

REASONED OPINION

Reasoned opinion on the modification of the existing MRLs for pymetrozine in lamb`'s lettuce and beans (with pods)¹

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ABSTRACT

In accordance with Article 6 of Regulation (EC) No 396/2005, the Netherlands, herewith referred to as the evaluating Member State (EMS), received an application from LTO Groeiservice to modify the existing MRLs for pymetrozine in lamb`'s lettuce and beans (with pods). In order to accommodate for the intended use of pymetrozine on these crops, the EMS proposed to raise the existing MRLs from 2 mg/kg to 15 mg/kg in lamb`'s lettuce and to 7 mg/kg in beans (with pods). The EMS 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. According to EFSA, the residue trials on lamb`'s lettuce and beans (with pods) were not valid because the samples were stored for a period for which integrity of the samples is not guaranteed. The proposal to compensate for the potential loss of residues during storage by applying a correction factor is not acceptable because the instability of pymetrozine residues in watery matrices is not only affected by the nature of the crop, but might depend also on other factors such as the preparation of samples and the design of the residue decline studies. EFSA therefore concludes that the available data are not sufficient to derive a MRL proposal for lamb`'s lettuce and beans (with pods) reflecting the intended GAP notified in this application.

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KEY WORDS

Pymetrozine, lamb`'s lettuce, beans (with pods), French beans, Regulation (EC) No 396/2005, consumer risk assessment, pyridine insecticide.

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SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005³, the Netherlands, herewith referred to as the evaluating Member State (EMS), received an application from LTO Groeiservice to modify the existing MRLs for pymetrozine in lamb's lettuce and beans (with pods). In order to accommodate for the intended use of pymetrozine on these crops, the EMS proposed to raise the existing MRLs from 2 mg/kg to 15 mg/kg in lamb's lettuce and to 7 mg/kg in beans (with pods). The EMS 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 29 November 2011. On 13 July 2012 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, partially addressing those data requirements, was submitted by the EMS on 20 September 2012 and taken into consideration by EFSA for finalization of this reasoned opinion. It is noted that the MRL review for pymetrozine according to Article 12 of Regulation (EC) No 396/2005 has been recently finalized.

EFSA bases its assessment on the evaluation report submitted by the EMS Netherlands, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC⁴ by the Rapporteur Member State (RMS) Germany, the Review Report on pymetrozine and the EFSA reasoned opinion on the review of the existing MRLs for pymetrozine according to Article 12 of Regulation (EC) No 396/2005.

The toxicological profile of pymetrozine was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.03 mg/kg bw per day and 0.1 mg/kg bw, respectively.

The metabolism of pymetrozine in primary crops was investigated for foliar application on fruits, root vegetables, oil seeds and on cereals. Since the metabolic pathways were well identified and metabolic patterns in the different studies were shown to be similar, the risk assessment and enforcement residue definition was established in all plant commodities as parent pymetrozine. For the uses on lamb's lettuce and beans (with pods), EFSA concludes that the metabolism of pymetrozine is sufficiently addressed and the residue definitions as agreed in the peer review and confirmed in Article 12 MRL review are applicable.

The submitted supervised residue trials on lamb's lettuce and beans (with pods) were found to be not valid because the samples were stored for a period for which integrity of the samples is not guaranteed. The proposal to compensate for the potential loss of residues during storage by applying a correction factor taking into account the degradation, is not acceptable because the instability of pymetrozine residues in watery matrices is not only affected by the nature of the crop, but might depend also on other factors such as the preparation of samples and the design of the residue decline studies (spiked/incurred residues). EFSA therefore concludes that the available data are not sufficient to derive a MRL proposal for lamb's lettuce and beans (with pods) reflecting the intended GAP notified in this application.

No studies are available investigating the nature and magnitude of pymetrozine residues in processed commodities. The residue behaviour in rotational crops and in livestock was assessed in the framework of the Article 12 MRL review and no further data are available which require a revision.

The dietary risk assessment for pymetrozine residues reflecting the existing authorized uses has been assessed in the framework of the Article 12 MRL review. Since no modification of the MRLs for lamb's lettuce and beans (with pods) is proposed, there is no need to update this risk assessment.

EFSA concludes that the available data are insufficient to make a proposal to modify the MRL for pymetrozine in lamb's lettuce and beans (with pods).

³ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

⁴ Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009, shall submit to a Member State, when appropriate, an application to modify an MRL in accordance with the provisions of Article 7 of that Regulation.

The Netherlands, hereafter referred to as the evaluating Member State (EMS), received an application from the company LTO Groeiservice⁵ to modify the existing MRLs for the active substance pymetrozine in lamb's lettuce and beans (with pods). 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 was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 November 2011.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2011-01266 and the following subject:

Pymetrozine - Application to modify the existing MRLs in lamb's lettuce and beans (with pods).

The EMS proposed to raise the existing MRL for pymetrozine in lamb's lettuce and beans (with pods) from 2 mg/kg to 15 mg/kg and 7 mg/kg, respectively.

On 13 July 2012 some data requirements were identified, which prevented EFSA to conclude on the consumer risk assessment. An updated evaluation report, partially addressing those data requirements, was submitted by the EMS on 20 September 2012 and taken into consideration by EFSA for finalization of this reasoned opinion.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

TERMS OF REFERENCE

In accordance with 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.

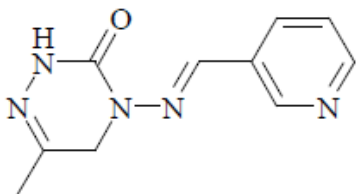
In accordance with Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months where more detailed evaluations need to be carried out) from the date of receipt of the application. Where EFSA requests 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 8 May 2012.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Pymetrozine is the ISO common name for (*E*)-4,5-dihydro-6-methyl-4-(3-pyridylmethyleneamino)-1,2,4-triazin-3(2*H*)-one (IUPAC).



Pymetrozine belongs to the group of pyridine compounds which are used as insecticides. It is a systemic insecticide with selective properties against *Homoptera* by blocking the feeding of the insects. Pymetrozine is used to control aphids and whitefly in various crops.

Pymetrozine was evaluated in the framework of Directive 91/414/EEC with Germany being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar applications on a wide range of crops. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2001/87/EC⁶, entering into force on 01 November 2001. According to Regulation (EU) No 540/2011⁷, pymetrozine is approved under Regulation (EC) No 1107/2009⁸. This approval is restricted to uses as insecticide only. As EFSA was not yet involved in the peer review of pymetrozine, a conclusion of EFSA on this active substance is not available.

The EU MRLs for pymetrozine are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for spinach and similar leaves (EFSA, 2010) which was legally implemented in Regulation (EU) No 524/2011⁹. Recently EFSA has finalized a MRL review for pymetrozine according to Article 12 of Regulation (EC) No 396/2005 (hereafter- Article 12 MRL review) (EFSA, 2012).

All existing EU MRLs, which are established for the parent compound only, are summarized in Appendix B to this document. In this appendix also the MRLs recommended in the framework of the Article 12 MRL review are reported. The existing EU MRLs for lamb's lettuce and beans (with pods) are set at 2 mg/kg. CXLs for pymetrozine are not available.

The details of the intended GAPs for pymetrozine on lamb's lettuce and beans (with pods) are given in Appendix A.

⁶ Commission Directive 2001/87/EC of 12 October 2006, OJ L 276, 19.10.2001, p. 17-20.

⁷ Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.

⁸ Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p. 1-50.

⁹ Regulation (EU) 524/2011 of 26 May 2011, OJ L 142, 28.5.2011, p. 1-56.

ASSESSMENT

EFSA bases its assessment on the updated evaluation report submitted by the EMS (The Netherlands, 2011), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Germany, 1998, 2000), the Review Report on pymetrozine (EC, 2002), the previous reasoned opinion on pymetrozine (EFSA, 2010) and the EFSA reasoned opinion on the review of the existing MRLs for pymetrozine according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹⁰ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

1. Method of analysis

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

According to the Article 12 MRL review, parent pymetrozine can be enforced in food of plant origin with an LOQ of 0.02 mg/kg in high water content commodities (EFSA, 2012). It is thus concluded that adequate analytical enforcement methods are available to control pymetrozine residues in lamb's lettuce and beans (with pods).

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 the crops under consideration are normally not fed to livestock.

