

Evaluation Report and Reasoned Opinion on the Assessment of Codex MRLs (CXLs)

Prepared for the 56th session of the Codex
Committee on Pesticide Residues

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Summary

Codex MRLs (CXLs) are internationally agreed food standards covering pesticide residues in or on food and feed.

The CXLs are based on the recommendations made by the JMPR (Joint Meeting of the FAO and WHO on Pesticide Residues). Each year the JMPR considers MRLs for new uses, MRLs for new active substances and undertakes reviews of existing active substances (periodic reviews). The MRLs recommended by the JMPR are proposed as draft CXLs by the Codex Committee on Pesticide Residues (CCPR).

As part of the preparation for the 56th session of the CCPR (September 2025), the Chemicals Regulation Division (CRD) of the Health and Safety Executive (HSE) has reviewed and undertaken risk assessments for the proposed draft CXLs at step 3 of the Codex procedures. HSE has reviewed a total of 37 active substances.

The review and risk assessments undertaken by HSE forms the basis of HSE's reasoned opinion; HSE has made recommendations for the proposed draft CXLs that can be adopted as GB MRLs.

HSE recommends the adoption of CXLs for acetamiprid, azoxystrobin, cyclobutrifluram, etonfenprox, fenpropidin, fipronil, flupyradifurone, difluoroacetic acid, folpet, pydiflumetofen, and tetraniliprole.

For the CXLs that are recommended for adoption as GB MRLs, HSE has concluded that the residue levels arising in food will not result in consumer exposures exceeding the toxicological reference values. Therefore, the residue levels for these CXLs are unlikely to have harmful effects on human health.

Where the JMPR has identified a public health concern or no draft CXLs were proposed, then a further consideration by HSE has not been undertaken.

The active substances cyclobutrifluram and tetraniliprole have never been considered for an approval in GB. CXLs for tetraniliprole were first considered for adoption as GB MRLs in 2024 (HSE, 2024). HSE recommends the adoption of the draft CXLs on the basis of the outcome of the consumer risk assessments using the toxicological reference values and residue definitions endorsed by the JMPR. GB specific assessments for these actives (for example for an import tolerance or for an approval of the active substance) will require the submission and assessment of a full toxicological and residues dossier.

A significant number of the proposed draft CXLs are not recommended for adoption as GB MRLs as the GB MRL in force is equivalent to or higher than the proposed draft CXL.

Other draft CXLs are not recommended for adoption as GB MRLs due to the following reasons:

- The residue data supporting the JMPR assessment were not compatible with the residue definitions in force in GB and/or;
- The latest approval/ non-approval decision relevant to GB identified consumer risk issues and/or;
- There are ongoing assessments/considerations for the active substance that may impact the MRLs adopted.

1 General Approach

This report outlines the review and risk assessments undertaken for the proposed draft CXLs being considered by the 56th session of the CCPR. The risk assessments have been undertaken by HSE.

The main objective in assessing the proposed draft CXLs is to ensure that a risk to consumers is unlikely. The proposed draft CXLs have been assessed to ensure that:

- They are based on residue definitions that are compatible with the residue definitions in force in GB.
- The residue levels arising from the proposed CXLs are safe for UK consumers.
- There are no GB specific assessments that may impact the adoption of a CXL.

The assessments undertaken by HSE have used the toxicological reference values agreed for the latest approval decision of the active substance as it applies in GB. The residue definitions are also taken from the latest approval decision as it applies in GB, unless amended by an MRL review adopted in GB. Where the proposed CXLs relate to an active substance that has never been considered for an approval in GB, the residue definitions and toxicological reference values endorsed by the JMPR have been used to undertake the UK specific consumer risk assessments. However, for a GB specific application (e.g. to set Import Tolerances) a full data package would still be required to establish residue definitions and toxicological reference values.

UK specific consumer risk assessments have been undertaken using the UK models and PRIMo.

The commodity descriptions used by the JMPR/CCPR are not always directly translatable into the commodity descriptions used in Part 1 of the GB MRL Statutory Register. In assessing the CXLs, HSE has outlined the equivalent commodity descriptions and code numbers for GB. For example, a CXL for 'stems of petioles, subgroup of' (codex code VS 2080) will be considered for cardoons (0270020), Celeries (0270030), Florence fennels (0270040) and Rhubarbs (0270070).

In GB, MRLs are currently only established for the raw agricultural commodity (RAC). CXLs are also recommended for processed foods (e.g. citrus oil, dried tomatoes, rape seed oil) and animal feed items (eg hay, straw and fodder). The proposed CXLs for these commodities have therefore not been presented in this report. It is important to note that for processed fractions the GB MRLs for the RAC apply taking into account changes in the

levels of pesticide residues caused by processing and/or mixing (Article 20 of Assimilated Regulation 396/2005).

Where the GB MRL in force is higher than the proposed draft CXL, HSE recommends that the CXL is not adopted, and the current GB MRL should be retained.

2 Assessment of the proposed draft CXLs

In this section the proposed draft CXLs currently at step 3 of the Codex procedures and being considered by the 56th Session of the CCPR for adoption as Codex Food Standards have been reviewed and assessed by HSE. The full list of proposed CXLs is available here: [Proposed draft CXLs for CCPR 56th](#).

The active substances are presented in alphabetical order. The number in brackets is the number assigned to the active substance by the JMPR. For each active substance the following information is presented:

- The approval status of the active substance in GB.
- The Part of the GB MRL Statutory Register in which GB MRLs have been established.
- The type of JMPR assessment e.g. new active substance for the JMPR, an evaluation of new uses, a periodic review.
- The toxicological reference values endorsed by the JMPR and those in force in GB
- The residue definitions endorsed by the JMPR and those in force in GB.

For the assessment the following general points should be noted:

- The residue definitions for livestock do not include a consideration of honey, as CXLs are not being considered for this commodity.
- Where HSE recommends that none of the proposed draft CXLs can be adopted (eg differences in residue definitions or due to the GB MRLs in force being higher than the proposed draft CXLs) then the dietary exposure assessments have not been undertaken.
- Where a proposed draft CXL can potentially be adopted as a GB MRL, then dietary exposure assessments have been undertaken. The results are summarised in this section with the full outputs available in the annexes.
- Where the JMPR has endorsed two distinct ARfD values, a more critical one for women of child-bearing age and a higher value for the rest of the general population, only the critical ARfD is reported.

- When an active substance has never been considered for approval in GB, the residue definitions and toxicological reference values endorsed by the JMPR have been used to undertake the consumer exposure assessments. Consistent with current practice, the most critical ARfD has been used in the UK specific consumer risk assessments and ensures protection of the most vulnerable groups.
- The use of the residue definitions and toxicological reference values endorsed by the JMPR in the assessment of the proposed draft CXLs does not negate the need within a specific GB application (eg to set Import Tolerances) to provide a full data package to establish GB specific residue definitions and toxicological reference values.

2.1 Acetamiprid (246)

Acetamiprid is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Acetamiprid was considered by the JMPR for new uses. Relevant background information is outlined in Tables 1 and 2.

Table 1 Toxicological reference values

	JMPR	GB	Units
ADI	0.07	0.025	mg/kg bw per day
ARfD	0.1	0.025	mg/kg bw

Table 2 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Acetamiprid	Acetamiprid	Yes
	Risk assessment	Acetamiprid	Acetamiprid	Yes
Livestock	Enforcement	Sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid	Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid	Yes
	Risk assessment	Sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid	Sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid	Yes

The residue definitions for plants and livestock for both risk assessment and enforcement are comparable between the JMPR and GB.

The proposed CXLs and their consideration are outlined in Table 3.

Table 3 CXL proposals for acetamiprid

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
Mung beans (dry)	Beans	0300010	0.4	0.15	The CXL can be adopted as a GB MRL
Dry beans, subgroup of (except soya beans and mung beans)	Beans	0300010	0.2	0.15	The CXL is covered by the CXL proposed for mung bean
Dry peas, subgroup of	Lentils	0300020	0.2	0.15	The CXL can be adopted as a GB MRL
Dry peas, subgroup of	Peas	0300030	0.2	0.15	The CXL can be adopted as a GB MRL
Dry beans, subgroup of (except soya beans and mung beans)	Lupins	0300040	0.2	0.15	The CXL can be adopted as a GB MRL

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 4. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 4 Summary of the consumer risk assessments for acetamiprid

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 19% of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of commodities treated with acetamiprid
	PRIMo	The highest IEDI is 17% of the ADI (NL toddler)	

Dietary exposure assessment	Model	Outcome	Comment
Acute exposure assessment	UK	The highest NESTI is 2.3% of the ARfD (infant / beans)	No health effects due to acute exposure are expected from the consumption of commodities treated with acetamiprid
	PRIMo	The highest IESTI is 2% of the ARfD (children / beans)	

Conclusions

The proposed draft CXLs are acceptable and no health effects are expected.

2.2 Acibenzolar-S-methyl (228)

Acibenzolar-S-methyl is an approved active substance in GB. MRLs are established in part 2 of the GB MRL Statutory Register.

Acibenzolar-S-methyl was considered by the JMPR for new uses. Relevant background information is outlined in Tables 5 and 6.

Table 5 Toxicological reference values

	JMPR	GB	Units
ADI	0.08	0.03	mg/kg bw per day
ARfD	0.5	0.03	mg/kg bw

Table 6 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid) (free and conjugates), expressed as	sum of acibenzolar-S-methyl and acibenzolar acid (1,2,3-benzothiadiazole-7-carboxylic acid) (free and conjugated),	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		acibenzolar-S-methyl	expressed as acibenzolar- S-methyl	
	Risk assessment	sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid), (free and conjugated) and 1,2,3-benzothiadiazole-4-hydroxy-7-carboxylic acid (4-OH acibenzolar acid) (free and conjugated), expressed as acibenzolar-S-methyl	For cereals, fruit and fruiting vegetables: sum of acibenzolar- S-methyl and acibenzolar acid (1,2,3-benzothiadiazole-7-carboxylic acid) (free and conjugated), expressed as acibenzolar- S-methyl For other commodities: Open – see below	See below The JMPR residue definition includes an additional metabolite 4-OH acibenzolar acid (free and conjugated). It is noted that the JMPR concluded that this metabolite was only prevalent in leafy crops. The RD-RA are considered further below.
Livestock	Enforcement	sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid) (free and conjugates),	sum of acibenzolar- S-methyl and acibenzolar acid (1,2,3-benzothiadiazole-7-carboxylic acid) (free and	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		expressed as acibenzolar-S-methyl	conjugated), expressed as acibenzolar- S-methyl	
	Risk assessment	sum of acibenzolar-S-methyl and 1,2,3-benzothiadiazole-7-carboxylic acid (acibenzolar acid) (free and conjugates), expressed as acibenzolar-S-methyl	sum of acibenzolar- S-methyl and acibenzolar acid (1,2,3-benzothiadiazole-7-carboxylic acid) (free and conjugated), expressed as acibenzolar- S-methyl	Yes

The residue definitions for livestock for both risk assessment and enforcement are comparable between the JMPR and GB. For plants, the residue definitions for enforcement are comparable between the JMPR and GB. For risk assessment, the GB residue definition was established for cereals, and fruit and fruiting vegetables only. It is noted that the metabolite 4-OH-acibenzolar acid may be considered for inclusion in the RD-RA for other commodities, 'depending on residue and tox data' (EFSA, 2014).

The JMPR residue definition includes the additional metabolite 4-OH acibenzolar acid (free and conjugated). However, in the metabolism studies, this metabolite was only identified in leafy crops. The GB and JMPR RD-RA for cereals and fruit crops are therefore identical.

The JMPR residue definition for risk assessment for other commodities, and in particular for leafy vegetables, is different to the GB residue definition.

The proposed draft CXLs include stem vegetables, which belong to the leafy vegetable metabolism group. The JMPR included an adjustment factor of 1.5 to account for residues of 4-OH acibenzolar acid (free and conjugated) which were not determined in the residue trials. This was on the basis of the residue levels observed in the lettuce metabolism study; the PHI in this study and in the GAP for stem vegetables is the same. Therefore, the adjustment factor applied by the JMPR is considered appropriate.

On the issue of toxicological information for 4-OH acibenzolar acid, acute oral toxicity and bacterial gene mutation assays were provided during the peer review of the active substance (EFSA, 2014). In addition, an LD50 value of >2000 mg/kg bw/day was determined. It was concluded that the information was insufficient to conclude on the relative toxicity to parent compound. The JMPR considered similar information and concluded that the metabolite was unlikely to be genotoxic. The JMPR noted that no further toxicological information was available on this metabolite. On the basis of the same LD50 value reported in the EFSA conclusion, the JMPR concluded that the metabolite is unlikely to be of greater toxicity than parent (JMPR, 2016).

Nevertheless, as the EFSA conclusion, which is relevant in GB, concluded that the information was insufficient to conclude on the relative toxicity, and considering that the JMPR did not evaluate any further information, the toxicological profile of the metabolite is considered as not addressed.

On this basis, the JMPR and GB RD-RAs are not comparable for leafy vegetables (which includes stem vegetables) – the CXLs may not be adopted at this time.

The proposed CXLs and their consideration are outlined in Table 7.

Table 7 CXL proposals for acibenzolar-S-methyl

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Apple	Apples	0130010	0.02	0.3	The CXL does not need to be adopted as the GB MRL is higher
Cardoon	Cardoons	0270020	0.2	0.01	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Celery	Celeries	0270030	0.2	0.01	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Fennel, bulb	Florence fennels	0270040	0.2	0.01	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Rhubarb	Rhubarbs	0270070	0.2	0.01	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of muscle (from mammals other than marine mammals)	All mammals-muscle [†]	1011010 1012010 1013010 1014010 1015010 1017010	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of mammalian fats (except milk fats)	All mammals-fat [†]	1011020 1012020 1013020 1014020 1015020 1017020	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of edible offal (mammalian)	All mammals - Liver [†]	1011030 1012030 1013030 1014030 1015030 1017030	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
	All mammals-kidney [†]	1011040 1012040 1013040 1014040 1015040 1017040	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
	All mammals - edible offals (other than liver and kidney) [†]	1011050 1012050 1013050 1014050 1015050 1017050	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of avian muscle	Poultry - muscle	1016010	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian fat	Poultry - fats	1016020	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian, edible offal of	Poultry - liver	1016030	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
	Poultry - kidney	1016040	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
	Poultry - edible offals (other than liver and kidney)	1016050	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of milks	Milk	1020000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of eggs	Birds eggs	1030000	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 8. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 8 Summary of the consumer risk assessments for acibenzolar-S-methyl

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 6% of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of

Dietary exposure assessment	Model	Outcome	Comment
			commodities treated with acibenzolar-S-methyl
	PRIMo	The highest IEDI is 6% of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 12.4% of the ARfD (infant/rhubarb)	No health effects due to acute exposure are expected from the consumption of commodities treated with acibenzolar-S-methyl
	PRIMo	The highest IESTI is 12% of the ARfD (children/ celeries)	

Conclusions

The proposed draft CXLs for apples and all animal matrices are all equivalent to or lower than the GB MRLs in force.

The proposed draft CXLs for all other commodities are acceptable and no health effects are expected.

2.3 Acynonapyr (333)

Acynonapyr is not an approved active substance in GB. No MRLs are currently established for acynonapyr and therefore the default LOQ MRL of 0.01* mg/kg applies.

Acynonapyr was considered by the JMPR as a new active substance. The JMPR was unable to recommend any MRLs.

2.4 Azoxystrobin (229)

Azoxystrobin is an approved active substance in GB. MRLs are established in part 2 of the GB MRL Statutory Register.

Azoxystrobin was considered by the JMPR for new uses. Relevant background information is outlined in Tables 9 and 10.

Table 9 Toxicological reference values for azoxystrobin

	JMPR	GB	Units
ADI	0.03	0.2	mg/kg bw per day
ARfD	-	-	mg/kg bw

It is noted that the JMPR ADI has been lowered from 0.2 mg/kg bw/day to 0.03 mg/kg bw/day. This is on the basis of newly evaluated data, the impact of this will be considered in a separate regulatory process in GB.

Table 10 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Azoxystrobin	Azoxystrobin	Yes
	Risk assessment	Azoxystrobin	Azoxystrobin	Yes
Livestock	Enforcement	Azoxystrobin	Azoxystrobin	Yes
	Risk assessment	Azoxystrobin	Azoxystrobin †	Yes †

† Tentative, depending on the toxicological relevance of metabolites L1, L4 and L9

The residue definitions for plants and livestock for both risk assessment and enforcement are comparable between the JMPR and GB. However, it is noted that the risk assessment residue definition in GB for livestock is tentative pending additional toxicological information on a number of metabolites; as no draft CXLs for animal commodities are being considered for adoption as GB MRLs, this is not relevant to the current assessment and has not been considered further. It is noted that the CXL for milk is 0.01 mg/kg; whilst the GB MRL is 0.01* mg/kg (i.e. same numerical value, set at the LOQ). Based on the dietary burden calculated by the JMPR, and with reference to the feeding studies considered by the JMPR, the maximum residue in milk was noted to be 0.002 mg/kg (JMPR, 2008; JMPR, 2024). As such, the GB MRL for milk is sufficient, and should remain at the LOQ.

The proposed CXLs and their consideration are outlined in Table 11.

Table 11 CXL proposals for azoxystrobin

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Avocado	Avocados	0163010	1.5	0.01*	The CXL can be adopted as a GB MRL
Fruiting vegetables, cucurbits, Group of (list of all crops)	Cucumbers	0232010	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Fruiting vegetables, cucurbits, Group of (list of all crops)	Gherkins	0232020	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Fruiting vegetables, cucurbits, Group of (list of all crops)	Courgettes	0232030	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Fruiting vegetables, cucurbits, Group of (list of all crops)	Others - cucurbits with edible peel	0232990	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Fruiting vegetables, cucurbits, Group of (list of all crops)	Pumpkins	0233020	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Fruiting vegetables, cucurbits, Group of (list of all crops)	Others - cucurbits with inedible peel	0233990	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Hops, dry	Hops	0700000	40	30	The CXL can be adopted as a GB MRL
Melons, except watermelons	Melons	0233010	5	1	The CXL can be adopted as a GB MRL

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Pineapple	Pineapples	0163080	2	0.01*	The CXL can be adopted as a GB MRL
Watermelon	Watermelons	0233030	5	1	The CXL can be adopted as a GB MRL
Group of avian, edible offal of	Poultry - liver	1016030	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian, edible offal of	Poultry - kidney	1016040	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian, edible offal of	Poultry - edible offals (other than liver and kidney)	1016050	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian fat	Poultry - fats	1016020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian muscle	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of eggs	Birds eggs	1030000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of muscle (from mammals) other than marine mammals)	All mammalian species - muscle	Various	0.01	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of mammalian fats (except milk fats)	All mammalian species- fats	Various	0.05	0.05	The CXL does not need to be adopted as the GB MRL is equivalent
Group of edible offal (mammalian)	All mammalian species – liver, kidney	various	0.07	0.07	The CXL does not need to be adopted as the GB MRL is equivalent

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
	and edible offals				
Group of milks	Milk	1020000	0.01	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 12. The outputs from the UK models and PRIMo can be seen in annexes 1-2.

Table 12 Summary of the consumer risk assessments for azoxystrobin

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 51% of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with acetamiprid
	PRIMo	The highest IEDI is 16% of the ADI (NL toddler)	
Acute exposure assessment	The active is not allocated	acutely toxic and an ARfD has	

Conclusions

The proposed draft CXLs for avocados, pineapples, melons, watermelons, and hops are acceptable and no health effects are expected.

The remaining proposed draft CXLs do not need to be adopted as GB MRLs, as the current GB MRL is equivalent to, or higher than, the draft CXL.

2.5 Buprofezin (173)

Buprofezin is an approved active substance in GB for use on non-edible crops only. Aniline can form on processing. In the approval assessment it was concluded that aniline is a carcinogen for which a genotoxic mechanism cannot be excluded, and hence toxicological reference values cannot be established.

MRLs are established in Part 5 of the GB MRL Statutory Register at the LOQ. Buprofezin was considered by the JMPR for new uses.

Table 13 Toxicological reference values for buprofezin

	JMPR	GB	Units
ADI	0.009	0.01	mg/kg bw per day
ARfD	0.5	0.5	mg/kg bw

Table 14 Toxicological reference values for aniline

	JMPR	GB	Units
ADI	0.02	Could not be established	mg/kg bw per day
ARfD	0.02	Could not be established	mg/kg bw

Table 15 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Buprofezin	Buprofezin	Yes
	Risk assessment	Buprofezin	Sum of buprofezin and BF4 conjugates analysed as BF9 + BF12 under acidic conditions and expressed as buprofezin	No
Livestock	Enforcement	Buprofezin	Buprofezin	Yes
	Risk assessment	Buprofezin	Not established	No

BF4: (2Z)-2-[(1-hydroxy-2-methylpropan-2-yl)imino]-5-phenyl-3-(propan-2-yl)-1,3,5-thiadiazinan-4-one

BF9: 5-phenyl-3-(propan-2-yl)-1,3,5- thiadiazinane-2,4-dione

BF12: 1-phenyl-3-propan-2-ylurea

The residue definitions for enforcement for both plants and livestock are comparable between GB and the JMPR. For plants the residue definition for risk assessment in GB contains additional metabolites. For livestock a residue definition for risk assessment has not been established in GB as the approval assessment did not result in residues in products of animal origin.

The proposed draft CXLs and their consideration are outlined in Table 16.

Table 16 CXL Proposals for buprofezin

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian fat	Poultry - fats	1016020	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian muscle	Poultry - muscle	1016010	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of edible offal	All mammalian species – liver,	various	0.05*	0.01*	Harmful effects for human health

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
(mammalian) †	kidney and edible offals				cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of eggs	Birds eggs	1030000	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of muscle (from mammals) other than marine mammals) †	All Mammalian species - muscle	Various	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of milks	Milk	1020000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent

†The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

An estimation of the dietary intakes has not been undertaken as the active substance is only approved for non-edible uses. The GB residue definitions for risk assessment for plants contain additional metabolites and there are no toxicological reference values currently established in GB for aniline. In addition, no residue definition for risk assessment in animal commodities is established in GB.

Conclusions

The proposed draft CXLs are not acceptable. Based on the risk assessment conducted for the approval of the active substance harmful effects on human health cannot be excluded for residues of buprofezin occurring in food. Consequently, the required level of protection has not been met.

2.6 Carfentrazone-ethyl (338)

Carfentrazone-ethyl is an approved active substance in GB. MRLs are currently established for carfentrazone-ethyl in part 2 of the GB Statutory Register.

Carfentrazone-ethyl was considered by the JMPR as a new active substance. The JMPR was unable to recommend any MRLs.

2.7 Chlorpyrifos (017)

Chlorpyrifos is not an approved active substance in GB. MRLs are currently established for chlorpyrifos in part 5 of the GB Statutory Register.

Chlorpyrifos was evaluated by the JMPR for a periodic review. The JMPR was unable to recommend any MRLs.

2.8 Chlormequat (015)

Chlormequat is an approved active substance in GB. MRLs are established in Part 3a of the GB MRL Statutory Register.

Chlormequat was considered by the JMPR for new uses. Relevant background information is outlined in Tables 17 and 18.

