

REASONED OPINION

Modification of the existing MRLs for prohexadione-calcium in cereals¹

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SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, France received an application from BASF Agro SAS to modify the existing MRLs for prohexadione-calcium in cereals. In order to accommodate for intended uses of prohexadione-calcium in Northern and Southern Europe, it is proposed to raise the existing MRLs in rye and oats from 0.05 mg/kg (set at the limit of quantification) to 0.1 mg/kg and to lower the existing MRL of 0.2 mg/kg in barley and wheat to 0.1 mg/kg. France drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 20 July 2009.

EFSA derived the following conclusions based on the above mentioned evaluation report, the Draft Assessment Report (DAR) and the Annex-I-renewal Draft Assessment Report (AIR-DAR) prepared under Directive 91/414/EEC.

Metabolism of prohexadione-calcium in primary plants was investigated in the framework of the peer review on cereals (rice and barley), fruit and fruiting vegetables (apples) and pulses and oilseeds (peanuts). Metabolism studies indicate that the metabolic pathway of prohexadione-calcium is similar in all crops assessed. Based on the available metabolism studies and the toxicological assessment of the active substance prohexadione-calcium and its metabolites, EFSA concludes that the current residue definition should be reconsidered and established as proposed by the RMS in the framework of the Annex I-renewal: *prohexadione (acid) and its salts expressed as prohexadione-calcium*. The proposed change of the residue definition does not have an impact on the MRLs already established, since the MRLs for all commodities of plant and animal origin are established at the LOQ, except for barley and wheat for which an amendment of the MRL is requested and assessed in this reasoned opinion. A sufficiently validated analytical method with an LOQ of 0.01 mg/kg is available to control the compliance of the proposed MRLs in cereals.

Submitted supervised field trials on barley and wheat indicate that a MRL of 0.05 mg/kg for barley and oats and a MRL of 0.1 mg/kg for rye and wheat would be sufficient to support the intended GAPs. Effects of processing to the nature and magnitude of prohexadione-calcium residues have not been investigated and no studies are available. Considering the low levels of prohexadione-calcium residues in cereal grain it is not expected that residues above 0.1 mg/kg will occur in processed commodities.

Metabolism of prohexadione-calcium in rotational crops is expected to proceed in a similar pathway than in primary crops. Significant prohexadione-calcium residues are not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

1 On request from the European Commission, Question No EFSA-Q-2009-00723, issued on 12 November 2009.

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The occurrence of prohexadione-calcium residues in commodities of animal origin was also investigated considering the livestock intake of cereal grain and straw. The livestock dietary burden was calculated with the EFSA livestock dietary burden calculator and did not exceed the trigger value of 0.1 mg/kg DM for any of the livestock species. To assess the exposure of livestock to tricarballic acid (TCA), which is the plant metabolite of prohexadione-calcium and was encountered in high levels in cereal straw, a provisional risk assessment was performed in the framework of the Annex I-renewal. Data indicated that livestock exposure to TCA residues from cereal straw and grain treated with prohexadione-calcium would be negligible compared to the natural background exposure to TCA which occurs naturally in grass and other plants. EFSA concludes that the livestock exposure to prohexadione residues following the intake of treated grain and straw will not result in residues above the LOQ in commodities of animal origin. The proposed enforcement and risk assessment residue definition for commodities of animal origin is *prohexadione (acid) and its salts expressed as prohexadione-calcium*.

Consumer intake assessment was performed with revision 2 of EFSA PRIMo. The existing MRLs as established in the Annex III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on cereals were used as input values in chronic consumer intake calculations. Acute intake assessment was not performed as no ARfD has been set for prohexadione-calcium.

No chronic consumer intake concerns were identified for any of the European diets. The total calculated intake values accounted for a maximum of 1.2% of the ADI. The contribution of wheat to the total consumer exposure to prohexadione calcium is the highest from all cereals and accounts for a maximum of 0.21% of the ADI for a WHO Cluster diet B.

The following recommendations are derived by EFSA:

- 1) EFSA recommends amending the existing enforcement residue definition (prohexadione and its salts expressed as prohexadione) to the residue definition as proposed by the RMS in the framework of the Annex I-renewal (see table below).
- 2) Considering that a new analytical enforcement method is now available with the achievable LOQ of 0.01 mg/kg in plant matrices with high water-, high-acid-, high oil content, in dry commodities and in all animal matrices (except fat), EFSA recommends amending the existing EC MRLs which are set at the LOQ.