2. Mammalian toxicology

The toxicological assessment of pymetrozine was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2002). These toxicological reference values are summarized in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Pymetrozine					
ADI	EC	2002	0.03 mg/kg bw per day	dog, 90 d and 1yr studies	100
ARfD	EC	2002	0.1 mg/kg bw	rabbit, developmental tox. study; rat, 28-d gavage study	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of pymetrozine in primary crops was investigated for foliar application on fruits (tomatoes), root vegetable (potatoes), oil seeds (cotton) and on cereals (rice) using [triazine-6-¹⁴C] and

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

[pyridine-5-¹⁴C] labelled pymetrozine (Germany, 1998, 2000). Study characteristics and results are discussed in detail in the EFSA reasoned opinion on the Article 12 MRL review (EFSA, 2012).

The Article 12 MRL review confirmed that the basic degradation route of pymetrozine is similar in all crops investigated. Therefore, a general metabolic pathway is proposed for all plants. Based on these studies, the residue definition for both enforcement and risk assessment in all crop groups is confirmed as pymetrozine only. The Article 12 MRL review noted that the above studies do not investigate the possible impact of plant metabolism on the possible isomerisation of pymetrozine and further investigation on this matter would in principle be required. Since guidance on the consideration of isomers in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

For the uses on lamb's lettuce and beans (with pods) EFSA concludes that the metabolism of pymetrozine is sufficiently addressed and the residue definitions agreed in the peer review and confirmed by the Article 12 MRL review are applicable.

3.1.1.2. Magnitude of residues

a. Lamb's lettuce

In support of the intended **indoor** use the applicant submitted 4 residue trials on lamb's lettuce which were performed in the Netherlands during the growing seasons of 2005 and 2006. Residue trials were not compliant with the GAP in terms of a number of applications since they were performed with three instead of two applications. Two residue trials were designed as decline trials. In these decline studies the residue concentration on lamb's lettuce declined within 7 days for *ca.* 30%. Thus, the trials performed with three instead of two applications might slightly overestimate the residues occurring if the plant protection product is used according to the notified GAP (Appendix A). Two of the trials were irrigated during the period where the pesticide application took place. In these trials the terminal residue concentration was significantly lower than in the non-irrigated trials. Another deficiency of the trials relates to the storage time of the samples which exceeded the period for which integrity of the samples was demonstrated (details see below).

No residue trials were submitted in support of the intended NEU **outdoor** use.

b. Beans (with pods)

In support of the intended **indoor** use, the applicant submitted 8 residue trials on beans (with pods). Trials have been performed in the Netherlands during the growing seasons of 2005 and 2006. Residue trials were not fully compliant with the GAP in terms of a number of applications since they were performed with three instead of two applications. Moreover, four trials which gave the highest results (1.8-3.2 mg/kg) were performed with individual application rates being at the upper acceptable 25% deviation limit. These trials were designed as decline trials and indicate that the number of applications do not have a significant impact on the final residue levels in the crop since residues on the day before treatment account at similar levels as after 7 days which is the intended treatment interval. Although the trials did not fully reflect the residue situation expected under conditions representative for the notified GAP, EFSA is of the opinion that the deviations are not expected to bias the results unduly.

The results of the residue trials are summarised in Table 3-1. According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for purpose (The Netherlands, 2011).

The potential degradation of residues during storage of the residues trials samples has been assessed. In the framework of the peer review, storage stability of pymetrozine was demonstrated at -18°C for a period of 24 months in commodities with high oil content (cotton seed), and 6 or 12 months in commodities with high water content (potato and tomato, respectively) (Germany, 1998). Additional

storage stability studies were evaluated by the RMS after the peer review, which demonstrated that storage stability of pymetrozine strongly depends on the matrix: in several high water content commodities (tomato, melon) pymetrozine was found to be stable for a period of 24 months while in lettuce and cucumber a residue decline above 30% occurred on month 3 and 6 of the storage, respectively (EFSA, 2012).

The conflicting results for high water content commodities were discussed during a meeting of experts in the framework of the Article 12 MRL review and it was agreed by all experts that the difference between the results might also be related to the sample preparation and that the reasons for the rapid degradation of residues during storage should be further elucidated. In particular, three key questions must be investigated:

- What are the degradation products formed during storage?
- What is the impact of the sample preparation on the storage stability?
- What is the impact of spiked compared to incurred residues on the storage stability?