Table 17 Toxicological reference values (expressed as chlormequat chloride)

	JMPR	GB	Units
ADI	0.05	0.04	mg/kg bw per day
ARfD	0.05	0.09	mg/kg bw

Table 18 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	chlormequat cation	sum of chlormequat and its salts, expressed as chlormequat chloride	No – but a molecular weight conversion factor of 1.29 is available to convert chlormequat cation to chlormequat chloride
	Risk assessment	chlormequat cation	sum of chlormequat and its salts, expressed as chlormequat chloride	No – see above
Livestock	Enforcement	chlormequat cation	sum of chlormequat and its salts, expressed as chlormequat chloride	No – see above
	Risk assessment	chlormequat cation	sum of chlormequat and its salts, expressed as chlormequat chloride	No – see above

The residue definitions for plants and livestock for both risk assessment and enforcement are not comparable between the JMPR and GB. However, this difference only relates to how the residue is expressed and a molecular weight conversion can be applied to express the CXLs in accordance with the GB residue definition.

The proposed CXLs and their consideration are outlined in Table 19.

Table 19 CXL proposals for chlormequat

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	CXL expressed as the residue definition for GB ‡ (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
Barley	Barley	0500010	5	7	7	The CXL does not need to be adopted as the GB MRL is equivalent
Group of muscle (from mammals other than marine mammals) †	All Mammalian species - muscle	Various	0.2	0.3	Swine, bovine, goat, equine – 0.3 Sheep – 0.4	The CXL does not need to be adopted as the GB MRL is equivalent or higher
Group of mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.1	0.15	0.15	The CXL does not need to be adopted as the GB MRL is equivalent
Group of edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	Various	0.5	0.7	Swine, bovine, goat, equine (liver, kidney and edible offals) – 1.5 Sheep (liver and edible offals) – 1.5	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	CXL expressed as the residue definition for GB ‡ (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
					Sheep (kidney) – 2.0	
Group of milks	Milk	1020000	0.2	0.3	0.5	The CXL does not need to be adopted as the GB MRL is higher
Group of avian muscle	Poultry - muscle	1016010	0.04 *	0.05*	0.05	The CXL does not need to be adopted as the GB MRL is higher
Group of avian fat	Poultry - fats	1016020	0.04 *	0.05*	0.05	The CXL does not need to be adopted as the GB MRL is higher
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals	Various	0.2	0.3	0.3	The CXL does not need to be adopted as the GB MRL is equivalent
Group of eggs	Birds eggs	1030000	0.2	0.3	0.3	The CXL does not need to be adopted as the

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	CXL expressed as the residue definition for GB ‡ (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
						GB MRL is equivalent

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

‡ The MRL proposal, expressed as chlormequat chloride, has been rounded to the nearest MRL class.

Consumer Risk Assessments

Dietary exposure estimates have not been undertaken as the proposed draft CXLs have been previously considered and are equivalent to, or lower than, the GB MRLs in force.

Conclusions

The draft CXLs do not need to be adopted as GB MRLs, as the current GB MRLs are equivalent to, or higher than, the draft CXLs.

2.9 Cyclobutrifluram (239)

Cyclobutrifluram has never been considered for an approval in GB. No specific MRLs have been established in GB and currently the default LOQ MRL of 0.01* mg/kg applies to all commodities.

Cyclobutrifluram was considered by the JMPR as a new active substance. Relevant background information is outlined in Tables 20 and 21.

Table 20 Toxicological reference values

	JMPR	GB	Units
ADI	0.2	n/a	mg/kg bw per day
ARfD	0.5	n/a	mg/kg bw

Table 21 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Cyclobutrifluram	n/a	n/a
	Risk assessment	Sum of residues of cyclobutrifluram (free and conjugated), N-[(1S,2R)-2-(2,4-dichlorophenyl)-2-hydroxy-cyclobutyl]-2-(trifluoromethyl)pyridine-3-carboxamide (SYN549104) (free and conjugated), 2-(trifluoromethyl)pyridine-3-carboxylic acid (SYN510260) (free and conjugated) and 2-(trifluoromethyl)pyridine-3-carboxamide (SYN510275) (free and conjugated), expressed as cyclobutrifluram.	n/a	n/a
Livestock	Enforcement	sum of residues of cyclobutrifluram and 2-(trifluoromethyl)pyridine-3-carboxamide (SYN510275), expressed as cyclobutrifluram.	n/a	n/a
	Risk assessment	sum of residues of cyclobutrifluram, N-[(1S,2R)-2-(2,4-dichlorophenyl)-2-hydroxy-cyclobutyl]-2-(trifluoromethyl)pyridine-3-carboxamide (SYN549104) (free and conjugated) and 2-(trifluoromethyl)pyridine-3-carboxamide (SYN510275) (free and conjugated), expressed as cyclobutrifluram.	n/a	n/a

There are currently no GB residue definitions for plants and livestock for risk assessment and enforcement.

The proposed CXLs and their consideration are outlined in Table 22.

Table 22 CXL proposals for cyclobutrifluram

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Banana	Banana	0163020	0.01*	0.01*	The CXL can be adopted as a GB MRL

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 4. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 23 Summary of the consumer risk assessments for cyclobutrifluram

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is <1 % of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of commodities treated with cyclobutrifluram
	PRIMo	The highest IEDI is 0.6 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 0.2 % of the ARfD (infant/bananas)	No health effects due to acute exposure are expected from the consumption of commodities treated with cyclobutriflurilam
	PRIMo	The highest IESTI is 0.2 % of the ARfD (children/bananas)	

Conclusions

The proposed draft CXL is acceptable and no health effects are expected.

2.10 Cyproconazole (239)

Cyproconazole is not an approved active substance in GB. MRLs are established in Part 3 of the GB MRL Statutory Register.

Cyproconazole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 24 and 25.

Table 24 Toxicological reference values

	JMPR	GB	Units
Cyproconazole			
ADI	0.02	0.02	mg/kg bw per day
ARfD	0.06	0.02	mg/kg bw
1,2,4-triazole (1,2,4-T)			
ADI	0.2	0.023	mg/kg bw per day
ARfD	0.3	0.1	mg/kg bw
Triazole alanine (TA)			
ADI	1	0.3	mg/kg bw per day
ARfD	Unnecessary	0.3	mg/kg bw
Triazole acetic acid (TAA)			
ADI	1	1	mg/kg bw per day
ARfD	Unnecessary	1	mg/kg bw
Triazole lactic acid (TLA)			
ADI	Not set	0.3	mg/kg bw per day
ARfD	Not set	0.3	mg/kg bw

Table 25 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Cyproconazole	Cyproconazole	Yes
	Risk assessment	Cyproconazole	1. Cyproconazole (sum of isomers) 2. TA and TLA 3. TAA 4. 1,2,4-T	No
Livestock	Enforcement	Cyproconazole	Cyproconazole	Yes
	Risk assessment	Free and conjugated cyproconazole	1. Cyproconazole (sum of isomers) and the	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			metabolites M36(Z2), M38(Z1) and M9/M14 (pair of diastereomers), expressed as cyproconazole 2. TA and TLA 3. TAA 4. 1,2,4-T	

Triazole derivative metabolites (TDMs):

TA: triazole alanine

TLA: triazole lactic acid

TAA: triazole acetic acid

1,2,4-T: 1,2,4-triazole

The plant and animal residue definitions for enforcement are comparable between the JMPR and GB. However, the plant and animal residue definitions for risk assessment are not comparable. The GB residue definitions for risk assessment include TDMs. There is insufficient information on the levels of TDMs in the residue trials evaluated by the JMPR. However, no further consideration is required in this assessment as the current GB MRLs are higher than, or equivalent to, the proposed draft CXLs.

The proposed CXLs and their consideration are outlined in Table 26.

Table 26 CXL proposals for cyproconazole

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Dry beans, subgroup of	Beans Lupins	0300010 0300040	0.02	0.08	The CXL does not need to be adopted as the GB MRL is higher
Dry peas, subgroup of	Lentils Peas	0300020 0300030	0.02	0.08	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of muscle (from mammals other than marine mammals)	All mammalian species - muscle	Various	0.01	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Group of mammalian fats (except milk fats)	All mammalian species - fat	Various	0.02	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Group of milks	Milk	1020000	0.01	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various	0.5	0.5	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian muscle	Poultry - muscle	1016010	0.01*	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Group of avian fat	Poultry - fats	1016020	0.01*	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Group of avian, edible offal of	Poultry – liver, kidney and edible offals	1016030 1016040 1016050	0.01*	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Group of eggs	Birds eggs	1030000	0.01*	0.05*	The CXL does not need to be adopted as the GB MRL is higher

Consumer Risk Assessments

Dietary exposure estimates have not been undertaken as the proposed draft CXLs are equivalent to, or lower than, the GB MRLs in force.

Conclusions

The proposed draft CXLs do not need to be adopted as they are equivalent to, or lower than, the GB MRLs in force.

2.11 Ethoxyquin (035)

Ethoxyquin is not an approved active substance in GB. MRLs are currently established for ethoxyquin in part 5 of the GB Statutory Register.

Ethoxyquin was evaluated by the JMPR for a periodic review. The JMPR withdrew the previous CXLs as insufficient data was provided in order to derive toxicological reference values.

2.12 Etofenprox (184)

Etofenprox is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Etofenprox was considered by the JMPR for new uses.

Relevant background information is outlined in Tables 27 and 28.

Table 27 Toxicological reference values

	JMPR	GB	Units
ADI	0.03	0.03	mg/kg bw per day
ARfD	1	1	mg/kg bw

Table 28 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Etofenprox	Etofenprox	Yes
	Risk assessment	Etofenprox	Sum of etofenprox plus α -CO, expressed as etofenprox	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Livestock	Enforcement	Etofenprox	Etofenprox (provisional) [†]	Yes
	Risk assessment	Etofenprox	Etofenprox (provisional) [†]	Yes

α -CO: 2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate

†The residue definitions for risk assessment and enforcement in animal commodities in GB are provisional pending the submission of new livestock metabolism studies with parent and metabolite α -CO and storage stability data for residues in animal tissues. MRL supplementary information to address the data requirements will be considered separately.

The residue definitions for plants and livestock for enforcement are comparable between the JMPR and GB.

While the residue definition for risk assessment in livestock is comparable between the JMPR and GB, the residue definition for risk assessment in plants is different due to the inclusion of the metabolite α -CO in GB.

The residue trials used by the JMPR to set the MRL for rice only contain information on etofenprox and not the metabolite α -CO. It is not possible to determine a reliable conversion factor from RD-Enf to RD-RA in rice based on the available information.

The proposed CXLs and their consideration are outlined in Table 29.

Table 29 CXL proposals for etofenprox

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Rice, husked	Rice	0500060	0.3	0.01*	The residues data do not cover the full residue definition for risk assessment in GB. The CXL should not be adopted as a GB MRL.
Group of edible offal (mammalian)	Swine, sheep, goat, other - liver	Various	0.1	0.05	The CXL can be adopted as a GB MRL
	Swine, sheep, goat,	Various	0.1	0.05	The CXL can be adopted as a GB MRL

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
	other - kidney				
	Swine, sheep, goat, other - edible offals (other than liver and kidney)	Various	0.1	1.5	The CXL does not need to be adopted as the GB MRL is higher
	Bovine, equine - liver	Various	0.1	0.06	The CXL can be adopted as a GB MRL
	Bovine, equine - kidney	Various	0.1	0.07	The CXL can be adopted as a GB MRL
	Bovine, equine - edible offals (other than liver and kidney)	Various	0.1	2	The CXL does not need to be adopted as the GB MRL is higher
Group of avian muscle	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian fats	Poultry - fats	1016020	0.5	0.04	The CXL can be adopted as a GB MRL
Group of avian, edible offal of	Poultry - liver	1016030	0.02	0.01*	The CXL can be adopted as a GB MRL
	Poultry - kidney	1016040	0.02	0.01*	The CXL can be adopted as a GB MRL
	Poultry - edible offals (other than liver and kidney)	1016050	0.02	0.04	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of mammalian fats (except milk fats)	Swine, sheep, goat, other - fat	Various	3	1.5	The CXL can be adopted as a GB MRL
	Bovine, equine - fat	Various	3	2	The CXL can be adopted as a GB MRL
Group of muscle (from mammals other than marine mammals)	Swine, sheep, goat, other - muscle	Various	0.07	0.05	The CXL can be adopted as a GB MRL
	Bovine, equine - muscle	Various	0.07	0.06	The CXL can be adopted as a GB MRL
Group of milks	Cattle, horse - milk	Various	0.1	0.07	The CXL can be adopted as a GB MRL
	Sheep, goat, others - milk	Various	0.1	0.04	The CXL can be adopted as a GB MRL
Group of eggs	Birds eggs	1030000	0.1	0.015	The CXL can be adopted as a GB MRL

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 30. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 30 Summary of the consumer risk assessments for etofenprox

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 51% of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with etofenprox
	PRIMo	The highest IEDI is 49% of the ADI (NL toddler)	

Dietary exposure assessment	Model	Outcome	Comment
Acute exposure assessment	UK	The highest NESTI is 1.2% of the ARfD (infant/milk)	No health effects due to acute exposure are expected from the consumption of commodities treated with etofenprox.
	PRIMo	The highest IESTI is 1% of the ARfD (UK infant/cattle milk)	

Conclusions

The proposed draft CXLs for mammalian and poultry edible offals (other than liver and kidney) and poultry muscle are all equivalent to or lower than the GB MRLs in force. The proposed draft CXLs for all other livestock commodities are acceptable and no health effects are expected.

The residues data used by the JMPR do not cover the full residue definition for risk assessment in plants GB. Therefore, the proposed draft CXL for rice should not be adopted as a GB MRL.

2.13 Fenpropidin (340)

Fenpropidin is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Fenpropidin was considered by the JMPR as a new active substance. Relevant background information is outlined in Tables 31 and 32.

Table 31 Toxicological reference values

	JMPR	GB	Units
ADI	0.02	0.02	mg/kg bw per day
ARfD	0.03	0.02	mg/kg bw

Table 32 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Fenpropidin	Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin)	Yes (see discussion below)
	Risk assessment	Fenpropidin	Sum of fenpropidin and its salts, expressed as fenpropidin	Yes
Livestock	Enforcement	Sum of fenpropidin and CGA 289267 {2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]propionic acid}, expressed as fenpropidin	Sum of fenpropidin, its salts and 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid expressed as fenpropidin	Yes
	Risk assessment	Sum of fenpropidin, CGA 289267 {2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]propionic acid}, and SYN 515213 {3-hydroxy-2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid} (free and conjugated), expressed as fenpropidin	Sum of fenpropidin and its salts, 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid, 3-hydroxy-2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propionic acid, 2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propan-1-ol and their conjugates expressed as fenpropidin	No

The residue definitions for plants, and the livestock residue definition for enforcement are comparable between the JMPR and GB. The residue definition for risk assessment for livestock is not comparable between the JMPR and GB.

The GB residue definition for plants for enforcement includes the salts of fenpropidin. These were not included in the JMPR residue definition. It is noted that the analytical methods considered by the JMPR for the analysis of fenpropidin in bananas, REM 164.04 and REM 164.09, analyse for fenpropidin and its salts in plant matrices (EFSA 2011, addendum to DAR 2007).

Residue levels of CGA 289268 (2-methyl-2-[4-(2-methyl-3-piperidin-1-yl-propyl)-phenyl]-propan-1-ol) were not included in the JMPR evaluation for products of animal origin. For the review of the MRLs (EFSA, 2011), conversion factors (from RD-Enf → RD-RA) were used to account for the metabolite CGA 289268 in animal matrices. The same conversion factors have been applied here, and the results of which are summarised in Table 33.

Table 33 Residue endpoints

Commodity	Residues according to GB RD-Enf (mg/kg)		CF	Residues according to GB RD-RA (mg/kg)	
	Median residue (mg/kg)	Highest residue (mg/kg)		Median residue (mg/kg)	Highest residue (mg/kg)
Mammalian muscle	0.017	0.021	2	0.034	0.042
Mammalian fat	0.016	0.021	3	0.048	0.063
Mammalian liver	0.098	0.32	5	0.49	1.6
Mammalian kidney	0.027	0.073	4	0.108	0.292
Poultry muscle	0.018	0.021	1	0.018	0.021
Poultry fat	0.018	0.021	1	0.018	0.021
Poultry liver	0.037	0.074	1	0.037	0.074
Milk	0.008	-	4	0.032	-
Eggs	0.018	0.021	1	0.018	0.021

The proposed CXLs and their consideration are outlined in Table 34.

Table 34 CXL proposals for fenpropidin

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Banana	Bananas	0163020	9.0	0.2	Acute intake concerns have been identified. The CXL should not be adopted as a GB MRL.
Barley	Barley	0500010	0.15	0.6	The CXL does not need to be adopted as the GB MRL is higher
Wheat	Wheat	0500090	0.05	0.1	The CXL does not need to be adopted as the GB MRL is higher
Triticale	Wheat	0500090	0.05	0.1	The CXL does not need to be adopted as the GB MRL is higher
Sugar beet	Sugar beet roots	0900010	0.03	0.07	The CXL does not need to be adopted as the GB MRL is higher
Group of muscle (from mammals other than marine mammals)	All Mammalian species [†] - muscle	Various	0.02	0.02*	The CXL can be adopted as a GB MRL
Group of mammalian fats (except milk fats)	All Mammalian species [†] - fats	Various	0.02	0.02*	The CXL can be adopted as a GB MRL
Group of edible offal (mammalian)	All mammalian species [†] –	Various	0.4	Swine: Liver – 0.2 Kidney – 0.05	The CXL does not need to be adopted as the GB MRL is

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
	liver, kidney and edible offals			Bovine, Sheep, Goat, Equine and Other farmed terrestrial animals: Liver – 0.5 Kidney – 0.1 All: Edible offals (other than liver and kidney) – 0.02*	higher for: Liver (Bovine, Sheep, Goat, Equine and Other farmed terrestrial animals) The CXL can be adopted as a GB MRL for: liver (Swine); kidney (All mammalian species); edible offals (other than liver and kidney) (all mammalian species)
Group of avian muscle	Poultry - muscle	1016010	0.02	0.02*	The CXL can be adopted as a GB MRL
Group of avian fats	Poultry - fats	1016020	0.02	0.02*	The CXL can be adopted as a GB MRL
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.08	0.02*	The CXL can be adopted as a GB MRL
Group of milks	Milk	1020000	0.02*	0.02	The CXL does not need to be adopted as the GB MRL is higher
Group of eggs	Birds eggs	1030000	0.02	0.02*	The CXL can be adopted as a GB MRL

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

It is noted that residues endpoints have been reported by the JMPR for the whole banana fruit, with some of the trials also analysing for residues in the pulp/flesh and peel. From the results in pulp/flesh, pulp to whole fruit ratios were determined and the median ratio applied to the results in whole fruit. The GAP for bananas considered by the JMPR had a PHI of 0 days, and no decline data are available at the GAP supporting the current CXL. Two decline trials are available that support a less critical GAP; however, all results are <0.01 mg/kg (<LOQ) and do not provide information on any potential changes in residue levels with an increase in PHI. Therefore, it is not clear if the residues in the flesh might increase at a longer PHI. The consumer risk assessments have therefore been performed using the residue levels in the whole fruit.

The outcome of the consumer risk assessments are summarised in table 35. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 35 Summary of the consumer risk assessments for fenpropidin

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 33 % of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of commodities treated with fenpropidin
	PRIMo	The highest IEDI is 21 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 2507.9 % of the ARfD (infant/bananas) The next highest NESTI is 64.6 % of the ARfD (infant/all types of liver)	An acute intake concern has been identified for bananas† No health effects due to acute exposure are expected from the consumption of all other commodities treated with fenpropidin
	PRIMo	The highest IESTI is 2912 % of the ARfD (children/ bananas) The next highest IESTI is 24 % of the ARfD (children/ swine: edible offals (other than liver and kidney))	

† As detailed above, the input was whole banana – had the JMPR value for pulp been used instead, an acute intake concern would still be observed in both the UK model and PRIMo.

Conclusions

The proposed draft CXL for bananas is not acceptable as it leads to dietary intakes that exceed the ARfD. Consequently, the required level of protection has not been met.

The proposed draft CXLs for barley, wheat, sugar beet roots, liver (bovine, sheep, goat, equine, and other farmed terrestrial animals), and milk, do not need to be adopted as GB MRLs, as the current GB MRL is equivalent to, or higher than, the draft CXL.

The proposed draft CXLs for all other commodities are acceptable and no health effects are expected.

2.14 Fenpyroximate (193)

Fenpyroximate is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Fenpyroximate was considered by the JMPR for new uses with additional consideration of new toxicological data resulting in a lower ADI and ARfD being endorsed by the JMPR. Relevant background information is outlined in Tables 36 and 37.

The lower JMPR toxicological reference values (TRVs) resulted from a one-year dog study. This study was also evaluated to support the approval of fenpyroximate in GB (DAR, 2007). The JMPR concluded on a NOAEL for the one-year dog study that was lower than the NOAEL derived for the GB approval. The GB TRVs are appropriate and HSE do not agree with the lower JMPR TRVs.

Table 36 Toxicological reference values

	JMPR	GB	Units
ADI	0.005	0.01	mg/kg bw per day
ARfD	0.005	0.02	mg/kg bw

Table 37 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Fenpyroximate	Fenpyroximate (fruit crops, pulses and oilseeds only)	Yes
	Risk assessment	Sum of parent fenpyroximate and tert-butyl (Z)- α -	Sum of fenpyroximate and its Z-isomer,	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		(1,3-dimethyl-5-phenoxy-pyrazol-4-yl)methyleneamino-oxy)-p-toluate (its Z-isomer M-1), expressed as fenpyroximate.	expressed as fenpyroximate (fruit crops, pulses and oilseeds only)	
Livestock	Enforcement	Sum of Sum of fenpyroximate and M-3) expressed as fenpyroximate	fenpyroximate Except ruminant Liver and Kidney Ruminant Liver and Kidney: Fenpyroximate (metabolite M-3, expressed as fenpyroximate)	No
	Risk assessment	Sum of fenpyroximate, Fen-OH, R-UL-1 and M-3, expressed as fenpyroximate	Sum of fenpyroximate, Fen-OH, metabolite M-3 and their Z-isomers, expressed as fenpyroximate	No

M3: (E)-4-[(1,3-dimethyl-5-phenoxy-pyrazol-4-yl) methyleneamino-oxy)methyl]benzoic acid

Fen-OH: 2-hydroxymethyl-2-propyl (E)-4-[(1,3-dimethyl-5-phenoxy-pyrazol-4-yl)-methylenamino-oxy)methyl]benzoate

R-UL-1: 2-hydroxy-2-methylpropyl (E)-α-(1,3-dimethyl-5- phenoxy-pyrazol-4-yl)methyleneamino-oxy)-p-toluate

The residue definitions for plants (both RD-Enf and RD-RA) are comparable between GB and the JMPR. The GB RD-RA is restricted to fruit crops and pulses and oilseeds only – the acceptable CXLs (as detailed in table 38) are only on fruit, fruiting vegetables and pulses. The residue definition for enforcement (livestock) in GB and for the JMPR are comparable for liver and kidney; however, for all other animal commodities the JMPR RD-Enf is more extensive. Based on the goat metabolism study, significant levels of M-3 are

not expected in any animal matrices other than liver and kidney. Therefore, the RD-Enfs are comparable in practice. No CXLs are proposed for poultry.