EFSA also concludes that the intended uses of prohexadione-calcium on cereals are acceptable as they will not result in consumer health concerns. The MRL proposals are presented below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Proposed enforcement residue definition: prohexadione (acid) and its salts expressed as prohexadione-calcium			
Barley	0.2	0.05	The proposed MRLs are sufficiently supported by data and no risk for consumers was identified for the intended uses. The lowering of MRLs for barley and wheat is acceptable provided that no other authorized uses of prohexadione-calcium on these crops exist in Europe supporting the existing MRLs.
Wheat (spelt triticale)	0.2	0.1	
Rye	0.05*	0.1	
Oats	0.05*	0.05	

(*): Indicates that the MRL is set at the limit of analytical quantification.

As the AIR-DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

KEY WORDS

Prohexadione-calcium, cereals, barley, wheat, rye, oats, triticale, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, carboxylate, plant growth regulator.

TABLE OF CONTENTS

Summary	1
Table of contents	4
Background	5
Terms of reference.....	5
The active substance and its use pattern.....	6
Assessment	7
1. Methods of analysis.....	7
1.1. Methods for enforcement of residues in food of plant origin	7
1.2. Methods for enforcement of residues in food of animal origin	7
2. Mammalian toxicology.....	7
3. Residues.....	8
3.1. Nature and magnitude of residues in plant.....	8
3.1.1. Primary crops.....	8
3.1.2. Rotational crops.....	12
3.2. Nature and magnitude of residues in livestock	12
3.2.1. Dietary burden of livestock	12
4. Consumer risk assessment	13
Conclusions and recommendations	15
References	16
Appendix A – Good Agricultural Practices (GAPs)	17
Appendix B – Pesticide Residues Intake Model (PRIMo).....	18
Appendix C – Existing EC MRLs.....	19
Abbreviations	23

BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from the company BASF Agro SAS³ to modify the existing MRL for the active substance prohexadione-calcium in barley, oats, rye and wheat (spelt triticale). This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 20 July 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00723 and the following subject:

Prohexadione - Application to modify the existing MRLs in barley, oats, rye and wheat.

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

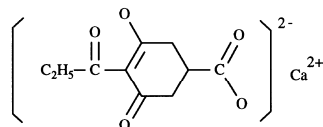
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 20 October 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Prohexadione-calcium (prohexadione-Ca) is the ISO common name for calcium 3-oxido-5-oxo-4-propionyl-3-cyclohexenecarboxylate (IUPAC):



The accepted ISO common name for the acid form of prohexadione-calcium (3,5-dioxo-4-propionylcyclohexanecarboxylic acid) is prohexadione.

MW for prohexadione-calcium: 250.26

MW for prohexadione (acid): 212.2

Prohexadione-calcium is a plant growth regulator. When applied as a foliar spray, it is absorbed via green tissues and translocated within plants primarily acropetally and to a lesser extent basipetally. Prohexadione-calcium inhibits certain stages of the biosynthesis of gibberellin. The resulting lower content of growth-active gibberellins leads to reduced longitudinal shoot growth. The active substance is used in different formulations depending on the target crop: formulation BAS 122 08 W is used in cereals to increase the resistance to pre-harvest plant lodging in cereals, especially in winter wheat and winter barley. BAS 125 10 W is used in apple orchards for the inhibition of vegetative growth and for the optimization of fruit yield in pome fruit.

Prohexadione-calcium was peer reviewed according to Commission Directive 91/414/EEC with France being the designated rapporteur Member State. The active substance was included in Annex I to Directive 91/414/EEC with the Commission Directive 2000/50/EC, which entered into force on 1 October 2000. The representative uses evaluated were ground application of the active substance on wheat grains. The Annex I inclusion which was supposed to expire on 1 October 2010 was extended until 31 December 2011 by Directive 2007/21/EC. In support of the renewal of Annex I inclusion, the Annex I-renewal Draft assessment Report (AIR-DAR) was prepared by the RMS France and co-RMS Slovakia and was recently submitted to EFSA. The representative uses for the Annex I-renewal (AIR) refer to a foliar application of prohexadione-calcium on cereals and apples. The peer review process of the Annex-I-renewal procedure is currently ongoing.

In 2001 EC MRLs have been established reflecting the use of prohexadione-calcium (Commission Directive 2001/39/EC). The residue definition for enforcement was defined as prohexadione and its salts, expressed as prohexadione. The current EC MRLs for this active substance as established in Annexes II and IIIB of Regulation (EC) No 396/2005 can be found in Appendix C. The current MRLs for barley, wheat (spelt triticale) are set at 0.2 mg/kg; for rye and oat the MRLs are set at the LOQ of 0.05 mg/kg. Prohexadione-calcium has not been evaluated by the JMPR and consequently no CXLs have been set.

