures after the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) has published the concept of the ARfD in 1998 (FAO, 1999). For oxadixyl no ARfD has been established by the bodies who have set the ADI values as reported in Table 2-1.

Toxicological data regarding metabolites or degradation products of oxadixyl are not available.

Since the scientific data available to EFSA do not permit a complete evaluation of the hazard of the active substance and its metabolites or degradation products, EFSA proposes to apply the precautionary principle and to use the most conservative ADI for the chronic consumer exposure assessment, i.e. the value derived by France. It is also appropriate to use the French ADI for chronic and for the acute risk assessment as a conservative surrogate for an ARfD.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Nature of residues

No metabolism studies for oxadixyl in primary crops were reported by Belgium. From other sources only limited information is available regarding the metabolism of oxadixyl in plants and the possible formation of compounds which are of relevance for consumer exposure.

According to the e-Pesticide Manual (BCPC, 2011), in plants the major part of the applied oxadixyl remains unchanged. A maximum of 9% penetrates the leaf surface after 42 days; 42% of this is metabolised. A metabolic pathway involving hydrolysis and oxidative reactions is described. To understand the relevance of these findings EFSA would require the original studies, reporting the details of the types of crops, application rates, nature of metabolites identified etc.

The US EPA has performed an assessment of the residue levels required for the intended US uses of oxadixyl. In the summary report (EPA, 1992) it is concluded that the residues for setting MRLs should be defined as oxadixyl and its desmethyl metabolite (2-hydroxy-N-(2-oxo-1,3-oxazolidin-3-yl)-aceto-2',6'-xylylide) expressed as oxadixyl. This residue definition gives a strong indication that the desmethyl metabolite was identified in plant metabolism studies in significant concentrations.

In 2008, when the temporary MRLs were established for all active substances for which no EU MRLs were yet in place, Member States and the European Commission agreed to apply a pragmatic approach and to set the residue definition for all the substances included in Annex III of the mentioned as parent compound only. Thus, the current enforcement residue definition for oxadixyl established in Regulation (EC) No 396/2005 refers to the parent compound only.

EFSA concludes that for the setting of MRLs the parent compound oxadixyl is the relevant compound. However, the poor database does not allow defining a risk assessment residue definition. On a provisional basis the residue definition for consumer risk assessment is assumed to comprise only parent oxadixyl noting that there are some indications that also the presence of metabolites might be expected in crops. To confirm the provisional risk assessment residue definition metabolism studies on plants would be required.

3.1.2. Magnitude of residues

Article 16 of Regulation (EC) No 396/2005 provides that temporary MRLs may be set in exceptional in particular were pesticide residues may arise as a result of environmental or other contamination, on the basis of monitoring data.

Belgium provided the results of monitoring results referring to samples analysed by the Belgian Food Safety Agency (AFSCA) between 2008 and 2011 and samples taken on Belgian auctions between 2009 and 2011. In addition results were provided for a specific producer of parsley where repeatedly problems with MRL exceedances were identified. The samples were analysed for parent oxadixyl only using a LC-MS/MS methodology with a LOQ of 0.01 mg/kg. There is no information available whether other metabolites/degradation products related to the active substance oxadixyl are co-occurring in the samples analysed. EFSA only received the aggregated data, without details which residue value was generated in which year or from which region the samples were originating. All these deficiencies have to be considered as uncertainties in the overall assessment. The lack of information regarding the presence of metabolites or degradation allows only a provisional risk assessment for the parent compound.

In addition to the monitoring results provided by the Belgian authorities, EFSA has analysed the monitoring data submitted by Member States in the framework of Article 31 of Regulation (EC) No 396/2005 for the preparation of the Annual Report on Pesticide Residues. For the reference period 2009 data are available in a format that can be used to support the request: in total 48.107 determinations were reported for oxadixyl. The major amount refers to results at the LOQ (99.9% of the results). EFSA excluded the results for food commodities produced outside the EU because in Third countries oxadixyl may still be used on primary crops and these results may bias the data analysis regarding residues resulting from soil contamination. Among the 33.278 results reported for products with EU origin only 48 results exceeded the LOQs achieved by the enforcement laboratories (between 0.002 and 0.02 mg/kg); 7 samples were exceeding the MRL. The 48 samples exceeding the LOQ originated from Austria (1 rucola sample), Belgium (2 samples for leek and basil, respectively, and 1 sample for lettuce, rucola, carrots and celery, respectively), Cyprus (1 sample of parsley, 1 sample of herbs, not further specified), Spain (1 sample of cucumbers), France (11 samples of lettuce, 1 sample of parsley), UK (2 samples of lettuce) and Italy (9 samples of rucola). The MRL exceedances are referring to 1 lettuce sample from France, 2 samples of basil from Belgium, 2 samples of leek⁶ from Belgium, 1 sample of parsley from France and 1 sample of celery⁷ from Belgium. An overview of the available monitoring data that can be used in support of this request, including the results of the EU monitoring, and the individual results for samples with residues above the LOQ, are presented in Table 3-1.

Table 3-1: Overview of the available monitoring results

| Commodity | Data source | Total number of samples | Number of positive samples (> LOQ) | Individual positive results (mg oxadixyl/kg) |
|-----------|-----------------------------------|-------------------------|------------------------------------|----------------------------------------------------------------------|
| Parsley | AFSCA | 21 | 6 | 0.030; 0.038; 0.040; 0.055; 0.081; 0.094 |
| | Auctions | 628 | 10 | 0.022; 0.029; 0.035; 0.037; 0.041; 0.110; 0.131; 0.180; 0.230; 0.280 |
| | Specific producer | 8 | 6 | 0.015; 0.020; 0.030; 0.030; 0.070; 0.080 |
| | EU monitoring 2009 ^(a) | 63 | 2 | 0.01; 0.02 |
| Celery | AFSCA | 39 | 4 | 0.022; 0.034; 0.050; 0.100 |
| | Auctions | 508 | 4 | 0.012; 0.015; 0.017; 0.022 |

⁶ The Belgian results for leek are identical with the data reported by Belgium in the Evaluation report.

⁷ The Belgian results for celery are identical with the data reported by Belgium in the Evaluation report.

| Commodity | Data source | Total number of samples | Number of positive samples (> LOQ) | Individual positive results (mg oxadixyl/kg) |
|-----------|-----------------------------------|-------------------------|------------------------------------|--------------------------------------------------------|
| | EU monitoring 2009 ^(a) | 122 | 0 | - |
| Leek | AFSCA | 62 | 2 | 0.032; 0.063 |
| | Auctions | 1792 | 8 | 0.011; 0.022; 0.025; 0.025; 0.026; 0.027; 0.033; 0.043 |
| | EU monitoring 2009 ^(a) | 204 | 0 | - |

(a): Only samples originating from EU Member States were considered. Samples that were analysed in Belgium were excluded because they have been reported in the data provided by AFSCA.

To derive MRL proposals on the basis of monitoring data, the methodology developed by JMPR can be applied (FAO, 2009). In Table 3-2 the statistical analysis of the datasets for parsley, celery and leek are summarised.