The JMPR RD-RA (livestock) is more extensive than the GB RD-RA and may overestimate the residue slightly. The JMPR residue definition includes an additional metabolite whereas the GB residue definition includes the z isomers. The goat metabolism study, evaluated for the approval in GB, indicates that significant levels of the z -isomer are not expected so this is unlikely to have an impact on consumers. The metabolite R-UL-1 is noted to be an unstable intermediate which metabolises rapidly to Fe-OH under basic and neutral conditions (JMPR, 2021) – this metabolite is therefore not considered relevant. The RD-RA for livestock is therefore considered sufficiently comparable for GB and the JMPR. Residues are fat soluble.

The proposed CXLs and their consideration are outlined in Table 38.

Table 38 CXL proposals for fenpyroximate

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Apple	Apples	0130010	0.1	0.3	The CXL does not need to be adopted as the GB MRL is higher
Oranges, sweet, sour (including orange-like hybrids), subgroup of	Oranges	0110020	0.15	0.7	The CXL does not need to be adopted as the GB MRL is higher
Mandarins, subgroup of	Mandarins	0110050	0.15	1	The CXL does not need to be adopted as the GB MRL is higher
Cherry tomato	Tomatoes	0231010	0.2	0.3	The CXL does not need to be adopted as the GB MRL is higher
Tomato	Tomatoes	0231010	0.2	0.3	The CXL does not need to be adopted as the GB MRL is higher
Cucumber	cucumbers	0232010	0.04	0.3	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various †	0.8	0.8	The CXL does not need to be adopted as the GB MRL is equivalent
Group of mammalian fats (except milk fats)	All mammalian species- fats	Various †	0.2	0.2	The CXL does not need to be adopted as the GB MRL is equivalent
Meat (from mammals) other than marine mammals)	All mammalian species - muscle	Various †	0.05	0.2	The CXL does not need to be adopted as the GB MRL is higher
Group of milks	Milk	1020000	0.01	0.01	The CXL does not need to be adopted as the GB MRL is equivalent

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Conclusions

The draft CXLs do not need to be adopted as GB MRLs, as the current GB MRLs are equivalent to, or higher than, the draft CXLs.

2.15 Fipronil (202)

Fipronil is a non-approved active substance in GB following the applicant withdrawing support for the renewal. MRLs are established in Part 5 of the GB MRL Statutory Register at the limit of quantification.

The JMPR assessment was a periodic review of the active substance (JMPR 2021) with revised GAP information (JMPR 2024) as a result of chronic intake concerns being identified in the periodic review. Relevant background information is outlined in Tables 39 and 40.

Table 39 Toxicological reference values

	JMPR	GB	Units
ADI	0.0002	0.0002	mg/kg bw per day
ARfD	0.03	0.009	mg/kg bw

Table 40 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Sum of fipronil and MB46136 expressed in terms of fipronil	Sum fipronil + sulfone metabolite(MB46136) expressed as fipronil (definition valid for seed treatment use only)	Yes
	Risk assessment	Sum of fipronil, MB46136, MB45950 and MB46513 expressed in terms of fipronil	Sum fipronil + sulfone metabolite(MB46136) expressed as fipronil (definition valid for seed treatment use only)	No
Livestock	Enforcement	Sum of fipronil and MB46136 expressed in terms of fipronil	Sum fipronil + sulfone metabolite(MB46136) expressed as fipronil	Yes
	Risk assessment	Sum of fipronil, MB46136, MB45950 and MB46513 expressed in terms of fipronil	Sum fipronil + sulfone metabolite(MB46136) expressed as fipronil	No

The residue definitions for plants and livestock for enforcement are comparable between the JMPR and GB.

The residue definitions for plants for risk assessment are not comparable for GB and the JMPR. The JMPR RD-RA is more extensive than the GB RD-RA for both plant and animal commodities; the JMPR evaluation is also more recent than the last GB residues evaluation for fipronil (EFSA, 2014). As the active is non-approved in GB, and the JMPR have evaluation represents a more up to date assessment, the JMPR residue definitions have been considered for consideration of the adoption of the CXLs.

For any future application to HSE, these residue definitions may need to be considered further.

Plant commodities

The plant metabolism studies presented in the JMPR evaluation show that parent and the metabolites fipronil-sulfone (MB46136), fipronil-sulfide (MB45950) and fipronil desulfinyl (MB46513) are the most significant residues among the commodities investigated. The residue definition for enforcement in plants is agreed based in the combination of fipronil and MB46136 which occurs in most crops with detectable residues. The JMPR concluded that the metabolites MB45950 and MB46513 are covered by the fipronil TRVs (JMPR, 2024). The JMPR further concluded that the metabolite RPA200766 does not need to be included in the residue definition as it was only detected occasionally in the residue trials, whilst the metabolite RPA104615 is not of toxicological concern (JMPR, 2024).

HSE agrees with the residue definition for risk assessment in plants, derived by the JMPR – as such, the consumer risk assessment will be undertaken on the basis of the more extensive JMPR residue definition for plants. As the JMPR residue definition is more extensive than the GB residue definition, the risk assessment performed with the JMPR residue definition is expected to be sufficiently conservative.

Livestock commodities

The JMPR evaluation concludes that the residue definition for enforcement is the sum of fipronil and fipronil-sulfone (MB46136) expressed as fipronil, as both are major components in the animal metabolism studies. To decide the residue definition for risk assessment, the occurrence and toxicological properties of each compound were considered. Using estimates of livestock dietary burden and assuming the same transfer rate to animal commodities as for fipronil, it was noted that MB46136, MB46513 and MB45950 could make a significant contribution to overall consumer exposure when compared with estimates for the sum of fipronil and fipronil-sulfone (MB46136).

The JMPR RD-RA for livestock was agreed on the basis of excluding the following metabolites based on their exposure and using the Threshold of Toxicological Concern

(TTC) approach: MB45897, MB46400, RPA105048, RPA105320, RPA108058 and RPA200761. The exposures were assessed against the Threshold for Cramer Class III (CC III) compounds. The details of the exposure assessments, using the TTC approach, undertaken by the JMPR are not readily available; therefore, HSE cannot perform the exposure assessments for UK consumers. HSE therefore cannot confirm the JMPR residue definition for risk assessment for products of animal origin. As such, the CXLs for products of animal origin cannot be adopted as GB MRLs. It is further noted that the STMR/HR values for animal commodities reported by the JMPR do not appear to reflect the separate contribution of fipronil and MB46513 in feed items; hence the STMR/HR values provided are likely to underrepresent the residue levels in products of animal origin.

As HSE cannot confirm the RD-RA for livestock and the STMR/HRs are likely to be underestimated, it is important that any treated plant commodities imported into GB that can also be used as feed items, do not give rise to significant residues in the diets of livestock. For this reason, the dietary burdens for livestock have been undertaken for this active substance (as outlined below).

The proposed CXLs and their consideration are outlined in Table 41.

Table 41 CXL proposals for fipronil

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Banana	Bananas	0163020	0.004*	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Potato	Potatoes	0211000	0.05	0.005*	A chronic intake concern has been identified. In addition, inclusion of the CXL in the dietary burden calculation leads to an exceedance of the DB trigger.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
					The CXL should not be adopted as a GB MRL.
Root and tuber vegetables, group of (list of all crops) ‡	All root and tuber vegetables (except potatoes and sugar beets)	Various	0.002	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Onion, bulb	Onions	0220020	0.03	0.005*	The CXL can be adopted as a GB MRL
Tomatoes, subgroup of	Tomatoes	0231010	0.004*	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Leafy Vegetables ‡	All leafy vegetables	Various	0.01	0.005*	The CXL can be adopted as a GB MRL
Dry beans, subgroup of	Beans, lupins/lupini beans	0300010, 0300040	0.008	0.005*	The CXL can be adopted as a GB MRL
Dry peas, subgroup of	Lentils, peas	0300020, 0300030	0.008	0.005*	The CXL can be adopted as a GB MRL
Sunflower seeds, Subgroup of	Sunflower seeds	0401050	0.01	0.005*	The CXL can be adopted as a GB MRL
Soya bean (dry)	Soyabeans	0401070	0.002	0.005*	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Cotton seed	Cotton seeds	0401090	0.003	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Barley, similar grains, and pseudocereals with husks, subgroup of	Barley, Buckwheat and other pseudocereals, Oats	0500010, 0500020, 0500050	0.002*	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Maize cereals, subgroup of	Maize/corn, Common millet/proso millet, Sorghum	0500030, 0500040, 0500080	0.01	0.005*	The CXL can be adopted as a GB MRL
Rice, husked	Rice	0500060	0.001*	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Wheat, similar grains, and pseudocereals without husks, subgroup of	Rye, wheat	0500070, 0500090	0.03	0.005*	The CXL can be adopted as a GB MRL
Sugar beet	Sugar beet roots	0900010	0.004	0.005*	The CXL does not need to be adopted as the GB MRL is higher
Sugar cane	Sugar canes	0900020	0.01	0.005*	The CXL can be adopted as a GB MRL

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of muscle (from mammals other than marine mammals) †	All Mammalian species - muscle	Various	0.015	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.15	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	Various	0.05	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian muscle	Poultry - muscle	1016010	0.02	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian fat	Poultry - fats	1016020	0.05	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.02	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of eggs	Birds eggs	1030000	0.04	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of milks	Milk	1020000	0.02	0.005*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

‡ The draft CXL for root and tuber vegetables (except potatoes) and leafy vegetables, are based on residues in rotational crops. These CXLs therefore apply to all root and tuber vegetables (except potatoes) and leafy vegetables listed in the GB MRL statutory register, except permanent crops (e.g. grape leaves, or witloof).

Dietary burden calculation

All current GB MRLs for products of animal origin are set at the LOQ (0.005* mg/kg). The draft CXLs for products of animal origin cannot be adopted, as outlined above. The draft CXLs (including for kales, carrots, potatoes, cereals, oilseeds) cover plants that can also be used as animal feeds. To ensure residues are not significant in the diets of livestock, and hence residues remain below the current GB MRLs set at the LOQ, the dietary burdens (DB) of livestock have been undertaken.

The dietary burden calculation has been performed considering the following:

- The CXLs which have been considered for adoption in GB (i.e. those higher than current LOQ MRLs) have been used as inputs in the dietary burden calculation.
- In addition, it is noted that rotational crop residues may be expected in root and tuber commodities, as well as leafy vegetables, CXLs are proposed to account for these rotational residues. As these may occur in crops imported into GB, these values have been included in the dietary burden calculation.
- Furthermore, in cases where the CXL is lower than the GB LOQ MRL, the CXL STMR/HR has been included in the calculation to reflect the fact that an authorisation exists globally.

The inputs for the dietary burden calculation are shown in Table 42.

Table 42 Dietary burden inputs for fipronil

Feed item	STMR (mg/kg)	HR (mg/kg)	Comment
Kale leaves	0.02919†	0.02919	CXL for leafy vegetables – based on rotational crops
Carrot, Cassava/tapioca, Swede, Turnip (culls)	0.00212†	0.00212	CXL for root/tuber vegetables – based on rotational crops
Potato culls	0.00495	0.0296	CXL for potatoes
Potato process waste	0.099	-	CXL for potatoes x default pf (20)
Potato dried pulp	0.188	-	CXL for potatoes x default pf (38)
Maize, millet, sorghum	0.004	-	CXL lower than GB MRL, input included to reflect existence of global authorisation
Barley, oats	0.002	-	CXL lower than GB MRL, input included to reflect existence of global authorisation
Wheat, rye grain	0.008	-	CXL considered for adoption as GB MRL
Bean, lupin, cowpea, field pea (dry seeds)	0.002	-	CXL considered for adoption as GB MRL
Cotton seed	0.002	-	CXL lower than GB MRL, input included to reflect existence of global authorisation
Soyabean seed	0.002	-	CXL lower than GB MRL, input included to reflect existence of global authorisation

Feed item	STMR (mg/kg)	HR (mg/kg)	Comment
Beet, sugar dried pulp	0.072	-	CXL lower than GB MRL, input included to reflect existence of global authorisation x default pf (18)
Beet, sugar, ensiled pulp	0.012	-	Beet, sugar x default pf (3)
Beet, sugar molasses	0.112	-	Beet, sugar x default pf (28)
Brewer's grain dried	0.007	-	Barley grain x default pf (3.3)
Corn, field milled by-pdts	0.004	-	Maize grain x default pf (1)
Corn, field hominy meal	0.024	-	Maize grain x default pf (6)
Corn, field gluten feed	0.010	-	Maize grain x default pf (2.5)
Corn, field gluten, meal	0.004	-	Maize grain x default pf (1)
Cotton meal	0.003	-	Cotton seed x default pf (1.3)
Distiller's grain dried	0.026	-	Wheat grain x default pf (3.3)
Lupin seed meal	0.002	-	Lupin seed x default pf (1.1)
Rice, bran/pollard	0.020	-	Rice grain x default pf (10)
Soybean, meal	0.003	-	Soyabean seed x default pf (1.3)
Soybean, hulls	0.026	-	Soyabean seed x default pf (13)
Sugarcane, molasses	0.096	-	Sugarcane x default pf (32)
Sunflower, meal	0.016	-	Sunflower seed x default pf (2)
Wheat gluten, meal	0.014	-	Wheat grain x default pf (1.8)
Wheat, milled by-pdts	0.056	-	Wheat grain x default pf (7)

† The JMPR reported the STMR for these commodities as 0 mg/kg; to reflect the potential for residues in rotational crops, the HR has also been applied to the mean dietary burden calculation.

The dietary burden calculation was undertaken with the EFSA Animal model 2017; the output is recorded in table 43 and 44. With inclusion of all commodities described above, the trigger (0.004 mg/kg bw) is exceeded for ruminants, with a maximum of 0.013 mg/kg bw (dairy cattle/ram/ewe) – this is driven by exposure of livestock to residues in potato process waste. Therefore, residues are significant in the diets of livestock, and there is the potential that residues may be found in products of animal origin.

Excluding the CXL for potatoes, the dietary burden is below the trigger for all species. Therefore, as the livestock dietary burdens are below the trigger of 0.004 mg/kg bw/day, then significant residues are not expected in the diets of livestock and residues are not expected in products of animal origin.

Residues are expected to be well below the GB LOQ MRLs for products of animal origin if the CXL for potatoes is not adopted as a GB MRL.

HSE recommends that the CXL for potatoes is not adopted as a GB MRL.

Table 43 Dietary burden output – including potato

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.011	0.013	0.38	0.41	Dairy cattle	Potato	process waste	Yes
Cattle (dairy only)	0.011	0.013	0.30	0.33	Dairy cattle	Potato	process waste	Yes
Sheep (all diets)	0.012	0.013	0.36	0.40	Ram/Ewe	Potato	process waste	Yes
Sheep (ewe only)	0.012	0.013	0.36	0.40	Ram/Ewe	Potato	process waste	Yes
Swine (all diets)	0.005	0.006	0.20	0.26	Swine (breeding)	Potato	process waste	Yes
Poultry (all diets)	0.004	0.005	0.05	0.06	Poultry broiler	Potato	dried pulp	Yes
Poultry (layer only)	0.003	0.004	0.04	0.05	Poultry layer	Potato	dried pulp	No

Table 44 Dietary burden output – excluding potato

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0.003	0.004	0.08	0.12	Dairy cattle	Kale	leaves	No
Cattle (dairy only)	0.003	0.004	0.08	0.12	Dairy cattle	Kale	leaves	No
Sheep (all diets)	0.003	0.004	0.06	0.10	Lamb	Kale	leaves	No
Sheep (ewe only)	0.002	0.003	0.05	0.10	Ram/Ewe	Kale	leaves	No
Swine (all diets)	0.001	0.003	0.06	0.12	Swine (finishing)	Potato	culls	No
Poultry (all diets)	0.001	0.003	0.02	0.05	Turkey	Potato	culls	No
Poultry (layer only)	0.001	0.002	0.02	0.03	Poultry layer	Potato	culls	No

Consumer Risk Assessment – Scenario 1

The outcome of the consumer risk assessments are summarised in table 45. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

The consumer risk assessment for scenario 1 has been undertaken with the following assumptions:

- The CXLs which have been considered for adoption in GB (i.e. those higher than current MRLs) have been used as inputs in the dietary burden calculation.
- Potato has been excluded based on the dietary burden calculation
- CXLs for products of animal origin have not been considered on the basis that the residue definitions are not comparable.
- For all remaining commodities, the existing MRL (LOQ – 0.005 mg/kg) has been included.

Table 45 Summary of the consumer risk assessments for fipronil – scenario 1

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 388 % of the ADI (infant)	A chronic intake concern has been identified
	PRIMo	The highest IEDI is 311 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 14% of the ARfD (infant/head cabbage†)	No health effects due to acute exposure are expected from the consumption of commodities treated with fipronil
	PRIMo	The highest IESTI is 14% of the ARfD (children/ kales)	

† surrogate for kale

The NESTI and IESTI are below the ARfD. Harm to human health is not expected as a result of acute exposure, and a further consideration is not required.

A chronic risk was observed in the consumer risk assessment for both the UK chronic model and PRIMo. A significant contribution to the chronic exposures is from milk and eggs, with residues at the LOQ. As the chronic exposures exceeded the ADI, harm to

human health cannot be excluded and the UK's appropriate level of protection has not been met.

The chronic risk assessment has been refined as outlined below under scenario 2.

Consumer Risk Assessment – scenario 2

The chronic risk assessment has been considered further, owing to the NEDIs and IEDIs exceeding the ADI.

For the most recent evaluation of the MRLs for fipronil, commodities for which there was no assessed use were not included in the chronic risk assessment (EFSA, 2014). A similar approach has been taken for the targeted review of the MRLs for emamectin benzoate (HSE, 2025).

The following considerations have been made for a refined chronic risk assessment:

- For commodities for which a CXL has been proposed, the input used in the chronic risk assessment is the highest of the STMR (CXL), or the current GB MRL.
- For the CXL on bananas, a zero residue situation was confirmed by the JMPR, therefore, this commodity has been excluded from the calculation.
- For beans with pods, a GAP was received by the JMPR, but based on the data received, no CXL could be recommended. Nevertheless, a global use exists, and this input (as the current MRL) was included in the CRA.
- For sugar beet and sugarcane, a processing factor (pf – 0.022, n=3) is available from the JMPR report for sugar – this has been applied to the chronic risk assessment to reflect the fact that sugarcane and sugar beet are not consumed raw.
- The products of animal origin, including milk and eggs (MRLs set at the LOQ), were excluded from the calculation (residue assumed to be zero). As outlined above residues will not be significant in the diets of livestock and residues are expected to be well below the LOQ MRLs, noting the CXL for potatoes should not be adopted to ensure residues are not found in products of animal origin.
- The remaining plant commodities (MRLs which are set at the LOQ), and no CXL proposed, were excluded from the calculation.

The outcome of the refined chronic consumer risk assessments are summarised in table 46. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 46 Summary of the refined chronic consumer risk assessments for fipronil – scenario 2

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 84% of the ADI (4-6 yr old)	No health effects due to chronic exposure are expected from the consumption of commodities treated with fipronil
	PRIMo	The highest IEDI is 78% of the ADI (GEMS food group 06)	

Conclusions

The draft CXLs for products of animal origin should not be adopted as GB MRLs as the residue definitions are not comparable and HSE is unable to assess the validity of the JMPR residue definition for risk assessment. It is further noted that the STMR/HR values for animal commodities reported by the JMPR do not appear to reflect the separate contribution of fipronil and MB46513 in feed items; hence the STMR/HR values provided are likely to underrepresent the residue levels in products of animal origin.

Given the nature and magnitude of residues in products of animal origin cannot be verified, it is important that the GB LOQ MRLs are not exceeded as a result of livestock being fed treated plant commodities that are imported. The draft CXL for potatoes should not be adopted as a GB MRL as it leads to the dietary burden of livestock exceeding the trigger of 0.004 mg/kg bw/day and hence may lead to significant residues in the diets of livestock. To ensure residues do not arise in products of animal origin, residues in the diets of livestock must be below the trigger.

The draft CXLs for bananas, all root and tuber vegetables (except potatoes and sugar beet), tomatoes, soyabeans, cotton seeds, barley, buckwheat and other pseudocereals, oats, rice, and sugar beet roots do not need to be adopted as GB MRLs, as the existing GB MRL is equivalent to, or greater than, the CXL.

The draft CXLs for onions, all leafy vegetables (based on rotational crops), beans, lupins/lupini beans, lentils, peas, sunflower seeds, maize/corn, common millet/proso millet, sorghum, rye, wheat, and sugar cane may be adopted as GB MRLs.

2.16 Florpyrauxifen-benzyl (341)

Florpyrauxifen-benzyl is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Florpyrauxifen-benzyl was considered by the JMPR as a new active substance. Relevant background information is outlined in Tables 47 and 48.

Table 47 Toxicological reference values

	JMPR	GB	Units
ADI	Not necessary	0.5	mg/kg bw per day
ARfD	Not necessary	Not necessary	n/a

Table 48 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Florpyrauxifen benzyl	Florpyrauxifen benzyl (limited to cereals only)	Yes (cereals only)
	Risk assessment	Not necessary	Florpyrauxifen-benzyl, florpyrauxifen (X11438848) and X11966341, expressed as parent (provisional) †	n/a
Livestock	Enforcement	Sum of florpyrauxifen-benzyl, X11966341 and X11438848, expressed as	Florpyrauxifen benzyl	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		florpyrauxifen-benzyl.		
	Risk assessment	Not necessary	Florpyrauxifen-benzyl, florpyrauxifen (X11438848) and X11966341, expressed as parent (provisional) †	n/a

† The expression of the RD-RA is provisional since the relative toxicity of X11966341 compared with florpyrauxifen-benzyl is not known.

The residue definitions for enforcement in plant commodities are comparable between the JMPR and GB.

The residue definition for risk assessment is not comparable for plants or animal commodities. No RD-RA was set by the JMPR as no toxicological reference values were considered necessary by the JMPR for florpyrauxifen-benzyl, or any of its relevant metabolites. CXL proposals for plant commodities have not been considered further as they are either, the same as, or lower than, the current GB MRL.

It is noted that the expression of the GB RD-RA for plant and animal commodities is provisional pending additional toxicological information on X11966341. For the approval of the active substance, no data gap was specifically listed in the EFSA conclusion and no formal supplementary requirement was listed in the GB MRL Statutory Register. It was noted in the EFSA conclusion that there was a very high margin of safety based on the representative use (rice) – and that further information on the relative toxicity of X11966341 was only required for the consideration of additional uses. Given that no CXLs are recommended for adoption as GB MRLs, no further information is required. It is further noted that the JMPR concluded that X11966341 was covered by the parent – this does not apply in GB and will be reconsidered if further MRLs are requested in the future.

For animal commodities, the inputs for the consumer risk assessment may be calculated in terms of the GB RD-RA. The STMR for all animal commodities (based on the GB RD-RA) is <0.03 mg/kg; no HR is required.

For animal commodities, the residue definition for enforcement is not comparable. The JMPR residue definition is more extensive and includes the metabolites 'X11438848' and 'X11966341'. However, all residues relevant to the consumer risk assessment (STMR only) are <LOQ. On the basis that no measurable residues (relevant to the consumer risk assessment) are expected in animal commodities based on the JMPR dietary burden calculation, the GB MRLs, set at 0.01* mg/kg are sufficient – no further consideration of the CXLs has been made.