The GAP for which an authorization is requested in Southern and Northern European Member States, refers to one application of prohexadione-calcium on cereals (barley, wheat, rye, oats and triticale) at a rate of 0.075 kg a.s./ha before the growth stage of 39. The summary of GAP is attached in Appendix A. **As the AIR-DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.**

ASSESSMENT

1. Methods of analysis

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

In the framework of the 1st peer review an analytical method (GC-MS) with the LOQ of 0.05 mg/kg was proposed as an enforcement analytical method for the determination of prohexadione-calcium in plant matrices (France, 1998). Consequently, all EC MRLs for prohexadione-calcium were established at these LOQs.

In the AIR-DAR an analytical method with the LOQ of 0.01 mg/kg is reported to be sufficiently validated for the determination of prohexadione residues in plant matrices with high water-, high acid-, and high oil content, in cereals and other dry crops (cereal forage, cereal grain, cereal straw) (France, 2009b). Quantification is performed using LC-MS/MS. Multi-residue methods are not considered applicable to prohexadione-calcium.

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

In the framework of the 1st peer review an analytical method (GC-MS) with the LOQ of 0.05 mg/kg was proposed as an enforcement analytical method for the determination of prohexadione-calcium in all animal matrices except milk (France, 1998). The achievable LOQ of residues in milk was 0.01 mg/kg.

In the AIR-DAR an analytical method with the LOQ of 0.01 mg/kg is reported to be sufficiently validated for the determination of prohexadione residues in all animal matrices except fat (muscle, liver, kidney, milk and egg) (France, 2009b). Quantification is performed using LC-MS/MS.

2. Mammalian toxicology

Toxicological reference values for prohexadione-calcium were derived in the framework of the peer review and have been confirmed in the Draft Assessment Report prepared in the framework of the Annex I renewal (France, 2009b).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Parent compound : prohexadione-calcium					
ADI	AIR-DAR	2009	0.2	1 yr dog	100
ARfD	AIR-DAR	2009		n.n.	

n.n. – not necessary

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of prohexadione-calcium in primary plants was investigated in the framework of the peer review on rice and barley (France, 1998) as well as in additional studies performed on apples and peanuts for the Annex I-renewal (France, 2009b):

- cereals: barley (BBCH 39, 0.14 kg a.s./ha; foliar application); rice (BBCH 47; 0.0336 kg a.s./ha and 0.336 kg a.s./ha)

- fruits and fruiting vegetables: apples (local application on fruit 1.97 kg a.s./ha)

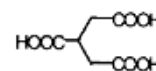
- pulses and oilseeds: peanuts (foliar application 1.12 kg a.s./ha)

In barley grain and straw samples (harvest, 66 DAT) the TRR accounted for 0.98 mg/kg and 2.38 mg/kg, respectively. Parent prohexadione was identified in chloroform organic fractions in grain (0.01 mg/kg), straw (0.15 mg/kg), stalks (0.02 mg/kg) and leaves (0.24 mg/kg). Studies indicate that tricarballic acid (TCA)⁴ is one of the major residues in straw (12.29% TRR, 0.29 mg/kg equiv.) and in leaves (13% TRR; 0.36 mg/kg equiv.). It is noted that tricarballic acid is not a specific metabolite of prohexadione-calcium, but it also occurs naturally in plants (e.g. grass). In grain none of the compounds which were identified in the chloroform aqueous dichloromethane organic extract exceeded 10% TRR. Another unidentified compound was identified in barley stalks (16.8% TRR) with a highly polar nature. The unextracted residues were associated with the lignin of both grain and straw.

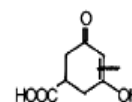
Rice samples were taken 25 and 50 DAT. At the highest application rate (0.336 kg a.s./ha) and 50 DAT, the concentration of TRR residues were 7 mg/kg in leaves, 2 mg/kg in full grain, 1.27 mg/kg in hulled grain and 1.83 mg/kg in husk. The major components of the TRR in hulled grain samples (50 DAT, application 0.336 kg a.s./ha) observed in the aqueous fraction was tricarballic acid and despropionyl-prohexadione⁵ accounting for 0.018 mg/kg (0.1% TRR) and 0.0011 mg/kg (<0.2% TRR), respectively. Parent prohexadione accounted for 0.026 mg/kg (0.1% TRR) in hulled grain. The majority of the TRR was measured in rice leaves (22%), rice stem (14.4%), and in hulled rice grain (2.5%).