It was suggested to address the first key question by a radiolabelled storage stability study but it was acknowledged that other possibilities may be available and that study protocols may be discussed with national authorities prior to conducting such a study. The other two key questions should allow risk assessors to derive clear recommendations for laboratories regarding the storage conditions and sample preparations prior to analysis and it was pointed out that several commodities should be investigated since the results are expected to differ between matrices. If the information required would indicate that storage stability is unpredictable and that clear recommendations cannot be derived for storage and preparation of samples, the residue definition for enforcement might be reconsidered as well (EFSA, 2012). Given these major uncertainties about the storage stability of pymetrozine residues in high acid¹¹ and high water content commodities, the MRLs for fruits and vegetables belonging to these matrix groups were proposed on a tentative basis by the Article 12 MRL review. It was also strongly recommended that for the elaboration of residue trials in the future, samples should be analysed as soon as possible after sampling in order to minimise decline of residues during storage (EFSA, 2012).

The residue trial samples of lamb's lettuce and beans (with pods) prior to analysis were stored for a maximum of 129 days and 122 days, respectively. No storage stability studies have been performed specifically with lamb's lettuce and beans (with pods). The applicant proposed to extrapolate the available storage stability data on lettuce to lamb's lettuce, considering the morphological similarities between these crops. The recently reported storage stability study on lettuce indicates a decline to *ca.* 55% of the initial residue concentration for the storage period of *ca.* 5 months. To compensate for the loss of residues in the lamb's lettuce trials during storage, the applicant proposes to apply a correction factor taking into account the expected degradation (correction factor 1.84). However, such an approach was not accepted by experts consulted in the Article 12 MRL review, because, according to the experts, the instability of pymetrozine residues in watery matrices is not only affected by the nature of the crop, but might depend also on the preparation of samples and the design of the residue decline studies (spiked/incurred residues). Given the high variability regarding the storage stability of pymetrozine in different matrices, the extrapolation of decline rates observed for certain crops to other high water content commodities is not acceptable. Given these arguments, EFSA is of the opinion that storage stability data on lettuce cannot be extrapolated to lamb's lettuce. Regarding beans (with pods), the same rationale for refusing the extrapolation of storage stability data is relevant.

¹¹ Decline of residues was not observed in acidic commodities. However, only one matrix was investigated and diverging degradation rates cannot be excluded in acidic commodities as pymetrozine decomposed in a more pronounced manner under acidic conditions in nature of residue studies under processing conditions. The data gap identified for high water content commodities is therefore also applicable to acidic commodities (EFSA, 2012).

EFSA concludes that residue data on lamb's lettuce and beans (with pods) are not sufficiently supported with regard to storage stability. Thus, no MRLs are proposed for pymetrozine in these crops. Adequate storage stability studies have to be performed taking into consideration the questions raised under the Article 12 MRL review.

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

Commodity	Residue region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments (e)
			Enforcement (Pymetrozine)	Risk assessment (Pymetrozine)					
Lamb's lettuce	EU	Indoor	0.05 ^g ; 0.13 ^g ; 5.6; 6.4	0.05 ^g ; 0.13 ^g ; 5.6; 6.4	-	-	-	-	Residue trials not valid since the samples were stored for a period for which integrity of the samples is not guaranteed.
	NEU	Outdoor	-	-	-	-	-	-	No residue trials submitted in support of the NEU outdoor use.
Beans (with pods) (French beans)	EU	Indoor	0.33; 0.39; 0.6; 0.94; 1.8; 2.6; 3.1; 3.2 ^f	0.33; 0.39; 0.6; 0.94; 1.8; 2.6; 3.1; 3.2 ^f	-	-	-	-	Residue trials not valid since the samples were stored for a period for which integrity of the samples is not guaranteed.

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (*i.e.* outdoor use) or Import (country code) (EC, 2011).

(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 residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R_{ber} , R_{max} ; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

(f): Residue higher at a longer PHI of 3 days.

(g): Irrigation of the crop during the period where the pesticide was applied (50-65 mm).

3.1.1.3. Effect of industrial processing and/or household preparation

Studies investigating the nature of residues during conditions representative for pasteurisation, cooking/boiling and sterilisation have not been made available neither for the peer review nor for the Article 12 MRL review (Germany, 1998, 2000, EFSA, 2012).

Studies investigating the magnitude of residues in processed beans (with pods) have not been presented either.

3.1.2. Rotational crops

The nature and magnitude of pymetrozine residues in rotational crops was assessed in the framework of the Article 12 MRL review (EFSA, 2012). The conclusions derived are applicable also for the current application and, considering the fact that no MRL proposals are derived in the framework of the current evaluation, no further considerations are needed.