From the available metabolism and feeding studies, residues of parent florpyrauxifen-benzyl are not expected in animal commodities at the maximum dietary burden calculated by the JMPR for mammals (18.851 mg/kg DM). It was further noted that florpyrauxifen-benzyl is not fully stable in liver and kidney and degrades to X11438848. Residues of 'X11438848' and 'X11966341' are greater than LOQ in liver and kidney at the maximum JMPR dietary burden. Therefore, the JMPR RD-Enf for products of animal origin, which includes the two metabolites, appears to have merit and would allow appropriate enforcement and monitoring. However, at this time HSE does not recommend that the GB RD-Enf is amended; any further consideration should be addressed as part of a specific application to amend GB MRLs and/or in the renewal assessment of the active substance.

The proposed CXLs and their consideration are outlined in Table 49.

Table 49 CXL proposals for florpyrauxifen-benzyl

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Maize	Maize/Corn	0500030	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Rice, husked	Rice	0500060	0.01*	0.02	The CXL does not need to be adopted as the GB MRL is higher
Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various †	0.09	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.
Group of mammalian	All mammalian species- fats	Various †	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
fats (except milk fats)					set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.
Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various †	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.
Group of milks	Milk	1020000	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.
Group of avian muscle	Poultry - muscle	1016010	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.
Group of avian fat	Poultry - fats	1016020	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of avian, edible offal of	Poultry – liver, kidney and edible offals (other than liver and kidney)	Various	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.
Group of eggs	Birds eggs	1030000	0.03*	0.01*	The GB MRL is equivalent to the CXL as the GB RD-Enf is less extensive and set on the basis of parent only (see text). The CXL does not need to be adopted as the GB MRL is equivalent.

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

Consumer risk assessments have not been undertaken, as no CXLs have been considered for adoption as GB MRLs.

Conclusions

No proposed draft CXLs are recommended for adoption as GB MRLs, as they are either lower or the same as the current GB MRLs. Specifically for products of animal origin, the GB MRLs are set on the basis of parent only and are equivalent to the CXLs which are based on a RD-Enf of the parent being summed with two metabolites.

2.17 Fluazinam (306)

Fluazinam is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Fluazinam was assessed by the JMPR for toxicological only. No residues evaluation was undertaken, and no MRLs were recommended.

2.18 Flubendiamide (242)

Flubendiamide is a non-approved active substance in GB. It was withdrawn as no application for renewal was received. MRLs are established in Part 3a of the GB MRL Statutory Register.

Flubendiamide was considered by the JMPR for new uses. Relevant background information is outlined in Tables 50 and 51.

Table 50 Toxicological reference values

	JMPR	GB	Units
ADI	0.02	0.017	mg/kg bw per day
ARfD	0.2	0.1	mg/kg bw

Table 51 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	flubendiamide	flubendiamide	Yes
	Risk assessment	flubendiamide	flubendiamide (based on representative uses on tomato and bell pepper) Reconsideration is required whether inclusion of non-rat metabolite NNI-0001 des-iodo in risk assessment is necessary for other uses	Yes (GB residue definition based on representative uses on tomato and bell pepper, reconsideration required for additional uses, however CXLs not being adopted as the GB MRL is higher so this has not been considered)
Livestock	Enforcement	flubendiamide	flubendiamide	Yes
	Risk assessment	flubendiamide and flubendiamide-iodophthalimide	Sum of parent flubendiamide (NNI-0001) and NNI-0001-iodophthalimide expressed as flubendiamide	Yes

GB residue definitions were established based on the representative uses (tomatoes and peppers). It was noted that if additional uses are sought in the future, the RD-RA may need to be reconsidered with respect to the potential inclusion of NNI 0001 des-iodo. It should be noted that a consideration of the need to include this metabolite in the RD-RA for teas was recently made by HSE (HSE, 2025). However, as the CXLs will not be adopted as the GB MRLs are higher, this has not been considered further.

The proposed CXLs and their consideration are outlined in Table 52.

Table 52 CXL proposals for flubendiamide

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Rice, husked	Rice	0500060	0.1	0.2	The CXL does not need to be adopted as the GB MRL is higher
Meat (from mammals) other than marine mammals)	All Mammalian species - muscle	Various	0.2	2	The CXL does not need to be adopted as the GB MRL is higher
Group of mammalian fats (except milk fats)†	All Mammalian species- fats	Various	2	2	The CXL does not need to be adopted as the GB MRL is equivalent
Group of edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	Various	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Group of milks	Milk	1020000	0.1	0.1	The CXL does not need to be adopted as the GB MRL is equivalent

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

Dietary exposure estimates have not been undertaken as the proposed draft CXLs are equivalent to, or lower than, the GB MRLs in force.

Conclusions

The proposed draft CXLs for all commodities are all equivalent to or lower than the GB MRLs in force.

2.19 Fluoxapiprolin (285)

Fluoxapiprolin is not currently an approved active substance in GB. However, an application for approval of the active substance in GB has been submitted. No specific MRLs have been established in GB and currently the default LOQ MRL of 0.01* mg/kg applies to all commodities. CXLs will not be considered for fluoxapiprolin at this time.

2.20 Flupyradifurone (285)

Flupyradifurone is an approved active substance in GB. MRLs are established in Part 3 of the GB MRL Statutory Register.

The use of flupyradifurone gives rise to residues of difluoroacetic acid (DFA) for which separate MRLs are established in Part 3 of the GB MRL Statutory Register.

Flupyradifurone was considered by the JMPR for new uses. Relevant background information is outlined in Tables 53 and 54.

Table 53 Toxicological reference values

	JMPR	GB	Units
ADI	0.08	0.064	mg/kg bw per day
ARfD	0.2	0.15	mg/kg bw

These toxicological reference values apply to both flupyradifurone and DFA

Table 54 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Flupyradifurone	1) Flupyradifurone 2) DFA, expressed as DFA	No
	Risk assessment	Sum of flupyradifurone, difluoroacetic acid and 6-chloronicotinic	Sum of flupyradifurone and DFA, expressed as flupyradifurone	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		acid, expressed as parent equivalents.		
Livestock	Enforcement	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.	1) Flupyradifurone 2) DFA, expressed as DFA	No
	Risk assessment	Sum of flupyradifurone and difluoroacetic acid, expressed as parent equivalents.	Sum of flupyradifurone and DFA, expressed as flupyradifurone	Yes

Plant commodities

There are two GB plant residue definitions for enforcement. The first residue definition is the same as the JMPR plant residue definition for enforcement, however there is also a second residue definition for the metabolite DFA. Therefore, overall the plant residue definitions for enforcement are not comparable. The JMPR evaluation provides levels of DFA in the residues trials. Given the residue levels of DFA associated with each trial were easily identified, the calculation of MRLs for DFA has been performed, see table 55.

The residue definitions for plants for risk assessment are not comparable for GB and the JMPR. The residue definition for the JMPR includes an additional metabolite and is therefore more extensive. As the JMPR residue definition is more extensive, the residue levels could be used to perform the risk assessment with an overestimation of the exposure compared to the GB residue definition. However, in this specific case, as the residue levels of DFA were already retrieved to calculate the MRLs for DFA, it was straightforward to calculate the residues according to the GB residue definition for risk assessment, as presented in Table 56.

Residues of DFA are also expected in rotational crops. The draft CXLs do not include the consideration of residues arising in the crops as a result of previous uses. Oilseed rape can be rotated. Olives (table and for oil production) are not considered a rotational crop; however as noted in the approval assessment the impact of accumulation from year on year use needs to be considered. In such cases residues may also remain in the soil and

be available for uptake in the next growing season for permanent and semi-permanent crops where there is an authorised use. Further MRL supplementary information was requested on this issue to support the MRLs established for flupyradifurone and DFA. The data requirements are outlined as footnotes in the GB MRL Statutory Register.

The proposed draft CXLs do not take into account the impact of residues arising in the crops from previous year on year use. However, no decision has yet been delivered on the MRL supplementary information relating to this issue. Therefore, the consideration of the draft CXLs has been considered without prejudice to the outcome of the MRL supplementary information assessment.

As noted, the draft CXLs do not include consideration of residues in rotational crops. Olives are a permanent crop, and accumulation does not need to be considered at this time. Oilseed rape may be rotated; the HR for DFA in rotational crops (winter rape) was 0.15 mg/kg as flupyradifurone; or 0.0495 mg/kg as DFA (30 day PBI), based on a rotational crop study dosed at 2 x125 g/ha on bare soil.

The GAP on which the CXL is based is 2 x 56 g a.s./ha at BBCH 69-79. The scaled HR for oilseed rape on this basis is 0.022 mg/kg. This is < 25 % of the HR for primary uses; as such, consideration of rotational crops is not required for the derivation of the MRL for DFA residues in oilseed rape. Residues of flupyradifurone were <LOQ in all rotated oilseed rape samples (4 trials).

Table 55 Calculation of MRLs for DFA using the JMPR evaluation

Codex commodity description	Residues of DFA, expressed as flupyradifurone† (mg/kg)	Residues of DFA, expressed as DFA†† (mg/kg)	MRL for DFA, expressed as DFA (mg/kg)
Olives	0.025, 0.047, 2 x 0.056, 2 x 0.076, 0.1, 0.17	0.008, 0.016, 2 x 0.018, 2 x 0.025, 0.033, 0.056	MRL _{OECD} : 0.083/ 0.09
Oilseed rape	0.045, 0.099, 0.13, 0.14, 0.15, 0.17, 0.18, 2 x 0.19, 3 x 0.2, 0.23, 0.26, 0.29, 0.48	0.015, 0.033, 0.043, 0.046, 0.050, 0.056, 0.059, 2 x 0.063, 3 x 0.066, 0.076, 0.086, 0.096, 0.158	MRL _{OECD} : 0.195/ 0.2

† Reported in JMPR evaluation; for decline trials, the highest single value of DFA was selected (after the relevant PHI), regardless of whether the highest total value occurred at a different timepoint

†† As the residues of DFA in the JMPR evaluation were expressed as flupyradifurone (MW 288), a molecular weight conversion factor of 0.33 was used to express residues as DFA (MW 96)

Table 56 Calculation of residues according to the GB residue definition for risk assessment

Codex commodity description	GB RD-RA: Sum of flupyradifurone and DFA, expressed as flupyradifurone (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Olives	0.2, 0.28, 0.340, 0.43, 0.56, 0.63, 0.91, 3.31	0.495	3.31
Oilseed rape	0.069, 0.208, 0.216, 0.229, 0.25, 0.256, 0.265, 0.27, 0.28, 0.3, 2 x 0.318, 2 x 0.35, 0.5, 0.64	0.275	0.49

Livestock

There are two GB livestock residue definitions for enforcement. The first residue definition is the same as the JMPR plant residue definition for enforcement, however there is also a second residue definition for the metabolite DFA. Therefore, the livestock residue definitions for enforcement are not comparable. The residue definitions for risk assessment are comparable.

A new set of feeding studies which dosed ruminants and poultry with the metabolite DFA has been evaluated by HSE. The studies demonstrate that residues of DFA in livestock can occur from two different sources: 1) exposure to flupyradifurone, and subsequent metabolism to DFA; 2) direct exposure to DFA through feed items. MRLs have been recalculated in GB based on exposure from both routes.

The JMPR only considered feeding studies dosed with parent flupyradifurone. Residues of DFA resulting from direct exposure via feed are significantly higher than residues which arise as a result of exposure to parent flupyradifurone – based on the most recent dietary burden calculation, residues of DFA in livestock may be as much as 106x higher from direct exposure, compared to exposure from parent compound (HSE, 2025). As such, the CXLs may underestimate exposure to DFA; additionally, specific MRLs are set in GB for DFA. As the levels of DFA cannot be confirmed by the JMPR evaluation, it is not possible to adopt any CXLs relating to flupyradifurone for animal commodities at this time.

In principle, if higher CXLs for products of animal origin cannot be adopted, then the CXLs for plants that can also be feed items should not be adopted as GB MRLs; in the context of an assessment of draft CXLs undertaking a comprehensive dietary burden for livestock is not possible. However, in this specific case a dietary burden assessment has been

undertaken as 1) MRLs for flupyradifurone and DFA for products of animal origin have recently been adopted by HSE and 2) only a CXL for oilseed rape needs to be considered.

Dietary burden impact of oilseed rape CXL

Oilseed rape may be used as an animal feed commodity. The impact of the CXL for oilseed rape on the calculated dietary burden for flupyradifurone and DFA has been considered, based on the most recent dietary burden calculations undertaken in GB (HSE, 2025).

Flupyradifurone

The STMR for flupyradifurone/oilseed rape is 0.11 mg/kg.

The previous dietary burden for parent flupyradifurone (HSE, 2025b) is detailed below; this is compared to the dietary burden with inclusion of the new CXL for oilseed rape.

Table 57 Current dietary burden compared to re-calculated dietary burden including OSR CXL - flupyradifurone

Relevant groups	Maximum DB (mg/kg DM – regulation 544/2011) – <u>HSE 2025</u>	Maximum DB (mg/kg DM – regulation 544/2011) – <u>Current assessment</u>	% difference
Cattle (all diets)	8.54	8.54	0
Cattle (dairy only)	8.54	8.54	0
Sheep (all diets)	16.36	16.36	0
Sheep (ewe only)	16.36	16.36	0
Swine (all diets)	1.29	1.29	0
Poultry (all diets)	3.26	3.26	0
Poultry (layer only)	3.26	3.26	0

The CXL for oilseed rape does not impact the calculated dietary burden for parent flupyradifurone.

DFA, as flupyradifurone

The STMR for DFA (as flupyradifurone)/oilseed rape is 0.19 mg/kg.

The previous dietary burden for DFA, as flupyradifurone (HSE, 2025b) is detailed below; this is compared to the dietary burden with inclusion of the new CXL for oilseed rape.

Table 58 Current dietary burden compared to re-calculated dietary burden including OSR CXL – DFA

Relevant groups	Maximum DB (mg/kg DM – regulation 544/2011) – <u>HSE 2025</u>	Maximum DB (mg/kg DM – regulation 544/2011) – <u>Current assessment</u>	% difference
Cattle (all diets)	8.59	8.59	0
Cattle (dairy only)	7.50	7.50	0
Sheep (all diets)	9.07	9.07	0
Sheep (ewe only)	9.07	9.07	0
Swine (all diets)	7.57	7.57	0
Poultry (all diets)	4.08	4.08	0
Poultry (layer only)	4.08	4.08	0

The CXL for oilseed rape does not impact the calculated dietary burden for DFA, as flupyradifurone.

Table 59 CXL proposals for flupyradifurone

Codex commodity description	GB commodity description	GB commodity code	CXL for flupyradifurone (mg/kg)	GB MRL for flupyradifurone (mg/kg)	MRL calculated for DFA using JMPR evaluation (mg/kg)	GB MRL for DFA (mg/kg)	Comment/ HSE the recommendation on CXL if Codex food accepted as a standard	
							Flupyradifurone	DFA
Table olives	Table olives	0161030	5	0.01*	0.09	0.02*	The CXL can be adopted as a GB MRL	The CXL can be adopted as a GB MRL
Rape seed	Rapeseeds/canola seeds	0401060	0.4	0.01*	0.2	0.05	The CXL can be adopted as a GB MRL	The CXL can be adopted as a GB MRL
Olives for oil production	Olives for oil production	0402010	5	0.01*	0.09	0.02*	The CXL can be adopted as a GB MRL	The CXL can be adopted as a GB MRL
Group of edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	4	Various (0.01* to 0.015)	-	-	CXLs for POAO considered at this	cannot be time, see discussion
Group of avian, edible offal of	Poultry – liver, kidney and edible offals (other than liver and kidney)	Various	4	Various (0.01* to 0.015)	-	-	CXLs for POAO considered at this	cannot be time, see discussion
Group of avian fat	Poultry - fats	1016020	0.3	0.01*	-	-	CXLs for POAO considered at this	cannot be time, see discussion
Group of avian muscle	Poultry - muscle	1016010	0.8	0.01*	-	-	CXLs for POAO considered at this	cannot be time, see discussion
Group of eggs	Birds eggs	1030000	0.7	0.01*	-	-	CXLs for POAO considered at this	cannot be time, see discussion
Group of mammalian fats (except milk fats) †	All mammalian species- fats	Various	1	0.01*	-	-	CXLs for POAO considered at this	cannot be time, see discussion

Codex commodity description	GB commodity description	GB commodity code	CXL for flupyradifurone (mg/kg)	GB MRL for flupyradifurone (mg/kg)	MRL calculated for DFA using JMPR evaluation (mg/kg)	GB MRL for DFA (mg/kg)	Comment/ HSE the CXL if Codex food	recommendation on accepted as a standard
							Flupyradifurone	DFA
Group of milks	Milk	1020000	0.7	0.01*	-	-	CXLs for POAO considered at this	cannot be time, see discussion
Group of muscle (from mammals) other than marine mammals) †	All mammalian species – muscle	Various	1.5	0.01*	-	-	CXLs for POAO considered at this	cannot be time, see discussion

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 60. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 60 Summary of the consumer risk assessments for flupyradifurone

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 73% of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with flupyradifurone
	PRIMo	The highest IEDI is 58% of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 31.7% of the ARfD (4-6 yr old child/oilseeds (based on olives))	No health effects due to acute exposure are expected from the consumption of commodities treated with flupyradifurone
	PRIMo	The highest IESTI is 7% of the ARfD (children/ table olives)	

Conclusions

The proposed draft CXLs for plant commodities are all acceptable and no health effects are expected.

The proposed draft CXLs for POAO should not be considered for adoption at this time. In GB the RD-RA for both plants and livestock include the metabolite DFA. The dietary

burden of livestock via the direct exposure to DFA and the resulting levels in products of animal origin need to be assessed.

2.21 Folpet (041)

Folpet is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

The JMPR assessment was a periodic review of the active substance. Relevant background information is outlined in Tables 61 and 62.

Table 61 Toxicological reference values

	JMPR	GB	Units
ADI	0.1	0.1	mg/kg bw per day
ARfD	Unnecessary	0.2	mg/kg bw

Table 62 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Folpet	Sum of folpet and phthalimide, expressed as folpet	No
	Risk assessment	1. Sum of folpet and phthalamic acid, expressed as folpet 2. Phthalic acid	Sum of folpet and phthalimide, expressed as folpet	No, see below (RD-RA ₁) No (RD-RA ₂)
Livestock	Enforcement	Folpet	Phthalimide, expressed as folpet	No
	Risk assessment	1. Sum of folpet and phthalamic	Sum of folpet and phthalimide,	No, see below (RD-RA ₁)

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		acid, expressed as folpet 2. Phthalic acid	expressed as folpet	No (RD-RA ₂)

The residue definition for both enforcement and risk assessment for plants and livestock are not comparable between the JMPR and GB.

The GB RD-Enf for plants additionally includes phthalimide (expressed as folpet). As the CXLs are expressed in accordance with the JMPR RD-Enf, they are based on residues of folpet only. As residue data for phthalimide is available, the CXLs can be expressed in accordance with the GB RD-Enf. This is presented in Table 62.

There are two JMPR residue definitions for risk assessment for plants. The 1st JMPR residue definition for risk assessment is described as 'sum of folpet and phthalamic acid, expressed as folpet' whereas the GB RD is described as 'sum of folpet and phthalimide, expressed as folpet'. In the JMPR evaluation, residue data for phthalimide is available; the calculated residues in accordance with the GB RD-RA are detailed in Table 61 below. From the JMPR evaluation, phthalimide was found at approximately 1.2x the level of phthalamic acid in bananas (unbagged). As such, the re-calculated STMR/HR based on the GB RD-RA is sufficiently conservative for banana. For barley, phthalimide was found at approximately 0.4x the level of phthalamic acid, as such, the JMPR STMR has been used in the risk assessment.

The 2nd JMPR residue definition for risk assessment is phthalic acid, this is not included in the GB RD-RA. In the JMPR evaluation, residue data for phthalic acid are available. Phthalic acid is a metabolite common to other active substances, it will be considered as part of the separate regulatory process consideration for phosmet (See 2.30).

The JMPR and GB residue definitions for enforcement and risk assessment are not comparable for livestock – the CXLs may not be adopted at this time. In addition, the draft CXLs and GB MRLs are all set at the LOQ for animal commodities; therefore, no further consideration is necessary at this time.

Table 63 Residue endpoints

Commodity	Residues according to GB RD-RA (mg/kg) [§]	STMR	HR
Banana †	0.29, 0.30, 0.49, 0.69, 0.73, 1.21, 1.72	0.69	1.72
Barley	0.11, 0.12, 2 x 0.19, 0.23, 0.30, 0.32, 0.42, 1.1	0.23	-

§ Sum of folpet and phthalimide, expressed as folpet. Phthalimide expressed as folpet using a conversion factor of 2 based on molecular weights (folpet: 296.56 and phthalimide: 147.1))

† Residues in whole fruit

The proposed CXLs and their consideration are outlined in Table 64.

Table 64 CXL proposals for folpet

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	CXL expressed as GB MRL (mg/kg) ‡	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
Wine-grapes	Wine grapes	151020	15	15	20	The CXL does not need to be adopted as the GB MRL is higher
Banana	Banana	0163020	2	3	0.03*	The CXL can be adopted as a GB MRL
Barley	Barley	0500010	1.5	2	1	The CXL can be adopted as a GB MRL
Wheat	Wheat	0500090	0.04	0.3	0.4	The CXL does not need to be adopted as the GB MRL is higher
Meat (from mammals) other than marine mammals)	All Mammalian species - muscle	Various	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	CXL expressed as GB MRL (mg/kg) ‡	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
						adopted as a GB MRL.
Group of mammalian fats (except milk fats)	All Mammalian species-fats	Various	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of avian muscle	Poultry - muscle	1016010	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of avian fat	Poultry - fats	1016020	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	CXL expressed as GB MRL (mg/kg) ‡	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of milks	Milk	1020000	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of eggs	Birds eggs	1030000	0.01*	-	0.05 *	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

‡ Sum of folpet and phthalimide, expressed as folpet

Consumer Risk Assessments

It is noted that residues endpoints have been reported by the JMPR for the whole banana fruit, the pulp/flesh and the peel. The GAP for bananas considered by the JMPR had a PHI of 0 days. Therefore, it is not clear if the residues in the flesh might increase at a longer PHI. The consumer risk assessments have therefore been performed using the residue levels in the whole fruit.

The outcome of the consumer risk assessments are summarised in table 65. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 65 Summary of the consumer risk assessments for folpet

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 59% of the ADI (adult)	No health effects due to chronic exposure are expected from the consumption of commodities treated with folpet
	PRIMo	The highest IEDI is 16% of the ADI (PT general)	
Acute exposure assessment	UK	The highest NESTI is 71.9% of the ARfD (infant/bananas)	No health effects due to acute exposure are expected from the consumption of commodities treated with folpet
	PRIMo	The highest IESTI is 83% of the ARfD (children/bananas)	

Conclusions

The proposed draft CXLs for banana and barley are acceptable and no health effects are expected.

The proposed draft CXLs for all other commodities are lower than the GB MRLs in force. Specifically for products of animal origin, the residue definitions are not compatible between GB and the JMPR.

2.22 Fosetyl (302)

Fosetyl is an approved active substance in GB. The variant of the active substance considered for the approval was fosetyl-AI. MRLs are established in Part 3 of the GB MRL Statutory Register.

Fosetyl was considered by the JMPR for new uses. Relevant background information is outlined in Tables 66 and 67.