In apple samples the concentration of the TRR at harvest (80 DAT) was 0.305 mg/kg. The characterisation/identification of compounds revealed that parent prohexadione in apples at harvest accounts for 1.83 % TRR (0.0056 mg/kg). Several metabolites were identified in amounts higher than

⁴ Tricarballic acid:



⁵ Despropionyl-prohexadione (KI-5376): 3-hydroxy-5-oxo-3-cyclohexane-1-carboxylic acid :



parent prohexadione: BX 112-I5⁶ (11.78% TRR; 0.036 mg/kg), BX112-M10⁷ (9.21% TRR; 0.028 mg/kg), 25F1-A (5.33% TRR), 27F2-B (2.6% TRR), 27F2-B⁸ (7.68% TRR) and despropionyl-prohexadione (5.55% TRR; 0.017 mg/kg). Several natural products as citric acid (2.44% TRR; 0.0074 mg/kg) were also identified. Tricarballic acid accounted for 1.24% TRR (0.0038 mg/kg). In apples prohexadione is metabolized to parent-like oxidative intermediates, despropionyl-prohexadione and ultimately to natural products such as citric and tricarballic acids. The metabolism of prohexadione-calcium is complex and forms many metabolites in small quantities.

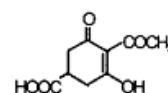
Peanuts treated with prohexadione-calcium were used for the characterization of the residues. The TRR concentration in the harvest vine, hay, dried nutmeat, dried peanut hulls were 18.3 mg/kg, 36.5 mg/kg, 4.15 mg/kg and 2.5 mg/kg, respectively. The main components of the TRR in peanut hay were tricarballic acid (12.7% TRR, 4.63 mg/kg) and prohexadione acid (35.1 % TRR; 12.8%). Similar situation was in peanut hulls where TCA accounted for 15.9% and prohexadione acid for 9.66% TRR. In nutmeat prohexadione acid and TCA accounted for 38.3% TRR (1.58 mg/kg) and 3.06% TRR, respectively. Sugars were identified for up to 8% TRR (0.35 mg/kg). Proposed metabolic pathway indicates extensive incorporation of radioactivity into natural products, tricarballic acid, sugars, carbohydrates, proteins, lipids and lignins. Prohexadione is metabolized to natural products via despropionyl-prohexadione, dioxopropyl-prohexadione and tricarballic acid intermediates.

In the peer review, which led to the inclusion in Annex I for prohexadione calcium in 2000, the RMS and experts derived on the basis of the metabolism studies in barley and rice the following residue definitions for risk assessment and enforcement:

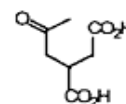
Prohexadione (prohexadione and its salts expressed as prohexadione)

Taking into account the additional metabolism studies on apples and peanuts (France, 2009b), the RMS and the co-RMS concluded that metabolism proceeds in a comparable pathway in all crop groups investigated. It proceeds from prohexadione acid to despropionyl-prohexadione (via alpha-oxidation and alpha-cleavage) to TCA and then incorporation into natural plant components. Only three metabolites were encountered in amounts exceeding 10% of the TRR: prohexadione acid (peanut), tricarballic acid (peanut hay and hull, barley straw), and BX 112-I5 (apples). Prohexadione acid is the acid form of parent compound which was also observed in rat metabolism. Therefore the acid is covered by the existing toxicity studies. Tricarballic acid according to the evaluation of the RMS is a naturally occurring higher acid detected in a wide range of plants; it was also observed in rat metabolism. The RMS concluded that therefore no additional toxicological assessment is necessary. For BX 112-I5 which occurs only in apples, the actual residue concentration was measured also in the supervised field trials. The results indicated that in practice the metabolite was not detectable and therefore the RMS was of the opinion that no further consideration of its toxicological relevance is necessary.

EFSA considers that metabolism of prohexadione-calcium in cereals is sufficiently addressed and no further studies are required.



⁶ BX 112-I5: 3-oxido-4-acetyl-5-oxo-3-cyclohexene carboxylic acid:



⁷ BX112-M10:

⁸ 27F2-B: 4-propionyl-3,5-dihydroxybenzoic acid

Based on the available metabolism studies and the toxicological assessment of the active substance prohexadione-calcium and its metabolites, EFSA concludes that the current residue definition should be reconsidered. EFSA proposes to amend both the residue definition for enforcement and for risk assessment as following:

Prohexadione (acid) and its salts expressed as prohexadione-calcium

This amendment would allow a direct comparison of the ADI which was established for prohexadione-calcium and the residue exposure calculated from the trials or measured in monitoring results, without correcting the residue findings for the different molecular weight for prohexadione (acid) and its calcium salt. The proposed change of the residue definition does not have an impact on the MRLs already established, since the MRLs for all commodities of plant and animal origin are established the LOQ, except for barley and wheat. For the latter an amendment of the MRL is requested and assessed in this application.