3.2. Nature and magnitude of residues in livestock

Since the crops under consideration are not normally fed to livestock, the nature and magnitude of pymetrozine residues in livestock is not assessed in the framework of this application.

4. Consumer risk assessment

As the available data on the magnitude of pymetrozine residues in lamb`s lettuce and beans (with pods) were considered insufficient to propose a modification of the existing MRLs in these crops (see 3.1.1.2.), the consumer risk assessment for pymetrozine performed in the framework of the Article 12 MRL review is still valid. In this risk assessment the consumer exposure to pymetrozine residues from the intake of all plant commodities that are treated with pymetrozine according to existing authorized uses, and resulting residues in commodities of animal origin, has been assessed (EFSA, 2012).

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of pymetrozine was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.03 mg/kg bw per day and 0.1 mg/kg bw, respectively.

The metabolism of pymetrozine in primary crops was investigated for foliar application on fruits, root vegetables, oil seeds and on cereals. Since the metabolic pathways were well identified and metabolic patterns in the different studies were shown to be similar, the risk assessment and enforcement residue definition was established in all plant commodities as parent pymetrozine. For the uses on lamb's lettuce and beans (with pods), EFSA concludes that the metabolism of pymetrozine is sufficiently addressed and the residue definitions as agreed in the peer review and confirmed in Article 12 MRL review are applicable.

The submitted supervised residue trials on lamb's lettuce and beans (with pods) were found to be not valid because the samples were stored for a period for which integrity of the samples is not guaranteed. The proposal to compensate for the potential loss of residues during storage by applying a correction factor taking into account the degradation, is not acceptable because the instability of pymetrozine residues in watery matrices is not only affected by the nature of the crop, but might depend also on other factors such as the preparation of samples and the design of the residue decline studies (spiked/incurred residues). EFSA therefore concludes that the available data are not sufficient to derive a MRL proposal for lamb's lettuce and beans (with pods) reflecting the intended GAP notified in this application.

No studies are available investigating the nature and magnitude of pymetrozine residues in processed commodities. The residue behaviour in rotational crops and in livestock was assessed in the framework of the MRL review and no further data are available which require a revision.

The dietary risk assessment for pymetrozine residues reflecting the existing authorized uses has been assessed in the framework of the Article 12 MRL review. Since no modification of the MRLs for lamb's lettuce and beans (with pods) is proposed, there is no need to update this risk assessment.

EFSA concludes that the available data are insufficient to make a proposal to modify the MRL for pymetrozine in lamb's lettuce and beans (with pods).

REFERENCES

- EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en.
- EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realisation of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414). SANCO/3029/99-rev.4. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010.
- EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9. Available from: http://ec.europa.eu/food/plant/protection/resources/publications_en
- EC (European Commission), 2002. Review report for the active substance pymetrozine. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 June 2001 in view of the inclusion of pymetrozine in Annex I of Council Directive 91/414/EEC. SANCO/7455/VI/98-Final, 02 July 2002.
- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers health arising from proposed temporary EU MRLs. Available online: www.efsa.europa.eu/efsajournal
- EFSA (European Food Safety Authority), 2010. Reasoned opinion on the modification of the existing MRL(s) for pymetrozine in spinach and similar leaves. EFSA Journal 2010;8(10):1881, [24 pp.] doi:10.2903/j.efsa.2010.1881. Available online: www.efsa.europa.eu/efsajournal.htm
- EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum levels (MRLs) for pymetrozine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012; 10(10):2919-67 pp. Available online: www.efsa.europa.eu/en/efsajournal.htm
- Germany, 1998. Draft assessment report on the active substance pymetrozine prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, April 1998.

Germany, 2000. Addendum to the draft assessment report on the active substance pymetrozine prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, March 2000

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

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL Calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available from: <http://www.oecd.org/env/pesticides>

The Netherlands, 2011. Evaluation report on the setting of MRLs for pymetrozine in lamb's lettuce and French beans prepared by the evaluating Member State (EMS) under Article 8 of Regulation (EC) No 396/2005, rev.2., 8 November 2011, 24 pp.