Table 66 Toxicological reference values

	JMPR	GB	Units
ADI	1 (for fosetyl- Al and for phosphonic acid expressed as fosetyl-Al)	3 (for fosetyl-Al) 2.25 (for phosphonic acid)	mg/kg bw per day
ARfD	N/A	N/A	mg/kg bw

Table 67 Residue definitions

Commodity	Residue definition type [†]	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl	Yes – comment below
	Risk assessment	Sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid	Phosphonic acid and its salts expressed as phosphonic acid	Yes – comment below
Livestock	Enforcement	Phosphonic acid	Sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl	Yes – comment below

Commodity	Residue definition type [†]	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Phosphonic acid	Phosphonic acid	Yes

[†] The molecular weight of fosetyl is 110 g/mol. The molecular mass of phosphonic acid is 82 g/mol. Therefore, the conversion factor to express the CXL on the basis of fosetyl rather than phosphonic acid is 1.34 (110/82).

The GB and JMPR plant residue definitions for enforcement are expressed differently. The CXLs can be expressed in accordance with the GB residue definition for enforcement using a molecular weight conversion factor (1.34). The GB and JMPR plant residue definitions for risk assessment are different as the GB residue definition includes fosetyl. As fosetyl is rapidly degraded to phosphonic acid in plants, the inclusion of fosetyl is not significant.

The GB and JMPR livestock residue definitions for risk assessment are comparable, however the livestock residue definitions for enforcement are different, as the GB residue definition includes fosetyl. As fosetyl is rapidly degraded to phosphonic acid in plants and animals, the inclusion of fosetyl is not significant. The CXLs expressed as phosphonic acid can be expressed as fosetyl using a molecular conversion factor (1.34).

The proposed draft CXLs and their consideration are outlined in Table 66.

Table 68 CXL proposals for fosetyl

Codex commodity description	GB commodity description	GB commodity code	CXL expressed as phosphonic acid (mg/kg)	CXL expressed as fosetyl (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
Oranges, sweet, sour (including orange-like hybrids), subgroup of	Oranges	0110020	50	67	75	The CXL does not need to be adopted as the GB MRL is higher
Rice (GC 0649) [†]	-	-	40	-	-	The CXL cannot be adopted as a

Codex commodity description	GB commodity description	GB commodity code	CXL expressed as phosphonic acid (mg/kg)	CXL expressed as fosetyl (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
						GB MRL. The commodity description is not compatible between the JMPR and GB.
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals	1016030 1016040 1016050	0.05*	0.07*	0.7*	The CXL does not need to be adopted as the GB MRL is higher
Group of avian fat	Poultry - fats	1016020	0.05*	0.07*	0.7*	The CXL does not need to be adopted as the GB MRL is higher
Group of avian muscle	Poultry - muscle	1016010	0.05*	0.07*	0.7*	The CXL does not need to be adopted as the GB MRL is higher
Group of edible offal (mammalian)	Swine - liver	1011030	0.5	0.7	0.9	The CXL does not need to be adopted as the GB MRL is higher
	Swine – kidney and edible offals	1011040 1011050	0.5	0.7	7	The CXL does not need to be adopted as the GB MRL is higher
	Bovine, sheep, goat, equine,	1012030 1013030 1014030 1015030	0.5	0.7	1.5	The CXL does not need to be adopted as the

Codex commodity description	GB commodity description	GB commodity code	CXL expressed as phosphonic acid (mg/kg)	CXL expressed as fosetyl (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
	other farmed terrestrial animals - liver	1017030				GB MRL is higher
	Bovine, sheep, goat, equine, other farmed terrestrial animals – kidney and edible offals	1012040 1012050 1013040 1013050 1014040 1014050 1015040 1015050 1017040 1017050	0.5	0.7	8	The CXL does not need to be adopted as the GB MRL is higher
Group of eggs	Birds eggs	1030000	0.05	0.07	0.7*	The CXL does not need to be adopted as the GB MRL is higher
Group of mammalian fats (except milk fats)	All mammalian species - fat	Various	0.3	0.4	2	The CXL does not need to be adopted as the GB MRL is higher
Group of milks	Milk	1020000	0.1	0.15	0.4	The CXL does not need to be adopted as the GB MRL is higher
Group of muscle (from mammals)	All mammalian species - muscle	Various	0.15	0.2	0.7*	The CXL does not need to be adopted as the

Codex commodity description	GB commodity description	GB commodity code	CXL expressed as phosphonic acid (mg/kg)	CXL expressed as fosetyl (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
other than marine mammals)						GB MRL is higher

† Insufficient data were available to estimate the residue level in brown rice (husked rice) in accordance with the commodity description for GB.

Consumer Risk Assessments

Dietary exposure estimates have not been undertaken as the proposed draft CXLs are lower than the GB MRLs in force; for rice, the commodity description was not compatible with the GB MRL, and no processing factor was available.

Conclusions

The proposed draft CXLs, except rice, do not need to be adopted as they are lower than the GB MRLs in force.

The proposed draft CXL for rice cannot be adopted as a GB MRL. The GB MRL is set for husked rice (CM 0639 – brown rice). The JMPR evaluation has proposed draft CXLs for rice (GC 0649 – paddy rice with hull/husk) and polished rice (CM 1205 – white rice). The JMPR evaluation did not report residues in brown rice in accordance with the GB commodity description.

2.23 Hexythiazox (176)

HSE are currently assessing new GB MRLs for hexythiazox in raspberries and blackberries, commodities belonging to the subgroup of cane berries. HSE identified chronic intake concerns associated with the existing GB MRLs for hexythiazox. HSE are therefore now undertaking a review of the existing GB MRLs. As part of this review, HSE are also considering the CXLs for hexythiazox. Therefore, HSE are giving no further consideration to the proposed draft CXLs for hexythiazox in the framework of the current evaluation.

2.24 Lambda-cyhalothrin (146)

Lambda-cyhalothrin is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Maleic hydrazide was assessed by the JMPR for toxicology only. A residues evaluation was not undertaken, and no MRLs were recommended.

2.25 Maleic hydrazide (102)

Maleic hydrazide is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Maleic hydrazide was assessed by the JMPR for toxicology only. A residues evaluation was not undertaken, and no MRLs were recommended.

2.26 Methoprene (147)

Methoprene has never been considered for an approval in GB. However, MRLs are established in Part 3 of the GB MRL Statutory Register.

HSE considered CXLs for methoprene as part of the preparation for the 53rd session of the CCPR (HSE, 2023). A chronic intake concern was identified and the CXLs were not recommended for adoption in GB. HSE's previous assessment remains applicable, therefore the proposed draft CXLs should not be adopted as GB MRLs.

2.27 Novaluron (217)

Novaluron is a non-approved active substance in GB. MRLs are established in Part 3 of the GB MRL Statutory Register.

Novaluron was considered by the JMPR for new uses. Relevant background information is outlined in Tables 69 and 70.

Table 69 Toxicological reference values

	JMPR	GB	Units
ADI	0.01	0.01 (provisional – see discussion)	mg/kg bw per day
ARfD	Not necessary	Not necessary	mg/kg bw

Table 70 Residue definitions for novaluron

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Novaluron	Novaluron	Yes
	Risk assessment	Novaluron	Novaluron (provisional – see discussion)	Yes – provisionally
Livestock	Enforcement	Novaluron	Novaluron	Yes
	Risk assessment	Novaluron	Novaluron (provisional – see discussion)	Yes – provisionally

A DAR was prepared by the UK in 2005; however, no conclusion was ever delivered by on the approval of the active substance. Provisional RD-RAs and TRVs(toxicological reference values) were derived in the DAR, but these toxicological reference values and residue definitions for risk assessment have not been formally established in GB.

Subsequently, a reasoned opinion on the adoption of an import tolerance MRL (cranberries) was published by EFSA in 2010. In this assessment, an import tolerance MRL was recommended (and later established) for cranberries on the basis of the provisional RD-RAs and TRVs derived in the DAR; the consumer risk assessment was also regarded as provisional.

It is therefore appropriate to perform a similar provisional risk assessment for the adoption of the CXLs.

The residue definitions for plants and livestock for enforcement and risk assessment are comparable between the JMPR and GB.

The proposed draft CXLs and their consideration are outlined in Table 71.

Table 71 CXL proposal for novaluron

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
Tree nuts, subgroup of	Tree nuts	0120000	0.08	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of muscle (from mammals other than marine mammals)	Swine, bovine, sheep, goat, equine, other farmed terrestrial animals – muscle	Various	0.2	10	The CXL does not need to be adopted as the GB MRL is higher
Group of mammalian fats (except milk fats)	Swine, bovine, sheep, goat, equine, other farmed terrestrial animals – fat	Various	3	10	The CXL does not need to be adopted as the GB MRL is higher
Group of edible offal (mammalian)	Swine, bovine, sheep, goat, equine, other farmed terrestrial animals – Liver, kidney and other edible offals	Various	0.2	0.7	The CXL does not need to be adopted as the GB MRL is higher
Group of avian fat	Poultry - fats	1016020	1.5	0.5	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian muscle	Poultry - muscle	1016010	0.04	0.5	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of avian, edible offal of	Poultry – Liver, kidney and other edible offals	1016030	0.1	0.1	The CXL does not need to be adopted as the GB MRL is equivalent
Group of milks	Milk	1020000	0.2	0.4	The CXL does not need to be adopted as the GB MRL is higher
Group of eggs	Birds eggs	1030000	0.3	0.1	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 72. The outputs from the UK models and PRIMo can be seen in annexes 1-2.

Table 72 Summary of the consumer risk assessments for novaluron

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 203% of the ADI (infant)	A chronic intake concern has been identified.
	PRIMo	The highest IEDI is 194% of the ADI (NL toddler)	
Acute exposure assessment	The active is not allocated. acutely toxic and an ARfD has not been		

Conclusions

The proposed draft CXLs for novaluron are not acceptable as chronic intake concerns have been identified based on the consideration of all uses.

2.28 Permethrin (120)

Permethrin is not an approved active substance in GB. MRLs are currently established for ethoxyquin in part 5 of the GB Statutory Register.

Permethrin was assessed by the JMPR for toxicology only. A residues evaluation was not undertaken, and no MRLs were recommended.

2.29 Phosphonic acid (301)

Phosphonic acid is related to fosetyl-Al; CXLs related to phosphonic acid were considered under fosetyl-Al.

2.30 Phosmet (103)

Phosmet is a non-approved active substance in GB. MRLs are established in Part 3 of the GB MRL Statutory Register.

The JMPR assessment was a periodic review of the active substance.

Phosmet is non-approved in GB and the current GB assessment has not been conducted to modern standards. In addition, the JMPR have evaluated additional toxicological studies which indicate the current GB toxicological reference values (TRVs) are not sufficient. HSE recommends that the CXLs are considered in a separate regulatory process which may include a wider consideration of the current GB TRVs and residue definitions.

2.31 Prochloraz (142)

Prochloraz is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

The JMPR assessment was a periodic review of the active substance. Relevant background information is outlined in Tables 73 and 74.

Table 73 Toxicological reference values

	JMPR	GB	Units
ADI	0.02	0.01	mg/kg bw per day
ARfD	0.2	0.025	mg/kg bw

Table 74 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	sum of prochloraz, N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea (BTS 44595) and N-formyl-N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea (BTS 44596), expressed as prochloraz	Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz	Yes
	Risk assessment	sum of prochloraz and N-formyl-N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea (BTS 44596), expressed as prochloraz	Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz	No - no CF available
Livestock	Enforcement	sum of prochloraz, N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea (BTS 44595) and N-formyl-N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea (BTS 44596), expressed as prochloraz	Sum of prochloraz, BTS 44595 and BTS 44596, expressed as prochloraz	Yes
	Risk assessment	sum of prochloraz, N-formyl-N-propyl-N-[2-(2,4,6-trichlorophenoxy)ethyl]urea (BTS 44596) and 2,4,6-trichlorophenoxyacetic acid (BTS 9608) (free and conjugated), all expressed as prochloraz	Sum of prochloraz and its metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz	No - no CF available

Residue definition for enforcement

The residue definitions for plants and livestock for enforcement are comparable between the JMPR and GB.

For plants, the JMPR included metabolite BTS 44595 in the residue definition for enforcement, but not in the residue definition for risk assessment; excluding a metabolite from the RD-RA and including it in the RD-Enf is a non-standard approach. The JMPR considered that parent prochloraz alone was not suitable for enforcement but that the sum of prochloraz, BTS 44595 and BTS 44596 sufficiently addressed prochloraz residues in the crops considered. When considering the RD-RA, BTS 44595 was a notable metabolite in many treated crops; as this metabolite was not covered by the TRVs for prochloraz and chemical specific TRVs could not be established, it was excluded from the RD-RA on the basis of its exposure being below the threshold for Cramer Class (CC) III compounds.

For animals, metabolite BTS 44595 is included in the residue definition for enforcement for the JMPR, but not in the residue definition for risk assessment. As with plants, it was considered that just parent prochloraz was not suitable for enforcement but that the sum of prochloraz, BTS 44595 and BTS 44596 would sufficiently address prochloraz residues. When considering the definition for risk assessment, BTS 44595 was a notable metabolite in most ruminant tissues but it was also concluded that this metabolite could be excluded on the basis of exposure and the threshold for CC III compounds. Metabolite 9608 was found in amounts higher than metabolite BTS 44596 in poultry muscle, fat and liver, and therefore the JMPR included this in the RD-RA.

Residue definition for risk assessment

The residue definitions for plants and livestock for risk assessment are not comparable between the JMPR and GB. The GB RD-RA for plants and animals include prochloraz and all metabolites containing the 2,4,6-TCP moiety, expressed as prochloraz. The JMPR RD-RA for plants include prochloraz and metabolites BTS 44596 and BTS 44595, expressed as prochloraz. The JMPR RD-RA for animals includes metabolites BTS 44596 and BTS 9608, expressed as prochloraz.

The JMPR considered that due to the method complexity and as 2,4,6-TCP may occur from other sources, that the common moiety residue definition was outdated and not specific. The majority of the supervised trials were analysed according to the common moiety method for total 2,4,6-TCP, expressed as prochloraz, however the JMPR did not consider any such residue trials for the CXLs recommended.

To assess comparability of residue definitions between the JMPR and GB, a consideration of the available metabolism studies has been made (JMPR, 2024).

Plant commodities

In Barley, residues in line with the JMPR RD-RA comprised 2.8% TRR in grain and 1.2% TRR in chaff/straw; residues in line with the GB RD-RA comprised 31% TRR in grain and 11.9% TRR in chaff/straw. A number of wheat metabolism studies were reported by the JMPR, none of these were similar in dose/application timing to the GAPs considered for cereals.

The GAP of the barley metabolism study was similar to the GAP considered by the JMPR for the cereal MRL recommendations. On this basis, the STMR/HRs derived by the JMPR for cereal grain may significantly under-represent the residue in accordance with the GB residue definition for risk assessment. It is not appropriate to apply a conversion factor. The residue definition for cereals are not comparable between GB and the JMPR.

Animal commodities

The table below details the %TRR identified in animal commodities in line with the JMPR RD-RA and the GB RD-RA.

Table 75 Relative TRR covered by JMPR and GB RD-RA for animal commodities

Matrix	%TRR (JMPR RD-RA)	%TRR (GB RD-RA)	% of GB RD-RA covered by JMPR RD-RA
Ruminant milk	23	89.9	25.6%
Ruminant liver	23	74	31.1%
Ruminant kidney	44	70	62.9%
Ruminant muscle	62	76	81.6%
Ruminant renal fat	74	93	79.6%
Ruminant lung	43	76	56.6%
Ruminant heart	69	91	75.8%
Poultry egg white	25	49	51.0%
Poultry egg yolk	55	75	73.3%
Poultry fat	31	39	79.5%
Poultry liver	32	37	86.5%
Poultry breast muscle	50	52	96.2%
Poultry thigh muscle	51	51	100.0%

Considering the metabolites specified in the JMPR residue definitions for both enforcement and risk assessment, these metabolites do not always represent the majority of the residue in animal tissues. Of the draft CXLs proposed by the JMPR, only the CXLs for edible offals (mammalian and avian) and eggs are greater than the current GB MRLs.

The metabolism studies suggest that the JMPR RD-RA covers an average of 63% of the TRR covered by the GB RD-RA in edible offals and eggs. As such, the STMR/HR derived by the JMPR is likely to underrepresent the residue. It is not appropriate to use conversion factors, and as such the CXLs for products of animal origin are not recommended for adoption as GB MRLs.

The proposed CXLs and their consideration are outlined in Table 76.

Table 76 CXL proposals for prochloraz

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Avocado	Avocados	0163010	5	7	The GB MRL is higher than the CXL. The CXL should not be adopted.
Barley	Barley	0500010	0.6	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Oats	Oats	0500050	0.5	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Rye	Rye	0500070	0.15	0.2	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL. Also, the GB MRL is higher than the CXL. The CXL should not be adopted.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Wheat	Wheat	0500090	0.4	0.2	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Meat (from mammals) other than marine mammals)	All Mammalian species - muscle	Various	0.01	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL. Also, the GB MRL is higher than the CXL. The CXL should not be adopted.
Group of mammalian fats (except milk fats)	All Mammalian species-fats	Various	0.02	(sheep, goat): 0.15 (bovine, equine): 0.07 (swine, other): 0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL. Also, the GB MRL is higher than the CXL. The CXL should not be adopted.
Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various	0.4	(swine, sheep, goat) Liver: 0.3 Kidney: 0.05 Edible offals: 0.03* (bovine, equine) Liver: 1.0, Kidney: 0.2 Edible offals: 0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL. Also, the GB MRL for bovine and equine liver is higher than the CXL. The CXL should not be adopted.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
				(other farmed terrestrial animals) Liver: 0.03* Kidney: 0.03* Edible offals: 0.03*	
Group of avian muscle	Poultry - muscle	1016010	0.01*	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL. Also, the GB MRL is higher than the CXL. The CXL should not be adopted.
Group of avian fat	Poultry - fats	1016020	0.01	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL. Also, the GB MRL is higher than the CXL. The CXL should not be adopted.
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals	Various	0.08	Liver - 0.04 Kidney - 0.03* Edible offals (other than liver and kidney) – 0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Group of milks	Milk	1020000	0.02	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
					MRL. Also, the GB MRL is higher than the CXL. The CXL should not be adopted.
Group of eggs	Birds eggs	1030000	0.2	0.1	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

Dietary exposure estimates have not been undertaken as the residue definitions are not compatible between GB and the JMPR.

Conclusions

For the CXLs for cereals and animal commodities, the residue definitions for risk assessment are not compatible between GB and the JMPR. In addition, for rye, mammalian muscle, mammalian fat, mammalian edible offal (except bovine/equine liver), poultry muscle, poultry fat, and milk, the GB MRL is equivalent to or higher than the CXL. Therefore, these proposed CXLs should not be adopted as GB MRLs.

The proposed draft CXL for avocados does not need to be adopted as it is lower than the GB MRLs in force.

2.32 Propiconazole (160)

Propiconazole is a non-approved active substance in GB. MRLs are established in Part 5 of the GB MRL Statutory Register at the limit of quantification.

Propiconazole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 77 and 78.

Table 77 Toxicological reference values

	JMPR	GB	Units
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ADI	0.07	0.04	mg/kg bw per day
ARfD	0.3	0.1	mg/kg bw

Table 78 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Propiconazole	Propiconazole (sum of isomers)	Yes
	Risk assessment	Propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole	Provisional Primary crops: 1. Propiconazole (sum of isomers) 2. CGA 118244 free and glucoside conjugate 3. CGA142856 (TAA) and CGA131013 (TA) Rotational crops: Open Processed commodities: Open	No
Livestock	Enforcement	Propiconazole	Propiconazole (sum of isomers)	Yes
	Risk assessment	Propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole	Provisional 1. Propiconazole and CGA 91305 and CGA 118244 2. 1,2,4-Triazole	No

The residue definitions for plants and livestock for enforcement are comparable between the JMPR and GB.

The residue definitions for plants and livestock for risk assessment are not comparable between the JMPR and GB. For plants the specific triazole derivative metabolites (TDMs) TA and TAA are included in the RD-RA. In addition, the GB RD-RA includes the metabolite CGA 118244 (free and glucoside conjugate). For livestock, the specific TDM 1,2-4-T is included. In addition, the GB RD-RA includes the metabolites CGA 91305 and CGA 118244. These metabolites are regarded as provisional as toxicological reference values for CGA 91305 and CGA 118244 could not be established.

The proposed CXLs and their consideration are outlined in Table 79.

Table 79 CXL proposals for propiconazole

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of edible offal (mammalian)	All mammalian species [†] - liver, kidney, edible offals (other than liver and kidney)	Various	0.2	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of eggs	Birds eggs	1030000	0.01*	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian, edible offal of	Poultry – liver, kidney, edible offals (other than liver and kidney)	Various	0.01*	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian fats	Poultry - fats	1016020	0.01*	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of avian muscle	Poultry - muscle	1016010	0.01*	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of mammalian fats (except milk fats)	All mammalian species [†] - fat	Various	0.05	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of muscle (from mammals other than marine mammals)	All mammalian species [†] - muscle	Various	0.01*	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Group of milks	Milk	Various	0.01*	0.01*	Harmful effects on human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Rice, polished	-	-	-	-	The proposed draft CXL is for polished rice. Part 1 of the GB MRL Statutory Register is for husked rice. The proposed draft CXL has not been considered further since harmful effects on human health cannot be excluded for this active substance.

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

As concluded in the renewal assessment (EFSA, 2017) and the MRL review for propiconazole (HSE, 2022), it is not possible to finalise the residue definitions for risk assessment for plants and livestock. Consequently, it is not known what residues humans and livestock may be exposed to as a result of crops treated with propiconazole.

The risk assessment was unable to demonstrate that the necessary requirements had been met for a range of metabolites that consumers will be exposed to, and toxicological reference values have not been established.

Harmful effects on human health cannot be excluded for residues of propiconazole occurring in food. This includes evidence of a potential risk for consumers from exposure to metabolites for which no toxicological reference values could be established. Consequently, the required level of protection has not been met.

Conclusions

The proposed draft CXLs are not acceptable as harmful effects on human health cannot be excluded for residues of propiconazole occurring in food.

2.33 Pydiflumetofen (309)

Pydiflumetofen is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Pydiflumetofen was considered by the JMPR for new uses. Relevant background information is outlined in Tables 80 to 82.

Table 80 Toxicological reference values

	JMPR	GB	Units
ADI	0.1	0.09	mg/kg bw per day
ARfD	0.3	0.3	mg/kg bw

Table 81 Toxicological reference values for SYN545547 and SYN547891

	JMPR	GB
Chronic risk assessment value	-	Cramer Class III TTC value of 1.5 µg/kg bw/d
Acute risk assessment value	-	Threshold value of 5 µg/kg bw

The metabolites SYN545547 and SYN547891 are found in primary and rotational crops and for the approval of the active substance in GB they were excluded from the RD-RA based on their exposures being below the relevant thresholds for Cramer Class III compounds. These exposure assessments need to be reconsidered for the adoption of new MRLs.