3.1.1.2. Magnitude of residues

In support of the intended GAP, 15 trials were performed on barley (12 in northern and 3 in southern Europe) and 21 trials on wheat (11 in northern and 10 in southern Europe) in 1991-1992 and 1999-2002. Applications took place before the growth stage of BBCH 39. Residues observed in grain ranged from <0.05 to 0.07 mg prohexadione-calcium/kg (wheat) and in straw from <0.05 to 0.08 mg prohexadione-calcium/kg (wheat). Submitted data are sufficient for the extrapolation from barley to oats and from wheat to rye and triticale.

EFSA derived also the MRL proposal for straw in case MRLs for feed will be set in the future.

Summary of residue trials is provided in Table 3-1.

The storage stability for prohexadione-calcium was evaluated for the inclusion of the active substance in Annex I to Directive 91/414/EEC. Prohexadione-calcium is stable for 24 months under deep freezer conditions in plant matrices with high water content and in dry matrices. Cereal samples from the residue trials prior analyses were stored deep frozen for a time period not exceeding 7 months.

The analytical method used for the determination of prohexadione residues in supervised field trial samples had the LOQ of 0.05 mg/kg. The determination was done with GS-MS. Prohexadione was determined as methylated prohexadione carboxylate (BW 125-M7) and recalculated to prohexadione-calcium. The analytical method was sufficiently validated and was considered fit for purpose.

Supervised residues field trial data indicate that a MRL of 0.05 mg/kg for barley, oats and a MRL of 0.1 mg/kg wheat and rye would be required for the intended GAP.

Table 3-1. Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Proposed enforcement and risk assessment residue definition: prohexadione (acid) and its salts expressed as prohexadione-calcium									
Barley grain → oats	NEU	Outdoor	12 x <0.05	12 x <0.05	0.05	0.05	0.05	1.0	Residue trials were performed on barley but residue data can be extrapolated to oats.
	SEU	Outdoor	3 x <0.05	3 x <0.05	0.05	0.05	0.05	1.0	
Barley straw	NEU	Outdoor	11 x <0.05; 0.05	11 x <0.05; 0.05	0.05	0.05	0.05	1.0	R _{max} =0.05 mg/kg R _{ber} =0.1 mg/kg
	SEU	Outdoor	3 x <0.05	3 x <0.05					
Wheat grain → rye and triticale	NEU	Outdoor	10 x <0.05; 0.07	10 x <0.05; 0.07	0.05	0.07	0.1	1.0	Residue trials were performed on wheat but residues data can be extrapolated to rye and triticale. R _{maxNEU} =0.069 mg/kg R _{berNEU} =0.1 mg/kg R _{maxSEU} =0.05 mg/kg R _{berSEU} =0.1 mg/kg
	SEU	Outdoor	9 x <0.05; 0.05	9 x <0.05; 0.05	0.05	0.05	0.1	1.0	
Wheat straw	NEU	Outdoor	11 x <0.05	11 x <0.05	0.05	0.05	0.05	1.0	R _{max} =0.05 mg/kg R _{ber} =0.1 mg/kg
	SEU	Outdoor	9 x <0.05; 0.08	9 x <0.05; 0.08	0.05	0.08	0.1	1.0	R _{max} =0.08mg/kg R _{ber} =0.1 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

3.1.1.3. Effect of industrial processing and/or household preparation

Effects of processing to the nature and magnitude of prohexadione-calcium residues have not been investigated and no studies are available (France, 1998, 2009b).

Considering the low levels of prohexadione-calcium residues in cereal grain it is not expected that residues above 0.1 mg/kg will occur in processed commodities. Therefore no further information is needed.

3.1.2. Rotational crops

For cereals the possible occurrence of residues in crops grown in crop rotation after cereals has to be assessed. Prohexadione-calcium degrades very rapidly in soil with a DT₉₀ of less than 10 days (France, 2009b). Although no relevant soil metabolites were detected, confined rotational crop studies on lettuce (leafy crop), turnips (root crop) and wheat (cereals) were performed. 31 day after application turnip, lettuce and wheat were planted and 121 DAT wheat was sown in a soil treated with 0.38 kg a.s./ha. At maturity crops were harvested.

No TRR above 0.01 mg/kg was detected in any plant sample except in wheat grain (31 DAT) and wheat straw (121 DAT) accounting for a maximum of 0.02 mg/kg. The concentration of TRR in leafy and root crops in soil aged for 30 days following treatment was <0.01 mg/kg. The majority of radioactivity in analysed plant samples was associated with carbohydrate fractions or unextractable (up to 57% TRR in wheat straw).