Table 3-2. Statistical analysis of the monitoring results on parsley

| | Parsley | Celery | Leek |
|----------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Total number of samples (n) | 713 ⁽¹⁾ | 669 | 2058 |
| Number of samples <LOQ | 694 | 661 | 2048 |
| Percent of samples exceeding MRL | 2.7% | 1.2% | 0.5% |
| Highest residue measured | 0.28 mg/kg | 0.10 mg/kg | 0.063 mg/kg |
| Data analysis for results > LOQ | | | |
| Mean residue concentration | 0.081 mg/kg | 0.034 mg/kg | 0.031 mg/kg |
| Median residue concentration | 0.041 mg/kg | 0.022 mg/kg | 0.027 mg/kg |
| 95th percentile | 0.240 mg/kg | 0.083 mg/kg | 0.054 mg/kg |
| Upper confidence interval level | Not calculated ⁽²⁾ | Not calculated ⁽¹⁾ | Not calculated ⁽²⁾ |
| Proposed MRL | 0.3 mg/kg | 0.1 mg/kg | 0.07 mg/kg |

⁽¹⁾ Only 1 value from the specific producer (highest result of 0.08 mg/kg) was included in the analysis to avoid that this source is biasing the analysis.

⁽²⁾ Minimum number of 58 results are required

According to the JMPR methodology the MRL derived from monitoring data should encompass at least 95% of the positive results (results >LOQ) with a probability of 95%. To satisfy this requirement a minimum number of 58 samples above the LOQ is required (FAO, 2009). Since the required number of positive results was not available, the calculation of the upper confidence interval level was not possible. The MRL proposals were therefore derived by rounding up the value calculated as 95th percentile to the next higher MRL class (EC, 2010). For celery and leek the MRL proposal took into account the highest residue measured.

Consequently, EFSA derives the following MRL proposals: 0.3 mg/kg for parsley, 0.1 mg/kg for celery and 0.07 mg/kg for leek.

3.1.3. Effect of industrial processing and/or household preparation

Among the crops under consideration, only leek is consumed mainly in processed form (cooked). No studies investigating the impact of processing on the nature and the magnitude of oxadixyl residues are available.

Although only a low intake is expected for the crops under consideration, information on the possible formation of degradation products would be desirable. The lack of information is an additional element contributing to the uncertainties of the provisional consumer risk assessment.

3.1.4. Residue behaviour in soil, uptake of residues via soil

The occurrence of residues in the crops under consideration is most likely resulting from residues in soil present as a result of the previous uses of oxadixyl.

About the behaviour of oxadixyl in soil only few data are available to EFSA. According to the US EPA evaluation (EPA, 1992) oxadixyl is persistent and mobile in the environment. In laboratory studies, oxadixyl was stable to hydrolysis at pH 5 and 7. At higher pH (pH 9) the active substance undergoes minor hydrolytic reaction with half-lives between 7 and 52 days at elevated temperature of 70 and 50°C, respectively. Oxadixyl was found to exhibit a similar aerobic and anaerobic soil metabolism with a half-life of 16 months. Leaching studies demonstrate that the parent compound is especially mobile in soils with a high percentage of sand and/or low organic matter content. EPA concluded that the properties and characteristics that oxadixyl demonstrated in laboratory studies are similar to those associated with chemicals detected in ground water.

In a report on the use and disposal of growing media prepared by ADAS Horticulture (Drakes *et al.* 2001) the DT₅₀ values range from 30 to 270 days. From this data a DT₉₀ of approximately 900 days (ca. 2.5 years) would be expected.

The e-Pesticide Manual (BCPC, 2011) reported DT_{50 field} values between 2 and 3 months; the DT_{50 lab} was found to be 6 to 9 months. In soil the main metabolite was identified as oxadixyl acid. Other metabolites that were found in soil are identical with plant and animal metabolites which result from hydrolysis at various points on the methoxyacetamide moiety of the molecule and oxidation of the methyl group on the phenyl ring to the corresponding alcohol.

In the Evaluation Report oxadixyl concentrations measured in Belgian soils are reported (Belgium, 2011). Since no information is available on the criteria used to select certain sites for soil analysis and on the nature of the soils analysed (organic matter content, sand, soils for glasshouses, treatment history). EFSA cannot judge whether these results are representative for soil contamination in Belgium. The samples were analysed with a multi-residue method using LC-MS-MS. No information on the method validation was reported. From the information presented in Table 3-3 it seems that in certain sites the residue concentrations in soil are extremely high (mean residue concentration in the top layer of 0.104 mg/kg⁸) compared with the expected residue concentrations predicted with the models currently used in the pesticide authorisation. Assuming the last application of oxadixyl in 2003 corresponding to the old Belgian GAP on potatoes, a maximum soil concentration of 0.004 mg/kg would be expected today⁹.

Table 3-3. Overview of the results on residues of oxadixyl in Belgian soil samples

⁸ Upon request Belgium confirmed that the results reported in the Evaluation Report are expressed in mg/kg.

⁹ Assuming an annual application rate of 3*200g active substance/ha, corresponding to the old GAP for potatoes notified by Belgium, 50% crop interception, a DT₅₀ of 16 months, and a soil density of 1.5, the immediate soil residue concentration after the last application is estimated to be 0.247 mg/kg soil (after soil mixing of the top 20 cm). 8 years after ceasing the use of oxadixyl the PEC_{soil} is estimated to amount 0.004 mg/kg (high end PEC_{soil}).

| Soil | Sampling depth | | |
|------------------------------|----------------|-------------|-------------|
| | 0-30 cm | 30-60 cm | 60-90 cm |
| Number of samples | 79 | 47 | 14 |
| Highest residue measured | 0.53 mg/kg | 0.19 mg/kg | 0.03 mg/kg |
| Mean residue concentration | 0.104 mg/kg | 0.08 mg/kg | 0.012 mg/kg |
| Median residue concentration | 0.075 mg/kg | 0.028 mg/kg | 0.012 mg/kg |
| 95th percentile | 0.282 mg/kg | 0.089 mg/kg | 0.03 mg/kg |

The unexpected high residue concentrations in Belgian soils are probably due to an error in the soil analysis or the reporting of the results. A potential misuse of oxadixyl should also be considered. However, if the results are confirmed, EFSA would also expect the presence of soil metabolites in significant concentrations, taking into account that the main pesticide use stopped in 2003 (the use as seed treatment on peas is expected to be of minor relevance to the soil residues because of the relative low application rate per hectare). In this case information on the nature and magnitude of soil metabolites, the magnitude of residues of soil metabolites in crops and data on the toxicological relevance of the soil metabolites would be required to decide on the risk assessment residue definition and to perform a quantitative risk assessment.

Because of the open questions regarding the soil degradation, no final conclusion can be drawn whether consumers are exposed to other compounds than the parent compound oxadixyl. EFSA therefore restricted the provisional risk assessment to the parent compound oxadixyl, noting that the data available do not allow to rule out a potential concern regarding the consumer exposure to soil metabolites.

As a first step to elucidate the soil metabolism and the possible uptake of soil metabolites in crops, EFSA would recommend to examine the chromatograms of the soil and crop analysis carefully: in particular, it might be useful to compare the peaks found in soil chromatograms with the chromatograms of plants grown in these soils. Considering the retention time and the spectra found with the LC-MS/MS methods, indications may be found regarding the presence/absence of soil metabolites in plant commodities.

3.2. Nature and magnitude of residues in livestock

Residues in livestock are not relevant in the context of the MRL request for parsley, celery and leek.

4. Consumer risk assessment

Because of the data gaps identified in the previous, only a provisional residue definition for risk assessment can be proposed at the moment. Thus, also the risk assessment performed by EFSA is only provisional, focussing on the parent compound oxadixyl.

In the context of risk assessment in the framework of pesticide authorisations, usually the consumer risk assessment is performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population¹⁰ (EFSA, 2007). For the given MRL request basically the PRIMo

¹⁰ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

model can be used for estimating the expected short-term and long-term exposure for oxadixyl; since only few Member States have reported mean food consumption data for individual fresh herbs consumption data for the whole group of fresh herbs are used to estimate the exposure for parsley and celery. This might lead to a slight overestimation of the consumer exposure. However, the exposure calculated with the EFSA PRIMo gives a rough estimate of the exposure to oxadixyl and the safety margin to the toxicological reference value.

The calculation of the provisional long-term exposure regarding parent oxadixyl includes the median residue concentration for parsley and leek derived from the monitoring data (see Table 3-2). For the remaining crops the existing MRL was included. The short-term exposure is calculated on the basis of the highest residues observed in the monitoring programmes for the crops under consideration. The input values for the exposure assessments are summarised in Table 4-1.

Table 4-1. Input values for the consumer dietary exposure assessment

| Commodity | Chronic exposure assessment | | Acute exposure assessment | |
|-------------------------------------------------------------------|-----------------------------|---------------------------------------------------------------------|----------------------------------------------|-----------------|
| | Input value (mg/kg) | Comment | Input value (mg/kg) | Comment |
| Risk assessment residue definition: oxadixyl (provisional) | | | | |
| Parsley | 0.041 | Median residue for parsley (consumption data for total fresh herbs) | 0.28 | Highest residue |
| Celery | | | 0.1 | Highest residue |
| Leek | 0.027 | Median residue | 0.06 | Highest residue |
| Other commodities of food and animal origin | MRL | See Appendix C | Not relevant in the context of this request. | |

The theoretical chronic and acute exposures calculated for the parent compound oxadixyl were compared with the French ADI of 0.01 mg/kg body weight per day, the toxicological reference value which was considered most appropriate for the long-term and short-term risk assessment. The details of the calculation are presented in Appendix B (PRIMO spreadsheet).

The long-term consumer intake of oxadixyl was estimated to account for 10.1% of the ADI. The crops under consideration contributed to a minor extent (max. 0.2% for leek and 0.03% for fresh herbs).

The acute consumer exposure to oxadixyl residues in leek accounted for 35.4% of the toxicological reference value; for celery and parsley an exposure of up to 5.7% and 2.1% of the toxicological reference value were calculated.

The provisional consumer risk assessment performed for the parent compound oxadixyl did not indicate a potential consumer health risk.

However, taking into account the lack of information regarding metabolites and/or degradation products a final conclusion on the consumer risk cannot be made at the moment.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

EFSA assessed the data made available by Belgium and the results of the EU monitoring programme reported to EFSA. Since the information reported in the Belgian evaluation report was very limited, EFSA took into account also other sources of information in the public domain.

The toxicological profile of oxadixyl was never assessed at EU level. Toxicological reference values for performing a long-term consumer risk assessment (Acceptable Daily Intake- ADI values) have been derived by several EU Member States and the US EPA in the framework of national pesticide authorisations. The ADI values ranged from 0.01 mg/kg bw/d (France) to 0.125 mg/kg bw/d (Belgium). Since the toxicological studies are not available to EFSA, EFSA decided to base the chronic risk assessment on the lowest ADI (i.e. 0.01 mg/kg bw/d). Lacking information on the acute toxicity and an ARfD value, EFSA is of the opinion that this ADI value is the most appropriate surrogate for assessing the short-term exposure regarding oxadixyl residues.

The submitted monitoring data demonstrated that in a low percentage of the samples of parsley, celery and leek the existing MRL of 0.01 mg/kg is exceeded (0.5% to 2.7% of the samples). Based on the results of the monitoring data EFSA concluded that in line with the current EU residue definition for enforcement, it would be necessary to raise the MRLs for the three crops to the following levels: 0.3 mg/kg for parsley, 0.1 mg/kg for celery, 0.07 mg/kg for leek. These MRL proposals would encompass 95 percent of the contaminated samples expected on the market with a probability of 95%. However, the consumer safety has to be demonstrated first.

Sufficiently validated analytical methods for enforcing MRLs for oxadixyl on these crops are available.

There are some indications that oxadixyl related metabolites may occur in the crops grown on contaminated soil resulting from the plant and soil metabolism. The co-occurrence of metabolites and/or degradation products should therefore be further assessed, e.g. by examining the chromatograms carefully. Lacking information on metabolism in plants, soil degradation, and uptake of soil metabolites in crops, a definite residue definition for risk assessment cannot be proposed by EFSA. On a provisional basis the residue definition for consumer risk assessment is assumed to comprise only parent oxadixyl.

Because of the data gaps identified by EFSA, only a provisional consumer risk assessment focussing on the parent compound oxadixyl was performed using the EFSA Pesticide Residue Intake Model (PRIMo) rev. 2. The long-term consumer intake of oxadixyl accounted for 10.1% of the ADI. The crops under consideration contributed to a minor extent (max. 0.2% for leek and 0.03% for fresh herbs). The acute consumer exposure for leek accounted for 35.4% of the toxicological reference value; for celery and parsley an exposure of up to 5.7% and 2.1% of the toxicological reference value were calculated. Thus, the provisional consumer risk assessment performed for the parent compound oxadixyl did not indicate a potential consumer health risk.

Before the open questions regarding the plant metabolism and soil degradation have been addressed satisfactorily, no final conclusion can be drawn regarding the nature and magnitude of oxadixyl related metabolites in crops grown on contaminated soils. Lacking supporting scientific data, at the moment a potential consumer exposure to oxadixyl related substances and a resulting consumer risk cannot be ruled out.

RECOMMENDATIONS

EFSA is of the opinion that before a risk management decision is taken to raise the existing MRLs for parsley, celery and leeks and to set temporary MRLs in Annex III of Regulation (EC) No. 396/2005 it has to be demonstrated

- that no oxadixyl related residues (plant or soil metabolites) are present in the crops under consideration or
- that the oxadixyl related plant and/or soil metabolites occurring in the crops under consideration are of no toxicological relevance or
- that the expected short-term and long-term exposure to oxadixyl related substances does not exceed the toxicological reference values for these substances.

EFSA also recommends that the residue situation in particular in leafy crops should be closely monitored by setting up specific programmes.

In addition, on suspect sites the presence of oxadixyl related residues in soil should be investigated. If relevant, the setting of risk management restrictions should be considered for contaminated soils, e.g. to set restrictions for the production of crops like leafy vegetables where a high transfer rate is expected.

REFERENCES

- Belgium, 2011. Evaluation report on the setting of MRLs for oxadixyl in parsley, celery and leek prepared by the evaluating Member State Belgium under Article 8 of Regulation (EC) No 396/2005, 21 October 2011, 16 pp.
- Belgium, 2012. Belgium answers to the data requirement identified by EFSA. 6.1.2012, 1 p.
- BfR (Bundesinstitut für Risikobewertung), 2002. Pflanzenschutzmittel-Wirkstoffe: ADI Werte und gesundheitliche Trinkwasser-Leitwerte. Published on the BfR website.
- BCPC (British Crop Protection Council (publisher)), 2011. The e-Pesticide Manual version 5.2, September 2011. ISBN 978 1 901 396 85 0.
- CEN (European Committee for Standardization), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662.2008. November 2008.
- Drakes D, Briercliffe T, Sightfood-Brown S., Arnold D and Mackay N, 2001. The use and disposal of growing media: Report to summarise current Practice (prepared for Pesticide Safety Directorate, Ministry of Agriculture Fisheries and food). March 2001.
- EC (European Commission), 2010. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs. EFSA Scientific Report (2007), 32, doi:10.2903/j.efsa.2007.32r (Pesticide Residues Intake Model for assessment of acute and chronic consumer exposure to pesticide residues-rev.2. Available from <http://www.efsa.europa.eu/en/mrls/mrlteam.htm>)
- EFSA, (European Food Safety Authority), 2008. Addendum to the reasoned opinion published on 15 March 2007. EFSA Scientific Report (2008), 132, 1-317.
- FAO (Food and Agriculture Organization of the United Nations), 1999. Procedures for estimating acute reference dose. Pesticide residues in food – 1998. Report of the JMPR 1998, FAO Plant Production and Protection Paper, 148, FAO, Rome, pp. 14-17.
- FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.
- Meier U, 2001. Growth Stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., Federal Biological Research Centre of Agriculture and Forest. Braunschweig, Germany. Available from: http://www.jki.bund.de/fileadmin/dam_uploads/_veroeff/bbch/BBCH-Skala_englisch.pdf
- Environmental Protection Agency (EPA), 1992. EPA Pesticide Fact Sheets – Oxadixyl, No 237. PB91-238492, available from:
<http://nepis.epa.gov/Exe/ZyNET.exe/2000TZH4.txt?ZyActionD=ZyDocument&Client=EPA&Index=1995%20Thru%201999%7C1976%20Thru%201980%7C2006%20Thru%202010%7C1991%20Thru%201994%7CHardcopy%20Publications%7C2000%20Thru%202005%7C1986%20Thru%201990%7C2011%20Thru%202015%7C1981%20Thru%201985%7CPrior%20to%201976&Docs=&Query=oxadixyl%20&Time=&EndTime=&SearchMethod=2&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&UseQField=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5CZYFILES%5CINDEX%20DATA%5C91THRU94%5CTX%5C00000016%5C2000TZH4.txt&User=ANONYMOUS&Password=anonymous&SortMethod=-%7C&MaximumDocuments=15&FuzzyDegree=0&ImageQuality=r85g16/r85g16/x150y150g16/i>

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APPENDICES

A. GOOD AGRICULTURAL PRACTICES (GAPS)

| Crop and/or situation (a) | Member State or Country | F G or I (b) | Pest or group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks (m) |
|------------------------------|-------------------------|--------------------------|------------------------------------------|-----------------|----------------------|------------------------|------------------------------|-----------------------|------------------|--------------------------------|--------------------|----------------------|-------------------|---------------------------------------------|
| | | | | type (d - f) | conc. of a.s. (i) | method kind (f - h) | growth stage & season (j) | number min max (k) | interval min max | kg as/hL min max | water L/ha min max | kg a.s./ha min max | | |
| Potatoes | BE | F | | | | Spray | | 3 | 15 | | | 200 | 14 | Registered until 25 July 2003 |
| Strawberries | BE | | | | | | After planting | | | 8 g/250 ml water | | | | |
| Ornamentals | BE | | | | | Spray | | * | 15 | | | 1.6 g/m ² | | |
| Peas | BE | F | | | | Seed treatment | | | | | | 50 g/100 kg seeds | | Essential use authorised until 30 June 2007 |

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 - (e) GCPF Technical Monograph No 2, 4th Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2nd Ed., 2001), including where relevant, information on season at time of application
 - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions (*i.e.* feeding, grazing)

B. PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

| Oxaixyl | | | | | | | | | |
|--------------------------------------------------------------------------------------------|---------------------------------------|----------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|------------------------------------------|----------------------------------|----------------------------|--|
| Status of the active substance: | | | | | Code no. | | | | |
| LOQ (mg/kg bw): 0,01 | | | | | proposed LOQ: | | | | |
| Toxicological end points | | | | | | | | | |
| ADI (mg/kg bw/day): 0,01 | | | | | ARfD (mg/kg bw): 0,01 | | | | |
| Source of ADI: FR | | | | | Source of ARfD: FR | | | | |
| Year of evaluation: 1984 | | | | | Year of evaluation: 1984 | | | | |
| | | | | | | | | | |
| Chronic risk assessment - refined calculations | | | | | | | | | |
| TMDI (range) in % of ADI minimum - maximum | | | | | | | | | |
| 2 10 | | | | | | | | | |
| No of diets exceeding ADI: --- | | | | | | | | | |
| Highest calculated TMDI values in % of ADI | MS Diet | Highest contributor to MS diet (in % of ADI) | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | pTMRs at LOQ (in % of ADI) | |
| 10,1 | FR toddler | 4,0 | Milk and cream, | 2,5 | Potatoes | 1,2 | Carrots | 5,9 | |
| 9,7 | NL child | 2,9 | Potatoes | 2,9 | Milk and cream, | 0,6 | Apples | 5,9 | |
| 8,7 | UK Infant | 3,9 | Milk and cream, | 1,6 | Potatoes | 1,0 | Sugar beet (root) | 6,3 | |
| 7,9 | UK Toddler | 2,3 | Sugar beet (root) | 2,1 | Milk and cream, | 1,7 | Potatoes | 5,9 | |
| 7,4 | WHO Cluster diet B | 1,3 | Potatoes | 0,9 | Wheat | 0,7 | Other tropical root and tuber | 3,6 | |
| 7,4 | FR infant | 2,6 | Milk and cream, | 2,1 | Potatoes | 1,3 | Carrots | 3,7 | |
| 7,0 | IE adult | 1,8 | Sweet potatoes | 1,1 | Potatoes | 0,3 | Parsnips | 2,9 | |
| 7,0 | DE child | 1,4 | Milk and cream, | 1,3 | Potatoes | 1,2 | Apples | 4,9 | |
| 5,7 | DK child | 1,3 | Milk and cream, | 1,2 | Potatoes | 0,7 | Carrots | 3,6 | |
| 5,5 | SE general population 90th percentile | 2,1 | Potatoes | 1,2 | Milk and cream, | 0,4 | Carrots | 2,7 | |
| 5,4 | WHO cluster diet E | 1,9 | Potatoes | 0,4 | Wheat | 0,4 | Other tropical root and tuber | 2,1 | |
| 5,0 | WHO regional European diet | 2,0 | Potatoes | 0,5 | Milk and cream, | 0,4 | Lettuce | 2,1 | |
| 4,9 | ES child | 1,3 | Milk and cream, | 0,9 | Potatoes | 0,4 | Wheat | 3,1 | |
| 4,7 | WHO cluster diet D | 2,0 | Potatoes | 0,7 | Wheat | 0,5 | Milk and cream, | 2,2 | |
| 4,7 | WHO Cluster diet F | 1,7 | Potatoes | 0,4 | Milk and cream, | 0,4 | Wheat | 1,9 | |
| 4,6 | PT General population | 2,7 | Potatoes | 0,4 | Wheat | 0,3 | Carrots | 1,4 | |
| 3,8 | NL general | 1,4 | Potatoes | 0,7 | Milk and cream, | 0,2 | Wheat | 1,9 | |
| 3,1 | LT adult | 1,6 | Potatoes | 0,4 | Milk and cream, | 0,2 | Apples | 1,3 | |
| 3,0 | ES adult | 0,5 | Lettuce | 0,5 | Milk and cream, | 0,5 | Potatoes | 1,8 | |
| 2,8 | FR all population | 0,6 | Potatoes | 0,4 | Wine grapes | 0,3 | Wheat | 1,6 | |
| 2,6 | PL general population | 1,7 | Potatoes | 0,2 | Apples | 0,2 | Carrots | 0,6 | |
| 2,6 | UK vegetarian | 0,7 | Potatoes | 0,4 | Sugar beet (root) | 0,3 | Milk and cream, | 1,6 | |
| 2,5 | DK adult | 0,7 | Potatoes | 0,5 | Milk and cream, | 0,2 | Carrots | 1,5 | |
| 2,5 | IT kids/toddler | 0,7 | Wheat | 0,4 | Potatoes | 0,3 | Lettuce | 1,5 | |
| 2,4 | UK Adult | 0,7 | Potatoes | 0,4 | Sugar beet (root) | 0,3 | Milk and cream, | 1,4 | |
| 2,1 | FI adult | 0,6 | Potatoes | 0,6 | Milk and cream, | 0,1 | Wheat | 1,2 | |
| 2,0 | IT adult | 0,4 | Wheat | 0,4 | Lettuce | 0,3 | Potatoes | 1,1 | |
| Conclusion: | | | | | | | | | |
| The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI. | | | | | | | | | |
| A long-term intake of residues of Oxaixyl is unlikely to present a public health concern. | | | | | | | | | |

| Acute risk assessment /children - refined calculations | | | | Acute risk assessment / adults / general population - refined calculations | | | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------|---------------|------------------------------|----------------------------------------------------------------------------|-----------------------|------------------------------|-------------------------------------------------------------|-------------------------------|------------------------------|-------------------------------------------------------------|-----------------------|------------------------------|
| The acute risk assessment is based on the ARfD. | | | | | | | | | | | | |
| For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation. | | | | | | | | | | | | |
| In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. | | | | | | | | | | | | |
| In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3. | | | | | | | | | | | | |
| Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD. | | | | | | | | | | | | |
| Unprocessed commodities | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | | --- | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | | --- |
| | IESTI 1 *) | | **) | IESTI 2 *) | | **) | IESTI 1 *) | | **) | IESTI 2 *) | | **) |
| | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | Commodities | pTMRL/ threshold MRL (mg/kg) |
| | 35,4 | Leek | 0,06 / - | 25,3 | Leek | 0,06 / - | 11,5 | Leek | 0,06 / - | 8,7 | Leek | 0,06 / - |
| | 5,7 | Celery leaves | 0,1 / - | 5,7 | Celery leaves | 0,1 / - | 3,4 | Parsley | 0,28 / - | 3,4 | Parsley | 0,28 / - |
| | 2,1 | Parsley | 0,28 / - | 2,1 | Parsley | 0,28 / - | 0,1 | Celery leaves | 0,1 / - | 0,1 | Celery leaves | 0,1 / - |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| No of critical MRLs (IESTI 1) | | | --- | No of critical MRLs (IESTI 2) | | | --- | No of critical MRLs (IESTI 1) | | | --- | |
| Processed commodities | No of commodities for which ARfD/ADI is exceeded: | | --- | No of commodities for which ARfD/ADI is exceeded: | | --- | No of commodities for which ARfD/ADI is exceeded: | | --- | No of commodities for which ARfD/ADI is exceeded: | | --- |
| | Highest % of ARfD/ADI | | Processed commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | | Processed commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARfD/ADI | | Processed commodities | pTMRL/ threshold MRL (mg/kg) |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| *) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported. | | | | | | | | | | | | |
| **) pTMRL: provisional temporary MRL | | | | | | | | | | | | |
| ***) pTMRL: provisional temporary MRL for unprocessed commodity | | | | | | | | | | | | |
| Conclusion: | | | | | | | | | | | | |
| For Oxadixyl IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. | | | | | | | | | | | | |
| No exceedance of the ARfD/ADI was identified for any unprocessed commodity. | | | | | | | | | | | | |

C. EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 16/01/2012 14:12))

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|---------------------------------------------------------------------------|----------|
| 100000 | 1. FRUIT FRESH OR FROZEN; NUTS | 0,01* |
| 110000 | (i) Citrus fruit | 0,01* |
| 110010 | Grapefruit (Shadocks, pomelos, sweeties, tangelo, ugli and other hybrids) | 0,01* |
| 110020 | Oranges (Bergamot, bitter orange, chinotto and other hybrids) | 0,01* |
| 110030 | Lemons (Citron, lemon) | 0,01* |
| 110040 | Limes | 0,01* |
| 110050 | Mandarins (Clementine, tangerine and other hybrids) | 0,01* |
| 110990 | Others | 0,01* |
| 120000 | (ii) Tree nuts (shelled or unshelled) | 0,01* |
| 120010 | Almonds | 0,01* |
| 120020 | Brazil nuts | 0,01* |
| 120030 | Cashew nuts | 0,01* |
| 120040 | Chestnuts | 0,01* |
| 120050 | Coconuts | 0,01* |
| 120060 | Hazelnuts (Filbert) | 0,01* |
| 120070 | Macadamia | 0,01* |
| 120080 | Pecans | 0,01* |
| 120090 | Pine nuts | 0,01* |
| 120100 | Pistachios | 0,01* |
| 120110 | Walnuts | 0,01* |
| 120990 | Others | 0,01* |
| 130000 | (iii) Pome fruit | 0,01* |
| 130010 | Apples (Crab apple) | 0,01* |
| 130020 | Pears (Oriental pear) | 0,01* |
| 130030 | Quinces | 0,01* |
| 130040 | Medlar | 0,01* |
| 130050 | Loquat | 0,01* |
| 130990 | Others | 0,01* |
| 140000 | (iv) Stone fruit | 0,01* |
| 140010 | Apricots | 0,01* |
| 140020 | Cherries (sweet cherries, sour cherries) | 0,01* |
| 140030 | Peaches (Nectarines and similar hybrids) | 0,01* |
| 140040 | Plums (Damson, greengage, | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| | mirabelle) | |
| 140990 | Others | 0,01* |
| 150000 | (v) Berries & small fruit | 0,01* |
| 151000 | (a) Table and wine grapes | 0,01* |
| 151010 | Table grapes | 0,01* |
| 151020 | Wine grapes | 0,01* |
| 152000 | (b) Strawberries | 0,01* |
| 153000 | (c) Cane fruit | 0,01* |
| 153010 | Blackberries | 0,01* |
| 153020 | Dewberries (Loganberries, Boysenberries, and cloudberry) | 0,01* |
| 153030 | Raspberries (Wineberries) | 0,01* |
| 153990 | Others | 0,01* |
| 154000 | (d) Other small fruit & berries | 0,01* |
| 154010 | Blueberries (Bilberries cowberries (red bilberries)) | 0,01* |
| 154020 | Cranberries | 0,01* |
| 154030 | Currants (red, black and white) | 0,01* |
| 154040 | Gooseberries (Including hybrids with other ribes species) | 0,01* |
| 154050 | Rose hips | 0,01* |
| 154060 | Mulberries (arbutus berry) | 0,01* |
| 154070 | Azarole (mediterranean medlar) | 0,01* |
| 154080 | Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries) | 0,01* |
| 154990 | Others | 0,01* |
| 160000 | (vi) Miscellaneous fruit | 0,01* |
| 161000 | (a) Edible peel | 0,01* |
| 161010 | Dates | 0,01* |
| 161020 | Figs | 0,01* |
| 161030 | Table olives | 0,01* |
| 161040 | Kumquats (Marumi kumquats, nagami kumquats) | 0,01* |
| 161050 | Carambola (Bilimbi) | 0,01* |
| 161060 | Persimmon | 0,01* |
| 161070 | Jambolan (java plum) (Java apple (water apple), pommerac, rose apple, Brazilian cherry (grumichama), Surinam cherry) | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|---------------------------------------------------------------------------------------------------------------------------|----------|
| 161990 | Others | 0,01* |
| 162000 | (b) Inedible peel, small | 0,01* |
| 162010 | Kiwi | 0,01* |
| 162020 | Lychee (Litchi) (Pulasan, rambutan (hairy litchi)) | 0,01* |
| 162030 | Passion fruit | 0,01* |
| 162040 | Prickly pear (cactus fruit) | 0,01* |
| 162050 | Star apple | 0,01* |
| 162060 | American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote) | 0,01* |
| 162990 | Others | 0,01* |
| 163000 | (c) Inedible peel, large | 0,01* |
| 163010 | Avocados | 0,01* |
| 163020 | Bananas (Dwarf banana, plantain, apple banana) | 0,01* |
| 163030 | Mangoes | 0,01* |
| 163040 | Papaya | 0,01* |
| 163050 | Pomegranate | 0,01* |
| 163060 | Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae) | 0,01* |
| 163070 | Guava | 0,01* |
| 163080 | Pineapples | 0,01* |
| 163090 | Bread fruit (Jackfruit) | 0,01* |
| 163100 | Durian | 0,01* |
| 163110 | Soursop (guanabana) | 0,01* |
| 163990 | Others | 0,01* |
| 200000 | 2. VEGETABLES FRESH OR FROZEN | |
| 210000 | (i) Root and tuber vegetables | 0,05 |
| 211000 | (a) Potatoes | 0,05 |
| 212000 | (b) Tropical root and tuber vegetables | 0,05 |
| 212010 | Cassava (Dasheen, eddoe (Japanese taro), tannia) | 0,05 |
| 212020 | Sweet potatoes | 0,05 |
| 212030 | Yams (Potato bean (yam bean), Mexican yam bean) | 0,05 |
| 212040 | Arrowroot | 0,05 |
| 212990 | Others | 0,05 |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|------------------------------------------------------------------------------|----------|
| 213000 | (c) Other root and tuber vegetables except sugar beet | 0,05 |
| 213010 | Beetroot | 0,05 |
| 213020 | Carrots | 0,05 |
| 213030 | Celeriac | 0,05 |
| 213040 | Horseradish | 0,05 |
| 213050 | Jerusalem artichokes | 0,05 |
| 213060 | Parsnips | 0,05 |
| 213070 | Parsley root | 0,05 |
| 213080 | Radishes (Black radish, Japanese radish, small radish and similar varieties) | 0,05 |
| 213090 | Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant)) | 0,05 |
| 213100 | Swedes | 0,05 |
| 213110 | Turnips | 0,05 |
| 213990 | Others | 0,05 |
| 220000 | (ii) Bulb vegetables | 0,01* |
| 220010 | Garlic | 0,01* |
| 220020 | Onions (Silverskin onions) | 0,01* |
| 220030 | Shallots | 0,01* |
| 220040 | Spring onions (Welsh onion and similar varieties) | 0,01* |
| 220990 | Others | 0,01* |
| 230000 | (iii) Fruiting vegetables | 0,01* |
| 231000 | (a) Solanaceae | 0,01* |
| 231010 | Tomatoes (Cherry tomatoes,) | 0,01* |
| 231020 | Peppers (Chilli peppers) | 0,01* |
| 231030 | Aubergines (egg plants) (Pepino) | 0,01* |
| 231040 | Okra, lady's fingers | 0,01* |
| 231990 | Others | 0,01* |
| 232000 | (b) Cucurbits - edible peel | 0,01* |
| 232010 | Cucumbers | 0,01* |
| 232020 | Gherkins | 0,01* |
| 232030 | Courgettes (Summer squash, marrow (patisson)) | 0,01* |
| 232990 | Others | 0,01* |
| 233000 | (c) Cucurbits-inedible peel | 0,01* |
| 233010 | Melons (Kiwano) | 0,01* |
| 233020 | Pumpkins (Winter squash) | 0,01* |
| 233030 | Watermelons | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|----------------------------------------------------------------------------------------------------------------------------------|----------|
| 233990 | Others | 0,01* |
| 234000 | (d) Sweet corn | 0,01* |
| 239000 | (e) Other fruiting vegetables | 0,01* |
| 240000 | (iv) Brassica vegetables | 0,01* |
| 241000 | (a) Flowering brassica | 0,01* |
| 241010 | Broccoli (Calabrese, Chinese broccoli, Broccoli raab) | 0,01* |
| 241020 | Cauliflower | 0,01* |
| 241990 | Others | 0,01* |
| 242000 | (b) Head brassica | 0,01* |
| 242010 | Brussels sprouts | 0,01* |
| 242020 | Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage) | 0,01* |
| 242990 | Others | 0,01* |
| 243000 | (c) Leafy brassica | 0,01* |
| 243010 | Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tсай), cow cabbage) | 0,01* |
| 243020 | Kale (Borecole (curly kale), collards) | 0,01* |
| 243990 | Others | 0,01* |
| 244000 | (d) Kohlrabi | 0,01* |
| 250000 | (v) Leaf vegetables & fresh herbs | 0,1 |
| 251000 | (a) Lettuce and other salad plants including Brassicaceae | 0,1 |
| 251010 | Lamb's lettuce (Italian comsalad) | 0,1 |
| 251020 | Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce) | 0,1 |
| 251030 | Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf) | 0,1 |
| 251040 | Cress | 0,1 |
| 251050 | Land cress | 0,1 |
| 251060 | Rocket, Rucola (Wild rocket) | 0,1 |
| 251070 | Red mustard | 0,1 |
| 251080 | Leaves and sprouts of Brassica spp (Mizuna) | 0,1 |
| 251990 | Others | 0,1 |
| 252000 | (b) Spinach & similar (leaves) | 0,01* |
| 252010 | Spinach (New Zealand spinach, turnip greens (turnip tops)) | 0,01* |
| 252020 | Purslane (Winter purslane) | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|--------------------------------------------------------------------------------------------------------------------------------|----------|
| | (miner's lettuce), garden purslane, common purslane, sorrel, glasswort) | |
| 252030 | Beet leaves (chard) (Leaves of beetroot) | 0,01* |
| 252990 | Others | 0,01* |
| 253000 | (c) Vine leaves (grape leaves) | 0,01* |
| 254000 | (d) Water cress | 0,01* |
| 255000 | (e) Witloof | 0,01* |
| 256000 | (f) Herbs | 0,01* |
| 256010 | Chervil | 0,01* |
| 256020 | Chives | 0,01* |
| 256030 | Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea) | 0,01* |
| 256040 | Parsley | 0,01* |
| 256050 | Sage (Winter savory, summer savory,) | 0,01* |
| 256060 | Rosemary | 0,01* |
| 256070 | Thyme (marjoram, oregano) | 0,01* |
| 256080 | Basil (Balm leaves, mint, peppermint) | 0,01* |
| 256090 | Bay leaves (laurel) | 0,01* |
| 256100 | Tamagou (Hyssop) | 0,01* |
| 256990 | Others | 0,01* |
| 260000 | (vi) Legume vegetables (fresh) | 0,01* |
| 260010 | Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans) | 0,01* |
| 260020 | Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea) | 0,01* |
| 260030 | Peas (with pods) (Mangetout (sugar peas)) | 0,01* |
| 260040 | Peas (without pods) (Garden pea, green pea, chickpea) | 0,01* |
| 260050 | Lentils | 0,01* |
| 260990 | Others | 0,01* |
| 270000 | (vii) Stem vegetables (fresh) | 0,01* |
| 270010 | Asparagus | 0,01* |
| 270020 | Cardoons | 0,01* |
| 270030 | Celery | 0,01* |
| 270040 | Fennel | 0,01* |
| 270050 | Globe artichokes | 0,01* |
| 270060 | Leek | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|-------------------------------------------------------------------------------------------|----------|
| 270070 | Rhubarb | 0,01* |
| 270080 | Bamboo shoots | 0,01* |
| 270090 | Palm hearts | 0,01* |
| 270990 | Others | 0,01* |
| 280000 | (viii) Fungi | 0,01* |
| 280010 | Cultivated (Common mushroom, Oyster mushroom, Shi-take) | 0,01* |
| 280020 | Wild (Chanterelle, Truffle, Morel) | 0,01* |
| 280990 | Others | 0,01* |
| 290000 | (ix) Sea weeds | 0,01* |
| 300000 | 3. PULSES, DRY | 0,01* |
| 300010 | Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) | 0,01* |
| 300020 | Lentils | 0,01* |
| 300030 | Peas (Chickpeas, field peas, chickling vetch) | 0,01* |
| 300040 | Lupins | 0,01* |
| 300990 | Others | 0,01* |
| 400000 | 4. OILSEEDS AND OILFRUITS | 0,02* |
| 401000 | (i) Oilseeds | 0,02* |
| 401010 | Linseed | 0,02* |
| 401020 | Peanuts | 0,02* |
| 401030 | Poppy seed | 0,02* |
| 401040 | Sesame seed | 0,02* |
| 401050 | Sunflower seed | 0,02* |
| 401060 | Rape seed (Bird rapeseed, turnip rape) | 0,02* |
| 401070 | Soya bean | 0,02* |
| 401080 | Mustard seed | 0,02* |
| 401090 | Cotton seed | 0,02* |
| 401100 | Pumpkin seeds | 0,02* |
| 401110 | Safflower | 0,02* |
| 401120 | Borage | 0,02* |
| 401130 | Gold of pleasure | 0,02* |
| 401140 | Hempseed | 0,02* |
| 401150 | Castor bean | 0,02* |
| 401990 | Others | 0,02* |
| 402000 | (ii) Oilfruits | 0,02* |
| 402010 | Olives for oil production | 0,02* |
| 402020 | Palm nuts (palmoil kernels) | 0,02* |
| 402030 | Palmfruit | 0,02* |
| 402040 | Kapok | 0,02* |
| 402990 | Others | 0,02* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|--------------------------------------------------------------------------------|----------|
| 500000 | 5. CEREALS | 0,01* |
| 500010 | Barley | 0,01* |
| 500020 | Buckwheat | 0,01* |
| 500030 | Maize | 0,01* |
| 500040 | Millet (Foxtail millet, teff) | 0,01* |
| 500050 | Oats | 0,01* |
| 500060 | Rice | 0,01* |
| 500070 | Rye | 0,01* |
| 500080 | Sorghum | 0,01* |
| 500090 | Wheat (Spelt Triticale) | 0,01* |
| 500990 | Others | 0,01* |
| 600000 | 6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA | 0,02* |
| 610000 | (i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis) | 0,02* |
| 620000 | (ii) Coffee beans | 0,02* |
| 630000 | (iii) Herbal infusions (dried) | 0,02* |
| 631000 | (a) Flowers | 0,02* |
| 631010 | Camomille flowers | 0,02* |
| 631020 | Hybiscus flowers | 0,02* |
| 631030 | Rose petals | 0,02* |
| 631040 | Jasmine flowers | 0,02* |
| 631050 | Lime (linden) | 0,02* |
| 631990 | Others | 0,02* |
| 632000 | (b) Leaves | 0,02* |
| 632010 | Strawberry leaves | 0,02* |
| 632020 | Rooibos leaves | 0,02* |
| 632030 | Maté | 0,02* |
| 632990 | Others | 0,02* |
| 633000 | (c) Roots | 0,02* |
| 633010 | Valerian root | 0,02* |
| 633020 | Ginseng root | 0,02* |
| 633990 | Others | 0,02* |
| 639000 | (d) Other herbal infusions | 0,02* |
| 640000 | (iv) Cocoa (fermented beans) | 0,02* |
| 650000 | (v) Carob (st johns bread) | 0,02* |
| 700000 | 7. HOPS (dried), including hop pellets and unconcentrated powder | 0,02* |
| 800000 | 8. SPICES | 0,02* |
| 810000 | (i) Seeds | 0,02* |
| 810010 | Anise | 0,02* |
| 810020 | Black caraway | 0,02* |
| 810030 | Celery seed (Lovage seed) | 0,02* |
| 810040 | Coriander seed | 0,02* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|--------------------------------------------------------------------|----------|
| 810050 | Cumin seed | 0,02* |
| 810060 | Dill seed | 0,02* |
| 810070 | Fennel seed | 0,02* |
| 810080 | Fenugreek | 0,02* |
| 810090 | Nutmeg | 0,02* |
| 810990 | Others | 0,02* |
| 820000 | (ii) Fruits and berries | 0,02* |
| 820010 | Allspice | 0,02* |
| 820020 | Anise pepper (Japan pepper) | 0,02* |
| 820030 | Caraway | 0,02* |
| 820040 | Cardamom | 0,02* |
| 820050 | Juniper berries | 0,02* |
| 820060 | Pepper, black and white (Long pepper, pink pepper) | 0,02* |
| 820070 | Vanilla pods | 0,02* |
| 820080 | Tamarind | 0,02* |
| 820990 | Others | 0,02* |
| 830000 | (iii) Bark | 0,02* |
| 830010 | Cinnamon (Cassia) | 0,02* |
| 830990 | Others | 0,02* |
| 840000 | (iv) Roots or rhizome | 0,02* |
| 840010 | Liquorice | 0,02* |
| 840020 | Ginger | 0,02* |
| 840030 | Turmeric (Curcuma) | 0,02* |
| 840040 | Horseradish | 0,02* |
| 840990 | Others | 0,02* |
| 850000 | (v) Buds | 0,02* |
| 850010 | Cloves | 0,02* |
| 850020 | Capers | 0,02* |
| 850990 | Others | 0,02* |
| 860000 | (vi) Flower stigma | 0,02* |
| 860010 | Saffron | 0,02* |
| 860990 | Others | 0,02* |
| 870000 | (vii) Aril | 0,02* |
| 870010 | Mace | 0,02* |
| 870990 | Others | 0,02* |
| 900000 | 9. SUGAR PLANTS | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 900010 | Sugar beet (root) | 0,01* |
| 900020 | Sugar cane | 0,01* |
| 900030 | Chicory roots | 0,01* |
| 900990 | Others | 0,01* |
| 1000000 | 10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS | 0,01* |
| 1010000 | (i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these | 0,01* |
| 1011000 | (a) Swine | 0,01* |
| 1011010 | Meat | 0,01* |
| 1011020 | Fat free of lean meat | 0,01* |
| 1011030 | Liver | 0,01* |
| 1011040 | Kidney | 0,01* |
| 1011050 | Edible offal | 0,01* |
| 1011990 | Others | 0,01* |
| 1012000 | (b) Bovine | 0,01* |
| 1012010 | Meat | 0,01* |
| 1012020 | Fat | 0,01* |
| 1012030 | Liver | 0,01* |
| 1012040 | Kidney | 0,01* |
| 1012050 | Edible offal | 0,01* |
| 1012990 | Others | 0,01* |
| 1013000 | (c) Sheep | 0,01* |
| 1013010 | Meat | 0,01* |
| 1013020 | Fat | 0,01* |
| 1013030 | Liver | 0,01* |
| 1013040 | Kidney | 0,01* |
| 1013050 | Edible offal | 0,01* |
| 1013990 | Others | 0,01* |
| 1014000 | (d) Goat | 0,01* |
| 1014010 | Meat | 0,01* |
| 1014020 | Fat | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 1014030 | Liver | 0,01* |
| 1014040 | Kidney | 0,01* |
| 1014050 | Edible offal | 0,01* |
| 1014990 | Others | 0,01* |
| 1015000 | (e) Horses, asses, mules or hinnies | 0,01* |
| 1015010 | Meat | 0,01* |
| 1015020 | Fat | 0,01* |
| 1015030 | Liver | 0,01* |
| 1015040 | Kidney | 0,01* |
| 1015050 | Edible offal | 0,01* |
| 1015990 | Others | 0,01* |
| 1016000 | (f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon | 0,01* |
| 1016010 | Meat | 0,01* |
| 1016020 | Fat | 0,01* |
| 1016030 | Liver | 0,01* |
| 1016040 | Kidney | 0,01* |
| 1016050 | Edible offal | 0,01* |
| 1016990 | Others | 0,01* |
| 1017000 | (g) Other farm animals (Rabbit, Kangaroo) | 0,01* |
| 1017010 | Meat | 0,01* |
| 1017020 | Fat | 0,01* |
| 1017030 | Liver | 0,01* |
| 1017040 | Kidney | 0,01* |
| 1017050 | Edible offal | 0,01* |
| 1017990 | Others | 0,01* |
| 1020000 | (ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd | 0,01* |
| 1020010 | Cattle | 0,01* |
| 1020020 | Sheep | 0,01* |
| 1020030 | Goat | 0,01* |

| Code number | Groups and examples of individual products to which the MRLs apply | Oxadixyl |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| 1020040 | Horse | 0,01* |
| 1020990 | Others | 0,01* |
| 1030000 | (iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter | 0,01* |
| 1030010 | Chicken | 0,01* |
| 1030020 | Duck | 0,01* |
| 1030030 | Goose | 0,01* |
| 1030040 | Quail | 0,01* |
| 1030990 | Others | 0,01* |
| 1040000 | (iv) Honey (Royal jelly, pollen) | 0,01* |
| 1050000 | (v) Amphibians and reptiles (Frog legs, crocodiles) | 0,01* |
| 1060000 | (vi) Snails | 0,01* |
| 1070000 | (vii) Other terrestrial animal products | 0,01* |
| ^(a) MRL value as proposed by EFSA in its reasoned opinion(s) (EFSA, YYYY, YYYY) and voted at the SCFCAH on dd mm yyyy. SANCO NNNN/YYYY. Not legally enforced by dd mm yyyy. | | |
| ^(b) MRL values as proposed by EFSA in its reasoned opinion(s) (EFSA, YYYY, YYYY) not yet voted in SCFCAH by dd mm yyyy. | | |

(*): Indicates lower limit of analytical determination
(x): Table footnote

ABBREVIATIONS

| | |
|------------------|-------------------------------------------------------------------------------------------|
| ADI | acceptable daily intake |
| ARfD | acute reference dose |
| a.s. | active substance |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| CEN | European Committee for Standardization (Comité Européen de Normalisation, <i>French</i>) |
| d | day |
| DAR | Draft Assessment Report |
| DT ₉₀ | period required for 90 % dissipation (define method of estimation) |
| EFSA | European Food Safety Authority |
| EMS | evaluating Member State |
| EU | European Union |
| EURLs | EU Reference Laboratories (former CRLs) |
| FAO | Food and Agriculture Organisation of the United Nations |
| GAP | good agricultural practice |
| GC | gas chromatography |
| ha | hectare |
| hL | hectolitre |
| HPLC | high performance liquid chromatography |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues |
| kg | kilogram |
| K _{oc} | organic carbon adsorption coefficient |
| L | litre |
| LC | liquid chromatography |
| LOAEL | lowest observed adverse effect level |
| LOD | limit of detection |
| LOQ | limit of quantification (determination) |
| MRL | maximum residue limit |
| MS | Member States |
| MS/MS | tandem mass spectrometry |

| | |
|----------|----------------------------------------------------------|
| NOAEL | no observed adverse effect level |
| MW | molecular weight |
| OECD | Organization for Economic Co-operation and Development |
| PHI | pre-harvest interval |
| P_{ow} | partition coefficient between n-octanol and water |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged, and Safe (method) |
| RAC | raw agricultural commodity |
| RD | residue definition |
| SCFCAH | Standing Committee on the Food Chain and Animal Health |
| t | tonne, mass unit equal to 1000 kg |
| TMDI | theoretical maximum daily intake |
| tMRL | temporary MRL |
| WHO | World Health Organisation |
| wk | week |
| yr | year |