Table 82 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	pydiflumetofen	Pydiflumetofen (sum of isomers)	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	pydiflumetofen	Pydiflumetofen (sum of isomers) †	Yes
Livestock	Enforcement	Pydiflumetofen (sum of isomers)	Pydiflumetofen (sum of isomers)	Yes
	Risk assessment	All animal commodities except for mammalian liver and kidney: Sum of pydiflumetofen and 2,4,6-TCP (2,4,6-trichlorophenol) and its conjugates, expressed as pydiflumetofen Mammalian liver and kidney: Sum of pydiflumetofen; 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates; and SYN547897 and its conjugates, expressed as pydiflumetofen.	All animal commodities except for mammalian kidney: Sum of Pydiflumetofen (sum of isomers) and 2,4,6-trichlorophenol (free and conjugated) expressed as pydiflumetofen Mammalian kidney: Sum of Pydiflumetofen (sum of isomers), 2,4,6-trichlorophenol (free and conjugated) and SYN548263 (free and conjugated), expressed as pydiflumetofen.	Yes – see below

SYN545547 = 3-(difluoromethyl)-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]pyrazole-4-carboxamide

SYN547891 = 3-(difluoromethyl)-N-methoxy-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide

SYN547897 = 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl)ethyl]pyrazole-4-carboxamide

SYN548263 = 2-[[3-(difluoromethyl)-1-methyl-pyrazole-4-carbonyl]-methoxy-amino]propanoic acid

† The metabolites SYN545547 and SYN547891 were excluded from the RD-RA on the basis that the exposures did not exceed the TTC CCIII level or acute threshold level relevant to CCIII compounds.

Plant commodities

The residue definitions for plants for both risk assessment and enforcement are comparable between the JMPR and GB. However, it is noted that the metabolites SYN545547 and SYN547891 were provisionally excluded from the GB RD-RA on the basis that the exposures did not exceed the threshold for Cramer Class III (CC III) compounds. The list of endpoints notes that exposure to these metabolites should be considered for any additional uses.

A consideration of exposure to SYN545547 and SYN547891 has been undertaken below.

Livestock commodities

The residue definition for animal commodities for enforcement are comparable between the JMPR and GB.

The residue definition for risk assessment in animal commodities (except mammalian liver and kidney) are comparable between the JMPR and GB.

The JMPR RD-RA for mammalian liver and kidney includes SYN547897; whilst the GB RD-RA for mammalian kidney includes SYN548263.

The GB RD-RA for mammalian kidney and liver did not include SYN547897 on the basis that anticipated exposures of this metabolite did not exceed the thresholds for CCIII values (HSE, 2024). The maximum calculated HSE dietary burden during the approval of the active was 2.5 mg/kg DM (sheep – all diets); the maximum calculated JMPR dietary burden was 45 mg/kg DM (cattle – Australia). The JMPR DB is greater than the GB DB by a factor of 18. On this basis, and by comparison to the exposure assessments undertaken for the approval of the active substance in GB, exposure to SYN547897 does not exceed the threshold for CC III compounds. Therefore, the metabolite SYN547897 can still be excluded from the GB RD-RA for livestock.

The GB RD-RA includes SYN548263 for mammalian kidney; the JMPR RD-RA does not. On the basis of the ruminant metabolism and feeding studies considered for the approval of the active substance, SYN547897 is expected to be present at up to 8 times the levels of SYN548263 in kidney and significantly higher than the levels of SYN548263 in liver (HSE, 2024). On this basis, the use of the JMPR RD-RA (sum of pydiflumetofen, 2,4,6-TCP (free and conjugates) and SYN547897) for mammalian liver and kidney will

overestimate exposure compared to the GB RD-RA for kidney (sum of pydiflumetofen, 2,4,6-TCP (free and conjugates) and SYN548263 (free and conjugated) and the GB RD-RA for liver (sum of pydiflumetofen and 2,4,6-TCP (free and conjugates)). Using the JMPR RD-RA for liver and kidney is acceptable as a first step in estimating the exposures for UK consumers.

For the purposes of considering the CXLs, the JMPR and GB residue definitions are sufficiently comparable.

For products of animal origin, the data available during the approval was not sufficient to exclude the possibility of preferential metabolism, or the possibility that stereoisomeric changes may occur – as such an assessment factor of x2 was applied to all inputs for animal commodities; the same approach is to be taken here (HSE, 2024).

The proposed CXLs and their consideration are outlined in Table 83.

In addition to the CXLs proposed for adoption by the current CCPR (CAC 56) – a number of CXLs have been previously adopted for pydiflumetofen. Some of these were considered by HSE in previous ER/ROs which supported the draft CXLs considered at the 52nd and 53rd CCPR. No CXLs were adopted as GB MRLs for pydiflumetofen as it was under evaluation as a new active substance in GB.

As a result, all CXLs (including those from the 2018, 2019, and 2021 JMPR Meetings) have been considered in the framework of the current assessment. The majority of the historic CXLs are being assessed in the framework of specific import tolerance/MRL evaluations and therefore have not been considered for adoption as GB MRLs in this assessment.

Table 83 CXL proposals for pydiflumetofen

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
2021	Citrus fruits (group)	Citrus fruits	0110000	0.9	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Tree nuts (group)	Tree nuts	0120000	0.05	0.01*	The CXL should not be adopted at this time as

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
						there is an ongoing assessment.
2021	Pome fruits (group) (except Persimmon, Japanese)	Pome fruits	0130000	0.2	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Peaches (including apricots and nectarine) (subgroup)	Apricots	0140010	1	0.01*	The CXL can be adopted as a GB MRL.
2021	Peaches (including apricots and nectarine) (subgroup)	Peaches	0140030	1	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Cherries (subgroup)	Cherries (sweet)	0140020	2	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Plums (including fresh prunes) (subgroup)	Plums	0140040	0.6	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2018	Small fruit vine climbing (subgroup)	Table grape, Wine grape	0151010, 0151020	1.5	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
2021	Low growing berries (subgroup) (except cranberries)	Strawberries,	0152000	1	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Low growing berries (subgroup) (except cranberries)	Cloudberries, Muntries, Partridge berries	0154020-001, 0154020-006, 0154020-007	1	0.01*	The CXL can be adopted as a GB MRL
2024	Cane berries, subgroup of	Cane fruits	0153000	4	0.01*	The CXL can be adopted as a GB MRL
2021	Bush berries (subgroup)	Blueberries,	0154010	5	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Bush berries (subgroup)	Currants (black, red and white), Gooseberries (green, red and yellow), Rose hips	0154030, 0154040, 0154050	5	0.01*	The CXL can be adopted as a GB MRL
2021	Elderberries	Elderberries	0154080	5	0.01*	The CXL can be adopted as a GB MRL
2021	Citrus fruits (group)	Kumquats	0161040	0.9	0.01*	The CXL can be adopted as a GB MRL
2024	Pitaya	Prickly pears/ cactus fruits	0162040	0.9	0.01*	The CXL can be adopted as a GB MRL
2024	Mango	Mangoes	0163030	0.08	0.01*	The CXL can be adopted as a GB MRL

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
2019	Tuberous and corm vegetables (subgroup)	Potatoes, Tropical root and tuber vegetables	0211000, 0212000	0.1	0.06	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Root vegetables (subgroup)	Other root and tuber vegetables, except sugar beets	0213000	0.3	0.06 or 0.2	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Bulb onions (subgroup)	Garlic, Onions, Shallots	0220010, 0220020, 0220030	0.3	0.06	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Green onions (subgroup)	Spring onions,	0220040,	1.5	0.06	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Fruiting vegetables, other than cucurbits (group) ‡	Tomatoes, Sweet peppers/ bell peppers, Aubergines/ eggplants	0231010, 0231020, 0231030	0.5	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Okra	Okra/lady's fingers	0231040	0.02	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Fruiting vegetables,	Cucurbits with edible peel	0232000	0.4	0.01*	The CXL should not be adopted at this time as

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
	cucurbits (group)					there is an ongoing assessment.
2019	Fruiting vegetables, cucurbits (group)	Cucurbits with inedible peel	0233000	0.4	0.01*	The CXL can be adopted as a GB MRL
2019	Sweet corns (subgroup)	Sweet corns	0234000	0.03	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Martynia	Other fruiting vegetables	0239000	0.02	0.01*	The CXL can be adopted as a GB MRL
2021	Flowerhead brassicas (subgroup)	Broccoli, Cauliflowers, Others - flowering brassica	0241010, 0241020, 0241990	3	0.06	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
2021	Head brassicas (subgroup)	Head brassicas	0242000	2	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Leaves of Brassicaceae (subgroup)	Leafy brassicas	0243000	0.1	0.01*	The CXL can be adopted as a GB MRL
2021	Stem Brassicas (subgroup)	Kohlrabies	0244000	0.1 (based on rotational crops)	0.06	The CXL should not be adopted at this time as there is an ongoing assessment.

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
2024	Lettuce, head	Lettuces	0251020	20	0.06	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
2024	Lettuce, leaf	Lettuces	0251020	30	0.06	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
2021	Green onions (subgroup)	Chives	0256020	1.5	0.06	The CXL can be adopted as a GB MRL
2021	Beans with pods (subgroup)	Beans (with pods)	0260010	0.7	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Succulent beans without pods (subgroup)	Beans (without pods)	0260020	0.15	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Peas with pods (subgroup)	Peas (with pods)	0260030	1.5	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Succulent peas without pods (subgroup)	Peas (without pods),	0260040	0.05	0.01*	The CXL should not be adopted at this time as there is an

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
						ongoing assessment.
2021	Succulent peas without pods (subgroup)	Lentils (fresh)	0260050	0.05	0.01*	The CXL can be adopted as a GB MRL
2021	Underground immature beans and peas (subgroup)	Legume vegetables - others	0260990	0.02 (based on rotational crops)	0.01*	The CXL can be adopted as a GB MRL
2021	Green onions (subgroup)	Leeks	0270060	1.5	0.06	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
2019	Stems and petioles (subgroup)	Cardoons, Celeries, Florence fennels, Rhubarbs	0270020, 0270030, 0270040, 0270070	15	0.06	Harmful effects for human health cannot be excluded with regards to the CXL for cardoons, celeries, rhubarbs and Florence fennels. The CXL should not be adopted as a GB MRL.
2019	Dry beans (subgroup)	Beans, Lupins, Soyabeans	0300010, 0300040, 0401070	0.4	0.01*	The CXL should not be adopted at this time as there is an

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
						ongoing assessment.
2019	Dry peas (subgroup)	Lentils, Peas	0300020, 0300030	0.4	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Small seed oilseeds (subgroup)	Linseeds, Poppy seeds, Rapeseeds/ canola seeds, Mustard seeds, Gold of pleasure seeds	0401010, 0401030, 0401060, 0401080, 0401130	0.9	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2019	Small seed oilseeds (subgroup)	Sesame seeds, Borage seeds	0401040, 0401120	0.9	0.01*	The CXL can be adopted as a GB MRL
2019	Peanut	Peanuts/ groundnuts	0401020	0.05	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Sunflower seeds (subgroup)	Sunflower seeds	0401050	0.5	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2024	Cotton seed	Cotton seeds	0401090	0.6	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment
2019	Barley, similar grains, and pseudocereals	Barley, Oats	0500010, 0500050	3	0.5	The CXL should not be adopted at this time as

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
	with husks (subgroup)					there is an ongoing assessment.
2019	Barley, similar grains, and pseudocereals with husks (subgroup)	Buckwheat and other pseudocereals	0500020	3	0.01*	The CXL can be adopted as a GB MRL
2019	Maize cereals (subgroup)	Maize/corn	0500030	0.04	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Sorghum grain and millet (subgroup) (except sorghum grain)	Common millet/ proso millet	0500040	0.03	0.01*	The CXL can be adopted as a GB MRL
2019	Rice cereals (subgroup)	Rice	0500060	0.03	0.01*	The CXL can be adopted as a GB MRL
2019	Wheat, similar grains, and pseudocereals without husks (subgroup)	Rye, Wheat	0500070, 0500090	0.4	0.08	The CXL should not be adopted at this time as there is an ongoing assessment.
2021	Sorghum grain	Sorghum	0500080	3	0.01*	The CXL should not be adopted at this time as there is an ongoing assessment.
2024	Coffee bean	Coffee beans	0620000	0.2	0.05*	The CXL can be adopted as a GB MRL

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
2019	Roselle	Hibiscus/ roselle	0631020	0.02	0.05*	The CXL does not need to be adopted as the GB MRL is higher
2021	Root vegetables (subgroup)	Sugar beet roots	0900010	0.3	0.06	The CXL can be adopted as a GB MRL
2024	Group of avian muscle	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
2024	Group of avian fat	Poultry - fats	1016020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
2024	Group of avian, edible offal of	Poultry edible offals	1016030, 1016040, 1016050	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
2024	Group of muscle (from mammals other than marine mammals)	All mammalian species - muscle	Various	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
2024	Group of mammalian fats (except milk fats)	All mammalian species - fats	Various	0.1	0.01*	The CXL can be adopted as a GB MRL
2024	Group of edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various	0.1	0.01*	The CXL can be adopted as a GB MRL
2024	Group of milks	Milk	1020000	0.01*	0.01*	The CXL does not need to be

Year of JMPR	Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
						adopted as the GB MRL is equivalent
2024	Group of eggs	Birds eggs	1030000	0.02	0.01*	The CXL can be adopted as a GB MRL

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

‡ This CXL typically also includes okra/ladys fingers, hibiscus/roselle and martynia – in this case, specific CXLs are set for each of these commodities.

SYN545547 and SYN547891

The GB RD-RA agreed for the approval of the active substance included a consideration of the metabolites SYN545547 and SYN547891. These metabolites were excluded from the RD-RA based on their exposures being below the relevant thresholds for CC III compounds. These exposure assessments need to be reconsidered for the adoption of new GB MRLs. The potential exposures has been assessed against the toxicological threshold values detailed in table 81.

The metabolites were not determined in the residue trials supporting the draft CXLs. In order to estimate the potential level of SYN545547 and SYN547891, the ratio of metabolite to parent were taken from the metabolism studies evaluated for the approval of the active substance (HSE, 2024). The ratios are detailed in the tables below. In addition, molecular weight conversion factors of 0.93 and 0.97 apply to SYN545547 and SYN547891, respectively.

Table 84: Conversion factors for SYN547891

Crop fraction (metabolism study)	Individual ratios	Median ratio	Commodities to which ratio applies
Tomato fruit	0.0063, 0.0104, 0.0153, 0.0174	0.01285	Fruit and fruiting vegetables
Oilseed rape seeds	0.0431	0.0431	Oilseeds
Wheat grain	0.0956, 0.102	0.0988	All remaining commodities †

† In the absence of data which covers all commodities, the worst case ratio has been applied to all other commodities

Table 85: Conversion factors for SYN545547

Crop fraction (metabolism study)	Individual ratios	Median ratio	Commodities to which ratio applies
Tomato fruit	0.0145, 0.0188, 0.0358, 0.0393, 0.0976‡	0.0358	Fruit and fruiting vegetables
Oilseed rape seeds	0.156	0.156	All remaining commodities †
Wheat grain	0.0319, 0.0356	0.03375	Cereal grains

† In the absence of data which covers all commodities, the worst case ratio has been applied to all other commodities

‡ As the individual ratios vary significantly for tomato fruit, the highest ratio has been applied in the acute assessment for fruit and fruiting vegetables.

The TTC assessment has been undertaken for all possible CXLs, including those which are to be assessed fully in the framework of a specific import tolerance assessment.

Taking into account the median ratios presented in the table above, STMR and HR values have been estimated for SYN547891 and SYN545547 (except for fruit and fruiting vegetables). For SYN545547, the individual ratios vary significantly for tomato fruit, the highest ratio shall apply for the determination of the HR for fruit and fruiting vegetables.

The estimated STMR and HR values are obtained by applying the median (or highest) ratio to the STMR and HR based on pydiflumetofen only and multiplying by the molecular weight conversion factor.

Table 86 Acute consumer risk inputs for SYN545547 and SYN547891

Commodity	HR (parent) (mg/kg)	Source of HR	HR-SYN545547 (mg/kg)	HR-SYN547891 (mg/kg)
Citrus fruits	0.16	JMPR, 2021	0.015	0.002
Tree nuts	0.03	JMPR, 2021	0.004	0.001
Pome fruit	0.13	JMPR, 2021	0.012	0.002
Apricots	0.8	JMPR, 2021	0.073	0.010
Cherries (sweet)	1.7	JMPR, 2021	0.154	0.020
Peaches	0.8	JMPR, 2021	0.073	0.010
Plums	0.37	JMPR, 2021	0.034	0.004

Commodity	HR (parent) (mg/kg)	Source of HR	HR-SYN545547 (mg/kg)	HR-SYN547891 (mg/kg)
Grapes	0.85	JMPR, 2018	0.077	0.010
Strawberries	0.62	JMPR, 2021	0.056	0.007
Cane fruit	2.6	JMPR, 2024	0.236	0.031
Blueberries	3.9	JMPR, 2021	0.354	0.047
Cranberries (Cloudberrries, Muntries, Partridge berries)	0.62	JMPR, 2021	0.056	0.007
Currants (red, black and white)	3.9	JMPR, 2021	0.354	0.047
Gooseberries (green, red and yellow)	3.9	JMPR, 2021	0.354	0.047
Rose hips	3.9	JMPR, 2021	0.354	0.047
Elderberries	3.9	JMPR, 2021	0.354	0.047
Kumquats	0.76	JMPR, 2021	0.069	0.009
Prickly pear/cactus fruits	0.03	JMPR, 2024	0.003	0.001
Mangoes	0.01	JMPR, 2024	0.001	0.001
Potatoes	0.084	JMPR, 2019	0.012	0.008
Tropical root and tuber vegetables	0.084	JMPR, 2019	0.012	0.008
Other root and tuber vegetables (except sugar beet)	0.25	JMPR, 2021	0.036	0.024

Commodity	HR (parent) (mg/kg)	Source of HR	HR-SYN545547 (mg/kg)	HR-SYN547891 (mg/kg)
Bulb vegetables (except spring onions)	0.2	JMPR, 2021	0.029	0.019
Spring onions	1.39	JMPR, 2021	0.202	0.133
Tomatoes, sweet peppers/ bell peppers, Aubergines/ eggplants	0.42	JMPR, 2019	0.038	0.005
Okra/ lady's fingers	0.02	JMPR, 2019	0.002	0.001
Cucurbits	0.27	JMPR, 2019	0.025	0.003
Sweet corn	0.03	JMPR, 2021	0.004	0.003
Flowering brassica	1.5	JMPR, 2021	0.218	0.144
Head brassica	0.22	JMPR, 2021	0.032	0.021
Leafy brassica	0.09	JMPR, 2019	0.013	0.009
Kohlrabi	0.09	JMPR, 2021	0.013	0.009
Lettuces	18	JMPR, 2024	2.35	1.55
Chives	1.39	JMPR, 2021	0.202	0.133
Beans with pods	0.047	JMPR, 2021	0.007	0.005
Beans without pods	0.099	JMPR, 2021	0.014	0.009
Peas with pods	0.84	JMPR, 2021	0.122	0.081
Peas without pods, lentils (fresh)	0.042	JMPR, 2021	0.006	0.004

Commodity	HR (parent) (mg/kg)	Source of HR	HR-SYN545547 (mg/kg)	HR-SYN547891 (mg/kg)
Legume vegetables – others	0.02	JMPR, 2021	0.003	0.002
Cardoons, celerics, Florence fennels, Rhubarbs	9.3	JMPR, 2019	1.35	0.891
Leeks	1.39	JMPR, 2021	0.202	0.133
Pulses†	0.028	JMPR, 2019	0.004	0.003
Linseeds, poppy seeds, sesame seeds, rapeseeds/ canola seeds, mustard seeds, borage seeds, gold of pleasure seeds †	0.095	JMPR, 2021	0.014	0.004
Peanuts/ groundnuts †	0.03	JMPR, 2021	0.004	0.001
Sunflower seeds †	0.09	JMPR, 2021	0.013	0.001
Soyabeans †	0.028	JMPR, 2021	0.004	0.003
Cotton seeds †	0.063	JMPR, 2024	0.009	0.003
Barley, oats †	0.1	HSE, 2024	0.010	0.015
Buckwheat and other pseudo- cereals †	0.23	JMPR, 2019	0.007	0.022
Maize/corn, common millet/proso millet, rice †	0.03	JMPR, 2019	0.001	0.003
Rye, wheat †	0.025	HSE, 2024	0.003	0.004

Commodity	HR (parent) (mg/kg)	Source of HR	HR-SYN545547 (mg/kg)	HR-SYN547891 (mg/kg)
Sorghum †	0.515	JMPR, 2021	0.016	0.049
Coffee beans	0.01	JMPR, 2024	0.002	0.001
Hibiscus/ roselle	0.02	JMPR, 2019	0.002	0.001
Sugar beet roots	0.25	JMPR, 2021	0.036	0.024

† Mixed commodities, STMR input used in the risk assessment.

Table 87 Chronic consumer risk inputs for SYN545547 and SYN547891

Commodity	STMR (parent) (mg/kg)	Source of STMR	STMR-SYN545547 (mg/kg)	STMR-SYN547891 (mg/kg)
Citrus fruits	0.05	JMPR, 2021	0.002	0.001
Tree nuts	0.01	JMPR, 2021	0.001	0.001
Pome fruit	0.06	JMPR, 2021	0.002	0.001
Apricots	0.21	JMPR, 2021	0.007	0.003
Cherries (sweet)	0.395	JMPR, 2021	0.013	0.005
Peaches	0.21	JMPR, 2021	0.007	0.003
Plums	0.15	JMPR, 2021	0.005	0.002
Grapes	0.29	JMPR, 2018	0.010	0.003
Strawberries	0.185	JMPR, 2021	0.006	0.002
Cane fruit	0.815	JMPR, 2024	0.027	0.010
Blueberries	0.88	JMPR, 2021	0.029	0.011
Cranberries	0.185	JMPR, 2021	0.006	0.002

Commodity	STMR (parent) (mg/kg)	Source of STMR	STMR-SYN545547 (mg/kg)	STMR-SYN547891 (mg/kg)
(Cloudberries, Muntries, Partridge berries)				
Currants (red, black and white)	0.88	JMPR, 2021	0.029	0.011
Gooseberries (green, red and yellow)	0.88	JMPR, 2021	0.029	0.011
Rose hips	0.88	JMPR, 2021	0.029	0.011
Elderberries	0.88	JMPR, 2021	0.029	0.011
Kumquats	0.21	JMPR, 2021	0.007	0.003
Prickly pear/cactus fruits	0.01	JMPR, 2024	0.001	0.001
Mangoes	0.01	JMPR, 2024	0.001	0.001
Potatoes	0.03	JMPR, 2019	0.004	0.003
Tropical root and tuber vegetables	0.03	JMPR, 2019	0.004	0.003
Other root and tuber vegetables (except sugar beet)	0.08	JMPR, 2021	0.016	0.008
Bulb vegetables (except spring onions)	0.07	JMPR, 2021	0.010	0.007
Spring onions	0.36	JMPR, 2021	0.052	0.035
Tomatoes, sweet peppers/ bell peppers,	0.11	JMPR, 2019	0.004	0.001

Commodity	STMR (parent) (mg/kg)	Source of STMR	STMR-SYN545547 (mg/kg)	STMR-SYN547891 (mg/kg)
Aubergines/ eggplants				
Okra/ lady's fingers	0.02	JMPR, 2019	0.003	0.001
Other fruiting vegetables	0.02	JMPR, 2019	0.003	0.001
Cucurbits	0.12	JMPR, 2019	0.004	0.001
Sweet corn	0.03	JMPR, 2021	0.004	0.003
Flowering brassica	0.39	JMPR, 2021	0.057	0.037
Head brassica	0.065	JMPR, 2021	0.009	0.006
Leafy brassica	0.02	JMPR, 2019	0.003	0.002
Kohlrabi	0.02	JMPR, 2021	0.003	0.002
Lettuces	5.3	JMPR, 2024	0.769	0.508
Chives	0.36	JMPR, 2021	0.052	0.035
Beans with pods	0.045	JMPR, 2021	0.007	0.004
Beans without pods	0.033	JMPR, 2021	0.005	0.003
Peas with pods	0.12	JMPR, 2021	0.017	0.012
Peas without pods, lentils (fresh)	0.031	JMPR, 2021	0.004	0.003
Legume vegetables – others	0.02	JMPR, 2021	0.003	0.002
Cardoons, celerics,	4.4	JMPR, 2019	0.638	0.422

Commodity	STMR (parent) (mg/kg)	Source of STMR	STMR-SYN545547 (mg/kg)	STMR-SYN547891 (mg/kg)
Florence fennels, Rhubarbs				
Leeks	0.36	JMPR, 2021	0.052	0.035
Pulses†	0.028	JMPR, 2019	0.004	0.003
Linseeds, poppy seeds, sesame seeds, rapeseeds/ canola seeds, mustard seeds, borage seeds, gold of pleasure seeds †	0.095	JMPR, 2021	0.014	0.004
Peanuts/ groundnuts †	0.03	JMPR, 2021	0.004	0.001
Sunflower seeds †	0.09	JMPR, 2021	0.013	0.001
Soyabeans †	0.028	JMPR, 2021	0.004	0.003
Cotton seeds †	0.063	JMPR, 2024	0.009	0.003
Barley, oats †	0.1	HSE, 2024	0.010	0.015
Buckwheat and other pseudo- cereals †	0.23	JMPR, 2019	0.007	0.022
Maize/corn, common millet/proso millet, rice †	0.03	JMPR, 2019	0.001	0.003
Rye, wheat †	0.025	HSE, 2024	0.003	0.004
Sorghum †	0.515	JMPR, 2021	0.016	0.049
Coffee beans	0.01	JMPR, 2024	0.001	0.001

Commodity	STMR (parent) (mg/kg)	Source of STMR	STMR-SYN545547 (mg/kg)	STMR-SYN547891 (mg/kg)
Hibiscus/ roselle	0.02	JMPR, 2019	0.001	0.001
Sugar beet roots	0.25	JMPR, 2021	0.012	0.008

† Mixed commodities, STMR input used in the risk assessment.