The metabolism of prohexadione-calcium in rotation crops is expected to proceed in a similar pathway as in primary crops. The studies with rotational crops were performed at an application rate corresponding to five times the intended rate on cereals. It is concluded that significant residues of prohexadione-calcium relevant for the residue definition will not be present in rotational or succeeding crops provided that the active substance on cereals is applied according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

According to the EU Guidance document on livestock feeding studies, cereals are potential livestock feeding items for dairy and meat ruminants, poultry and pigs. EFSA calculated the exposure of livestock to residues of prohexadione-calcium following the intake of treated cereal grain and straw according to the EU guidance document (European Commission, 1997). Input values for the calculation are summarized in Table 3-2.

Table 3-2. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: prohexadione (acid) and its salts expressed as prohexadione-calcium				
Barley, oat grain	0.05	STMR	0.05	STMR
Barley, oat straw	0.05	STMR	0.05	HR
Wheat, rye grain	0.05	STMR	0.05	STMR
Wheat, rye straw	0.05	STMR	0.08	HR

The results of the dietary burden calculation are summarized in Table 3-3.

Table 3-3. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded?
Risk assessment residue definition: prohexadione (acid) and its salts expressed as prohexadione-calcium					
Dairy ruminants	0.00152	0.00127	Wheat grain	0.04	No
Meat ruminants	0.00324	0.00249	Wheat grain	0.08	No
Poultry	0.00257	0.00257	Wheat grain	0.04	No
Pigs	0.00186	0.00186	Wheat grain	0.05	No

Results indicate that livestock exposure to residues of prohexadione-calcium following the intake of treated cereal grain and straw will not exceed the trigger value of 0.1 mg/kg DM for any of the livestock species. Thus, no significant residues of prohexadione-calcium are expected in food commodities of animal origin.

The plant metabolism studies demonstrated, that in straw the main residue is tricarballylic acid (TCA) which is expected in higher concentrations than parent prohexadione-calcium. Moreover, TCA is a natural compound present in grass. In this regard experts involved in the peer review of the active substance performed a provisional assessment of livestock exposure to TCA by comparing the intake of TCA from grass and from straw treated with prohexadione-calcium. Results indicated that the livestock exposure to TCA from the cereal straw would be negligible (below 0.1 mg/kg DM) compared with the background exposure from natural sources and was not further discussed. The risk assessment and enforcement residue definition as proposed by the RMS for commodities of animal origin is “prohexadione (acid) and its salts expressed as prohexadione-calcium”.

EFSA concludes that the livestock exposure to prohexadione residues following the intake of treated grain and straw will not result in residues above the LOQ in food commodities of animal origin. Since a new analytical method for the determination of prohexadione-calcium in animal commodities (except fat) is available with the achievable LOQ of 0.01 mg/kg, the lowering of the current MRLs from 0.05* mg/kg to 0.01* mg/kg have to be considered.

4. Consumer risk assessment

Consumer intake assessment was performed with revision 2 of EFSA PRIMo (EFSA, 2007). The existing MRLs as established in Regulation (EC) No 396/2005 as well as the STMR values as derived for the intended use on cereals were used as input values in chronic consumer intake calculations.

Acute intake assessment was not performed as there is no ARfD set for prohexadione-calcium.

Input values are summarized in the table below.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment	Acute risk assessment
-----------	-------------------------	-----------------------

	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Proposed risk assessment residue definition: prohexadione (acid) and its salts expressed as prohexadione-calcium				
Barley, oat, rye, wheat grain	0.05	STMR	Acute intake assessment not undertaken since ARfD is not established.	
Other commodities	MRL	Appendix C		

The summary of the consumer intake calculations is available in Appendix B.

No chronic consumer intake concerns were identified for any of the European diets. The total calculated intake values accounted for a maximum of 1.2% of the ADI. The contribution of wheat to the total consumer exposure to prohexadione-calcium residues is the highest from all cereals and accounts for a maximum of 0.21% of the ADI for a WHO Cluster diet B.

EFSA concludes that the intended uses of prohexadione-calcium on cereals are acceptable as they will not raise any consumer health concerns.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

Metabolism of prohexadione-calcium in primary plants was investigated in the framework of the peer review on cereals (rice and barley), fruit and fruiting vegetables (apples) and pulses and oilseeds (peanuts). Metabolism studies indicate that the metabolic pathway of prohexadione-calcium is similar in all crops assessed. Based on the available metabolism studies and the toxicological assessment of the active substance prohexadione-calcium and its metabolites, EFSA concludes that the current residue definition should be reconsidered and established as proposed by the RMS in the framework of the Annex I-renewal: *prohexadione (acid) and its salts expressed as prohexadione-calcium*. The proposed change of the residue definition does not have an impact on the MRLs already established, since the MRLs for all commodities of plant and animal origin are established at the LOQ, except for barley and wheat for which an amendment of the MRL is requested and assessed in this reasoned opinion. A sufficiently validated analytical method with an LOQ of 0.01 mg/kg is available to control the compliance of the proposed MRLs in cereals.