APPENDICES

A. GOOD AGRICULTURAL PRACTICE (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		
Lamb's lettuce	NL	F	<i>Myzus persicae</i> , <i>Macrosiphum euphorbiae</i> ,	WG	500 g/L	Foliar	BBCH 19-49 May-Aug	1-2	7	0.025-0.1	200-800	0.2	14	
	NL	G	<i>Aulacorthum solani</i> , <i>Nasonovia ribisnigri</i>				BBCH 19-49 Jan-Dec	1-2	7	0.02-0.04	500-1000	0.2	14	
Slicing bean, green bean, runner bean, yard long bean	NL	G	<i>Aphis gossypii</i> , <i>Myzus persicae</i> , <i>Myzus nicotianae</i> , <i>Macrosiphum euphorbiae</i>	WG	500 g/L	Foliar	BBCH 19-89 Jan-Dec	1-2	7	0.01	500-1500	0.05-0.15	1	
	NL	G	<i>Trialeurodes vaporariorum</i>							0.03	500-1500	0.15-0.45	1	

- 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 sucking 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. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs ((File created on 12/10/2012 12:14))

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
100000	1. FRUIT FRESH OR FROZEN; NUTS		
110000	(i) Citrus fruit	0,3	0,3
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, uglı and other hybrids)	0,3	
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,3	
110030	Lemons (Citron, lemon)	0,3	
110040	Limes	0,3	
110050	Mandarins (Clementine, tangerine and other hybrids)	0,3	
110990	Others	0,3	
120000	(ii) Tree nuts (shelled or unshelled)	0,02*	
120010	Almonds	0,02*	
120020	Brazil nuts	0,02*	
120030	Cashew nuts	0,02*	
120040	Chestnuts	0,02*	0,05
120050	Coconuts	0,02*	
120060	Hazelnuts (Filbert)	0,02*	0,05
120070	Macadamia	0,02*	
120080	Pecans	0,02*	
120090	Pine nuts	0,02*	
120100	Pistachios	0,02*	
120110	Walnuts	0,02*	0,05
120990	Others	0,02*	
130000	(iii) Pome fruit	0,02*	
130010	Apples (Crab apple)	0,02*	0,02*
130020	Pears (Oriental pear)	0,02*	0,02*
130030	Quinces	0,02*	
130040	Medlar	0,02*	
130050	Loquat	0,02*	
130990	Others	0,02*	
140000	(iv) Stone fruit		
140010	Apricots	0,05	0,03
140020	Cherries (sweet cherries, sour cherries)	0,02*	
140030	Peaches (Nectarines and similar	0,05	0,03

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
	hybrids)		
140040	Plums (Damson, greengage, mirabelle)	0,02*	
140990	Others	0,02*	
150000	(v) Berries & small fruit		
151000	(a) Table and wine grapes	0,02*	
151010	Table grapes	0,02*	
151020	Wine grapes	0,02*	
152000	(b) Strawberries	0,5	0,3
153000	(c) Cane fruit		
153010	Blackberries	3	3
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*	0,02*
153030	Raspberries (Wineberries)	3	3
153990	Others	0,02*	
154000	(d) Other small fruit & berries		
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*	0,5
154020	Cranberries	0,02*	0,02*
154030	Cumrants (red, black and white)	0,5	0,5
154040	Gooseberries (Including hybrids with other ribes species)	0,5	0,5
154050	Rose hips	0,02*	
154060	Mulberries (arbutus berry)	0,02*	
154070	Azarole (mediterranean medlar)	0,02*	
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,02*	
154990	Others	0,02*	
160000	(vi) Miscellaneous fruit	0,02*	
161000	(a) Edible peel	0,02*	
161010	Dates	0,02*	
161020	Figs	0,02*	
161030	Table olives	0,02*	
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*	
161050	Caranbola (Bilimbi)	0,02*	
161060	Persimmon	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*	
161990	Others	0,02*	
162000	(b) Inedible peel, small	0,02*	
162010	Kiwi	0,02*	
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*	
162030	Passion fruit	0,02*	
162040	Prickly pear (cactus fruit)	0,02*	
162050	Star apple	0,02*	
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,02*	
162990	Others	0,02*	
163000	(c) Inedible peel, large	0,02*	
163010	Avocados	0,02*	
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*	
163030	Mangoes	0,02*	
163040	Papaya	0,02*	
163050	Pomegranate	0,02*	
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*	
163070	Guava	0,02*	
163080	Pineapples	0,02*	
163090	Bread fruit (Jackfruit)	0,02*	
163100	Durian	0,02*	
163110	Soursop (guanabana)	0,02*	
163990	Others	0,02*	
200000	2. VEGETABLES FRESH OR FROZEN		
210000	(i) Root and tuber vegetables	0,02*	
211000	(a) Potatoes	0,02*	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*	

Modification of the existing MRLs for pymetrozine in lamb's lettuce and beans (with pods)

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*	
212020	Sweet potatoes	0,02*	
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*	
212040	Arrowroot	0,02*	
212990	Others	0,02*	
213000	(c) Other root and tuber vegetables except sugar beet	0,02*	
213010	Beetroot	0,02*	
213020	Carrots	0,02*	
213030	Celeriac	0,02*	0,02*
213040	Horseradish	0,02*	
213050	Jerusalem artichokes	0,02*	
213060	Parsnips	0,02*	
213070	Parsley root	0,02*	
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*	
213100	Swedes	0,02*	
213110	Turnips	0,02*	
213990	Others	0,02*	
220000	(ii) Bulb vegetables	0,02*	
220010	Garlic	0,02*	
220020	Onions (Silverskin onions)	0,02*	
220030	Shallots	0,02*	
220040	Spring onions (Welsh onion and similar varieties)	0,02*	
220990	Others	0,02*	
230000	(iii) Fruiting vegetables		
231000	(a) Solanacea		
231010	Tomatoes (Cherry tomatoes,)	0,5	0,5
231020	Peppers (Chilli peppers)	1	3
231030	Aubergines (egg plants) (Pepino)	0,5	0,5
231040	Okra, lady's fingers	1	1
231990	Others	0,02*	
232000	(b) Cucurbits - edible peel	0,5	1
232010	Cucumbers	0,5	
232020	Gherkins	0,5	
232030	Courgettes (Summer squash, marrow (patisson))	0,5	
232990	Others	0,5	
233000	(c) Cucurbits-inedible peel	0,2	0,3
233010	Melons (Kiwano)	0,2	
233020	Pumpkins (Winter squash)	0,2	
233030	Watermelons	0,2	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
233990	Others	0,2	
234000	(d) Sweet corn	0,02*	0,02*
239000	(e) Other fruiting vegetables	0,02*	
240000	(iv) Brassica vegetables		
241000	(a) Flowering brassica	0,02*	0,03
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*	
241020	Cauliflower	0,02*	
241990	Others	0,02*	
242000	(b) Head brassica		
242010	Brussels sprouts	0,02*	0,08
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05	0,05
242990	Others	0,02*	
243000	(c) Leafy brassica	0,2	
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,2	0,2
243020	Kale (Borecole (curly kale), collards)	0,2	0,06
243990	Others	0,2	
244000	(d) Kohlrabi	0,02*	0,02*
250000	(v) Leaf vegetables & fresh herbs		
251000	(a) Lettuce and other salad plants including Brassicacea	2	
251010	Lamb's lettuce (Italian cornsalad)	2	3
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	2	3
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	2	0,6
251040	Cress	2	0,6
251050	Land cress	2	3
251060	Rocket, Rucola (Wild rocket)	2	3
251070	Red mustard	2	0,6
251080	Leaves and sprouts of Brassica spp (Mizuna)	2	3
251990	Others	2	
252000	(b) Spinach & similar (leaves)		
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,4	0,6
252020	Purslane (Winter purslane (miner's lettuce), garden	0,4	0,4

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
	purslane, common purslane, sorrel, glasswort)		
252030	Beet leaves (chard) (Leaves of beetroot)	0,4	0,6
252990	Others	0,02*	
253000	(c) Vine leaves (grape leaves)	0,02*	
254000	(d) Water cress	0,02*	
255000	(e) Witloof	0,02*	
256000	(f) Herbs		
256010	Chervil	2	3
256020	Chives	2	3
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	2	3
256040	Parsley	2	3
256050	Sage (Winter savory, summer savory,)	1	3
256060	Rosemary	1	3
256070	Thyme (marjoram, oregano)	1	3
256080	Basil (Balm leaves, mint, peppermint)	1	3
256090	Bay leaves (laurel)	1	3
256100	Tarragon (Hyssop)	1	3
256990	Others	2	
260000	(vi) Legume vegetables (fresh)		
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	2	2
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	1	1
260030	Peas (with pods) (Mangetout (sugar peas))	1	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	1	
260050	Lentils	1	
260990	Others	1	
270000	(vii) Stem vegetables (fresh)	0,02*	
270010	Asparagus	0,02*	
270020	Cardoons	0,02*	
270030	Celery	0,02*	0,04
270040	Fennel	0,02*	0,04
270050	Globe artichokes	0,02*	0,02*
270060	Leek	0,02*	
270070	Rhubarb	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
270080	Bamboo shoots	0,02*	
270090	Palm hearts	0,02*	
270990	Others	0,02*	
280000	(vii) Fungi	0,02*	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*	
280020	Wild (Chanterelle, Truffle, Morel)	0,02*	
280990	Others	0,02*	
290000	(ix) Sea weeds	0,02*	
300000	3. PULSES, DRY	0,02*	
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,02*	
300020	Lentils	0,02*	
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*	
300040	Lupins	0,02*	
300990	Others	0,02*	
400000	4. OILSEEDS AND OILFRUITS		
401000	(i) Oilseeds		
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*	0.01*
401070	Soya bean	0,02*	
401080	Mustard seed	0,02*	
401090	Cotton seed	0,05	0.03
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*	
500000	5. CEREALS	0,02*	
500010	Barley	0,02*	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
500020	Buckwheat	0,02*	
500030	Maize	0,02*	
500040	Millet (Foxtail millet, teff)	0,02*	
500050	Oats	0,02*	
500060	Rice	0,02*	
500070	Rye	0,02*	
500080	Sorghum	0,02*	
500090	Wheat (Spelt Triticale)	0,02*	
500990	Others	0,02*	
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*	5
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*	
632000	(b) Leaves	0,1*	5
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	15	15
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*	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
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*	
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) Aril	0,1*	
870010	Mace	0,1*	
870990	Others	0,1*	
900000	9. SUGAR PLANTS	0,02*	
900010	Sugar beet (root)	0,02*	
900020	Sugar cane	0,02*	
900030	Chicory roots	0,02*	
900990	Others	0,02*	
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*	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
1011010	Meat	0,01*	0.01*
1011020	Fat free of lean meat	0,01*	0.01*
1011030	Liver	0,01*	0.01*
1011040	Kidney	0,01*	0.01*
1011050	Edible offal	0,01*	
1011990	Others	0,01*	
1012000	(b) Bovine	0,01*	
1012010	Meat	0,01*	0.01*
1012020	Fat	0,01*	0.01*
1012030	Liver	0,01*	0.01*
1012040	Kidney	0,01*	0.01*
1012050	Edible offal	0,01*	
1012990	Others	0,01*	
1013000	(c) Sheep	0,01*	
1013010	Meat	0,01*	0.01*
1013020	Fat	0,01*	0.01*
1013030	Liver	0,01*	0.01*
1013040	Kidney	0,01*	0.01*
1013050	Edible offal	0,01*	
1013990	Others	0,01*	
1014000	(d) Goat	0,01*	
1014010	Meat	0,01*	0.01*
1014020	Fat	0,01*	0.01*
1014030	Liver	0,01*	0.01*
1014040	Kidney	0,01*	0.01*
1014050	Edible offal	0,01*	
1014990	Others	0,01*	
1015000	(e) Horses, asses, mules or hinnies	0,01*	

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
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*	0.02* ^a

Code number	Groups and examples of individual products to which the MRLs apply	Pymetrozine (existing MRLs)	Pymetrozine (proposed MRLs in MRL review)
1020020	Sheep	0,01*	0.02* ^a
1020030	Goat	0,01*	0.02* ^a
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*	

(*) Indicates lower limit of analytical determination
(a)For the residue definition "pymetrozine, 6-hydroxymethyl pymetrozine and its phosphate conjugate, expressed as pymetrozine" as proposed in the Article 12 MRL review.

ABBREVIATIONS

ADI	acceptable daily intake
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report
EFSA	European Food Safety Authority
EMS	evaluating Member State
GAP	good agricultural practice
GCPF	Global Crop Protection Federation (former GIFAP)
GLP	Good Laboratory Practice
GS	growth stage
ha	hectare
hL	hectolitre
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram
L	litre
LOQ	limit of quantification
MRL	maximum residue level
NEU	northern European Union
PHI	pre-harvest interval
RD	residue definition
RMS	rappporteur Member State
SEU	Southern European Union
WG	water dispersible granule