Dietary exposure estimates for SYN545547 and SYN547891

Exposure to each metabolite has been estimated on the basis of the STMR and HR values derived above and the consumption data in the UK model and PRIMo. The extrapolations applied to estimate the metabolite levels are regarded as appropriate for the assessment of the potential exclusion of the metabolites from the RD-RA.

SYN545547

The acute exposures for the majority of crops is below 5.0 µg/kg bw; the table below details the commodities for which the exposures exceed the acute threshold. The full consumer risk output is detailed in Annexes 1-4 of this report.

Table 88 Acute consumer risk outputs SYN545547 – UK model & PRIMo

Commodity	UK model		PRIMo	
	Acute exposure (µg/kg bw)	Critical consumer	Acute exposure (µg/kg bw)	Critical consumer
Lettuces (lettuce leaf)	41.4	4-6 yr old	89	Child
Lettuces (lettuce head)	23	4-6 yr old	49.4	Child
Celeries	11.1	Vegetarian	51	Child
Florence fennels	25.2	Vegetarian	25 (26 – boiled fennel)	Adult
Cardoons	No consumption data	n/a	14 (16 – boiled cardoons)	Adult
Leeks	No exceedance	n/a	12	Child
Rhubarbs	50	Toddler	50	child
Cauliflowers	12.6	Infant	13 (15 – boiled cauliflower)	Child

Broccoli	5.4	4-6 yr old	9.1 (17 – boiled broccoli)	Child
Table grapes	4.7	Toddler	5.6	Child
Peaches	4.0	Toddler	6.9	Child

The chronic exposure to SYN545547 has been calculated excluding the above commodities for which an acute exceedance was identified. The critical chronic exposure to SYN545547 is 0.84 µg/kg bw/day (toddler) using UK consumption data and 0.23 µg/kg bw/day (ES adult) using PRIMo consumption data.

SYN547891

The acute exposures for the majority of crops is below 5.0 µg/kg bw; the table below details the commodities for which the exposures exceed the acute threshold. The full consumer risk output is detailed in Annexes 1-4 of this report.

Table 89 Acute consumer risk outputs SYN547891 – UK model & PRIMo

Commodity	UK model		PRIMo	
	Acute exposure (µg/kg bw)	Critical consumer	Acute exposure (µg/kg bw)	Critical consumer
Lettuces (lettuce leaf)	27.6	4-6 yr old	59	Child
Lettuces (lettuce head)	15.3	4-6 yr old	32.8	Child
Celeries	7.4	Vegetarian	33	Child
Florence fennels	16.6	Vegetarian	17 (40 – boiled fennel)	Adult
Cardoons	No consumption data	n/a	9.2 (11 – boiled cardoons)	Adult
Leeks	No exceedance	n/a	7.8	Child
Rhubarbs	33.1	Toddler	33.2	Child
Cauliflowers	8.3	Infant	8.3 (10 – boiled cauliflower)	Child
Broccoli	No exceedance	n/a	6.0 (11 – boiled broccoli)	Child

The chronic exposure to SYN547891 has been calculated excluding the above commodities for which an acute exceedance was identified. The critical chronic exposure to SYN547891 is 0.53 µg/kg bw/day (toddler) using UK consumption data and 0.17 µg/kg bw/day (NL toddler) using PRIMo consumption data

Conclusion on exposure to SYN545547 and SYN547891

It was concluded in the DAR that, for both SYN545547 and SYN547891, the Cramer Class III TTC value of 1.5 µg/kg bw/d is applicable for the chronic dietary risk assessment and a threshold value of 5 µg/kg bw is applicable for the acute dietary risk assessment, and that exposures do not need to be combined for SYN545547 and SYN547891 due to low plausibility for additive toxicity.

The calculated chronic exposures for both compounds are lower than the TTC set for Cramer Class III substances.

The calculated acute exposures exceed the acute threshold value for lettuces, celeries, Florence fennels, cardoons, leeks, cauliflowers and broccoli. The acute exposures for all other commodities are below the threshold value.

For peaches, table grapes, lettuces, celeries, Florence fennels, cardoons, rhubarbs, leeks, cauliflowers and broccoli:

As the acute exposure estimates exceed the threshold value of 5 µg/kg bw, harmful effects to human health cannot be excluded for these commodities. CXLs for table grapes, peaches, lettuces, celeries, Florence fennels, cardoons, leeks, cauliflowers and broccoli should not be adopted as GB MRLs.

For the remaining CXLs:

As the chronic exposure estimates are all below the Cramer Class III TTC value of 1.5 µg/kg bw/d and the acute exposures are below the threshold value of 5 µg/kg bw, no health effects are expected from the potential exposure to the metabolites SYN545547 and SYN547891.

The conclusion is only applicable to the uses considered in this application and the exposure estimates would need to be reconsidered for any additional or more critical uses.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 90. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

The consumer risk assessment has only been conducted considering the CXLs which are not under consideration in a separate regulatory process, as detailed below:

Apricots, cane fruits, cranberries (cloudberry, muntries, partridge berries), currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries, kumquats, prickly pear/cactus fruits, mangoes, leeks, chives, cucurbits with inedible peel, other fruiting vegetables, others – flowering brassica, leafy brassica, lettuces, lentils (fresh), legume vegetables – others, cardoons, celeries, Florence fennels, rhubarbs, sesame seeds, borage seeds, buckwheat and other pseudo cereals, common millet/proso millet, rice, coffee beans, hibiscus/roselle, sugar beet roots and mammalian edible offals.

It is noted that the CXLs for lettuces, celeries, Florence fennels, cardoons, rhubarbs, and leeks lead to acute exceedances of the CCIII TTC value for SYN545547 and SYN547891; and as such, these CXLs should not be adopted as GB MRLs.

The CXLs for peaches, table grapes, and flowering brassica also leads to acute exceedances of the CCIII TTC value for SYN545547 and/or SYN547891; peaches, table grapes, broccoli and cauliflower are to be considered in a separate regulatory process. The CXL for flowering brassica also applies to 'other-flowering brassica' – in view of the acute exceedance for broccoli and cauliflower, and in the absence of specific consumption data for 'other-flowering brassica', the CXL should not be adopted for 'other-flowering brassica'.

In addition, the current GB MRL is higher than the CXL for hibiscus/roselle.

Table 90 Summary of the consumer risk assessments for pydiflumetofen

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 10% of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of commodities treated with pydiflumetofen
	PRIMo	The highest IEDI is 6 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest IESTI is 14 % of the ARfD (children/ blackberries)	No health effects due to chronic exposure are expected from the consumption of commodities treated with pydiflumetofen
	PRIMo	The highest IESTI is 14 % of the ARfD (children/ melons)	

Conclusions

The proposed draft CXLs for lettuces, celeries, Florence fennels, cardoons, leeks, rhubarbs, cauliflowers and broccoli result in an exceedance of the acute threshold value for the metabolites SYN545547 and SYN547891; as such, harmful effects to human health cannot be excluded and these CXLs should not be adopted as GB MRLs.

The proposed draft CXLs for hibiscus/roselle, milks, mammalian muscle, and all poultry tissues are lower than or equal to the current GB MRLs in force.

The following draft CXLs are acceptable and no health effects are expected: apricots, cane fruits, cloudberry, munties, partridge berries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries, kumquats, prickly pear/cactus fruits, mangoes, chives, cucurbits with inedible peel, other fruiting vegetables, leafy brassica, lentils (fresh), legume vegetables – others, sesame seeds, borage seeds, buckwheat and other pseudo cereals, common millet/proso millet, rice, coffee beans, sugar beet roots, mammalian fat, mammalian edible offals and birds eggs.

The proposed draft CXLs for all other commodities will be considered in the framework of an ongoing import tolerance and MRL evaluation.

2.34 Spinosad (203)

Spinosad is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Spinosad was considered by the JMPR for new uses. Relevant background information is outlined in Tables 91 and 92.

Table 91 Toxicological reference values

	JMPR	GB	Units
ADI	0.02	0.024	mg/kg bw per day
ARfD	Not necessary	Not necessary	mg/kg bw

Table 92 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Sum of spinosyn A and spinosyn D	Spinosad, sum of spinosyn A and spinosyn D	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Sum of spinosyn A and spinosyn D	Spinosad, sum of spinosyn A and spinosyn D	Yes
Livestock	Enforcement	Sum of spinosyn A and spinosyn D	Spinosad, sum of spinosyn A and spinosyn D	Yes
	Risk assessment	Sum of spinosyn A and spinosyn D	Sum of spinosyn A and spinosyn D, with the exception of poultry liver and bird's eggs. Poultry liver and bird's eggs: spinosad, sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and N-demethylated spinosyn D	Yes, with the exception of poultry liver and bird's eggs.

The residue definitions for plants for both risk assessment and enforcement are comparable between the JMPR and GB. The residue definitions for livestock for risk assessment and enforcement are comparable between the JMPR and GB, except for poultry liver and bird's eggs where the risk assessment definition for GB includes O-demethylated spinosyn D and N-demethylated spinosyn D. There is no CXL recommendation for poultry liver, and the CXL for birds eggs is lower than the current GB MRL. Therefore, there is no impact from the differences in residue definitions and this has not been considered further.

The proposed CXLs and their consideration are outlined in Table 93.

Table 93 CXL proposals for spinosad

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Mango	Mangoes	0163030	0.01*	0.02*	The CXL does not need to be adopted as the GB MRL is higher.
Tea, Green, Black (Black fermented and dried)	Teas	0610000	10	0.1*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Cattle fat	Bovine - fat	1012020	3	3	The CXL does not need to be adopted as the GB MRL is equivalent
Cattle meat	Bovine - muscle	1012010	0.3	0.3	The CXL does not need to be adopted as the GB MRL is equivalent
Group of muscle (from mammals other than marine mammals) [except cattle]	Various	Various	2	2-3	The CXL does not need to be adopted as the GB MRL is equivalent or higher
Group of mammalian fats (except milk fats) [except cattle]	Various	Various	2	2-3	The CXL does not need to be adopted as the GB MRL is equivalent or higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of edible offal (mammalian) [except cattle]	Various	Various	0.5	0.5-3	The CXL does not need to be adopted as the GB MRL is equivalent or higher
Group of avian muscle	Poultry - muscle	1016010	0.01	0.2	The CXL does not need to be adopted as the GB MRL is higher
Group of avian fat	Poultry - fats	1016020	0.2	1	The CXL does not need to be adopted as the GB MRL is higher
Group of eggs	Birds eggs	1030000	0.01	0.2	The CXL does not need to be adopted as the GB MRL is higher

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 94. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 94 Summary of the consumer risk assessments for spinosad

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 111% of the ADI (infant)	A chronic intake concern has been identified
	PRIMo	The highest IEDI is 114% of the ADI (NL toddler)	
Acute exposure assessment	The active is not allocated	acutely toxic and an	ARfD has not been.

Conclusions

The draft CXLs for spinosad for all commodities, except tea, do not need to be adopted as GB MRLs as the GB MRL is equivalent or higher.

The draft CXL for tea results in chronic exposures that exceed the ADI and therefore should not be adopted as a GB MRL.

2.35 Tebuconazole (189)

Tebuconazole is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register.

Tebuconazole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 95 and 96.

Table 95 Toxicological reference values

	JMPR	GB	Units
Tebuconazole			
ADI	0.03	0.03	mg/kg bw per day
ARfD	0.3	0.03	mg/kg bw
1,2,4-triazole (1,2,4-T)			
ADI	0.2	0.023	mg/kg bw per day
ARfD	0.3	0.1	mg/kg bw
Triazole alanine (TA)			
ADI	1	0.3	mg/kg bw per day
ARfD	Unnecessary	0.3	mg/kg bw
Triazole acetic acid (TAA)			
ADI	1	1	mg/kg bw per day
ARfD	Unnecessary	1	mg/kg bw
Triazole lactic acid (TLA)			
ADI	Not set	0.3	mg/kg bw per day
ARfD	Not set	0.3	mg/kg bw

Table 96 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Tebuconazole	Tebuconazole	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Tebuconazole	1. Tebuconazole (sum of enantiomers) 2. TA and TLA 3. TAA 4. 1,2,4-T	No
Livestock	Enforcement	Tebuconazole	Sum of tebuconazole, hydroxy-tebuconazole and their conjugates, expressed as tebuconazole	No
	Risk assessment	Tebuconazole	1. Sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole 2. TA and TLA 3. TAA 4. 1,2,4-T	No

The residue definitions for plants for enforcement are comparable between GB and the JMPR, but the residue definitions for risk assessment are different. The GB residue definition includes the TDMs. As the GB MRL is higher than the proposed CXL, the CXL does not need to be adopted so this issue has not been considered further.

For livestock, the residue definitions for both risk assessment and enforcement are not comparable for GB and the JMPR. As no CXLs are proposed for products of animal origin, this issue has not been considered further. The proposed CXLs and their consideration are outlined in Table 97.

Table 97 CXL proposals for tebuconazole

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Cumin seed	Cumin seed	0810050	0.9	1.5	The CXL does not need to be adopted as the GB MRL is higher

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as the proposed draft CXL is lower than the current GB MRL in force.

Conclusions

The proposed draft CXL for cumin seeds is lower than the GB MRL in force.

2.36 Tebufenozide (189)

Tebufenozide is an approved active substance in GB. MRLs are established in part 2 of the GB MRL Statutory Register.

Tebufenozide was considered by the JMPR for new uses. Relevant background information is outlined in Tables 98 and 99.

Table 98 Toxicological reference values

	JMPR	GB	Units
ADI	0.02	0.02	mg/kg bw per day
ARfD	0.9	n/a	mg/kg bw

Table 99 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Tebufenozide	Tebufenozide	Yes
	Risk assessment	Tebufenozide	Sum of tebufenozide and all metabolites containing ethylphenyl and dimethylphenyl,	No, but tentative conversion factors are available.

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			expressed as tebufenozide	
Livestock	Enforcement	Tebufenozide	Tebufenozide	Yes
	Risk assessment	Tebufenozide	Sum of tebufenozide and all metabolites containing ethylphenyl and dimethylphenyl, expressed as tebufenozide	No, but tentative conversion factors are available.

The residue definitions for plants and livestock for enforcement are comparable between the JMPR and GB.

The residue definitions for plants and livestock for risk assessment are not comparable between the JMPR and GB.

Tentative conversion factors were derived in the EFSA MRL review (EFSA, 2018) for some crop groups (fruits, leafy crops and cereals). These conversion factors are deemed to be tentative as they were determined from metabolism studies rather than from residue trials, since no residue trials were performed according to the residue definition for risk assessment. MRL supplementary information requirements were set for 8 trials for lettuce/escaroles and for rice to be fully compliant with the relevant GAPs and RD-RA.

Tentative conversion factors were also derived for animal matrices in the EFSA MRL review. Similarly, these conversion factors were tentative as they were derived from metabolism studies rather than from feeding studies. However, no MRL supplementary data was required to avoid additional vertebrate studies being performed.

The proposed CXLs and their consideration are outlined in Table 100.

Table 100 CXL proposals for tebufenozide

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL if accepted as a Codex food standard
Rice, husked	Rice	0500060	0.6	3.0	The CXL does not need to be adopted as the GB MRL is higher

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of muscle (from mammals other than marine mammals)	All mammals-muscle (except other farmed terrestrial animals) [†]	1011010 1012010 1013010 1014010 1015010	0.03	0.05	The CXL does not need to be adopted as the GB MRL is higher
	Other farmed terrestrial animals - muscle	1017010	0.03	0.01*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Group of mammalian fats (except milk fats)	All mammals-fat (except other farmed terrestrial animals) [†]	1011020 1012020 1013020 1014020 1015020	0.2	0.05	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
	Other farmed terrestrial animals - fat	1017020	0.2	0.02*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Group of edible offal (mammalian)	All mammals-liver (except other farmed terrestrial animals) [†]	1011030 1012030 1013030 1014030 1015030	0.06	0.05	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
	Other farmed terrestrial animals - liver	1017030	0.06	0.02*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
	All mammals-kidney [‡]	1011040 1012040 1013040 1014040 1015040 1017040	0.06	0.02*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
	All mammals - edible offals other than liver and kidney (except other farmed terrestrial animals) [†]	1011050 1012050 1013050 1014050 1015050	0.06	0.05	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
	Other farmed terrestrial animals-edible offals (other than liver and kidney)	1017050	0.06	0.02*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Group of avian muscle	Poultry-muscle	1016010	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian fat	Poultry-fats	1016020	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian, edible offal of	Poultry-liver, kidney and edible offals	1016030 1016040 1016050	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of milks	Milk	1020000	0.02	0.01*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Group of eggs	Birds eggs	1030000	0.02*	0.02*	The CXL does not need to be adopted as the GB MRL is equivalent

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat and equine matrices

‡ The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 101. The outputs from the UK models and PRIMo can be seen in annexes 1-2.

Table 101 Summary of the consumer risk assessments for tebufenozide

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 109 % of the ADI (toddler)	A chronic intake concern has been identified
	PRIMo	The highest IEDI is 68 % of the ADI (NL toddler)	
Acute exposure assessment	The active is not acutely toxic and an ARfD has not been allocated		

Conclusions

The draft CXLs for tebufenozide for all commodities, except rice, mammalian fat, mammalian edible offal and milk, do not need to be adopted as GB MRLs as the GB MRL is equivalent or higher.

The remaining draft CXLs result in chronic exposures that exceed the ADI and therefore should not be adopted as GB MRLs.

2.37 Tetraniliprole (324)

Tetraniliprole has never been considered for an approval in GB; CXLs for tetraniliprole were first adopted as GB MRLs in 2024 (HSE, 2024). MRLs are established in Part 3 of the GB MRL Statutory Register.

Tetraniliprole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 102 and 103.

Table 102 Toxicological reference values

	JMPR	GB	Units
ADI	2.0	-	mg/kg bw per day
ARfD	Unnecessary	-	mg/kg bw

Table 103 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Tetraniliprole	-	N/A
	Risk assessment	Tetraniliprole + tetraniliprole-N-methyl-quinazolinone, expressed as tetraniliprole	-	N/A
Livestock	Enforcement	Tetraniliprole	-	N/A
	Risk assessment	Tetraniliprole + tetraniliprole-N-methyl-quinazolinone, expressed as tetraniliprole	-	N/A

The proposed CXLs and their consideration are outlined in Table 104.

Table 104 CXL proposals for tetraniliprole

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Barley, similar grains, and pseudocereals with husks, subgroup of	Barley	500010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Barley, similar grains, and pseudocereals with husks, subgroup of	Buckwheat and other pseudocereals	500020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Barley, similar grains, and pseudocereals with husks, subgroup of	Oats	500050	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Rice, husked	Rice	500060	0.03	0.01*	The CXL can be adopted as a GB MRL
Wheat, similar grains, and pseudocereals without husks, subgroup of	Rye	500070	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Wheat, similar grains, and pseudocereals without husks, subgroup of	Wheat	500090	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian muscle	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Group of avian fat	Poultry - fats	1016020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of avian, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of eggs	Birds eggs	1030000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Group of mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.15	0.15	The CXL does not need to be adopted as the GB MRL is equivalent
Group of edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	1	1	The CXL does not need to be adopted as the GB MRL is equivalent
Group of milks	Milk	1020000	0.15	0.15	The CXL does not need to be adopted as the GB MRL is equivalent
Meat (from mammals) other than marine mammals)	All Mammalian species - muscle	Various	0.07	0.1	The CXL does not need to be adopted as the GB MRL is higher

† The CXL would apply to GB MRLs for swine, bovine, sheep, goat, equine and other farmed terrestrial animals

CXLs have been proposed for Rice cereals, Subgroup of (GC 2088). As outlined in Part 1 of the GB MRL Statutory Register, in GB MRLs are established for brown rice (husked rice), defined as rice after the removal of the hull from paddy rice (GB commodity 0500060). Therefore, the proposed draft CXL for rice, husked, has been considered for adoption as a GB MRL.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 105. The outputs from the UK models and PRIMo can be seen in annexes 1-2.

Table 105 Summary of the consumer risk assessments for tetraniliprole

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is <1% of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of commodities treated with tetraniliprole.
	PRIMo	The highest IEDI is <1 % of the ADI (NL toddler)	
Acute exposure assessment	The active is not acutely toxic and an ARfD has not been allocated		

Conclusions

The proposed draft CXLs for poultry (fats, muscle, edible offal), bird eggs, mammalian commodities (edible offal, fats and meat), milks, barley and wheat are all equivalent to or lower than the GB MRLs in force.

The proposed draft CXL for husked rice is acceptable and no health effects are expected.

3 Consumer risk assessments

Acute exposure

The acute exposure represents a one-off exposure to a residue or the total exposure in a 24-hour period. The acute dietary exposure assessments are based on a high level consumption (97.5th consumption percentile for consumers only) and the highest residue (HR) supporting the GAP assessed by the JMPR.