Submitted supervised field trials on barley and wheat indicate that a MRL of 0.05 mg/kg for barley and oats and a MRL of 0.1 mg/kg for rye and wheat would be sufficient to support the intended GAPs. Effects of processing to the nature and magnitude of prohexadione-calcium residues have not been investigated and no studies are available. Considering the low levels of prohexadione-calcium residues in cereal grain it is not expected that residues above 0.1 mg/kg will occur in processed commodities.

Metabolism of prohexadione-calcium in rotational crops is expected to proceed in a similar pathway than in primary crops. Significant prohexadione-calcium residues are not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

The occurrence of prohexadione-calcium residues in commodities of animal origin was also investigated considering the livestock intake of cereal grain and straw. The livestock dietary burden was calculated with the EFSA livestock dietary burden calculator and did not exceed the trigger value of 0.1 mg/kg DM for any of the livestock species. To assess the exposure of livestock to tricarballylic acid (TCA), which is the plant metabolite of prohexadione-calcium and was encountered in high levels in cereal straw, a provisional risk assessment was performed in the framework of the Annex I-renewal. Data indicated that livestock exposure to TCA residues from cereal straw and grain treated with prohexadione-calcium would be negligible compared to the natural background exposure to TCA which occurs naturally in grass and other plants. EFSA concludes that the livestock exposure to prohexadione residues following the intake of treated grain and straw will not result in residues above the LOQ in commodities of animal origin. The proposed enforcement and risk assessment residue definition for commodities of animal origin is *prohexadione (acid) and its salts expressed as prohexadione-calcium*.

Consumer intake assessment was performed with revision 2 of EFSA PRIMo. The existing MRLs as established in the Annex III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on cereals were used as input values in chronic consumer intake calculations. Acute intake assessment was not performed as no ARfD has been set for prohexadione-calcium.

No chronic consumer intake concerns were identified for any of the European diets. The total calculated intake values accounted for a maximum of 1.2% of the ADI. The contribution of wheat to the total consumer exposure to prohexadione calcium is the highest from all cereals and accounts for a maximum of 0.21% of the ADI for a WHO Cluster diet B.

The following recommendations are derived by EFSA:

1) EFSA recommends amending the existing enforcement residue definition (prohexadione and its salts expressed as prohexadione) to the residue definition as proposed by the RMS in the framework of the Annex I-renewal (see table below).

2) Considering that a new analytical enforcement method is now available with the achievable LOQ of 0.01 mg/kg in plant matrices with high water-, high-acid-, high oil content, in dry commodities and in all animal matrices (except fat), EFSA recommends amending the existing EC MRLs which are set at the LOQ.

EFSA also concludes that the intended uses of prohexadione-calcium on cereals are acceptable as they will not result in consumer health concerns.

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Proposed enforcement residue definition: prohexadione (acid) and its salts expressed as prohexadione-calcium			
Barley	0.2	0.05	The proposed MRLs are sufficiently supported by data and no risk for consumers was identified for the intended uses. The lowering of MRLs for barley and wheat is acceptable provided that no other authorized uses of prohexadione-calcium on these crops exist in Europe supporting the existing MRLs.
Wheat (spelt triticale)	0.2	0.1	
Rye	0.05*	0.1	
Oats	0.05*	0.05	

(*): Indicates that the MRL is set at the limit of analytical quantification.

As the AIR-DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

REFERENCES

- France, 2009a. Evaluation report on the modification of MRLs for prohexadione-calcium in wheat, barley, rye, oat and triticale prepared by the evaluating Member State France under Article 8 of Regulation (EC) No 396/2005, 26 June 2009.
- France, 1998. Draft Assessment Report (DAR) on the active substance prohexadione-calcium prepared by the rapporteur Member State France in the framework of Directive 91/414/EEC, April 1998.
- France, 2009b. Additional Report prepared in the context of the renewal of the inclusion of prohexadione calcium in Annex I of Council Directive 91/414/EEC. May 2009.
- European Commission, 1996. Appendix G – Livestock Feeding Studies. 7031/VI/95 rev.4, 22 July 1996.
- EFSA, 2007. Pesticide Residue Intake Model, rev.2, 2007.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	Product Name	F, G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application per treatment			PHI (days)	Remarks (m)
				type (d-f)	Conc of as g/l (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between applications (days)	kg as/ha min-max	water l/ha; min-max	kg as/ha min-max		
Cereals	BAS 122 08W	F	Plant growth regulator	SC	50 g/L	spray	Before BBCH 39	1	Not applicable	0.025-0.0500	150-300	0.075		