The acceptability of the acute exposure is assessed against the acute reference dose (ARfD) which is the amount of residue that can be consumed in one meal or within a 24 hour period with no appreciable risk to human health.

Chronic exposure

The chronic exposure represents a long term constant daily exposure to a residue over a life-time.

The chronic exposure assessments have taken into account all registered uses of the active substance. The assessments have used the relevant supervised trial median residue (STMR) values supporting the GB MRLs and the STMRs supporting the GAPs assessed by the JMPR. In some cases, the STMRs supporting the GB MRLs are not currently available and the GB MRL has been used in the chronic dietary exposure assessment.

The chronic exposure in the PRIMo are based on the mean consumption of the whole population and the STMR. In the UK model, two consumption values per commodity per consumer group are available; a population mean consumption value and a 97.5th percentile consumption value derived from the mean consumption of each individual that consumed the commodity. The model calculates intakes using the STMR and the two different consumption values with the overall chronic exposure calculated using the 'Rees-Day' approach:

Σ 2 highest 97.5th percentile intakes + mean population intakes for all other foods.

The acceptability of the chronic exposure is assessed against the acceptable daily intake (ADI) which is the amount of residue that can be consumed daily over a life-time with no appreciable risk to human health.

The detailed outputs for the consumer risk assessments from the UK models and PRIMo are outlined in annexes 1 - 4 which have been published separately: [GB MRL publications spreadsheet - HSE](#).

Consumption data

Consumption data for some commodities is currently unavailable in the UK models. For these commodities consumption data for other commodities have been used as a surrogate i.e. it is assumed that consumption levels for all consumer groups will be similar to the surrogate commodity. The following surrogate commodities have been used in the assessment of the draft CXLs:

Commodity	Surrogate commodity
Watermelon	Melon
Cloudberries, Muntries, Partridge berries	Blackcurrants
Rose hips, elderberries	Raspberries and blackberries
Kumquats	Lemons and limes
Prickly pears/cactus fruits	Kiwi (unit weight of 0.15 kg)
Chives	Parsley
Kale	Head cabbage
Cardoons	Celery, fennel, rhubarb
Sugar cane	Sugar beet roots

Where no suitable surrogate crop has been identified to cover the lack of consumption data then the dietary exposures calculated using PRIMo are likely to cover UK consumers. In addition, the PRIMo includes the WHO/GEMS food consumption data and includes European consumption data that are in the same WHO/GEMS food clusters as the UK.

4 The recommendations of the Competent Authority

The competent authority has reviewed and undertaken consumer risk assessments for the proposed draft CXLs considered at the 56th session of the CCPR.

HSE recommends the adoption of CXLs for acetamiprid, azoxystrobin, cyclobutrifluram, etonfenprox, fenpropidin, fipronil, flupyradifurone, difluoroacetic acid, folpet, pydiflumetofen, and tetraniliprole.

For the CXLs that are recommended for adoption as GB MRLs, HSE has concluded that the residue levels arising in food will not result in consumer exposures exceeding the toxicological reference values. Therefore, the residue levels for these CXLs are unlikely to have harmful effects on human health.

Where the JMPR has identified a public health concern or no draft CXLs were proposed, then a further consideration by HSE has not been undertaken.

The active substances cyclobutrifluram and tetraniliprole have never been considered for an approval in GB. CXLs for tetraniliprole were first considered for adoption as GB MRLs in 2024 (HSE, 2024). HSE recommends the adoption of the draft CXLs on the basis of the outcome of the consumer risk assessments using the toxicological reference values and residue definitions endorsed by the JMPR. GB specific assessments for these actives (for example for an import tolerance or for an approval of the active substance) will require the submission and assessment of a full toxicological and residues dossier.

A significant number of the proposed draft CXLs are not recommended for adoption as GB MRLs as the GB MRL in force is equivalent to or higher than the proposed draft CXL. Other draft CXLs are not recommended for adoption as GB MRLs due to the following reasons:

- The residue data supporting the JMPR assessment were not compatible with the residue definitions in force in GB and/or;
- The latest approval/ non-approval decision relevant to GB identified consumer risk issues and/or;
- There are ongoing assessments/considerations for the active substance that may impact the MRLs adopted.

A summary of the recommendations for each active substance are outlined in Table 104. The CXLs recommended by HSE for adoption as GB MRLs are outlined in Table 105.

These CXLs should only be adopted as GB MRLs if they are established as Codex Food Standards.

Table 106 The recommendations of the Competent Authority for each active substance

Active substance (JMPR number)	Recommendation	Explanation
Acetamiprid (246)	The CXLs can be adopted	No health effects are expected.
Acibenzolar-S-methyl (228)	No CXLs can be adopted.	The GB and JMPR RD-RAs are not comparable, additionally, tox information is missing for metabolites which are included in the provisional GB RD.
Acynonapryr (333)	No CXLs were recommended	-
Azoxystrobin (229)	All the CXLs which are higher than the GB MRLs can be adopted.	No health effects are expected.
Buprofezin (173)	No CXLs can be adopted.	Harmful effects on human health cannot be excluded for residues of buprofezin occurring in food.
Carfentrazone-ethyl (338)	No CXLs were recommended	-
Chlorpyrifos (017)	No CXLs were recommended	-
Chlormequat (015)	The CXLs do not need to be adopted.	The draft CXLs are lower or equivalent to the GB MRL.
Cyclobutrifluram (239)	The CXLs can be adopted	No health effects are expected.
Cyproconazole (239)	The CXLs do not need to be adopted.	The draft CXLs are lower or equivalent to the GB MRL.
Ethoxyquin (035)	No CXLs were recommended	-
Etofenprox (184)	No CXLs can be adopted.	The draft CXLs for animal commodities are all equivalent to, or lower than, the GB MRLs in force. The draft CXLs for plant commodities cannot be adopted as GB MRLs as the GB and JMPR RD-RAs are not comparable

Active substance (JMPR number)	Recommendation	Explanation
Fenpropidin (340)	The CXL for bananas cannot be adopted. All remaining CXLs which are higher than the GB MRLs can be adopted.	Acute intake concerns were identified for bananas. The CXLs for barley, wheat, sugar beet roots, ruminant liver, and milk, are equivalent to, or lower than the current GB MRL. For the remaining commodities, no health effects are expected.
Fenpyroximate (193)	The CXLs do not need to be adopted.	The draft CXLs are lower or equivalent to the GB MRL.
Fipronil (202)	The CXLs for onions, all leafy vegetables (based on rotational crops), beans, lupins/lupini beans, lentils, peas, sunflower seeds, maize/corn, common millet/proso millet, sorghum, rye, wheat, and sugar cane may be adopted. All remaining CXLs cannot, or do not need to be adopted.	CXLs for animal commodities cannot be adopted as the GB and JMPR RD-RAs are not comparable; in addition the CXLs may underrepresent the residue. The CXL for potatoes cannot be adopted as exceeds the livestock dietary burden trigger. The CXLs for bananas, all root and tuber vegetables (except potatoes and sugar beet), tomatoes, soyabeans, cotton seeds, barley, buckwheat and other pseudocereals, oats, rice, and sugar beet roots are equivalent to, or lower than, the current GB MRL. The remaining draft CXLs are acceptable and no health effects are expected.
Florpyrauxifen-benzyl (341)	The CXLs do not need to be adopted.	The draft CXLs are lower or equivalent to the GB MRL.
Fluazinam (306)	No CXLs were recommended	-

Active substance (JMPR number)	Recommendation	Explanation
Flubendiamide (242)	The CXLs do not need to be adopted.	The draft CXLs are lower or equivalent to the GB MRLs.
Fluoxapiprolin (285)	The CXLs should not be adopted as GB MRLs.	The active substance is currently being evaluated as a new active substance for approval in GB.
Flupyradifurone (285)	The CXLs for plant commodities can be adopted as GB MRLs. The CXLs for animal commodities should not be adopted as GB MRLs.	The CXLs for plant commodities are acceptable and no health effects are expected. The CXLs for animal commodities may underestimate potential exposure to the metabolite DFA.
Folpet (041)	The CXLs for banana and barley may be adopted as GB MRLs. All remaining CXLs do not need to be adopted.	The CXLs for banana and barley are acceptable and no health effects are expected. All remaining CXLs are lower or equivalent to the GB MRL.
Fosetyl-AI (302)	No CXLs can be adopted.	The draft CXL for rice does not comply with the GB commodity description (brown/husked rice). The remaining CXLs are all equivalent to, or lower than, the GB MRLs in force.
Hexythiazox (176)	No CXLs can be adopted.	An MRL review is ongoing in GB for hexythiazox.
Lambda-cyhalothrin (146)	No CXLs were recommended	-
Maleic hydrazide (102)	No CXLs were recommended	-
Methoprene (147)	The CXL cannot be adopted.	Chronic intake concerns were identified.
Novaluron (217)	The CXLs cannot be adopted.	Chronic intake concerns were identified.

Active substance (JMPR number)	Recommendation	Explanation
Permethrin (120)	No CXLs were recommended	-
Phosphonic acid (301)	See fosetyl.	-
Phosmet (103)	No CXLs can be adopted.	The CXLs for phosmet will be considered in a separate regulatory process.
Prochloraz (142)	No CXLs can be adopted.	For cereals and animal commodities, the GB and JMPR RD-RAs are not comparable. The remaining CXLs are all equivalent to, or lower than, the GB MRLs in force.
Propiconazole (160)	No CXLs can be adopted.	Harmful effects cannot be excluded for residues of propiconazole occurring in food.
Pydiflumetofen (309)	The following draft CXLs are acceptable: apricots, cane fruits, cloudberries, muntries, partridge berries, currants (black, red and white), gooseberries (green, red and yellow), rose hips, elderberries, kumquats, prickly pear/cactus fruits, mangoes, chives, cucurbits with inedible peel, other fruiting vegetables, leafy brassica, lentils (fresh), legume vegetables – others, sesame seeds, borage seeds, buckwheat and other pseudo cereals, common millet/proso millet, rice, coffee beans, hibiscus/roselle, sugar beet roots and mammalian edible offals. The remaining CXLs cannot, or do not need to be adopted.	The CXLs listed in the previous column are acceptable and no health effects are expected. Harmful effects cannot be excluded for peaches, table grapes, lettuces, celeries, Florence fennels, cardoons, leeks, rhubarbs, cauliflowers and broccoli. The CXLs for hibiscus/roselle, milks, mammalian muscle, mammalian fat, and all poultry tissues are lower than or equal to the current GB MRL in force. The remaining CXLs not mentioned will be considered in a separate regulatory process.

Active substance (JMPR number)	Recommendation	Explanation
Spinosad (203)	The CXLs cannot be adopted.	The draft CXL is lower than the GB MRL for all CXLs except teas. Chronic intake concerns were identified for teas.
Tebuconazole (189)	The CXL does not need to be adopted.	The draft CXL is lower than the GB MRL.
Tebufofenozide (189)	The CXLs cannot be adopted.	The draft CXLs for all commodities, except rice, mammalian fat, mammalian edible offal and milk, are lower than or equivalent than the GB MRL. Chronic intake concerns were identified for the remaining draft CXLs.
Tetraniliprole (324)	The CXL for rice can be adopted. All remaining CXLs do not need to be adopted.	The CXL for rice is acceptable and no health effects are expected. The remaining CXLs are lower or equivalent to the GB MRL.

Table 107 CXLs recommended by the Competent Authority for adoption as GB MRLs†

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
Acetamiprid				
Enforcement residue	definition for	products of plants	origin: Acetamiprid	
	0300010	Beans	0.15	0.4
	0300020	Lentils	0.15	0.2
	0300030	Peas	0.15	0.2
	0300040	Lupins	0.15	0.2
Azoxystrobin				
Enforcement residue	definition for	products of plants	origin: Azoxystrobin	
	0163010	Avocados	0.01*	1.5
	0163080	Pineapples	0.01*	2
	0233010	Melons	1	5
	0233030	Watermelons	1	5
	0700000	Hops	30	40
Cyclobutrifluram				
Enforcement residue	definition for	products of plants	origin: Cyclobutrifluram	
	0163020	Bananas	0.01* ‡	0.01*
Etofenprox				
Enforcement residue	definition for	products of animal	origin: Etofenprox	
	1011010	Muscle – swine	0.05	0.07
	1011020	Fat – swine	1.5	3
	1011030	Liver – swine	0.05	0.1
	1011040	Kidney – swine	0.05	0.1
	1012010	Muscle – bovine	0.06	0.07
	1012020	Fat – bovine	2	3
	1012030	Liver – bovine	0.06	0.1

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	1012040	Kidney – bovine	0.07	0.1
	1013010	Muscle – sheep	0.05	0.07
	1013020	Fat – sheep	1.5	3
	1013030	Liver – sheep	0.05	0.1
	1013040	Kidney – sheep	0.05	0.1
	1014010	Muscle – goat	0.05	0.07
	1014020	Fat – goat	1.5	3
	1014030	Liver – goat	0.05	0.1
	1014040	Kidney – goat	0.05	0.1
	1015010	Muscle – equine	0.06	0.07
	1015020	Fat – equine	2	3
	1015030	Liver – equine	0.06	0.1
	1015040	Kidney – goat	0.07	0.1
	1016020	Fat – poultry	0.04	0.5
	1016030	Liver – poultry	0.01*	0.02
	1016040	Kidney – poultry	0.01*	0.02
	1017010	Muscle – other farmed terrestrial animals	0.05	0.07
	1017020	Fat – other farmed terrestrial animals	1.5	3
	1017030	Liver – other farmed terrestrial animals	0.05	0.1
	1017040	Kidney – other farmed terrestrial animals	0.05	0.1
	1020010	Cattle – milk	0.07	0.1

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	1020020	Sheep – milk	0.04	0.1
	1020030	Goat – milk	0.04	0.1
	1020040	Horse – milk	0.07	0.1
	1020990	Others – milk and cream	0.04	0.1
	1030000	Birds eggs	0.015	0.1
Fenpropidin				
Enforcement residue methyl-3-piperidin-1-	definition for yl-propyl)-phenyl]	products of animal -propionic acid	origin: Sum of fenpropidin, its salts and 2-methyl-2-[4-(2-	expressed as fenpropidin
	1011010	Muscle – swine	0.02*	0.02
	1011020	Fat – swine	0.02*	0.02
	1011030	Liver – swine	0.2	0.4
	1011040	Kidney – swine	0.05	0.4
	1011050	Edible offals, other than liver and kidney – swine	0.02*	0.4
	1012010	Muscle – bovine	0.02*	0.02
	1012020	Fat – bovine	0.02*	0.02
	1012040	Kidney – bovine	0.1	0.4
	1012050	Edible offals, other than liver and kidney – bovine	0.02*	0.4
	1013010	Muscle – sheep	0.02*	0.02
	1013020	Fat – sheep	0.02*	0.02
	1013040	Kidney – sheep	0.1	0.4

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	1013050	Edible offals, other than liver and kidney – sheep	0.02*	0.4
	1014010	Muscle – goat	0.02*	0.02
	1014020	Fat – goat	0.02*	0.02
	1014040	Kidney – goat	0.1	0.4
	1014050	Edible offals, other than liver and kidney – goat	0.02*	0.4
	1015010	Muscle – equine	0.02*	0.02
	1015020	Fat – equine	0.02*	0.02
	1015040	Kidney – equine	0.1	0.4
	1015050	Edible offals, other than liver and kidney – equine	0.02*	0.4
	1016010	Muscle – poultry	0.02*	0.02
	1016020	Fat – poultry	0.02*	0.02
	1016030	Liver – poultry	0.02*	0.08
	1016040	Kidney – poultry	0.02*	0.08
	1016050	Edible offals, other than liver and kidney – poultry	0.02*	0.08
	1017010	Muscle – other farmed terrestrial animals	0.02*	0.02
	1017020	Fat – other farmed terrestrial animals	0.02*	0.02

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	1017040	Kidney – other farmed terrestrial animals	0.1	0.4
	1017050	Edible offals, other than liver and kidney – other farmed terrestrial animals	0.02*	0.4
	1030000	Birds eggs	0.02*	0.02
Fipronil				
Enforcement residue definition for products of plant origin: Sum fipronil + sulfone metabolite (MB46136) expressed as fipronil				
	0220020	Onions	0.005*	0.03
	0243000	Leafy brassica	0.005*	0.01
	0251000	Lettuces and salad plants	0.005*	0.01
	0252000	Spinaches and similar leaves	0.005*	0.01
	0300010	Beans	0.005*	0.008
	0300020	Lentils	0.005*	0.008
	0300030	Peas	0.005*	0.008
	0300040	Lupins/lupini beans	0.005*	0.008
	0401050	Sunflower seeds	0.005*	0.01
	0500030	Maize/corn	0.005*	0.01
	0500040	Common millet/proso millet	0.005*	0.01
	0500070	Rye	0.005*	0.03

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	0500080	Sorghum	0.005*	0.01
	0500090	Wheat	0.005*	0.03
	0900020	Sugar canes	0.005*	0.01
Flupyradifurone				
Enforcement residue	definition for	products of plant	origin: Flupyradifurone	
	0161030	Table olives	0.01*	5
	0401060	Rapeseeds/canola seeds	0.01*	0.4
	0402010	Olives for oil production	0.01*	5
Difluoroacetic acid				
Enforcement residue	definition for	products of plant	origin: DFA, expressed as DFA	
	0161030	Table olives	0.02*	0.09
	0401060	Rapeseeds/canola seeds	0.05	0.2
	0402010	Olives for oil production	0.02*	0.09
Folpet				
Enforcement residue	definition for	products of plant	origin: Sum folpet and phthalimide, expressed as folpet	
	0163020	Banana	0.03*	3
	0500010	Barley	1	2
Pydiflumetofen				
Enforcement residue	definition for	products of plant	and animal origin: Pydiflumetofen (sum of isomers)	
	0140010	Apricots	0.01*	1
	0154020-001	Cloudberries	0.01*	1
	0154020-006	Muntries	0.01*	1
	0154020-007	Partridge berries	0.01*	1
	0153000	Canefruit	0.01*	4

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	0154030	Currants (black, red and white)	0.01*	5
	0154040	Gooseberries (green, red and yellow)	0.01*	5
	0154050	Rose hips	0.01*	5
	0154080	Elderberries	0.01*	5
	0161040	Kumquats	0.01*	0.9
	0162040	Prickly pears/ cactus fruits	0.01*	0.9
	0163030	Mangoes	0.01*	0.08
	0233000	Cucurbits with inedible peel	0.01*	0.4
	0239000	Other fruiting vegetables	0.01*	0.02
	0243000	Leafy brassicas	0.01*	0.1
	0256020	Chives	0.06	1.5
	0260050	Lentils (fresh)	0.01*	0.05
	0260990	Legume vegetables – others	0.01*	0.02
	0401040	Sesame seeds	0.01*	0.9
	0401120	Borage seeds	0.01*	0.9
	0500020	Buckwheat and other pseudocereals,	0.01*	3
	0500040	Common millet/ proso millet	0.01*	0.03

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	0500060	Rice	0.01*	0.03
	0620000	Coffee beans	0.05*	0.2
	0900010	Sugar beet roots	0.06	0.3
	1011020	Fat – swine	0.01*	0.1
	1011030	Liver – swine	0.01*	0.1
	1011040	Kidney – swine	0.01*	0.1
	1011050	Edible offals (other than liver and kidney) – swine	0.01*	0.1
	1012020	Fat – bovine	0.01*	0.1
	1012030	Liver – bovine	0.01*	0.1
	1012040	Kidney – bovine	0.01*	0.1
	1012050	Edible offals (other than liver and kidney) – bovine	0.01*	0.1
	1013020	Fat – sheep	0.01*	0.1
	1013030	Liver – sheep	0.01*	0.1
	1013040	Kidney – sheep	0.01*	0.1
	1013050	Edible offals (other than liver and kidney) – sheep	0.01*	0.1
	1014020	Fat – goat	0.01*	0.1
	1014030	Liver – goat	0.01*	0.1
	1014040	Kidney – goat	0.01*	0.1
	1014050	Edible offals (other than liver and kidney) – goat	0.01*	0.1

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	1015020	Fat – equine	0.01*	0.1
	1015030	Liver – equine	0.01*	0.1
	1015040	Kidney – equine	0.01*	0.1
	1015050	Edible offals (other than liver and kidney) – equine	0.01*	0.1
	1017020	Fat – other farmed terrestrial animals	0.01*	0.1
	1017030	Liver – other farmed terrestrial animals	0.01*	0.1
	1017040	Kidney – other farmed terrestrial animals	0.01*	0.1
	1017050	Edible offals (other than liver and kidney) – other farmed terrestrial animals	0.01*	0.1
	1030000	Birds eggs	0.01*	0.02
Tetraniliprole				
Enforcement residue	definition for	products of plant	origin: Tetraniliprole	
	0500060	Rice	0.01*	0.03

† The CXLs should only be adopted once accepted as Codex Food Standards and hence included in the Codex Pesticide Residues in Food Online Database

‡ Default LOQ MRL

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Abbreviations

ADI	Acceptable daily intake
ADME	Absorption, distribution, metabolism and excretion
Animal model 2017	EFSA model used to calculate the dietary burden of livestock using the OECD feeding tables
ARfD	Acute reference dose
a.s.	Active substance
BBCH	Growth stages of mono- and dicotyledonous plants
bw	Body weight
CF	Conversion factor
cGAP	Critical GAP
CXL	Codex maximum residue limit
DAR	Draft assessment report
DAT	Days after treatment
DT ₉₀	Period required for 90% dissipation (define method of estimation)
DT ₅₀	Period required for 50% dissipation (define method of estimation)
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GB	Great Britain
GC-MS	Gas chromatography with mass spectrometry

GLP	Good laboratory practice
HPLC-MS/MS (LC-MS/MS)	High-performance liquid chromatography with tandem mass spectrometry
HR	Highest residue
HSE	Health and Safety Executive
IEDI	International estimate of daily intake
IESTI	International estimate of short-term intake
ILV	Independent laboratory validation
ISO	International Organisation for Standardization
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC ₅₀	Lethal concentration, median
LD ₅₀	Lethal dose, median
LOAEL	Lowest observed adverse effect level
LOD	Limit of detection or limit of determination (should be defined)
LoEP	List of endpoints
LOQ	Limit of quantification NB the limit of quantification and limit of determination are the same. Assimilated Regulation 396/2005 refers to the limit of determination Assimilated Regulation 1107/2009 refers to the limit of quantification MRLs marked with an asterisk (e.g. 0.01* mg/kg) are MRLs set at the limit of determination/quantification
MRL	Maximum residue level
NEDI	National estimate of dietary intake
NESTI	National estimate of short-term intake

NOAEL	No observed adverse effect level
NRL	National reference laboratory
OECD	Organisation for Economic Co-operation and Development
PBI	Plant-back interval
PES	Post-extraction solids
Pf	Processing factor
PHI	Preharvest interval
PRIMo	(EFSA) Pesticide Residue Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA	Risk assessment
RD	Residue definition
RD-Enf	Residue definition for enforcement (also referred to as RD-Mo i.e. residue definition for monitoring)
RD-RA	Residue definition for risk assessment
RTI	Re-treatment interval
STMR	Supervised trials median residue
TRR	Total radioactive residue
TTC	Threshold of toxicological concern
WG	Water dispersible granule
WHO	World Health Organization