- a. For crops, the EU and Codex classifications (both) 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 sucking insects, soil born insects, foliar fungi, weed
- d. E.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- e. GCPF codes - GIFAP Technical monograph No2, 1989
- 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. Concentration in g ai/kg of g ai/L
- j. Growth stage at last treatment (BBCH monograph, Growth stages of plants, 1997, Blackwell, ISBN 3-8263-3152-4)
- k. The minimum and maximum number of applications possible under practical conditions must be provided.
- l. PHI - minimum pre-harvest interval
- m. Remarks may include: extent of use / economic importance / restrictions

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Prohexadione-calcium			
Status of the active substance:	AIR	Code no.:	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.2	ARfD (mg/kg bw):	n.n.
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2009	Year of evaluation:	2009

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum 0 1						
		No of diets exceeding ADI:		---				
	Highest calculated TMDI values in % of ADI	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	pTMRLs at LOQ (in % of ADI)
	MS Diet							
	1.16	UK Toddler	0.57	Sugar beet (root)	0.1	Milk and cream,	0.10	Wheat
	1.13	WHO Cluster diet B	0.21	Wheat	0.1	Tomatoes	0.07	Potatoes
	1.09	NL child	0.16	Apples	0.1	Potatoes	0.15	Milk and cream,
	1.05	DE child	0.30	Apples	0.1	Wheat	0.10	Oranges
	0.92	UK Infant	0.25	Sugar beet (root)	0.2	Milk and cream,	0.08	Potatoes
	0.90	IE adult	0.09	Sweet potatoes	0.1	Maize	0.06	Maize
	0.90	FR toddler	0.20	Milk and cream,	0.1	Potatoes	0.07	Apples
	0.76	DK child	0.14	Wheat	0.1	Rye	0.06	Milk and cream,
	0.72	WHO cluster diet E	0.10	Wheat	0.1	Potatoes	0.04	Wine grapes
	0.65	ES child	0.11	Wheat	0.1	Milk and cream,	0.05	Oranges
	0.63	WHO cluster diet D	0.16	Wheat	0.1	Potatoes	0.03	Tomatoes
	0.60	FR infant	0.13	Milk and cream,	0.1	Potatoes	0.07	Carrots
	0.59	WHO Cluster diet F	0.09	Wheat	0.1	Potatoes	0.03	Soya bean
	0.59	WHO regional European diet	0.10	Potatoes	0.1	Wheat	0.04	Swine
	0.56	SE general population 90th percentile	0.10	Potatoes	0.1	Wheat	0.06	Milk and cream,
	0.53	PT General population	0.13	Potatoes	0.1	Wheat	0.06	Wine grapes
	0.45	NL general	0.07	Potatoes	0.1	Wheat	0.04	Oranges
	0.42	FR all population	0.10	Wine grapes	0.1	Wheat	0.03	Potatoes
	0.41	IT kids/toddler	0.17	Wheat	0.0	Other cereal	0.04	Tomatoes
	0.40	ES adult	0.06	Wheat	0.0	Oranges	0.02	Milk and cream,
	0.38	UK vegetarian	0.09	Sugar beet (root)	0.1	Wheat	0.03	Potatoes
	0.35	UK Adult	0.10	Sugar beet (root)	0.0	Wheat	0.03	Potatoes
	0.33	LT adult	0.08	Potatoes	0.0	Apples	0.03	Swine
	0.32	DK adult	0.05	Wheat	0.0	Potatoes	0.03	Wine grapes
	0.30	IT adult	0.10	Wheat	0.0	Tomatoes	0.02	Apples
	0.25	FI adult	0.03	Potatoes	0.0	Milk and cream,	0.02	Wheat
	0.24	PL general population	0.09	Potatoes	0.1	Apples	0.02	Tomatoes

Conclusion:
 The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
 A long-term intake of residues of Prohexadione-calcium is unlikely to present a public health concern.

APPENDIX C – EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 04/11/2009 12:14)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
100000	I. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweetsies, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomeric, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
	white sapote, green sapote, canistel (yellow sapote), and mamme sapote)	
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*
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),	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
	Mexican yam bean)	
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celery	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	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes,)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian comsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar leaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadone (prohexadone and its salts expressed as prohexadone)
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel...)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadone (prohexadone and its salts expressed as prohexadone)
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	0,2
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,2
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadone (prohexadone and its salts expressed as prohexadone)
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadone (prohexadone and its salts expressed as prohexadone)
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Airl	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
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	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
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*
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,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prohexadione (prohexadione and its salts expressed as prohexadione)
	frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

*Indicates lowest limit of analytical quantification

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
D	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GC-MS	gas chromatography-mass spectrometry
GR	granule
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K _{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10 ⁻⁶)
PRIMo	Pesticide Residues Intake Model
RMS	rappporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation