

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

Prepared for the 52nd session of the Codex
Committee on Pesticide Residues (CCPR)

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Contents

Summary	4
1 General Approach	6
2 Assessment of the proposed draft CXLs	8
2.1 Acetochlor (280)	10
2.2 Afidopyropen (312)	13
2.3 Azoxystrobin (229)	22
2.4 Benzovindiflupyr (261)	24
2.5 Bifenthrin (178)	26
2.6 Boscalid (221)	26
2.7 Buprofezin (173)	31
2.8 Chlorantraniliprole (230)	34
2.9 Chlorothalonil (081)	36
2.10 Clethodim (187)	39
2.11 Cyclaniliprole (296)	40
2.12 Cypermethrin (118)	47
2.13 Cyprodinil (207)	50
2.14 Dicamba (240)	52
2.15 Dimethoate (027)	60
2.16 Fenazaquin (297)	60
2.17 Flonicamid (282)	65
2.18 Fluazifop-P-butyl (283)	68
2.19 Fluensulfone (265)	73
2.20 Flupyradifurone (285)	78
2.21 Fluxapyroxad (256)	83
2.22 Fosetyl-Al (302)	88
2.23 Glyphosate (158)	93
2.24 Isofetamid (290)	95

2.25	Kresoxim-methyl (199)	99
2.26	Mandestrobin (307)	101
2.27	Mesotrione (277)	106
2.28	Metaflumizone (236)	109
2.29	Metconazole (313)	116
2.30	Methoprene (147)	123
2.31	Pendimethalin (292)	125
2.32	Penthiopyrad (253)	127
2.33	Picoxystrobin (258)	130
2.34	Propiconazole (160)	134
2.35	Pydiflumetofen (309)	136
2.36	Pyflubumide (314)	145
2.37	Pyraclostrobin (210)	145
2.38	Pyridate (315)	149
2.39	Pyrifluquinazon (316)	150
2.40	Pyriofenone (310)	150
2.41	Pyriproxyfen (200)	154
2.42	Spirotetramat (234)	155
2.43	Tebuconazole (189)	159
2.44	Thiabendazole (065)	162
2.45	Tolclofos-methyl (191)	167
2.46	Tolfenpyrad (269)	172
2.47	Triflumuron (317)	179
2.48	Valifenalate (318)	179
2.49	MRLs for Spices	182
3	Consumer risk assessments	187
	Acute exposure	187
	Chronic exposure	187
	Consumption data	188
4	The recommendations of the Competent Authority	189

References	208
Abbreviations	212
Annexes	215

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 52nd session of the CCPR, 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 48 active substances as well as two additional active substances used on spices.

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.

The competent authority recommends the adoption of CXLs for afidopyropen, azoxystrobin, benzovindiflupyr, boscalid, cypermethrin, cyprodinil, flupyradiflurone (and difluoroacetic acid (DFA)), fluxapyroxad, fosetyl, glyphosate, isofetamid, mandestrobin, penthiopyrad, pyraclostrobin, spirotetramat, tolfenpyrad, valifenalate and MRLs for spices (acetamiprid and carbendazim).

For CXLs that are recommended for adoption as GB MRLs the competent authority 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.

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

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 proposed draft CXL for dicamba/cotton seed is not recommended for adoption as the authorisation considered by the JMPR is for a GM variety of cotton that is not currently approved in GB.

For pydiflumetofen, the competent authority recommends that the CXLs are not adopted as GB MRLs owing to the ongoing approval and import tolerance assessments.

For all other proposed draft CXLs not recommended for adoption in GB the competent authority identified the following issues:

- The residue data supporting the JMPR assessment were not compatible with the residue definitions in force in GB; and/or
- Exceedances of the GB toxicological reference values; and/or
- The latest approval assessment for the active substance identified concerns for human health

For these proposed draft CXLs, as the required level of protection has not been met, HSE recommends they are not adopted as GB MRLs.

The CXLs recommended by the Competent Authority for adoption as GB MRLs are outlined in section 4 of this report. These CXLs should only be adopted as GB MRLs when they are established as Codex Food Standards.

1 General Approach

In accordance with Article 5(3) of the General Food Law,¹ where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in Great Britain.

In addition, point (e) of Article 13 of the General Food Law requires Great Britain to promote consistency between international technical standards and food law while ensuring that the high level of protection adopted in Great Britain is not reduced.

This report outlines the review and risk assessments undertaken for the proposed draft CXLs being considered by the 52nd session of the CCPR. The risk assessments have been undertaken by the Chemicals Regulation Division of the Health and Safety Executive.

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 (eg to set Import Tolerances) a full data package would still be required to establish residue definitions and toxicological reference values.

¹ [The General Food Law \(as adopted in GB\)](#)

UK specific consumer risk assessments have been undertaken using the UK models and EFSA PRIMo rev. 3.1.

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 (eg citrus oil, dried tomatoes, rape seed oil) and animal feed items (eg cereal 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 Regulation (EC) No 396/2005 as it applies in GB).

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 52nd 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 CXLs for CCPR 52](#).

The active substances are presented in alphabetical order, with the CXLs considered for spices presented at the end of section 2. 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 eg 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 endorsed by the JMPR 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.
- An asterisk indicates that the MRL is set at the limit of quantification/ determination.

The risk assessments were based on the information available to HSE prior to the 52nd session of the CCPR (26 – 30 July 2021).

The final recommendations from HSE are outlined in the conclusion section for each active substance. An overall summary of the recommendations is outlined in section 4 of this report.

2.1 Acetochlor (280)

Acetochlor 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.

Acetochlor 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	0.01	0.0036	mg/kg bw per day
ARfD	0.1	1.5	mg/kg bw

Table 2 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Sum of compounds hydrolysable with base to EMA and HEMA, expressed in terms of acetochlor	Acetochlor	No
	Risk assessment	Sum of compounds hydrolysable with base to EMA and HEMA, expressed in terms of acetochlor	All compounds forming EMA and HEMA on hydrolysis plus N-oxamic acid, expressed as acetochlor (applicable to cereal grains and rotational crops)	No
Livestock	Enforcement	Sum of compounds	Acetochlor	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		hydrolysable with base to EMA and HEMA, expressed in terms of acetochlor		
	Risk assessment	Sum of compounds hydrolysable with base to EMA and HEMA, expressed in terms of acetochlor	No definition established	No

EMA: 2-ethyl-6-methylaniline

HEMA: 2-(1-hydroxyethyl)-6-methylaniline

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

The residue definition for plants in GB for enforcement is acetochlor only. The available metabolism data demonstrate that acetochlor is extensively metabolised in plants giving rise to a complex metabolic profile. This includes the formation of a number of metabolites including t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid. These metabolites are all hydrolysable to EMA and HEMA. Acetochlor residues are not expected in plant commodities. Therefore, the enforcement residue definition for plants may not be appropriate. However, the JMPR residue definition uses a common moiety method that is not compatible with multi-residue methods. In addition, EMA and HEMA are not unique metabolites to acetochlor (eg they may arise from use of metolachlor). In the MRL review (EFSA, 2013) the metabolite t-sulfinyllactic acid was proposed as a potential suitable marker compound for compliance with MRLs. However, there are currently no validated analytical methods available for this analyte.

Therefore, at this time HSE recommends no changes to the residue definitions for acetochlor.

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

Table 3 CXL proposals for acetochlor

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
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	0.05	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Soya bean (dry)	soyabeans	0401070	1.5	0.01*	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

Consumer Risk Assessments

For the approval of the active substance, it was agreed that the toxicological reference values for acetochlor could be applied to the metabolites t-oxanilic acid, t-sulfinylacetic acid, t-sulfonic acid and s-sulfonic acid (provided they are present with an isomer ratio of 1:1). Based on the available data, it was concluded that the toxicological reference values of acetochlor could apply to the metabolite N-oxamic acid. For the representative use considered in the approval assessment it was concluded that as all metabolites forming EMA and HEMA would be below the limit of quantification then the toxicological reference values for acetochlor could be applied. This position was confirmed in the MRL review (EFSA, 2013) and an MRL reasoned opinion (EFSA, 2015). In conclusion the toxicological reference values for acetochlor cannot be applied when residues of EMA and HEMA above the limit of quantification are found.

An estimation of the dietary intakes has not been undertaken as toxicological reference values have not been established to cover residues of EMA and HEMA.

Conclusions

The proposed draft CXLs are not acceptable as the residue definitions for the JMPR and GB are not comparable. In addition, based on the risk assessment conducted for the approval of the active substance harmful effects on human health cannot be excluded for residues of acetochlor occurring in food. Consequently, the required level of protection has not been met.

2.2 Afidopyropen (312)

Afidopyropen has never been considered for an approval in GB. Therefore, no specific MRLs have been established in the GB MRL Statutory Register and currently the default LOQ MRL of 0.01* mg/kg applies to all commodities.

Afidopyropen was considered by the JMPR as a new active substance. Relevant background information is outlined in Tables 4 and 5.

Table 4 Toxicological reference values

	JMPR	GB	Units
ADI	0.08	N/A	mg/kg bw per day
ARfD	0.2	N/A	mg/kg bw

N/A = Not applicable. The active has not been considered in GB.

Table 5 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Afidopyropen	N/A	N/A
	Risk assessment	Sum of afidopyropen plus M007 †	N/A	N/A
Livestock	Enforcement	Afidopyropen	N/A	N/A
	Risk assessment	All commodities (except liver): Afidopyropen + M001 + CPA/M061 + CPA-carnitine conjugate/M060, expressed as afidopyropen Liver: Afidopyropen + (M001) + CPCA/M061 + CPCA-carnitine	N/A	N/A

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		conjugate/M060 + M017 expressed as afidopyropen		

N/A = Not applicable. The active has not been considered in GB

† The JMPR 2021 (summary report issued October 2021) confirm the residue definition for plants for risk assessment is the sum of afidopyropen plus M007. The JMPR 2019 stated the residue definition was afidopyropen plus M007 expressed as afidopyropen. In this case, stoichiometric correction to parent compound equivalents ($\times 2$) and for molecular weight ($\times 0.5$) would result in an overall factor of 1 and leads to a simple summation of residue concentrations. The JMPR confirmed that this has no impact on the STMRs, HRs and CXLs recommended by the JMPR in 2019.

M001: 3S,4R,4aR,6S, 6aS, 12R,12aS,12bS)-3,6,12-trihydroxy-4-(hydroxymethyl)-4,6a, 12b-trimethyl--9-(pyridin-3-yl)-1, 3,4,4a,5,6,6a,12, 12a,12b-decahydro-2H,11H-benzo- [f] pyrano[4,3-b]chromen-11-one

M007: Dimer of [(3R,6R,6aR,12S,12bR)-3-[(cyclopropanecarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-11-oxo-9-(pyridin-3-yl)-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H,11H-naphtho[2,1-b]pyrano[3,4-e]pyran-4-yl]methyl rac-cyclopropanecarboxylate

CPA/M061: Cyclopropane carboxylic acid

CPA-carnitine conjugate/M060: 2R)-3-carboxy-2- [(cyclopropylcarbonyl)oxy]- N, N, N-trimethylpropan-1- aminium chloride

M017: [(3S,4R,4aR,6S,6aS,12R,12aS,12bS)-3-(cyclopropylcarbonyl)oxy]-6,12-dihydroxy-4,6a,12b-trimethyl-9-(1-oxidopyridin-3-yl)-11-oxo-1,3,4,4a,5,6,6a,12,12a,12b-decahydro-2H, 11H-benzo[f]pyrano[4,3-b]chromen-4-yl]methyl cyclopropane-carboxylate

The proposed CXLs and their consideration are outlined in Table 6.

Table 6 CXL proposals for afidopyropen

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
Cabbages, Head	Head cabbages	0243020	0.5	0.01*	The CXL can be adopted as a GB MRL
Cherries, subgroup of	Cherries (sweet)	0140020	0.03	0.01*	The CXL can be adopted as a GB MRL
Citrus fruits, subgroup of	Citrus fruits	0110000	0.15	0.01*	The CXL can be adopted as a GB MRL
Citrus fruits, subgroup of	Kumquats	0161040	0.15	0.01*	The CXL can be adopted as a GB MRL
Coriander Leaves	Celery leaves [§]	0256030	5	0.01*	The CXL can be adopted as a GB MRL Note the three entries for celery leaves
Cotton seed	Cotton seeds	0401090	0.08	0.01*	The CXL can be adopted as a GB MRL
Cucumber	Cucumbers	0232010	0.7	0.01*	The CXL can be adopted as a GB MRL
Dill leaves	Celery leaves [§]	0256030	5	0.01*	The CXL can be adopted as a GB MRL Note the three entries for celery leaves
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	0.2	0.01*	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
Eggs	Birds eggs	1030000	0.01*	0.01*	The CXL can be adopted as a GB MRL
Eggplants, subgroup of	Aubergines/eggplants	0231030	0.15	0.01*	The CXL can be adopted as a GB MRL
Flowerhead brassicas, subgroup of	Flowering brassicas	0241000	0.4	0.01*	The CXL can be adopted as a GB MRL
Fruiting vegetables, cucurbits - melon, pumpkins and winter squashes, subgroup of	Cucurbits with inedible peel	0233000	0.05	0.01*	The CXL can be adopted as a GB MRL
Ginger (Fresh)	Horseradishes	0213040	0.01*	0.01*	The MRL for fresh ginger root is covered by the MRL for horseradishes. The CXL can be adopted as a GB MRL.
Leafy greens, subgroup of	Lettuces	0251020	2	0.01*	The CXL can be adopted as a GB MRL
Leafy greens, subgroup of	Escarole/ broad leaved endive	0251030	2	0.01*	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
Leafy greens, subgroup of	Spinaches and similar leaves	0252000	2	0.01*	The CXL can be adopted as a GB MRL
Leafy greens, subgroup of	Grape leaves and similar species	0253000	2	0.01*	The CXL can be adopted as a GB MRL
Leafy greens, subgroup of	Chervil	0256010	2	0.01*	The CXL can be adopted as a GB MRL
Leafy greens, subgroup of	Celery leaves ^s	0256030	2	0.01*	CXLs has also been proposed for the commodity dill leaves and coriander leaves (see above). These commodities are listed in Part 1B and the MRL for celery leaves would cover them both. As all commodities are minor, and the CXLs for coriander and dill are acceptable a GB MRL of 5 mg/kg can be adopted for celery leaves.
Leaves of brassicacea, subgroup of	Leafy brassicas	0243000	5	0.01*	An acute intake concern has been identified. The CXL should not be adopted as a GB MRL.
Mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.01*	0.01*	The CXL can be adopted as a GB MRL
Meat (from mammals) other than	All Mammalian species - muscle	Various	0.01*	0.01*	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
marine mammals) †					
Milks	Milk	1020000	0.001*	0.01*	The CXL can be adopted as a GB MRL but at an LOQ of 0.01 mg/kg
Parsley Leaves	Parsley	0256040	5	0.01*	The CXL can be adopted as a GB MRL
Peaches subgroup of	Apricots	0140010	0.015	0.01*	The CXL can be adopted as a GB MRL
Peaches subgroup of	Peaches	0140030	0.015	0.01*	The CXL can be adopted as a GB MRL
Peppers, subgroup of, excluding okra, martynia and roselle	Sweet peppers/bell peppers	0231020	0.1	0.01*	The CXL can be adopted as a GB MRL
Plums, subgroup of	Plums	0140040	0.01*	0.01*	The CXL can be adopted as a GB MRL
Pome fruits, group of, excluding persimmon	Pome fruits	0130000	0.03	0.01*	The CXL can be adopted as a GB MRL
Poultry, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.01*	0.01*	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
Poultry fats	Poultry - fats	1016020	0.01*	0.01*	The CXL can be adopted as a GB MRL
Poultry meat	Poultry - muscle	1016010	0.01*	0.01*	The CXL can be adopted as a GB MRL
Soya bean (dry)	Soyabeans	0401070	0.01*	0.01*	The CXL can be adopted as a GB MRL
Stem and Petioles, subgroup of	Cardoons	0270020	3	0.01*	The CXL can be adopted as a GB MRL
Stem and Petioles, subgroup of	Celeries	0270030	3	0.01*	The CXL can be adopted as a GB MRL
Stem and Petioles, subgroup of	Florence fennels	0270040	3	0.01*	The CXL can be adopted as a GB MRL
Stem and Petioles, subgroup of	Rhubarbs	0270070	3	0.01*	The CXL can be adopted as a GB MRL
Summer squash	Courgettes	0232030	0.07	0.01*	The CXL can be adopted as a GB MRL
Tomatoes, subgroup of	Tomatoes	0231010	0.15	0.01*	The CXL can be adopted as a GB MRL
Tree nuts, subgroup of	Tree nuts	0120000	0.01*	0.01*	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
Tuberous and corm vegetables, Subgroup of	Potatoes	0211000	0.01*	0.01*	The CXL can be adopted as a GB MRL
Tuberous and corm vegetables, Subgroup of	Tropical root and tuber vegetables	0212000	0.01*	0.01*	The CXL can be adopted as a GB MRL
Turmeric root (fresh)	Turmeric/ curcuma	0840030	0.01*	0.01*	MRLs in GB are established for the dried spice. As the data indicate a zero-residue situation, then setting a higher MRL to cover the dried spice is not recommended.

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

§ Note the three entries for celery leaves and the explanation in the table on the GB MRL that can be adopted

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 7. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 7 Summary of the consumer risk assessments for afidopyropen

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 9 % of the ADI (infant and toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with afidopyropen
	EFSA	The highest IEDI is 5 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 103 % of the ARfD (infants/kale - using consumption data for head cabbage) The next highest NESTI is 53 % of the ARfD (7-10 year olds/Chinese cabbage)	An acute intake concern has been identified for kales. No health effects due to acute exposure are expected from the consumption of all other commodities treated with afidopyropen.
	EFSA	The highest IESTI is 106 % of the ARfD (children/kale) The next highest IESTI is 86 % of the ARfD (children/processed escaroles)	

Conclusions

The proposed draft CXL for leaves of brassicacea, subgroup of, 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 all other commodities are acceptable and a risk to consumers is unlikely.

2.3 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 8 and 9.

Table 8 Toxicological reference values

	JMPR	GB	Units
ADI	0.2	0.2	mg/kg bw per day
ARfD	N/A	N/A	mg/kg bw

Table 9 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 (tentative residue definition, EFSA 2013).	Yes

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

For livestock, the enforcement residue definitions are comparable between GB and the JMPR. For risk assessment, the residue definition for livestock is only tentative for GB pending the outcome of the assessment of MRL supplementary information requirements. 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 10.

Table 10 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
Guava	Guavas	0163070	0.2	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 11. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 11 Summary of the consumer risk assessments for azoxystrobin

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 62 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with Azoxystrobin
	EFSA	The highest IEDI is 20 % of the ADI (DE child)	
Acute exposure assessment	UK	The active is not acutely toxic and an ARfD has not been allocated	
	EFSA		

Conclusions

The proposed draft CXL for guava is acceptable and a risk to consumers is unlikely.

2.4 Benzovindiflupyr (261)

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

Benzovindiflupyr was considered by the JMPR for new uses. Relevant background information is outlined in Tables 12 and 13.

Table 12 Toxicological reference values

	JMPR	GB	Units
ADI	0.05	0.05	mg/kg bw per day
ARfD	0.1	0.1	mg/kg bw

Table 13 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Benzovindiflupyr	Benzovindiflupyr	Yes
	Risk assessment	Benzovindiflupyr	Benzovindiflupyr	Yes
Livestock	Enforcement	Benzovindiflupyr	Benzovindiflupyr	Yes
	Risk assessment	Benzovindiflupyr	Benzovindiflupyr and mono-hydroxylated benzovindiflupyr, free and conjugated (SYN546039), expressed as benzovindiflupyr	No

SYN546039: N-[(1R,2R,4S)-9-(dichloromethylene)-2-hydroxy-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxamide

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

For livestock, the residue definitions for enforcement are comparable for GB and the JMPR. However, the residue definitions for risk assessment are different. As no CXLs are proposed for products of animal origin, this issue has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 14.

Table 14 CXL proposals for benzovindiflupyr

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
Bulb onion, subgroup of	Garlic	0220010	0.02	0.01*	The CXL can be adopted as a GB MRL
Bulb onion, subgroup of	Onions	0220020	0.02	0.01*	The CXL can be adopted as a GB MRL
Bulb onion, subgroup of	Shallots	0220030	0.02	0.01*	The CXL can be adopted as a GB MRL
Sugar cane	Sugar canes	0900020	0.4	0.04	The CXL can be adopted as a GB MRL

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 15. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 15 Summary of the consumer risk assessments for benzovindiflupyr

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDIs is 7 % of the ADI (11-14 year olds)	No health effects due to chronic exposure are expected from the consumption of commodities treated with benzovindiflupyr.
	EFSA	The highest IEDI is 5 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 0.3 % of the ARfD (children/onions)	No health effects due to acute exposure are expected from the consumption of commodities treated with benzovindiflupyr
	EFSA	The highest IESTI is 0.3 % of the ARfD (children/onions)	

Conclusions

The proposed draft CXLs are all acceptable and a risk to consumers is unlikely.

2.5 Bifenthrin (178)

A non-approval decision was delivered for bifenthrin following the applicant withdrawing support for the renewal. With regards to the residues/dietary exposure assessment for the approval, toxicological reference values were established, and no consumer intake concerns were identified for the representative uses.

MRLs are established in Part 2 of the GB MRL Statutory Register.

CXLs are proposed for strawberries and straw and fodder (dry) of cereal grains. MRLs are currently not implemented in GB for animal feed items and hence the proposed draft CXL for straw and fodder has not been considered further. For the proposed draft CXL for strawberries, the JMPR identified a public health concern related to the acute exposure. Therefore, this CXL has not been considered further.

Conclusion

A public health concern has been identified by the JMPR for the proposed draft CXL for strawberries and therefore the CXL is not acceptable.

2.6 Boscalid (221)

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

Boscalid was considered by the JMPR for new uses. Relevant background information is outlined in Tables 16 and 17.

Table 16 Toxicological reference values

	JMPR	GB	Units
ADI	0.04	0.04	mg/kg bw per day
ARfD	Not required	Not required	mg/kg bw

Table 17 Residue definitions

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

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Boscalid	Boscalid	Yes
Livestock	Enforcement	Boscalid	All commodities, except liver and kidney: Boscalid. Liver and kidney: sum of boscalid plus its hydroxy metabolite M510F01 including its conjugates expressed as boscalid	No
	Risk assessment	Sum of boscalid and M510F01, including its conjugate, expressed as boscalid.	All commodities, except liver and kidney: Boscalid. kidney: sum of boscalid plus its hydroxy metabolite M510F01 including its conjugates expressed as boscalid.	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			Liver: sum of boscalid, its hydroxy metabolite M510F01 (free and conjugated) and its bound residues (measured as M510F53 and M510F52), expressed as boscalid	

M510F01: 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide

M510F53: N-(4'-chlorobiphenyl-2-yl) acetamide

M510F52: N-(4'-chlorobiphenyl-2-yl) formamide

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

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 draft CXLs and their consideration are outlined in Table 18.

Table 18 CXL proposals for boscalid

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
Cherries, subgroup of	Cherries (sweet)	0140020	5	4	The CXL can be adopted as a GB MRL
Mango	Mangoes	0163030	2	0.01	The CXL can be adopted as a GB MRL
Peaches subgroup of	Apricots	0140010	4	5	The CXL does not need to be adopted as the GB MRL is higher
Peaches subgroup of	Peaches	0140030	4	5	The CXL does not need to be adopted as the GB MRL is higher
Plums, subgroup of	Plums	0140040	1.5	3	The CXL does not need to be adopted as the GB MRL is higher
Pome fruits, group of	Apples	0130010	2	2	The CXL does not need to be adopted as the GB MRL is equivalent
Pome fruits, group of	Pears	0130020	2	1.5	The CXL can be adopted as a GB MRL
Pome fruits, group of	Quinces	0130030	2	1.5	The CXL can be adopted as a GB MRL
Pome fruits, group of	Medlars	0130040	2	0.01*	The CXL can be adopted as a GB MRL
Pome fruits, group of	Loquats/ Japanese medlars	0130050	2	0.01*	The CXL can be adopted as a GB MRL
Pome fruits, group of	Others - pome fruits	0130990	2	0.01*	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
Tea, Green, Black (Black fermented and dried)	Teas	0610000	40	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 19. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 19 Summary of the consumer risk assessments for boscalid

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 62 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with boscalid
	EFSA	The highest IEDI is 74 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The active is not acutely toxic and therefore an ARfD has not been allocated	
	EFSA		

Conclusions

The proposed draft CXLs for apricots, peaches, plums and apples are all equivalent to or lower than the GB MRLs in force.

The proposed draft CXLs for all other commodities are acceptable and a risk to consumers is unlikely.

2.7 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. Toxicological reference values could also not be established for several metabolites included in the residue definition for risk assessment.

MRLs are established in Part 5 of the GB MRL Statutory Register at the LOQ.

Buprofezin was considered by the JMPR for new uses along with an additional consideration of the exposure to aniline.

Relevant background information is outlined in Tables 20 and 21.

Table 20a 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 20b 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

It is noted that the JMPR has evaluated additional data, including a new in vivo genotoxicity study, that was not assessed as part of the risk assessment for the approval of buprofezin. A consideration of these data along with a full review of all the available data would be required in order to establish toxicological reference values for aniline in GB.

Table 21 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	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			under acidic conditions and expressed as buprofezin	
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 for products of animal origin are all at the LOQ and therefore this issue has not been considered further.

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

Table 22 CXL Proposals for buprofezin

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
Eggs	Bird eggs	1030000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Mammalian fats except milk fats	Milk	1020000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry, edible offal of	Poultry – liver, kidney, edible offal	Various	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
Poultry fats	Poultry Fat	1016020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry meat	Poultry muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Tree nuts	Tree nuts	0120000	0.05*	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.

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.

Conclusion

The proposed draft CXLs for products of animal origin are all at the LOQ and are equivalent to the GB MRLs.

The proposed draft CXL for tree nuts is recommended at an LOQ of 0.05* mg/kg which is higher than the current GB MRL of 0.01* mg/kg. The proposed draft CXL is 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.

2.8 Chlorantraniliprole (230)

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

Chlorantraniliprole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 23 and 24.

Table 23 Toxicological reference values

	JMPR	GB	Units
ADI	2	1.56	mg/kg bw per day
ARfD	N/A	N/A	mg/kg bw

Table 24 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Chlorantraniliprole	Chlorantraniliprole	Yes
	Risk assessment	Chlorantraniliprole	Chlorantraniliprole	Yes
Livestock	Enforcement	Chlorantraniliprole	Chlorantraniliprole	Yes
	Risk assessment	Chlorantraniliprole	Sum of chlorantraniliprole and the metabolites IN-HXH44 and IN-K9T00, expressed as chlorantraniliprole	No

IN-HXH44: 3-bromo-N-[4-chloro-2-(hydroxymethyl)-6-(methylcarbamoyl)phenyl]-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide

IN-K9T00: 3-bromo-N-{4-chloro-2-(hydroxymethyl)-6-[(hydroxymethyl)carbamoyl]phenyl}-1-(3-chloro-2-pyridinyl)-1H-pyrazole-5-carboxamide

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

For livestock, the residue definitions for enforcement are comparable between GB and the JMPR. However, the residue definitions for risk assessment are different. As no CXLs are proposed for products of animal origin, this issue has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 25.

Table 25 CXL proposals for chlorantraniliprole

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 (except soya beans)	Beans	0300010	0.3	0.3	The CXL does not need to be adopted as the GB MRL is equivalent
Dry peas, subgroup of	Peas	0300030	0.3	0.3	The CXL does not need to be adopted as the GB MRL is equivalent
Palm fruit	Oil palms fruits	0402030	0.8	0.8	The CXL does not need to be adopted as the GB MRL is equivalent

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as no CXLs are being recommended for adoption as GB MRLs.

Conclusion

The proposed draft CXLs are equivalent to the GB MRLs in force.

2.9 Chlorothalonil (081)

Chlorothalonil is a non-approved active substance in GB. In the assessment for the renewal of the approval several concerns were raised that impact human health, including evidence of a potential genotoxic risk to consumers. Therefore the risk assessment was unable to demonstrate that the necessary requirements were satisfied.

MRLs are established in Part 2 of the GB MRL Statutory Register.

Chlorothalonil was considered by the JMPR for new uses. Relevant background information is outlined in Tables 26 and 27.

Table 26a Toxicological reference values for chlorothalonil

	JMPR	GB	Units
ADI	0.02	0.015	mg/kg bw per day
ARfD	0.6	0.05	mg/kg bw

Table 26b Toxicological reference values for SDS-3701

	JMPR	GB	Units
ADI	0.008	Could not be established	mg/kg bw per day
ARfD	0.03	Could not be established	mg/kg bw

SDS-3701: 2,4,5-trichloro-6-hydroxybenzene-1,3- dicyanonitrile (2,5,6-trichloro-4-hydroxyisophthalonitrile)

Table 26c Toxicological reference values for SDS-46851

	JMPR	GB	Units
ADI	Covered by chlorothalonil	0.5	mg/kg bw per day
ARfD	Covered by chlorothalonil	0.83	mg/kg bw

SDS-46851: 3-carbamoyl-2,4,5-trichlorobenzoic acid

Table 26d Toxicological reference values for R417888

	JMPR	GB	Units
ADI	Covered by chlorothalonil	Could not be established	mg/kg bw per day
ARfD	Covered by chlorothalonil	Could not be established	mg/kg bw

R417888: 2-carbamoyl-3,5,6-trichloro-4-cyanobenzene-1- sulfonic acid

Table 27 Residue definitions

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

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	1) Chlorothalonil 2) SDS 3701	1) Chlorothalonil and its conjugates 2) SDS 3701 and its conjugates 3) R613636 for processed commodities 4) R611965 and conjugates of metabolites R613636, R613800 and R611968 (for rotational crops) (Provisional)	No
Livestock	Enforcement	SDS-3701	SDS-3701	Yes
	Risk assessment	SDS-3701	SDS-3701 (provisional)	Yes

SDS-3701: 2,4,5-trichloro-6-hydroxybenzene-1,3- dicarbonitrile (2,5,6-trichloro-4-hydroxyisophthalonitrile)

R613636: 2,3,4,6-tetrachloro-5-cyanobenzamide

R611965: 3-carbamoyl-2,4,5-trichlorobenzoic acid

R613800: 2,5-dichloro-4,6-bis(sulfanyl)benzene-1,3- dicarbonitrile

R611968: 2,4,5-trichloro-3-cyano-6-hydroxybenzamide

The residue definitions for enforcement for both plants and livestock are comparable between GB and the JMPR. The residue definitions for risk assessment for plants are not comparable. The GB residue definition is only provisional and contains additional metabolites. The residue definition is provisional on the basis of the data

gaps identified for the plant metabolism studies, storage stability studies and the toxicity of the metabolites.

The GB residue definitions for risk assessment for livestock are comparable between GB and the JMPR. However, for GB the residue definition is only provisional as further information on the metabolism in ruminants and the toxicity of metabolites is required.

The proposed draft CXLs and their consideration are outlined in Table 28.

Table 28 CXL Proposals for chlorothalonil

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
Cranberry	Cranberries	0154020	15	5	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.

Consumer Risk Assessments

An estimation of the dietary intakes has not been undertaken as the risk assessment undertaken for the approval of the active substance identified several concerns that impact human health, including evidence of a potential genotoxic risk to consumers. Therefore the risk assessment was unable to demonstrate that the necessary requirements were satisfied.

Conclusion

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

2.10 Clethodim (187)

Clethodim is an 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. The JMPR has recommended that all CXLs are withdrawn. The JMPR was unable to conclude on the toxicological relevance of a number of metabolites and hence residue definitions could not be proposed for risk assessment.

Conclusion

A public health concern has been identified by the JMPR and as all CXLs were recommended to be withdrawn they are not acceptable.

2.11 Cyclaniliprole (296)

The active was previously assessed for approval as a new active substance in GB. The active was voluntarily withdrawn in October 2016 and a non-approval decision has been delivered.

Substantial data gaps were identified in the assessment that impact the dietary exposure assessment. This included the residue level of several metabolites in crops and processed fractions, that consumers will be exposed to through the diet, for which a genotoxic potential could not be excluded.

MRLs are established in Part 5 of the GB MRL Statutory Register.

Cyclaniliprole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 29 and 30.

Table 29 Toxicological reference values

	JMPR	GB	Units
ADI	0.04	0.0043	mg/kg bw per day
ARfD	Not required	Not required	mg/kg bw

Table 30 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Cyclaniliprole	Cyclaniliprole	Yes
	Risk assessment	Cyclaniliprole + NK-1375, expressed as cyclaniliprole	Cyclaniliprole and metabolite NK-1375 (provisional)	No
Livestock	Enforcement	Cyclaniliprole	Cyclaniliprole	Yes
	Risk assessment	Cyclaniliprole	Cyclaniliprole and	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			metabolites NSY-28 and NK-1375 (provisional)	

NK-1375: 3-bromo-2((2-bromo-4H-pyrazolo[1,5d]pyrido[3,2-b]-[1,4]oxazin4-ylidene)amino)-5-chloro-N(1-cyclopropylethyl) benzamide

NSY-28: -chloropyridin-2-yl)-1H-pyrazol-5-yl]-6-chloroquinazolin-4(3H)-one

The residue definitions for enforcement for both plants and livestock are comparable between GB and the JMPR. The residue definitions for risk assessment for both plants and livestock cannot be considered comparable as for GB the residue definitions are only provisional.

For plants, the residue definition for risk assessment is provisional in GB as additional information on the toxicity of NK-1375 is required. In addition, a conclusion on the residue definition for processed foods could not be established as additional information on the metabolites YT-1327 (3-bromo-N-[(1RS)-1-cyclopropylethyl]-1H-pyrazole-5-carboxamide), BCPBA (3-bromo-5-chloro-2-[(3-chloropyridin-2-yl)amino]benzoic acid) and BPQO (4-bromo-2,6-dichloro-11H-pyrido[2,1-b]quinazolin-11-one) is required. These metabolites were not identified in the plant metabolism studies or the ADME studies. Therefore, additional information on their toxicity and their levels in food is required.

For livestock, the residue definition for risk assessment is provisional in GB as additional information on the toxicity of NK-1375 is required. The toxicity of cyclanilprole covers the toxicity of the metabolite NSY-28.

The proposed draft CXLs and their consideration are outlined in Table 31.

Table 31 CXL proposals for cyclaniliprole

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
Almonds	Almonds	0120010	0.03	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Bushberries, subgroup of	Various berries ††	Various	1.5	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Cane berries, subgroup of	Cane fruits	0153000	0.8	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Cherries, subgroup of	Cherries (sweet)	0140020	0.7	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Cabbages, head	Head cabbages	0242020	0.7	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Citrus fruit, group of	Citrus fruits	0110000	0.4	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Cucumbers and summer squashes, subgroup of	Cucurbits with edible peel	0232000	0.05	0.01*	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
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	Various	0.2	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Eggplants, subgroup of,	Aubergines/eggplants	0231030	0.15	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Eggs	Bird eggs	1030000	0.01*	0.01*	Harmful effects for human health cannot be excluded. In this case the CXL is equivalent to the GB MRL which is set at the LOQ. The CXL should not be adopted as a GB MRL.
Elderberries and Guelder rose	Elderberries Guelder rose berries	0154080	1.5	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Flowerhead brassicas, subgroup of	Flowering brassica	0241000	0.8	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Grapes	Grapes	0151000	0.6	0.01*	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
Leafy greens, subgroup of	Lettuces	0251020	7	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Leaves of brassicaceae	Leafy brassicas	0243000	10	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Low growing berries, subgroup of (except cranberries)	Various berries ††	Various	0.4	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Meat (from mammals other than marine mammals) †	All Mammalian species - muscle	Various	0.25 (fat)	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Melons, pumpkins and winter squashes, subgroup of	Cucurbits with inedible peel	0233000	0.1	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.25	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Milks	Milk	1020000	0.01	0.01*	Harmful effects for human health cannot be excluded. In this case the

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
					CXL is equivalent to the GB MRL which is set at the LOQ.
Peppers, subgroup of (except martynia, okra and roselle)	Sweet peppers/bell peppers	0231020	0.15	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Peaches (including apricots and nectarines), subgroup of	Peaches	0140030	0.3	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Pome fruits, group of (excluding Japanese persimmons)	Pome fruits	0130000	0.2	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Plums, subgroup of	Plums	0140040	0.15	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Poultry, edible offal	Poultry - liver, kidney, edible offals	Various	0.01*	0.01*	Harmful effects for human health cannot be excluded. In this case the CXL is equivalent to the GB MRL which is set at the LOQ.

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
Poultry, fats	Poultry fat	1016020	0.01*	0.01*	Harmful effects for human health cannot be excluded. In this case the CXL is equivalent to the GB MRL which is set at the LOQ.
Poultry, meat	Poultry muscle	1017010	0.01*	0.01*	Harmful effects for human health cannot be excluded. In this case the CXL is equivalent to the GB MRL which is set at the LOQ.
Tea, green, black (black, fermented and dried)	Teas	0610000	50	0.05*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Tomatoes, subgroup of	Tomatoes	0231010	0.08	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Tuberous and corm vegetables, subgroup of	Various root and tuber vegetables ††	Various	0.01*	0.01*	Harmful effects for human health cannot be excluded. In this case the CXL is equivalent to the GB MRL which is set at the LOQ.

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

†† The full list of commodities that the proposed draft CXL would apply to have not been listed as the CXL is not acceptable

Consumer Risk Assessments

An estimation of the dietary intakes has not been undertaken as the approval assessment identified additional metabolites that consumers may be exposed to for which a conclusion on the genotoxicity could not be established.

Conclusion

The proposed draft CXLs are not acceptable as the residue definitions for risk assessment in GB are only provisional. Additional information is required on the toxicity of metabolites that consumers will be exposed to and on the magnitude of the residue levels in processed fractions. Based on the risk assessment conducted for the approval of the active substance harmful effects on human health cannot be excluded for residues of cyclaniliprole occurring in food. Consequently, the required level of protection has not been met.

2.12 Cypermethrin (118)

The JMPR assessment covers cypermethrin (including alpha- and zeta-cypermethrin). Cypermethrin and alpha cypermethrin are approved active substances in GB. The approval for zeta cypermethrin has expired. There is also the isomer beta cypermethrin which received a non-approval decision in 2017. However, toxicological reference values have been established.

MRLs are established in Part 2 of the GB MRL Statutory Register.

Cypermethrin was considered by the JMPR for new uses. Relevant background information is outlined in Tables 32 and 33.

The JMPR in 2006 endorsed toxicological reference values to cover cypermethrin, alpha-cypermethrin and zeta-cypermethrin. For GB, there are individual toxicological reference values for the isomers of cypermethrin.

Table 32a Toxicological reference values for cypermethrin

	JMPR	GB	Units
ADI	0.02	0.05	mg/kg bw per day
ARfD	0.04	0.2	mg/kg bw

Table 32b Toxicological reference values for alpha cypermethrin

	JMPR	GB	Units
ADI	-	0.00125	mg/kg bw per day
ARfD	-	0.00125	mg/kg bw

Table 32c Toxicological reference values for beta cypermethrin

	JMPR	GB	Units
ADI	-	0.04	mg/kg bw per day
ARfD	-	0.125	mg/kg bw

Table 32d Toxicological reference values for zeta cypermethrin

	JMPR	GB	Units
ADI	-	0.0016	mg/kg bw per day
ARfD	-	0.0016	mg/kg bw

Table 33 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Cypermethrin (sum of isomers)	Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes
	Risk assessment	Cypermethrin (sum of isomers)	Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes
Livestock	Enforcement	Cypermethrin (sum of isomers)	Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Cypermethrin (sum of isomers)	Cypermethrin including other mixtures of constituent isomers (sum of isomers)	Yes

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

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

Table 34 CXL proposals for cypermethrin

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
Ginseng	-	-	0.03*	-	The GB commodity is a herbal infusion expressed on a dry weight basis. Therefore, it is the CXL proposal for the dried product (0.15 mg/kg) that is relevant to GB.
Ginseng, dried including red ginseng	Ginseng	0633020	0.15	0.1*	
Ginseng, extracts	-	-	0.06*	-	There are no consumption data for ginseng in the UK models. In PRIMo there are only data for acute consumption of ginseng. The CXL for ginseng (dried) can be adopted as a GB MRL.

Consumer Risk Assessments

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.

There is no consumption data for ginseng in the UK models. In PRIMo there is only data for acute consumption of ginseng. However, consumption is expected to be low.

Table 35 Summary of the consumer risk assessments for cypermethrin

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	There is no consumption data for ginseng, however consumption is expected to be low. Therefore, no health effects due to chronic exposure are expected from the consumption of ginseng treated with cypermethrin.	
	EFSA		
Acute exposure assessment	UK	There is no consumption data for ginseng.	
	EFSA	The highest IESTI was 0.03 % of the ARfD (Adult/ ginseng) [†]	No health effects due to acute exposure are expected from the consumption of ginseng treated with cypermethrin

[†] The consumer risk assessment was performed using the GB ARfD for cypermethrin, reflecting the apparent authorised use considered for the proposed draft CXL. However, if the residue was the most toxic isomer (alpha cypermethrin) the highest IESTI would be 5 % of the ARfD of 0.00125 mg/kg bw for adults.

Conclusions

The proposed draft CXL for ginseng is acceptable and a risk to consumers is unlikely.

2.13 Cyprodinil (207)

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

Cyprodinil was considered by the JMPR for one new use. Relevant background information is outlined in Tables 36 and 37.

Table 36 Toxicological reference values

	JMPR	GB	Units
ADI	0.03	0.03	mg/kg bw per day
ARfD	Not required	Not required	mg/kg bw

Table 37 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Cyprodinil	Cyprodinil	Yes
	Risk assessment	Cyprodinil	Cyprodinil	Yes
Livestock	Enforcement	Cyprodinil	All products except milk and honey: Sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil Milk: Sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil	No
	Risk assessment	Cyprodinil	All products except milk and honey: Sum of cyprodinil and CGA 304075 (free), expressed as cyprodinil Milk: Sum of cyprodinil and CGA 304075 (free and conjugated), expressed as cyprodinil	No

CGA 304075: 4-(4-cyclopropyl-6-methyl-pyrimidin-2-yl-amino)-phenol

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

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 draft CXL and its consideration are outlined in Table 38.

Table 38 CXL proposals for cyprodinil

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
Soya bean (dry)	Soya beans	0401070	0.3	0.02*	The CXL can be adopted as a GB MRL

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 39. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 39 Summary of the consumer risk assessments for cyprodinil

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDIs is 52 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with cyprodinil
	EFSA	The highest IEDI is 57 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The active is not acutely toxic and therefore an ARfD has not been allocated	
	EFSA		

Conclusion

The proposed draft CXL for soya bean is acceptable and a risk to consumers is unlikely.

2.14 Dicamba (240)

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

Dicamba was considered by the JMPR for new uses on GM crops of cotton seed, soyabeans and maize. The GM crops are all dicamba tolerant varieties and therefore new metabolism studies to support the use on these crops were evaluated by the

JMPR. The metabolism in the dicamba tolerant cotton seed, soyabeans and maize was qualitatively different from the metabolism in conventional crops and therefore the JMPR endorsed new residue definitions specific to these crops. The residue definitions endorsed by the JMPR for soya bean, maize, and cotton now specifically cover the residues that may arise for both conventional and GM crops; however, it is important to note that the metabolites now included in the JMPR residue definitions for these crops are unlikely to arise in conventional crops.

Relevant background information is outlined in Tables 40 and 41. Table 42 outlines the approval status of the GM crops in GB.

Table 40a Toxicological reference values for dicamba and 5-OH-dicamba

	JMPR	GB	Units
ADI	0.3	0.3	mg/kg bw per day
ARfD	0.5	0.3	mg/kg bw

Table 40b Toxicological reference values for DCSA and DCGA

	JMPR	GB	Units
ADI	0.3	0.04	mg/kg bw per day
ARfD	0.5	0.3	mg/kg bw

Table 41 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Soya bean, maize, and cotton: Sum of dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated), expressed as dicamba Other plant commodities:	GM Soyabean: Sum of DCSA and its conjugates, expressed as DCSA Other plant commodities: Dicamba	For conventional crops: Yes The residues definitions are not comparable for GM crops. See comment below.

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		Dicamba		
	Risk assessment	Soya bean, maize, and cotton: Sum of dicamba, 2,5-dichloro-3-hydroxy-6-methoxybenzoic acid (5-OH dicamba), 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated) and 2,5-dichloro-3,6-dihydroxybenzoic acid (DCGA; free and conjugated), expressed as dicamba; Other plant commodities: Sum of dicamba and 5-OH dicamba, expressed as dicamba	GM Soyabean: Sum of DCSA, DGSA and their conjugates, expressed as DCSA Other plant commodities: Sum of dicamba, 5-OH-dicamba and their conjugates, expressed as dicamba	For conventional crops: Yes The residue definitions are not comparable for GM crops. See comment below.
Livestock	Enforcement	Sum of dicamba and DCSA, expressed as dicamba	Dicamba	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Sum of dicamba and DCSA, expressed as dicamba	Dicamba (free and conjugated)	No

DCSA = 3,6-dichloro-2-hydroxybenzoic acid (3,6-dichloro-salicylic acid)

DCGA = 2,5-dichloro-3,6-dihydroxybenzoic acid (3,6-dichloro-gentisic Acid)

DGSA = 3,6-dichloro-2,5-dihydroxybenzoic acid

DCGA = DGSA

Table 42 Authorisation status of the GM Crops in GB

Crop	GM Variety	Authorisation status in GB
Cotton seed	Mon 88701	Unauthorised
Soyabean	Mon 87708	Authorised
maize	Mon 87419	Unauthorised

Conventional crops

All crops except soya bean, maize, and cotton

The residue definitions for conventional crops for enforcement are comparable between GB and the JMPR. It is noted that for risk assessment the GB residue definition includes conjugates of dicamba and 5-OH-dicamba. Provided the analytical method includes a hydrolysis step then the conjugates will be included as part of the residue determined and therefore the residue definitions can be regarded as comparable.

Soya bean, maize, and cotton

The residue definitions for conventional crops endorsed by the JMPR no longer include cotton seed, soyabeans and maize as these crops are now covered by new residue definitions encompassing both conventional and GM crops. With regards to the residue definitions for conventional crops of soyabean, cotton and maize, the JMPR residue definitions are more extensive than the GB residue definitions.

The additional analytes included in the residue definitions by the JMPR are found specifically in GM crops and are unlikely to be found in conventional crops. Hence the inclusion of the additional metabolites will have no impact on the numerical value of the residue levels determined for conventional crops; as such the JMPR and GB residue definitions for all conventional crops can be regarded as comparable.

GM crops

The use on dicamba resistant soyabean has been considered previously (EFSA, 2013). The GM variety considered was the authorised GM crop variety MON 87708. The following residue definitions have been endorsed specifically for GM soyabean and apply in GB:

- Enforcement: Sum of DCSA and its conjugates, expressed as DCSA
- Risk assessment: Sum of DCSA, DGSA and their conjugates, expressed as DCSA

The current MRLs in force in GB for soyabeans are:

- 10 mg/kg for conventional crops
- 0.4 mg/kg for GM crops

The MRL for GM soyabeans is included in the GB MRL Statutory Register by means of a footnote entry.

The JMPR has endorsed the following residue definitions specifically for cotton seed, soyabeans and maize to cover uses on both conventional and GM crops:

- Enforcement: sum of dicamba and 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated), expressed as dicamba
- Risk assessment: sum of dicamba, 2,5-dichloro-3-hydroxy-6-methoxybenzoic acid (5- OH dicamba), 3,6-dichloro-2-hydroxybenzoic acid (DCSA; free and conjugated) and 2,5-dichloro-3,6-dihydroxybenzoic acid (DCGA; free and conjugated), expressed as dicamba

The residue definitions for GM plants for both risk assessment and enforcement are not comparable for GB and the JMPR.

Livestock

The residue definitions for GB and the JMPR are not comparable. No CXLs have been proposed for products of animal origin so the difference has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 43.

Table 43 CXL proposals for dicamba

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	3	0.05*	The GM crop variety is MON 88701. This GM crop is not currently authorised in GB. The CXL should not be adopted as a GB MRL.
Maize	Maize/Corn	0500030	0.01*	0.5	The GM crop variety is MON 87419. This is not currently authorised in GB. However, as no trials matched the GAP on the GM crop the CXL recommended is for conventional crops only. The CXL does not need to be adopted as the GB MRL is higher.
Soya bean (dry)	Soyabeans	0401070	10	10	The GM crop variety is MON 87708. This crop is authorised in GB. The GB MRL is 10 mg/kg for conventional soyabean. An MRL of 0.4 mg/kg applies to the GM soyabean † The CXL is for the conventional crop as the GAP is more critical than the GAP for the GM crop.

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 does not need to be adopted as the GB MRL is equivalent.

† The residue definition for enforcement for GM soyabean is the Sum of DCSA and its conjugates, expressed as DCSA.

Cotton seed

The CXL for cotton seed is on a GM crop (dicamba tolerant variety) that is not currently authorised in GB. The residue levels and the proposed draft CXLs are directly relevant to this dicamba tolerant variety only. As this GM crop cannot be imported into GB then the CXL should not be considered further at this time. If the GM crop variety is authorised in the future then the adoption of the CXL can be re-considered.

Maize

No trials data matching the GAP for GM maize was available to the JMPR.

The current CXL is 0.01* mg/kg based on a use on conventional crops. The JMPR proposed a new CXL (the proposed draft CXL now at step 3 of the process) on the basis of the new residue definition covering GM crops. However, as the new residue definitions include additional metabolites that are relevant to GM maize only, it has no impact on the numerical CXL value for conventional crops.

The GB MRL is 0.5 mg/kg.

Soyabean

Residue trials covering the GAP for GM soyabean were considered by the JMPR. However, it was noted that the residue levels were significantly below the current CXL of 10 mg/kg.

The current CXL of 10 mg/kg is to support a use on conventional soyabean and as this covers the new use on the GM soyabean then a new CXL specifically for GM soyabean was not recommended by the JMPR. The proposed draft CXL now being considered at step 3 of the Codex procedures is the current CXL but now based on the new residue definitions endorsed by the JMPR. However, as the new residue definitions include additional metabolites that are relevant to GM soyabean only, it has no impact on the numerical CXL value for conventional crops.

The GB MRL is 10 mg/kg.

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as no CXLs are being recommended for adoption as GB MRLs.

Conclusion

The proposed draft CXL for GM cotton seeds is not acceptable as the GAP considered by the JMPR is for a GM crop that is not currently authorised in GB.

The proposed draft CXLs for GM maize and soyabeans are equivalent to or lower than the GB MRLs in force.

2.15 Dimethoate (027)

Dimethoate is a non-approved active substance in GB. With regards to the residues/dietary exposure assessment, genotoxic concerns were identified for dimethoate and the degradation product omethoate. No toxicological reference values were established.

MRLs are established at the LOQ in Part 5 of the GB MRL Statutory Register.

The JMPR undertook a periodic review of the active substance and recommended that all current CXLs are withdrawn. As a result of concerns relating to the genotoxicity of omethoate and other related metabolites, the JMPR was unable to conclude on a residue definition for dietary risk assessment.

Conclusions

As the JMPR could not conclude on the residue definitions for risk assessment, no CXLs were recommended.

2.16 Fenazaquin (297)

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

Fenazaquin was considered by the JMPR for new uses. Relevant background information is outlined in Tables 44 and 45.

Table 44a Toxicological reference values for fenazaquin

	JMPR	GB	Units
ADI	0.05	0.005	mg/kg bw per day
ARfD	0.1	0.1	mg/kg bw

Table 44b Toxicological reference values for TBPE

	JMPR	GB	Units
ADI	-	0.002	mg/kg bw per day
ARfD	-	0.002	mg/kg bw

TBPE: 2 -(4-tert-butylphenyl)ethanol

The JMPR agreed that the ADI and ARfD for fenazaquin could be applied to TBPE.

Table 45 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	fenazaquin	fenazaquin	Yes
	Risk assessment	fenazaquin	fenazaquin and TBPE, considered separately	No
Livestock	Enforcement	the sum of fenazaquin and the metabolite 2-hydroxy-fenazaquin acid expressed as fenazaquin equivalents	fenazaquin	No
	Risk assessment	the sum of fenazaquin and the metabolites 2-(4-{2-[(2-hydroxyquinazolin-4-yl)oxy]ethyl}phenyl)-2-methylpropanoic acid (2-hydroxy-fenazaquin acid) and quinazolin-4-ol and 3,4-dihydroquinazolin-4-one (tautomeric forms of 4-hydroxyquinazoline), expressed as fenazaquin equivalents	fenazaquin	No

For plants, the residue definitions for enforcement are comparable between GB and the JMPR. The residue definitions for risk assessment are not comparable. In GB the residue definition includes TBPE which is assessed for dietary exposure separately from fenazaquin.

For livestock, the residue definitions for enforcement and risk assessment are not comparable between GB and the JMPR. The GB residue definitions are fenazaquin only whereas the residue definitions for the JMPR include additional metabolites.

The proposed draft CXLs and their consideration are outlined in Table 46.

Table 46 CXL proposals for fenazaquin

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
Edible offal (mammalian) †	All mammalian species (edible offal)	Various	0.02*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent †††
Mammalian fats (except milk fats) †	All mammalian species - fats	Various	0.02*	0.01*	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	0.02*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Milks	Milk	1020000	0.02*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Tree nuts, except coconut	Almonds	0120010	0.02	0.02	The CXL does not need to be adopted as the GB MRL is equivalent
Tree nuts, except coconut	All other tree nuts except coconut and almonds ††	Various	0.02	0.01*	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

†† The GB MRLs for all other tree nuts are at the LOQ of 0.01* mg/kg

††† All the CXLs for POAO are proposed at the LOQ. The higher LOQ is as a result of an additional analyte in the residue definition endorsed by the JMPR. Therefore, GB MRLs cover the CXL proposals.

The GAP for tree nuts considered by the JMPR was 1 x 0.504 kg a.s./ha with a PHI of 7 days. This is the same GAP that supports the GB MRL of 0.02 mg/kg for almond (EFSA, 2018). Additional residue trials conducted on pecan were evaluated by the JMPR, but the trials did not include results for TBPE. The almond data supporting the GB MRL showed that residues of TBPE were < 0.01 mg/kg. However, extrapolation is not possible to the whole group of tree nuts based on these data (either for GB or for CXLs). On the basis of the information available, robust conversion factors for the residue definition for enforcement to risk assessment cannot be established. It is also not known if TBPE could be formed on processing as the fate of the phenyl ring moiety under processing conditions was not addressed for the approval of the active substance. Therefore, as the residue levels of TBPE cannot be confirmed, no further consideration of the CXLs for tree nuts has been undertaken.

Consumer risk assessments

Dietary exposure assessments have not been undertaken as the residue definitions are not compatible between GB and the JMPR and therefore it is not possible to conclude on the consumer risk assessment.

Conclusions

The proposed draft CXL for almonds is equivalent to the GB MRL. The proposed draft CXL for other tree nuts, except coconuts, is not acceptable as the residue trials did not include the metabolite TBPE. Therefore, it is not possible to conclude on the acceptability of the dietary exposure.

The proposed draft CXLs for products of animal origin are all at the LOQ. The LOQ CXL for products of animal origin is 0.02* mg/kg as the residue definition is the sum of fenazaquin and 2-hydroxy-fenazaquin. The current GB MRLs of 0.01* mg/kg set on a residue definition of fenazaquin only and therefore covers the proposed draft CXLs.

2.17 Flonicamid (282)

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

The JMPR considered new uses for the active substance. Relevant background information is outlined in Tables 47 and 48.

Table 47 Toxicological reference values

	JMPR	GB	Units
ADI	0.07	0.025	mg/kg bw per day
ARfD	Not required	0.025	mg/kg bw

Table 48 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	flonicamid	sum of flonicamid and the metabolites TFNA and TFNG, expressed as flonicamid	No
	Risk assessment	flonicamid	sum of flonicamid and the metabolites TFNA and TFNG, expressed as flonicamid	No
Livestock	Enforcement	flonicamid and the metabolite TFNA-AM	sum of flonicamid and TFNA-AM expressed as flonicamid	Yes
	Risk assessment	flonicamid and the metabolite TFNA-AM	sum of flonicamid and TFNA-AM expressed as flonicamid	Yes

TFNA: 4-(trifluoromethyl)nicotinic acid

TFNG: N-[4-(trifluoromethyl) nicotinoyl] glycine

TFNA-AM: 4-(trifluoromethyl) pyridine-3-carboxamide

The residue definitions for plants for both risk assessment and enforcement are not comparable for GB and the JMPR. The residue definitions for GB include two additional metabolites and are therefore more extensive. The JMPR evaluation does

not include the levels of these two metabolites in the residue trials and therefore it is not possible to estimate GB MRLs.

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

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

Table 49 CXL proposals for flonicamid

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
Lemons and Limes, subgroup of (includes all commodities in this subgroup)	Lemons	0110030	1.5	0.15	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
	Limes	0110040	1.5	0.15	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
	Kumquats	0161040	1.5	0.03*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Oranges, Sweet, Sour, subgroup of (includes all commodities in this subgroup)	Oranges	0110020	0.4	0.15	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Pumelo and grapefruit (including Shaddock-like hybrids) Subgroup of (including all	Grapefruits	0110010	0.3	0.15	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
commodities in this subgroup)					

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as the residue definitions for risk assessment are not compatible between GB and the JMPR and therefore it is not possible to conclude on the consumer risk assessment.

Conclusions

The proposed draft CXLs are not acceptable as the residue trials did not include the metabolites TFNA and TFNG. Therefore, it is not possible to calculate the GB MRLs and conclude on the acceptability of the dietary exposure.

2.18 Fluazifop-P-butyl (283)

Fluazifop-P is an approved active substance in GB. The variant of the active substance considered for the approval was fluazifop-P-butyl. MRLs are established in Part 2 of the GB MRL Statutory Register.

Fluazifop-P-butyl 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	0.004	0.01	mg/kg bw per day
ARfD	0.4	0.017	mg/kg bw

Table 51 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop	Yes - see comment below
	Risk assessment	The sum of fluazifop-P-butyl, fluazifop-P-acid (II), 2-[4-(3-hydroxy-5-trifluoromethyl-2-phenoxy)pyridyloxy] propionic acid (XL), 5-trifluoromethyl-2-pyridone (X) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop	No
Livestock	Enforcement	Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates, expressed as fluazifop-P-acid	Sum of all the constituent isomers of fluazifop, its esters and its conjugates, expressed as fluazifop	Yes – see comment below
	Risk assessment	Total fluazifop, defined as the sum of fluazifop-P-butyl, fluazifop-P-acid (II) and their conjugates,	Sum of all the constituent isomers of fluazifop, its esters and	Yes – see comment below

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		expressed as fluazifop-P-acid	its conjugates, expressed as fluazifop	

The residue definitions for enforcement for both plants and livestock and the residue definition for risk assessment for livestock are comparable between the JMPR and GB. Whilst the JMPR has specified the determination of fluazifop-p-butyl, the GB residue definitions include all isomers of fluazifop. However, the analytical methods employed to support the residue trials and those employed for enforcement do not discriminate between the isomeric forms.

The residue definitions for plants for risk assessment are not comparable for GB and the JMPR. The residue definition for the JMPR includes two additional metabolites and is therefore more extensive. As the residue trials did not include the two metabolites the JMPR applied a multiplication factor of 1.05. Therefore, the overestimation of the exposure for UK consumers will be minimal. Therefore, the proposed draft CXLs have been considered in the dietary exposure assessment.

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

Table 52 CXL proposals for fluazifop-p-butyl

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
Bush berries, subgroup of	Blueberries	0154010	0.3	0.1	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Bush berries, subgroup of	Currants (black, red and white)	0154030	0.3	0.1	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Bush berries, subgroup of	Gooseberries (green, red and yellow)	0154040	0.3	0.1	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Bush berries, subgroup of	Rose hips	0154050	0.3	0.1	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Cane berries, subgroup of	Cane fruits	0153000	0.08	0.01*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Elderberries	Elderberries	0154080	0.3	0.1	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Guelder rose	Elderberries	0154080	0.3	0.1	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Strawberry	Strawberries	0152000	3	0.3	Chronic and acute intake concerns have been identified. The CXL should not be adopted as a GB MRL.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in table 53. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 53 Summary of the consumer risk assessments for fluazifop-P-butyl

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 346 % of the ADI (toddler) The lowest NEDI is 135 % of the ADI (elderly own home)	A chronic intake concern has been identified
	EFSA	The highest IEDI is 148% of the ADI (GEMS/ G11 diet [†])	
Acute exposure assessment	UK	The highest NESTI was 61.2 % of the ARfD (4-6 year olds/ strawberries)	An acute intake concern has been identified for strawberries. No health effects due to acute exposure are expected from the consumption of all other commodities treated with fluazafop-p-butyl
	EFSA	The highest IESTI was 144 % of the ARfD (Children/ strawberries) The IESTIs of all other commodities were less than the ARfD	

† The Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (of the WHO) has placed the UK in cluster diet G07.

The main contributor to the chronic exposure is oilseeds. The proposed draft CXLs do not contribute significantly to the chronic exposure with strawberries being the highest contributor at 3.4 % of the ADI.

Refinement of the dietary exposure assessments is currently not possible without further data on robust processing factors and the consumption of the individual fractions of oilseeds.

Conclusions

The proposed draft CXL for strawberries is not acceptable as it leads to a dietary intake that exceeds the ARfD.

For all the CXLs a chronic intake concern has been identified based on the consideration of all uses, therefore the proposed CXLs should not be adopted.

2.19 Fluensulfone (265)

Fluensulfone has never been considered in GB for an approval. Currently the default LOQ MRL of 0.01* mg/kg applies to all commodities.

HSE evaluated an import tolerance application in 2016. This included a full assessment to establish toxicological reference values and residue definitions for the active substance.

Fluensulfone was considered by the JMPR for new uses. Relevant background information is outlined in Tables 54 and 55.

Table 54 Toxicological reference values

	JMPR	GB (proposed)†	Units
ADI	0.01	0.01	mg/kg bw per day
ARfD	0.3	0.25	mg/kg bw

†The endpoints were proposed by HSE in an Import Tolerance assessment. As no MRLs were recommended these endpoints have not been endorsed.

Table 55 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Sum of fluensulfone and BSA, expressed as fluensulfone equivalents	Could not be established	No
	Risk assessment	Fluensulfone	Could not be established	No
Livestock	Enforcement	Fluensulfone	Could not be established	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Fluensulfone	Could not be established	No

BSA: 3,4,4-trifluorobut-3-ene-1-sulfonic acid

It is noted that the JMPR has endorsed a residue definition for plants for enforcement that includes an additional metabolite compared to the residue definition endorsed for risk assessment.

The available plant metabolism data show that residues of fluensulfone are not expected to occur, so it would be unsuitable as a marker compound on which to base MRLs. Including the determination of a residue for compliance with MRLs, which is then not used in the dietary exposure assessment, is a non-standard approach and therefore, there is no clear link between the residue definition for enforcement and risk assessment.

It is further noted that the metabolite methylsulfone (MeS, *M*-3626) may need to be included in the residue definitions for risk assessment. This metabolite was not observed in the plant materials during the metabolism studies. This is in contrast to positive residues found in some crops in the residue trials (in particular cucurbits).

The detection of metabolites in the residue trials that were not found in the metabolism studies is of concern. Without further information it is not known if the available metabolism studies are acceptable, representative of the proposed uses and that the residue definitions are appropriate.

The proposed draft CXLs and their consideration are outlined in Table 56.

Table 56 CXL Proposals for fluensulfone

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 pseudo-cereals with husks, subgroup of	Barley	0500010	0.08	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Coffee bean	Coffee beans	0620000	0.05	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Citrus fruit, group of	Citrus fruits	0110000	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.
Maize cereals, subgroup of	Maize/Corn	0500030	0.15	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Pome fruit, group of (except Persimmon, Japanese)	Pome fruits	0130000	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
Rice cereals, subgroup of	Rice	0500060	0.04	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Small fruit vine climbing, Subgroup of	Various berries††	various	0.7	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Sorghum grain and millet, subgroup of	Sorghum	0500080	0.04	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Stone fruit, group of	Stone fruits	0140000	0.09	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Sugar cane	Sugar canes	0900020	0.06	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Sweet corns, subgroup of	Sweet corn	0234000	0.15	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
Tree nuts, group of	Tree nuts	0120000	0.025*	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Wheat, similar grains, and pseudo-cereals without husks, subgroup of	Wheat	0500090	0.08	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.

†† The full list of commodities that the proposed draft CXL would apply to have not been listed as the CXL is not acceptable

As HSE does not support the residue definition for plants for enforcement then no further consideration of the proposed draft CXLs has been made.

Consumer Risk Assessments

An estimation of the dietary intakes has not been undertaken as the residue definitions endorsed by the JMPR are not compatible with the previous HSE assessment.

Conclusion

The proposed draft CXLs are not acceptable as there is uncertainty around the robustness of the residue definitions.

2.20 Flupyradifurone (285)

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

Flupyradifurone was considered by the JMPR for new uses. Relevant background information is outlined in Tables 57 and 58.

Table 57 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 (difluoroacetic acid).

Table 58 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

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, 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 and the calculation of MRLs for DFA was easy to perform, MRLs have been calculated for DFA in Table 59. Residues of DFA are expected in rotational crops, however the proposed draft CXLs relate to crops which are not grown in rotation.

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 residues 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 60.

For livestock, the residue definitions for enforcement is not comparable for GB and the JMPR. The residue definitions for risk assessment are comparable. As no CXLs are proposed for products of animal origin, the differences in the residue definitions for enforcement has not been considered further.

Table 59 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)
Avocado	3 x <0.05, 0.22	3 x <0.017, 0.073	0.15
Cacao beans	0.041, 0.049, 0.060, 0.061, 0.077, 0.089, 0.097	0.014, 0.016, 2 x 0.020, 0.026, 0.030, 0.032	0.07
Cane berries, subgroup of	3 x <0.02, 0.034, 0.035, 0.047, 0.12, 0.12, 0.13, 0.14	3 x <0.007, 0.011, 0.012, 2 x 0.040, 0.043, 0.047	0.1
Coffee bean	3 x <0.05, 3 x 0.08, 2 x 0.10, 0.11, 0.12, 2 x 0.13, 0.15, 0.27, 0.30, 0.41, 0.42	3 x <0.017, 3 x 0.027, 2 x 0.033, 0.040, 0.043, 0.050, 0.090, 0.100, 0.137, 0.140	0.3
Hops, dry	<0.5, 0.80, 0.96, 3.3	0.167, 0.267, 0.320, 1.110	3

† Reported in JMPR evaluation

†† As the residues of DFA in the JMPR evaluation were expressed as flupyradifurone (MW 288), a molecular weight conversion factor of 3 was used to express residues as DFA (MW 96)

Table 60 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)
Avocado	0.076, 0.27, 0.29, 0.31	0.28	0.31
Cane berries, subgroup of	0.84, 0.86, 1.0, 2 x 1.1, 1.7, 2.2, 2 x 2.5, 4.1	1.4	4.1
Coffee bean	2 x <0.06, 2 x 0.10, 0.17, 0.20, 0.24, 2 x 0.29, 0.30, 0.41, 0.47, 0.56, 0.61, 0.75, 0.85	0.29	0.85
Hops, dry	3.2, 3.3, 3.3, 7.9	3.3	7.9

† Calculated using JMPR evaluation

The proposed draft CXLs for flupyradifurone and MRLs calculated for DFA using the JMPR evaluation and their consideration are outlined in Table 61.

Table 61 CXL proposals for flupyradifurone and MRLs calculated for DFA using JMPR evaluation

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 recommendation on the CXL
Avocado	Avocados	0163010	0.6	0.01*	0.15	0.02*	The CXL can be adopted as a GB MRL
Cacao beans	Cocoa beans	0640000	0.01*	0.05*	0.07	0.1*	The CXL does not need to be adopted as the GB MRL is higher
Cane berries, subgroup of	Blackberries	0153010	6	1.5	0.1	0.07	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Dewberries	0153020	6	0.01*	0.1	0.02*	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Raspberries (red and yellow)	0153030	6	1.5	0.1	0.07	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Other cane berries	0153990	6	0.01*	0.1	0.02*	The CXL can be adopted as a GB MRL

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 recommendation on the CXL
Coffee bean	Coffee beans	0620000	0.9	0.05*	0.3	0.1*	The CXL can be adopted as a GB MRL
Hops, dry	Hops	0700000	10	4	3	0.3	The CXL can be adopted as a GB MRL

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 62. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 62 Summary of the consumer risk assessments for flupyradifurone

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 29 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with flupyradifurone
	EFSA	The highest IEDI is 19 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 29.3 % of the ARfD (toddler/blackberries)	No health effects due to acute exposure are expected from the consumption of commodities treated with flupyradifurone
	EFSA	The highest IESTI is 29 % of the ARfD (Children/blackberries)	

Conclusions

The proposed draft CXLs for flupyradifurone and the MRLs calculated for DFA for avocado, cane berries, coffee bean and hops are acceptable and a risk to consumers is unlikely.

The proposed draft CXL for cacao beans and the MRL calculated for DFA are lower than the GB MRLs in force.

2.21 Fluxapyroxad (256)

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

Fluxapyroxad was considered by the JMPR in response to specific concerns raised by the CCPR.

In 2018, the JMPR proposed an MRL for fluxapyroxad on Citrus Fruit as a whole group. A concern was raised at the CCPR 51 on the proposed MRLs given the residue populations of oranges, lemons, and grapefruit were significantly different and the CCPR did not support the JMPR's approach. Furthermore, only one trial was submitted for mandarin. Therefore, the JMPR in 2019 revised its approach and proposed different MRLs for different subgroups within the citrus fruit group.

Relevant background information is outlined in Tables 63 and 64.

Table 63 Toxicological reference values

	JMPR	GB	Units
ADI	0.02	0.02	mg/kg bw per day
ARfD	0.3	0.25	mg/kg bw

Table 64 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Fluxapyroxad	Fluxapyroxad	Yes
	Risk assessment	Sum of fluxapyroxad and 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)- 1-(β-D-glucopyranosyl)-N-(3',4',5'-trifluorobipheny-2-yl)-1H-pyrazole-4-carboxamide (M700F048) and expressed as parent equivalents	Fluxapyroxad	No
Livestock	Enforcement	Fluxapyroxad	Fluxapyroxad	Yes
	Risk assessment	Sum of fluxapyroxad and 3-(difluoromethyl)- N-	Sum of fluxapyroxad and metabolite	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (M700F008) expressed as parent equivalents	M700F008, expressed as parent equivalent	

M700F008: 3-(difluoromethyl)- N-(3',4',5'-trifluoro[1,1'- biphenyl]-2-yl)-1H-pyrazole-4-carboxamide

The residue definitions for plants for enforcement are comparable between GB and the JMPR. The JMPR residue definition for risk assessment includes two additional metabolites and is therefore more extensive.

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

The proposed draft CXLs and their consideration are outlined in Table 65.

Table 65 CXL proposals for fluxapyroxad

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL
Lemons and limes (including citron), subgroup of	Lemons	0110030	1	0.01*	The CXL can be adopted as a GB MRL
Lemons and limes (including citron), subgroup of	Limes	0110040	1	0.01*	The CXL can be adopted as a GB MRL
Lemons and limes (including citron), subgroup of	Kumquats	0161040	1	0.01*	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
Mandarins, subgroup of	Mandarins	0110050	1	0.01*	The CXL can be adopted as a GB MRL
Oranges, sweet, sour (including orange-like hybrids), subgroup of	Oranges	0110020	1.5	0.3	The CXL can be adopted as a GB MRL
Pummelo and grapefruits (including shaddock-like hybrids, among other grapefruits), subgroup of	Grapefruits	0110010	0.6	0.3	The CXL can be adopted as a GB MRL

As the proposed draft CXLs are higher than the GB MRLs a further consideration on the different residue definitions for risk assessment for plants has been undertaken.

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 residues levels of fluxapyroxad can be easily calculated from the JMPR assessment they have been presented in Table 66.

Table 66 Calculation of STMRs and HRs according to the GB plant residue definition for risk assessment

GB commodities	Trials crop	Residues fluxapyroxad (mg/kg)	Extrapolation to Codex commodity subgroups	STMR fluxapyroxad (mg/kg)	HR fluxapyroxad (mg/kg)
Lemons Limes Mandarins Kumquats	Lemon	0.15, 0.16, 0.37, 0.38, 2 x 0.40, 0.45	Subgroup of Lemons and Limes Subgroup of Mandarins	0.38	0.45

-	Mandarin	0.33	Not used, JMPR extrapolated data from lemon to Subgroup of Mandarins	-	-
Oranges	Orange	0.16, 0.18, 0.32, 0.33, 0.37, 0.38, 0.44, 0.50, 0.52, 0.58	Subgroup of Oranges, Sweet, Sour	0.375	0.58
Grapefruits	Grapefruit	0.10, 2 x 0.15, 0.24, 0.27	Subgroup of Pummelo and Grapefruits	0.15	0.27

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 67. The outputs from PRIMo and the UK models can be seen in annexes 1-4.

Table 67 Summary of the consumer risk assessments for fluxapyroxad

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 81 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with fluxapyroxad
	EFSA	The highest IEDI is 64 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 30.8 % of the ARfD (infant/ oranges)	No health effects due to acute exposure are expected from the consumption of commodities treated with fluxapyroxad
	EFSA	The highest IESTI is 31 % of the ARfD (Children/ oranges)	

Conclusions

The proposed draft CXLs are acceptable and a risk to consumers is unlikely.

2.22 Fosetyl-Al (302)

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

Fosetyl-Al was considered by the JMPR for new uses. Relevant background information is outlined in Tables 68 and 69.

Table 68 Toxicological reference values

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

Table 69 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	Sum of fosetyl, phosphonic acid and their	Yes

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

† The molecular mass 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 residue definitions for plants for risk assessment are comparable between GB and the JMPR, however the residue definitions for enforcement are expressed differently. The CXLs can be expressed in accordance with the GB residue definition for enforcement using a molecular conversion factor (1.34).

For livestock, the residue definitions for risk assessment are comparable between GB and the JMPR, however the residue definitions for enforcement are different. The GB residue definition includes fosetyl. However, the available studies demonstrate that fosetyl is rapidly degraded to phosphonic acid in plants and animals. Therefore, the non-inclusion of fosetyl in the residue definition for enforcement for the CXLs for products of animal origin is not critical. The CXLs expressed as phosphonic acid can easily be expressed as fosetyl using a molecular conversion factor (1.34).

The proposed draft CXLs and their consideration are outlined in Table 70.

Table 70 CXL proposals for fosetyl

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg) (Expressed as phosphonic acid)	CXL (mg/kg) (Expressed as fosetyl) †	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Blackberries	Blackberries	0153010	70	94	300	The CXL does not need to be adopted as the GB MRL is higher
Coffee bean	Coffee beans	0620000	30	40	5*	The CXL can be adopted as a GB MRL
Eggs	Birds eggs	1030000	0.05*	0.07*	0.1*	The CXL does not need to be adopted as the GB MRL is higher
Flowerhead brassicas, subgroup of	Flowering brassicas	0241000	0.2*	0.3*	10	The CXL does not need to be adopted as the GB MRL is higher
Head brassicas, subgroup of	Head brassicas	0242000	0.2*	0.3*	10	The CXL does not need to be adopted as the GB MRL is higher
Kale	Kales	0243020	0.2*	0.3*	10	The CXL does not need to be adopted as the GB MRL is higher
Kiwifruits	Kiwi fruits (green, red and yellow)	0162010	150	200	150	The CXL can be adopted as a GB MRL
Mammalian fats (except milk fats) ††	All mammalian species - fats	Various	0.3	0.4	0.5*	The CXL does not need to be adopted as the GB MRL is higher
Pineapple	Pineapples	0163080	15	20	50	The CXL does not need to be adopted as the GB MRL is higher
Poultry meat	Poultry - muscle	1016010	0.05*	0.07*	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) (Expressed as phosphonic acid)	CXL (mg/kg) (Expressed as fosetyl) †	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Poultry, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	various	0.05*	0.07*	0.5*	The CXL does not need to be adopted as the GB MRL is higher
Poultry fats	Poultry - fats	1016020	0.05*	0.07*	0.5*	The CXL does not need to be adopted as the GB MRL is higher

† Multiplied by 1.34 and rounded to appropriate MRL class

†† 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 71. The outputs from UK models and PRIMo can be seen in annexes 1-4.

The dietary exposure assessments have been undertaken in accordance with the residue definition for risk assessment, which is the sum of fosetyl, phosphonic acid and their salts, expressed as phosphonic acid. Residues of phosphonic acid (from the approved actives disodium phosphonate and potassium phosphonates) will also give rise to phosphonic acid residues and have also been taken into account in the chronic risk assessment.

It should be noted that the dietary exposure assessments have been undertaken using the MRL currently in force for several commodities as the STMR values are not currently available to HSE. Therefore, the intakes are likely to have overestimated the exposure.

There is no consumption data for coffee beans in the UK model. The assessment using PRIMo covers coffee beans.

Table 71 Summary of the consumer risk assessments for fosetyl

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 74 % of the ADI (toddler)	No chronic health effects are expected from the consumption of treated commodities
	EFSA	The highest IEDI is 48 % of the ADI (NL Toddler)	
Acute exposure assessment	UK	The active is not acutely toxic and an ARfD has not been allocated.	
	EFSA		

Conclusions

The proposed draft CXLs for all commodities, except kiwi and coffee beans, are lower than the GB MRLs in force.

The proposed draft CXLs for kiwi and coffee bean are acceptable and a risk to consumers is unlikely.

2.23 Glyphosate (158)

Glyphosate is an approved active substance in GB. MRLs have been established in Part 2 of the GB MRL Statutory Register.

Glyphosate was considered by the JMPR for new uses. Relevant background information is outlined in Tables 72 and 73.

Table 72 Toxicological reference values

	JMPR	GB	Units
ADI	1	0.5	mg/kg bw per day
ARfD	Not required	0.5	mg/kg bw

Table 73 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	For soya bean, maize and oil seed rape: Sum of glyphosate and N-acetylglyphosate, expressed as glyphosate For other crops: Glyphosate	Glyphosate	soya bean, maize and oil seed rape No All other crops Yes
	Risk assessment	Glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate	Sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl-AMPA, expressed as glyphosate	Yes
Livestock	Enforcement	Sum of glyphosate and N-acetylglyphosate,	Glyphosate	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		expressed as glyphosate		
	Risk assessment	Glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate	Sum of glyphosate, AMPA, N-acetylglyphosate and N-acetyl-AMPA expressed as glyphosate	Yes

AMPA: (aminomethyl)phosphonic acid

N-acetyl-AMPA: (acetamidomethyl)phosphonic acid

N-acetyl-glyphosate: N-acetyl-N-(phosphonomethyl)glycine

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

For livestock, the residue definitions for 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 residue definitions for plants for enforcement with respect to soyabeans, maize and oil seed rape are not comparable for GB and the JMPR. The residue definition for the JMPR includes two additional metabolites and is therefore more extensive. As the JMPR residue definition is more extensive, the GB MRL required would be equivalent or lower than the proposed draft CXL. As no CXLs are proposed for soyabeans, maize and oil seed rape, this issue has not been considered further. With respect to the draft proposed CXLs (beans and peas) the residue definition for enforcement is glyphosate only and is comparable between GB and the JMPR.

The proposed draft CXLs and their consideration are outlined in Table 74.

Table 74 CXL proposals for glyphosate

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment/HSE recommendation on the CXL
Dry beans, subgroup of (except soya beans)	Beans	0300010	15	2	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
Dry peas, subgroup of	Peas	0300030	10	10	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 75. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 75 Summary of the consumer risk assessments for glyphosate

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 76 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with glyphosate
	EFSA	The highest IEDI is 33 % of the ADI (GEMS Food G11)	
Acute exposure assessment	UK	The highest NESTI is 3.4 % of the ARfD (infants/ beans)	No health effects due to acute exposure are expected from the consumption of commodities treated with glyphosate
	EFSA	The highest IESTI is 3 % of the ARfD (Children/ beans)	

Conclusions

The proposed draft CXL for beans is acceptable and a risk to consumers is unlikely.

The proposed draft CXL for peas is equivalent to the GB MRL in force.

2.24 Isofetamid (290)

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

Isofetamid was considered by the JMPR as a follow up evaluation (original consideration was for new uses) due to an EU comment in the 2018 CCPR. The EU had noted that for bush berries an MRL of 4 mg/kg instead of 5 mg/kg would be sufficient and that for dry beans and dry peas the OECD MRL calculator suggested a MRL of 0.09 mg/kg rather than 0.05 mg/kg.

Relevant background information is outlined in Tables 76 and 77.

Table 76 Toxicological reference values

	JMPR	GB	Units
ADI	0.05	0.02	mg/kg bw per day
ARfD	3	1	mg/kg bw

Table 77 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Isofetamid	Isofetamid	Yes
	Risk assessment	Isofetamid	Sum of isofetamid and GPTC, expressed as isofetamid	No
Livestock	Enforcement	sum of isofetamid and PPA, expressed as isofetamid	Isofetamid (provisional) †	No
	Risk assessment	sum of isofetamid and PPA, expressed as isofetamid	Sum of isofetamid and PPA expressed as isofetamid (provisional)†	Yes

PPA: 2-[3-methyl-4-[2-methyl-2-(3-methylthiophene-2-carboxamido)propanoyl]phenoxy]propanoic acid

GPTC: N-{1-[4-(D-glucopyranosyloxy)-2-methylphenyl]-2-methyl-1-oxopropan-2-yl}-3-methylthiophene-2-carboxamide

† The residue definitions were only established provisionally on the basis that the registered uses do not currently lead to significant intakes in the diets of livestock. The residue definitions need to be reconsidered if substantive MRLs need to be established for products of animal origin.

For plants, the residue definitions for enforcement are comparable between GB and the JMPR. The residue definitions for risk assessment are not comparable. The residue definition for GB includes the additional metabolite GPTC.

The following conversion factors are available in the EFSA conclusion for the approval of the active substance (EFSA, 2015):

Peaches, plums, grapes: 1.1

Lettuce: 1.3

The conversion factor of 1.1 for grapes can be applied to bush berries (blueberries, currants (black, red and white), gooseberries and rose hips).

Conversion factors are not available for pulses; this may lead to an underestimation of the residue levels, although this would not be expected to exceed the safety margin observed in the consumer risk assessments.

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

The proposed draft CXLs and their consideration are outlined in Table 78.

Table 78 CXL proposals for isofetamid

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
Bush berries, subgroup of	Blueberries	0154010	4	0.01*	The CXL can be adopted as a GB MRL
Bush berries, subgroup of	Currants (black, red and white)	0154030	4	0.01*	The CXL can be adopted as a GB MRL
Bush berries, subgroup of	Gooseberries (green, red and yellow)	0154040	4	0.01*	The CXL can be adopted as a GB MRL
Bush berries,	Rose hips	0154050	4	0.01*	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
subgroup of					
Dry beans, subgroup of	Beans	0300010	0.09	0.01*	The CXL can be adopted as a GB MRL
Dry peas, subgroup of	Peas	0300030	0.09	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 79. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 79 Summary of the consumer risk assessments for isofetamid

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDIs is 46 % of the ADI (vegetarian)	No health effects due to chronic exposure are expected from the consumption of commodities treated with isofetamid
	EFSA	The highest IEDI is 29 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 3.5 % of the ARfD (toddler/ bushberries - using consumption data for blackberries)	No health effects due to acute exposure are expected from the consumption of commodities treated with isofetamid
	EFSA	The highest IESTI is 3% of the ARfD (Child/ Currants (red, black and white))	

Conclusions

The proposed draft CXLs are all acceptable and a risk to consumers is unlikely.

2.25 Kresoxim-methyl (199)

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

Kresoxim-methyl was considered by the JMPR for new uses. Relevant background information is outlined in Tables 80 and 81.

Table 80 Toxicological reference values

	JMPR	GB	Units
ADI	0.3	0.4	mg/kg bw per day
ARfD	Not required	Not required	mg/kg bw

Table 81 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Kresoxim-methyl	Kresoxim-methyl	Yes
	Risk assessment	Sum of kresoxim-methyl and metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1) and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) including their conjugates expressed as kresoxim-methyl	Sum of kresoxim-methyl and the metabolites BF 490-2 and BF 490-9, free and conjugated, expressed as parent	No
Livestock	Enforcement	Sum of metabolites (2E)-(methoxyimino){2-	Kresoxim-methyl (BF-490-9,	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) expressed as kresoxim-methyl	expressed as parent)	
	Risk assessment	Sum of metabolites (2E)-(methoxyimino){2-[(2-methylphenoxy)methyl]phenyl}acetic acid (490M1), and (2E)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid (490M9) expressed as kresoxim-methyl	Sum of metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent (ruminant matrices and milk only)	No

BF 490-1 (490M1): (*E*)-methoxyamino(α -(*o*-tolylloxy)-*o*-tolyl]acetic acid

BF 490-2: (490M2): (2*E*)-(2-{[2-(hydroxymethyl)phenoxy]methyl}phenyl)(methoxyimino)acetic acid

BF 490-9: (490M9): (2*E*)-{2-[(4-hydroxy-2-methylphenoxy)methyl]phenyl}(methoxyimino)acetic acid

The residue definitions for plants for enforcement are comparable between GB and the JMPR. However, the residue definition for plants for risk assessment are not comparable for GB and the JMPR. For GB, the residues definition for plants for risk assessment includes the metabolite 490M2 whereas the JMPR residue definition includes the metabolite 490M1. The metabolite 490M2 was included as it was found to be a major metabolite in grapes. This metabolite was not found in significant amounts in the apple, wheat and sugar beet metabolism studies. However, the

metabolite was found in significant levels in fruit crops in the residue trials. Therefore, the STMRs calculated by the JMPR may result in an underestimate of the exposure. As the only proposed draft CXL is lower than the GB MRL in force, this issue has not been considered further.

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

The proposed draft CXLs and their consideration are outlined in Table 82.

Table 82 CXL proposals for kresoxim-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
Pome fruits, group of	Pome fruits	0130000	0.15	0.2	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 no CXLs are being recommended for adoption as GB MRLs.

Conclusions

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

2.26 Mandestrobin (307)

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

Mandestrobin was considered by the JMPR as a new active substance. Relevant background information is outlined in Tables 83 and 84.

Table 83 Toxicological reference values

	JMPR	GB	Units
ADI	0.2	0.19	mg/kg bw per day
ARfD	3	Not required	mg/kg bw

Table 84 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	mandestrobin	mandestrobin	Yes
	Risk assessment	mandestrobin	sum of mandestrobin, De-Xy-S-2200, 4-OH-S-2200 conjugate, 2-CH ₂ OH-S-2200 conjugate, expressed as mandestrobin	No
Livestock	Enforcement	mandestrobin	mandestrobin	Yes
	Risk assessment	See †	mandestrobin	No

† The sum of parent, (2RS)-2-[2-(4-hydroxy-2,5-dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide (4-OH-mandestrobin) + (2RS)-2-(2-hydroxymethylphenyl)-2-methoxy-N-methylacetamide (De-XY-mandestrobin) + (2RS)-2-[2-(2-hydroxymethyl-5-methylphenoxy)methyl]phenyl]-2-methoxy-N-methylacetamide (2-CH₂-OH-mandestrobin) + 2-({2-[(1RS)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (2-COOH-mandestrobin), + 3-({2-[(1RS)-1-methoxy-2-(methylamino)-2-oxoethyl]benzyl}oxy)-4-methylbenzoic acid (5-COOH-mandestrobin) and their conjugates, expressed as parent compound

De-Xy-S-2200: (2RS)-2-(2-hydroxymethylphenyl)-2-methoxy-N-methylacetamid

4-OH-S-2200: (2RS)-2-[2-(4-hydroxy-2,5- dimethylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamid

2-CH₂OH-S-2200: (2RS)-2-[2-(2-hydroxymethyl-5- methylphenoxy)methyl]phenyl)-2-methoxy-N-methylacetamide

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

For plants, the residue definitions for risk assessment are not comparable as the residue definition in GB includes three additional metabolites. For the approval of the active substance (EFSA, 2015) a conversion factor of 4 was established for oilseed rape. The conversion factor was considered acceptable for the GAP 1 x 200 g a.s./ha applied at BBCH 63 – 67. Residues of mandestrobin and the three metabolites were all less than the LOQ at harvest in the seeds; therefore basing a conversion factor on residues of less than the LOQ would not be in accordance with the OECD guidance. Application of this conversion factor directly to the GAP

considered by the JMPR (1 x 420 g a.s./ha applied at BBCH 62 – 65, with a PHI of 35 days) for which positive residues are obtained, would also not be appropriate. Metabolism data specifically on oil seed rape is available from the approval assessment. The metabolism data were generated at application rates of 2 x 400 g a.s./ha (applied at BBCH 55-61 and BBCH 66-67) and 1 x 400 g a.s./ha (applied at BBCH 55-61) with the latter data being more relevant to the GAP. Only data taken after a PHI of 54 days is reported, which does not reflect the GAP. It is noted that the JMPR assessment included some trials in which the three metabolites were analysed (included free and conjugated forms of the metabolites); but this did not include sufficient data for those trials selected to establish the MRL. Overall, there are insufficient data to determine a conversion factor.

The same GAPs evaluated by the JMPR for grapes and strawberries have been considered by EFSA (EFSA, 2018) and conversion factors of 1.06 and 1.10 determined for grapes and strawberries respectively.

In the approval assessment the toxicological properties of the plant metabolite 2-CH₂OH-S-2200 (2-CH₂OH-M) and its conjugate were not considered addressed. It is noted that the lack of toxicological data was not listed as a specific data gap, the residue definition was not marked as provisional and there was no confirmatory data requirement set to address the toxicity of this metabolite.

The JMPR assessment concluded that 2-CH₂OH-S-2200 has a similar toxicity to mandestrobin. Importantly, the data from the JMPR and EFSA (2018) show this metabolite was less than the LOQ of 0.02* mg/kg.

For GB, residues in the diets of livestock have not been considered and therefore the residue definition for risk assessment is parent only. As the JMPR has recommended all MRLs for products of animal origin at the LOQ of 0.01* mg/kg then the difference in residue definitions between GB and the JMPR has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 85.

Table 85 CXL proposals for mandestrobin

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
Edible offal (mammalian) †	All mammalian species - liver, kidney and edible offals	Various	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Eggs	Birds eggs	1030000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Grapes	Grapes	0151000	5	0.01*	The CXL can be adopted as a GB MRL
Mammalian fats (except milk fats) †	All mammalian species - fats	Various	0.01*	0.01*	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	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Milks	Milk	1020000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry fats	Poultry - fats	1016020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry meat	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry, edible offal of	Poultry – Liver, kidney and edible	Various	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
	offals (other than liver and kidney)				
Rape seed	Rapeseeds/canola seeds	0401060	0.2	0.01*	The residue definitions are not compatible between GB and the JMPR and there is no CF. The CXL should not be adopted as a GB MRL.
Strawberry	Strawberries	0152000	3	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

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 86. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 86 Summary of the consumer risk assessments for mandestrobin

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDIs is 9 % of the ADI (Adult and vegetarians)	No health effects due to chronic exposure are expected from the consumption of commodities treated with mandestrobin
	EFSA	The highest IEDI is 2 % of the ADI (PT general)	
Acute exposure assessment	UK	The active is not acutely toxic and an ARfD has not been allocated	
	EFSA		

Conclusions

The proposed draft CXL for rape seed is not acceptable as the residue definitions between the JMPR and GB are not comparable and a conversion factor cannot be determined.

The proposed draft CXLs for grape and strawberries are acceptable and a risk to consumers is unlikely. The proposed draft CXLs for products of animal origin are lower than the GB MRLs in force.

2.27 Mesotrione (277)

Mesotrione is an approved active substance in GB. MRLs have been established in Part 2 of the GB MRL Statutory Register.

Mesotrione was considered by the JMPR for new uses. Relevant background information is outlined in Tables 87 and 88.

Table 87 Toxicological reference values

	JMPR	GB	Units
ADI	0.5	0.01	mg/kg bw per day
ARfD	Not required	0.02	mg/kg bw

Table 88 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Mesotrione	Mesotrione	Yes
	Risk assessment	Mesotrione	Food commodities: Mesotrione (cereals and pulses/oilseeds only) Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional	No
Livestock	Enforcement	Mesotrione	Mesotrione	Yes
	Risk assessment	Mesotrione	Not required for representative uses (provisional)	No

AMBA: 2-amino-4-(methylsulfonyl)benzoic acid

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

For plants, the residue definition for risk assessment in GB only covers cereals and pulses/oilseeds whereas the proposed draft CXLs are for crops categorised as fruits for plant metabolism. For livestock, a residue definition for risk assessment has not been established in GB as the representative use considered in the renewal assessment did not give rise to significant residues in products of animal origin. This

residue definition will need to be reconsidered if authorisations or uses in other jurisdictions give rise to significant residues in products of animal origin.

As the proposed draft CXLs are all recommended at the LOQ of 0.01* mg/kg, and these are equivalent to the GB MRLs in force, then the issues outlined with the residue definitions has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 89.

Table 89 CXL proposals for mesotrione

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
Citrus fruits, subgroup of	Citrus fruits	0110000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Citrus fruits, subgroup of	Kumquats	0161040	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Pome fruits, group of	Pome fruits	0130000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Stone fruit, group of	Stone fruits	0140000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Tree nuts, subgroup of	Tree nuts	0120000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as no CXLs are being recommended for adoption as GB MRLs.

Conclusions

The proposed draft CXLs are equivalent to the GB MRLs in force.

2.28 Metaflumizone (236)

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

Metaflumizone was considered by the JMPR for new uses. Relevant background information is outlined in Tables 90 and 91.

Table 90 Toxicological reference values

	JMPR	GB	Units
ADI	0.1	0.01	mg/kg bw per day
ARfD	Not required	0.13	mg/kg bw

Table 91 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer	Metaflumizone (sum of E- and Z-isomers)	Yes
	Risk assessment	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer	Metaflumizone (sum of E- and Z-isomers)	Yes
Livestock	Enforcement	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer	Metaflumizone (sum of E- and Z-isomers)	Yes
	Risk assessment	Metaflumizone, sum of metaflumizone E-isomer and metaflumizone Z-isomer	Metaflumizone (sum of E- and Z-isomers)	Yes

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

The proposed draft CXLs and their consideration are outlined in Table 92.

Table 92 CXL proposals for metaflumizone

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	0.9	0.05*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Coffee bean	Coffee beans	0620000	0.15	0.1*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Grapes	Table grapes	0151010	5	0.05*	Acute and chronic intake concerns have been identified. The CXL should not be adopted as a GB MRL.
Grapes	Wine grapes	0151020	5	0.05*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Lemons and limes (including citron), subgroup of	Lemons	0110030	2	0.05*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Lemons and limes (including citron), subgroup of	Limes	0110040	2	0.05*	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
Lemons and limes (including citron), subgroup of	Kumquats	0161040	2	0.05*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Maize	Maize/Corn	0500030	0.04	0.05*	The CXL does not need to be adopted as the GB MRL is higher.
Melons, except water melons	Melons	0233010	1	0.05*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Oranges, sweet, sour (including orange-like hybrids), subgroup of	Oranges	0110020	3	0.05*	Acute and chronic intake concerns have been identified. The CXL should not be adopted as a GB MRL.
Soya bean (dry)	Soyabeans	0401070	0.2	0.05*	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Sugar cane	Sugar canes	0900020	0.02*	0.05*	The CXL does not need to be adopted as the GB MRL is higher.
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	Various	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
Eggs	Birds eggs	1030000	0.02	0.02	The CXL does not need to be adopted as the GB MRL is equivalent
Mammalian fats (except milk fats) †	All mammalian species - fats	Various	0.15	0.02	A chronic intake concern has been identified. The CXL should not be adopted as a GB MRL.
Meat (from mammals) other than marine mammals) †	All mammalian species - muscle	Various	0.02* (fat)	0.02	The CXL does not need to be adopted as the GB MRL is equivalent
Milks	Milk	1020000	0.02	0.02	The CXL does not need to be adopted as the GB MRL is equivalent
Milk fats	N/A	N/A	0.7	N/A	MRLs not set in GB for milk fats
Poultry, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.02*	0.02	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry fats	Poultry - fats	1016020	0.08	0.1	The CXL does not need to be adopted as the GB MRL is higher
Poultry meat	Poultry - muscle	1016010	0.02* (fat)	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

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 93. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 93 Summary of the consumer risk assessments for metaflumizone

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 233% of the ADI (toddler). Refining the risk assessment (as outlined below) results the highest NEDI being 117% of the ADI (toddler).	A chronic intake concern has been identified.
	EFSA	The highest IEDI is 107% of the ADI (NL toddler). With the proposed draft CXLs for oranges and table grapes removed (due to acute intake concerns, see below), the highest IEDI was 79% of the ADI (NL toddler).	
Acute exposure assessment	UK	For oranges the highest NESTI is 138% of the ARfD for infants. For table grapes the highest NESTI is 127% of the ARfD for toddlers.	An acute intake concern has been identified for oranges and table grapes. No health effects due to acute exposure are expected from the

Dietary exposure assessment	Model	Outcome	Comment
		The NESTIs for all other commodities are less than the ARfD.	consumption of all other commodities treated with metaflumizone.
	EFSA	For oranges the highest IESTI is 138% of the ARfD (UK infant). For table grapes the highest IESTI is 152% of the ARfD (FI child 3 years). The IESTIs for all other commodities are less than the ARfD.	

Given there was an exceedance of the ADI using the UK chronic consumer model, the UK chronic risk assessment was refined. The STMRs supporting the proposed draft CXLs for oranges and table grapes were removed due to acute intake concerns from the adoption of the CXLs. A processing factor of 0.08 was used for production of wine from wine grapes. This processing factor was derived by the JMPR 2019 extra meeting as part of the CXL proposals (FAO, 2019):

Commodity	Processed fraction	Processing factors	Median processing factor
Grapes	Wine	<0.01, <0.01, <0.08, <0.08, <0.11, <0.11	<0.08

An STMR of 5.25 mg/kg was used for beansprouts. In the unrefined risk assessment, the current GB MRL of 10 mg/kg was used which led to beansprouts being a major contributor to the exposure. The STMR supporting this MRL is not available to HSE. However, during the ongoing EU MRL review, an MRL of 20 mg/kg was tentatively proposed for beansprouts with a corresponding STMR of 5.25 mg/kg (EFSA, 2020). It is likely this STMR is worst-case compared to the STMR supporting the current GB MRL of 10 mg/kg. Despite these refinements there was still an exceedance of the ADI.

Conclusions

The proposed draft CXLs are not acceptable as the chronic exposure exceeds the ADI. For table grapes and oranges the acute exposures exceed the ARfD.

2.29 Metconazole (313)

Metconazole is an approved active substance in GB. MRLs have been established in Part 2 of the GB MRL Statutory Register.

Metconazole was considered by the JMPR as a new active (for the JMPR). Relevant background information is outlined in Tables 94 and 95.

Table 94 Toxicological reference values

	JMPR	GB	Units
Metconazole			
ADI	0.04	0.01	mg/kg bw per day
ARfD	0.04	0.01	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	Not required	0.3	mg/kg bw
Triazole acetic acid (TAA)			
ADI	1	1	mg/kg bw per day
ARfD	Not required	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 95 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Metconazole (sum of cis and trans isomer)	Metconazole (sum of isomers)	Yes
	Risk assessment	Metconazole (sum of cis and trans isomer)	1) Metconazole (sum of isomers) 2) TA and TLA 3) TAA	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			4) 1,2,4-T	
Livestock	Enforcement	Metconazole (sum of cis and trans isomer)	Metconazole (sum of isomers)	Yes
	Risk assessment	See †	1) Metconazole (sum of isomers) 2) TA and TLA 3) TAA 4) 1,2,4-T	No

Triazole derivative metabolites (TDMs):

TA: triazole alanine

TLA: triazole lactic acid

TAA: triazole acetic acid

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

† Sum of metconazole (cis and trans-isomer) and metabolites (1SR,2SR,5RS)-5-(4-chlorobenzyl)-2-(hydroxymethyl)-2-methyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol (M1; free and conjugated) and (1RS,2SR,3RS)-3-(4-chlorobenzyl)-2-hydroxy-1-methyl-2-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanecarboxylic acid (M12; free and conjugated), expressed as metconazole

The residue definitions for both plants and livestock for enforcement are comparable between GB and the JMPR. For risk assessment the GB residue definitions include the triazole derivative metabolites. In addition, for livestock the JMPR residue definition includes the metabolites M1 and M12.

With regards to the residue levels of the triazole metabolite pesticides, limited residues data for some of the crops are available in the JMPR evaluation. However, residues of TLA were not determined in any of the trials. Limited data for the triazole derivative metabolites is also available in the JMPR evaluation for 1,2,4-T in poultry commodities. However, residues of TA, TAA and TLA were not determined in the feeding studies.

The proposed draft CXLs and their consideration are outlined in Table 96.

Table 96 CXL proposals for metconazole

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	0.1*	0.1	The CXL does not need to be adopted as the GB MRL is equivalent
Blueberries	Blueberries	0154010	0.5	0.4	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Beans, except broad bean and soya bean	Beans (with pods)	0260010	0.05*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Cherries, subgroup of	Cherries (sweet)	0140020	0.3	0.2	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Cotton seed	Cotton seeds	0401090	0.3	0.3	The CXL does not need to be adopted as the GB MRL is equivalent
Dry beans, subgroup of	Beans	0300010	0.04*	0.15	The CXL does not need to be adopted as the GB MRL is higher
Dry peas, subgroup of	Peas	0300030	0.15	0.15	The CXL does not need to be adopted as the GB MRL is equivalent
Edible offal (mammalian) †	All Mammalian species	Various	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Eggs	Birds eggs	1030000	0.04*	0.02*	Incomplete residues data for the TDM. 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
Garlic	Garlic	0220010	0.05*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Maize	Maize/Corn	0500030	0.015	0.1	The CXL does not need to be adopted as the GB MRL is higher
Mammalian fats (except milk fats) †	All Mammalian species - fats	Various	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Meat (from mammals) other than marine mammals) †	All Mammalian species - muscle	Various	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Milks	Milk	1020000	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Onion, bulb	Onions	0220020	0.05*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Peanut	Peanuts/groundnuts	0401020	0.04*	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Peaches subgroup of	Apricots	0140010	0.2	0.1	Incomplete residues data for the TDM. 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
Peaches subgroup of	Peaches	0140030	0.2	0.1	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Plums, subgroup of	Plums	0140040	0.1	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Poultry, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Poultry fats	Poultry - fats	1016020	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Poultry meat	Poultry - muscle	1016010	0.04*	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Rape seed	Rapeseeds/canola seeds	0401060	0.15	0.2	The CXL does not need to be adopted as the GB MRL is higher.
Sunflower seeds, subgroup of	Sunflower seeds	0401050	1.5	0.7	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Sunflower seeds, subgroup of	Safflower seeds	0401110	1.5	0.05*	Incomplete residues data for the TDM. 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
Tree nuts, subgroup of	Tree nuts	0120000	0.04*	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Tuberous and corm vegetables, subgroup of	potatoes	0211000	0.04*	0.04*	The CXL does not need to be adopted as the GB MRL is equivalent
Tuberous and corm vegetables, subgroup of	Cassava roots/manioc	0212010	0.04*	0.04*	The CXL does not need to be adopted as the GB MRL is equivalent
Tuberous and corm vegetables, subgroup of	Sweet potatoes	0212020	0.04*	0.04*	The CXL does not need to be adopted as the GB MRL is equivalent
Tuberous and corm vegetables, subgroup of	Yams	0212030	0.04*	0.04*	The CXL does not need to be adopted as the GB MRL is equivalent
Tuberous and corm vegetables, subgroup of	Arrowroots	0212040	0.04*	0.04*	The CXL does not need to be adopted as the GB MRL is equivalent
Tuberous and corm	Jerusalem artichokes	0213050	0.04*	0.02*	Incomplete residues data for the TDM. 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
vegetables, subgroup of					
Sugar beet	Sugar beet roots	0900010	0.07	0.06	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Soya bean (dry)	Soyabeans	0401070	0.04	0.05*	The CXL does not need to be adopted as the GB MRL is higher
Sugar cane	Sugar canes	0900020	0.06	0.02*	Incomplete residues data for the TDM. The CXL should not be adopted as a GB MRL.
Sweet corn (Corn-on-the-cob)	sweet corn	0234000	0.015	0.02*	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

Consumer Risk Assessments

An estimation of the dietary intakes has not been undertaken as it is not possible to conclude on the consumer risk assessments as data are not available for all the triazole derivative metabolites.

Conclusion

The proposed draft CXLs are not acceptable as insufficient residues data are available for the triazole derivative metabolites.

2.30 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.

The JMPR assessed new uses for the active substance. Relevant background information is outlined in Tables 97 and 98.

Table 97 Toxicological reference values

	JMPR	GB	Units
ADI	For the R,S racemate: 0.09 For S-methoprene: 0.05	N/A	mg/kg bw per day
ARfD	Not required	N/A	mg/kg bw

N/A Not applicable. The active has not been considered in GB.

Table 98 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Methoprene	Methoprene	Yes
	Risk assessment	Methoprene	N/A	N/A
Livestock	Enforcement	Methoprene	Methoprene	Yes
	Risk assessment	Methoprene	N/A	N/A

N/A The active has not been considered in GB.

The residue definition established in GB for enforcement is methoprene. The JMPR has noted that the active is fat soluble. It is noted from the JMPR assessment in 2005 that the partition coefficient is 4 for methoprene and 6 for s-methoprene. In the animal metabolism studies, the concentration of residues was significantly higher in fat and egg yolk compared to muscle and egg whites. However, methoprene was metabolised quickly and extensively by animals, so its accumulation in fat was temporary.

The proposed draft CXL and its consideration is outlined in Table 99.

Table 99 CXL proposals for methoprene

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Peanut, whole	Peanuts/gro undnuts	0401020	5	0.05*	A chronic intake concern was also identified. The CXL should not be adopted as a GB MRL.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 100. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

The proposed draft CXL is based on the application of s-methoprene. Therefore, the dietary exposure assessments have been conducted using the ADI of 0.05 mg/kg bw per day.

Table 100 Summary of the consumer risk assessments for methoprene

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 148 % of the ADI (toddlers)	The chronic exposures were undertaken using the STMR for the proposed draft CXL and the MRLs for all other commodities. The main contribution to the overall exposure is
	EFSA	The highest NEDI is 135 % of the ADI (NL toddler)	

Dietary exposure assessment	Model	Outcome	Comment
			the current MRLs for cereal. A chronic intake concern has been identified
Acute exposure assessment	UK	The active is not considered acutely toxic by the JMPR and therefore an ARfD has not been allocated.	
	EFSA		

In Part 3 of the GB MRL Register, MRLs are set for all cereals at 5 mg/kg. It appears that these MRLs are based on historic CXLs. Refinement of the chronic risk assessment using the STMR values for cereals is not possible as these data are not available to HSE. The CXLs for cereals were raised to 10 mg/kg, with an STMR of 4.85 mg/kg, in 2006.

Conclusions

The chronic consumer exposure assessment indicates a risk to consumers. Therefore, the proposed draft CXLs should not be adopted as GB MRLs.

2.31 Pendimethalin (292)

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

Pendimethalin was considered by the JMPR for new uses. Relevant background information is outlined in Tables 101 and 102.

Table 101 Toxicological reference values

	JMPR	GB	Units
ADI	0.1	0.125	mg/kg bw per day
ARfD	1	0.3	mg/kg bw

Table 102 Residue definitions

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

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

The proposed draft CXLs and their consideration are outlined in Table 103.

Table 103 CXL proposals for pendimethalin

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
Bush berries, subgroup of	Blueberries	0154010	0.05*	0.05*	The CXL does not need to be adopted as the GB MRL is equivalent
Bush berries, subgroup of	Currants (black, red and white)	0154030	0.05*	0.05*	The CXL does not need to be adopted as the GB MRL is equivalent
Bush berries, subgroup of	Gooseberries (green, red and yellow)	0154040	0.05*	0.05*	The CXL does not need to be adopted as the GB MRL is equivalent
Bush berries, subgroup of	Rose hips	0154050	0.05*	0.05*	The CXL does not need to be adopted as the GB MRL is equivalent
Cane berries, subgroup of	Cane fruits	0153000	0.05*	0.05*	The CXL does not need to be adopted as the GB MRL is equivalent
Mints	Basil and edible flowers	0256080	0.2	0.6	The CXL does not need to be adopted as the GB MRL is higher
Strawberry	Strawberries	0152000	0.05*	0.05*	The CXL does not need to be adopted as the GB MRL is equivalent

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as no CXLs are being recommended for adoption as GB MRLs.

Conclusions

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

2.32 Penthiopyrad (253)

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

Penthiopyrad was considered by the JMPR for new uses. Relevant background information is outlined in Tables 104 and 105.

Table 104 Toxicological reference values

	JMPR	GB	Units
ADI	0.1	0.1	mg/kg bw per day
ARfD	1	0.75	mg/kg bw

Table 105 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Penthiopyrad	Penthiopyrad	Yes
	Risk assessment	Sum of penthiopyrad and PAM, expressed as penthiopyrad	1) sum of penthiopyrad and metabolite 753-A-OH, expressed as penthiopyrad. 2) Metabolite PAM	No
Livestock	Enforcement	Sum of penthiopyrad and PAM, expressed as penthiopyrad	Penthiopyrad	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Sum of penthiopyrad and PAM, expressed as penthiopyrad	1) Penthiopyrad 2) Metabolite PAM	No

PAM: 1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide

753-A-OH: N-[2-(3-hydroxy-1,3-dimethyl-butyl) thiophen-3-yl]-1-methyl-3-trifluoromethyl-1H-pyrazole-4-carboxamide

Penthiopyrad has potential to be fat soluble (Log POW > 3) however residues do not accumulate in fat. PAM: log POW < 0.5.

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

The residue definitions for risk assessment in plants for GB and for the JMPR are not comparable. The residue definition for GB includes an additional metabolite (753-A-OH) and includes the metabolite PAM as a separate definition, rather than determined as a sum. The JMPR evaluation does not include levels of the metabolites 753-A-OH in the residue trials. The JMPR evaluation includes levels of penthiopyrad and PAM. A conversion factor between risk assessment and monitoring residue definitions in GB have not been established for the relevant crops (berries and small fruits). However, conversion factors for similar fruits crops (strawberry, cherry, peach and plum) were established with a value of 1 (EFSA, 2012). Additionally, as stated in EFSA, 2012, from the available metabolism data in fruit crops, the main components of the residue are expected to be penthiopyrad and PAM. Therefore, levels of the metabolite 753-A-OH are expected to be low and not contribute significantly to exposure. The lack of conversion factor may lead to an underestimation of the residue levels, however, there is sufficient evidence any contribution to exposure from residues of the metabolite 753-A-OH is not expected to exceed the safety margin observed in the consumer risk assessments.

It is noted that agreed toxicological reference values for the metabolite PAM have not been established in GB. The following is listed as outstanding active substance confirmatory data in the GB active substance approvals register: *'the toxicological profile and the reference values of the metabolite PAM'*. The assessment of the CXLs has therefore been undertaken without prejudice to the outcome of the active substance confirmatory data assessment.

For livestock, the residue definitions for enforcement and risk assessment 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 draft CXLs and their consideration are outlined in Table 106.

Table 106 CXL proposals for penthiopyrad

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
Bush berries, subgroup of	Blueberries	0154010	7	0.01*	The CXL can be adopted as a GB MRL
Bush berries, subgroup of	Currants (black, red and white)	0154030	7	0.01*	The CXL can be adopted as a GB MRL
Bush berries, subgroup of	Gooseberries (green, red and yellow)	0154040	7	0.01*	The CXL can be adopted as a GB MRL
Bush berries, subgroup of	Rose hips	0154050	7	0.01*	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Blackberries	0153010	10	0.01*	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Dewberries	0153020	10	0.01*	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Raspberries (red and yellow)	0153030	10	0.01*	The CXL can be adopted as a GB MRL
Cane berries, subgroup of	Other cane berries	0153990	10	0.01*	The CXL can be adopted as a GB MRL
Elderberries	Elderberries	0154080	7	0.01*	The CXL can be adopted as a GB MRL
Guelder rose	Elderberries	0154080	7	0.01*	The CXL is covered by the GB MRL for elderberries

Consumer Risk Assessments

The outcomes of the consumer risk assessments are summarised in Table 107. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

The assessment of the proposed draft CXLs has been undertaken without prejudice to the outcome of the active substance confirmatory data assessment with regards to establishing toxicological reference values for the metabolite PAM.

Table 107 Summary of the consumer risk assessments for penthiopyrad

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 21 % of the ADI (toddlers)	No health effects due to chronic exposure are expected from the consumption of commodities treated with penthiopyrad
	EFSA	The highest IEDI is 12 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI is 6.9 % of the ARfD (toddlers/blackberries)	No health effects due to acute exposure are expected from the consumption of commodities treated with penthiopyrad
	EFSA	The highest NESTI is 7 % of the ARfD (children/blackberries)	

Conclusions

The proposed draft CXLs are acceptable and a risk to consumers is unlikely.

2.33 Picoxystrobin (258)

Picoxystrobin is a non-approved active substance in GB. With regards to the residues/dietary exposure assessment a genotoxic concern could not be excluded for residues to which consumers will be exposed. Therefore the risk assessment was unable to demonstrate that the necessary requirements were satisfied.

MRLs are established in Part 5 of the GB MRL Statutory Register at the LOQ.

Picoxystrobin was considered by the JMPR for new uses. Relevant background information is outlined in Tables 108 and 109.

Table 108 Toxicological reference values

	JMPR	GB	Units
ADI	0.09	Could not be established	mg/kg bw per day
ARfD	0.09	Could not be established	mg/kg bw

During the renewal assessment the genotoxic potential of picoxystrobin could not be completed based on the information available in the dossier and therefore toxicological reference values were not established for the active substance. The toxicity of several metabolites could also not be concluded on. The genotoxic potential of metabolite IN-H8612 could not be excluded as equivocal results were observed in the *in vivo* micronucleus test, and no toxicological data were provided for IN-K2122 and IN-QGU64.

Table 109 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Picoxystrobin	Picoxystrobin (provisional)	Yes
	Risk assessment	Picoxystrobin	Could not be established	No
Livestock	Enforcement	Picoxystrobin	Picoxystrobin (provisional)	Yes
	Risk assessment	Picoxystrobin	Could not be established	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable

The residue definitions for both plants and livestock for enforcement are comparable between GB and the JMPR. However, for GB the residue definitions are only provisional as further toxicological data on a number of metabolites is required.

For risk assessment, as a result of the lack of toxicological data on the metabolites it is not possible to conclude on the residue definitions for GB.

The proposed draft CXLs and their consideration are outlined in Table 110.

Table 110 CXL Proposals for picoxystrobin

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
Coffee bean	Coffee beans	0620000	0.04	0.05*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Cottonseed	Cotton seeds	0401090	2	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Sorghum grain	Sorghum	0500080	0.02	0.01*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Tea, green, black (black, fermented and dried)	Teas	0610000	15	0.05*	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	0.02	0.1*	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
Mammalian fats (except milk fats) †	All Mammalian species-fats	Various	0.02	0.1*	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	0.02 (fat)	0.1*	The CXL does not need to be adopted as the GB MRL is higher
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

Dietary exposure assessments have not been undertaken as residue definitions for risk assessment and toxicological reference values have not been established in GB.

Conclusion

The proposed draft CXLs are not acceptable as the residue definitions and toxicological reference values have not been established in GB. Based on the risk assessment conducted for the approval of the active substance harmful effects on human health cannot be excluded for residues of picoxystrobin occurring in food. Consequently, the required level of protection has not been met.

It is noted that the proposed draft CXLs for products of animal origin, except milk, are lower than the LOQ MRLs established in the GB MRL Statutory Register.

2.34 Propiconazole (160)

Propiconazole is a non-approved active substance in GB. For the renewal of approval assessment it was not possible to conclude on the residue definition for risk assessment. Further toxicological data are required for the metabolites CGA118244 (to address general toxicity and genotoxic potential) and CGA91305 (to address general toxicity). Therefore the risk assessment was unable to demonstrate that the necessary requirements were satisfied.

MRLs are currently established in Part 2 of the GB MRL Statutory Register.

Propiconazole was considered by the JMPR for new uses. Relevant background information is outlined in Tables 111 and 112.

Table 111 Toxicological reference values

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

Table 112 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	1) Propiconazole (sum of isomers) 2) CGA 118244 free and glucoside conjugated. 3) TAA and TA (provisional)	No
Livestock	Enforcement	Propiconazole	Propiconazole (sum of isomers)	Yes
	Risk assessment	Propiconazole plus all metabolites convertible to 2,4-dichlorobenzoic acid, expressed as propiconazole	1) Propiconazole, CGA91305 (free and conjugated) and CGA118244 2) 1,2,4-T (provisional)	No

CGA 118244 : 3,5-dideoxy-1,2-O-[(1RS)-1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl)ethylidene]-D,L-pentitol)

TAA: Triazole acetic acid

TA: Triazole alanine

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

CGA91305: (1RS)-1-(2,4-dichlorophenyl)-2-(1H-1,2,4-triazol-1-yl) ethanol

The residue definitions for both plants and livestock for enforcement are comparable between GB and the JMPR. For risk assessment, residues are determined for the JMPR assessment using a common moiety method. The GB residue definitions require the specific levels of propiconazole and a number of metabolites to be determined. The residue definitions for GB are also only provisional as additional toxicological data on the metabolites is required and this may have an impact on how the final residue definitions for risk assessment are expressed.

The proposed draft CXLs and their consideration are outlined in Table 113.

Table 113 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
Peaches, subgroup of	Peaches	0140030	4	5	Harmful effects for human health cannot be excluded. The CXL should not be adopted as a GB MRL.

[†] The GB MRLs will need to be reviewed in light of the decision on the renewal of the approval of the active substance.

Consumer Risk Assessments

An estimation of the dietary intakes has not been undertaken as a conclusion on the general toxicity and genotoxicity of several metabolites that consumers will be exposed to could not be reached in the approval assessment.

Conclusion

The proposed draft CXL is not acceptable as a residue definition for risk assessment could not be established. Based on the risk assessment conducted for the approval of the active substance harmful effects on human health cannot be excluded for residues of propiconazole occurring in food. Consequently, the required level of protection has not been met.

2.35 Pydiflumetofen (309)

Pydiflumetofen is not currently an approved active substance in GB, however applications for approval of the active substance in GB and for import tolerances have 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.

The JMPR assessed new uses for the active substance and proposed MRLs to cover residues that may arise in rotational crops. Relevant background information is outlined in Tables 114 and 115.

Table 114 Toxicological reference values

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

N/A Not applicable. The active substance approval is currently ongoing

Table 115 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Pydiflumetofen	N/A	N/A
	Risk assessment	Pydiflumetofen	N/A	N/A
Livestock	Enforcement	Pydiflumetofen	N/A	N/A
	Risk assessment	All commodities, except liver and kidney: Sum of pydiflumetofen and 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, expressed as pydiflumetofen. Liver and kidney: Sum of pydiflumetofen, 2,4,6-trichlorophenol (2,4,6-TCP) and its conjugates, and 3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichloro-3-hydroxy-phenyl)ethyl]pyrazole-4-carboxamide (SYN547897)	N/A	N/A

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		and its conjugates, expressed as pydiflumetofen		

N/A = Not applicable. The active substance approval is currently ongoing

The proposed draft CXLs and their consideration are outlined in Table 116.

Table 116 CXL proposals for Pydiflumetofen (to cover primary and rotational crops)

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 pseudo-cereals with husks, Subgroup of	Barley	0500010	3	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Brassica vegetables (except Brassica leafy vegetables), group of	Various	Various	0.1	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Cottonseed	Cotton seeds	0401090	0.3	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Dry beans, subgroup of	Beans	0300010	0.4	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Dry peas, subgroup of	Peas	0300030	0.4	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Edible offal (mammalian)	All mammalian species – liver, kidney and edible offals	Various	0.1	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.

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
Eggs	Birds eggs	1030000	0.02	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Fruiting vegetables, Cucurbits, group of	cucurbits with edible peel and with inedible peel	Various	0.4	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Fruiting vegetables, other than cucurbits, group of (except martynia, okra and roselle)	Solanaceae and Malvaceae	Various	0.5	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Leafy greens, subgroup of	Various	Various	40	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Leaves of Brassicaceae, subgroup of	Various	Various	0.1	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Leaves of root and tuber vegetables, subgroup of (except leaves of tuber vegetables)	Various	Various	0.07	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.

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
Legume vegetables, group of	Various	Various	0.02	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Maize cereals, subgroup of	Various	Various	0.04	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Martynia	Solanaceae and Malvaceae - others	0232990	0.02	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Mammalian fats (except milk fats)	All Mammalian species- fats	Various	0.1	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Meat (from mammals other than marine mammals)	All Mammalian species - muscle	Various	0.1 (fat)	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Milks	Milk	1020000	0.01*	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.

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
Okra	Okra/lady's fingers	0231040	0.02	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Peanut	Peanuts/groundnuts	0401020	0.05	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Peppers, chili, dried	N/A	N/A	5	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Poultry, edible offal of	Poultry – Liver, kidney and edible offals (other than liver and kidney)	Various	0.01*	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Poultry fats	Poultry - fats	1016020	0.01*	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Poultry meat	Poultry - muscle	1016010	0.01*	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.

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 cereals, subgroup of	Rice	0500060	0.03	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Root vegetables, subgroup of	Various	Various	0.1	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Roselle	Solanaceae and Malvaceae - others	0232990	0.02	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Small seed oilseeds, Subgroup of	Various	Various	0.9	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Sorghum Grain and Millet, Subgroup of	Sorghum	0500080	0.03	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Stems and petioles, Subgroup of	Various	Various	15	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.

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
Sunflower seeds, subgroup of	Sunflower seeds	0401050	0.3	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Sweet Corns, subgroup of	Sweet corn	0234000	0.03	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Tuberous and corm vegetables, subgroup of	Various	Various	0.1	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.
Wheat, similar grains, and pseudo-cereals without husks, subgroup of	Wheat	0500090	0.4	0.01*	The CXL should not be adopted as a GB MRL owing to the ongoing approval and import tolerance assessments.

† The full list of commodities that the proposed draft CXLs would apply to have not been listed as the CXLs have not been fully considered by HSE at this time owing to the ongoing approval and import tolerance assessments.

The JMPR assessment identified that pydiflumetofen is persistent in soil. The DT₉₀ is > 500 days and hence accumulation of residues in soil from year on year use and subsequent uptake by rotational crops needs to be addressed. Subsequently, this issue needs to be considered further as part of the active substance approval process in GB so that appropriate MRLs can be established to cover residues in rotational crops for GB PPP authorisations and import tolerances. Therefore, no further consideration of the CXLs has been made at this time.

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as no CXLs are being recommended for adoption as GB MRLs.

Conclusion

The proposed draft CXLs have not been considered owing to the ongoing approval and import tolerance assessments.

2.36 Pyflubumide (314)

Pyflubumide has never been considered for an approval in GB. Therefore, no specific MRLs have been established in the GB MRL Statutory Register and currently the default LOQ MRL of 0.01* mg/kg applies to all commodities.

Pyflubumide was considered by the JMPR as a new active substance. CXLs are proposed for apple and tea. However, the JMPR has identified a public health concern as a result of acute exposure for both CXLs. Therefore, the CXLs have not been considered further.

Conclusion

A public health concern has been identified by the JMPR for the proposed draft CXLs and therefore the CXLs are not acceptable.

2.37 Pyraclostrobin (210)

Pyraclostrobin is an approved active substance in GB. MRLs have been established in Part 2 of the GB MRL Statutory Register.

Pyraclostrobin was considered by the JMPR in response to specific concerns raised by the CCPR. At the CCPR 2019, it was noted the 2018 JMPR report contained an incorrect HR value for spinach, and that the MRL recommendation for root vegetables should exclude sugar beet. Therefore, the JMPR revised its MRL recommendations.

Relevant background information is outlined in Tables 117 and 118.

Table 117 Toxicological reference values

	JMPR	GB	Units
ADI	0.03	0.03	mg/kg bw per day
ARfD	0.7	0.03	mg/kg bw

Table 118 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Pyraclostrobin	Pyraclostrobin	Yes
	Risk assessment	Pyraclostrobin	Pyraclostrobin	Yes
Livestock	Enforcement	Pyraclostrobin	Pyraclostrobin	Yes
	Risk assessment	Pyraclostrobin	Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1H-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1-pyrazole moiety, expressed as pyraclostrobin	No

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

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

The proposed draft CXLs and their consideration are outlined in Table 119.

Table 119 CXL proposals for pyraclostrobin

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
Root vegetables, subgroup of	Beetroots	0213010	0.5	0.1	The CXL can be adopted as a GB MRL
Root vegetables, subgroup of	Carrots	0213020	0.5	0.5	The CXL does not need to be adopted as the GB MRL is equivalent.
Root vegetables, subgroup of	Celeriacs/turnip rooted celeries	0213030	0.5	0.5	The CXL does not need to be adopted as the GB MRL is equivalent
Root vegetables, subgroup of	Horseradishes	0213040	0.5	0.3	The CXL can be adopted as a GB MRL
Root vegetables, subgroup of	Parsnips	0213060	0.5	0.3	The CXL can be adopted as a GB MRL
Root vegetables, subgroup of	Parsley roots/Hamburg roots parsley	0213070	0.5	0.1	The CXL can be adopted as a GB MRL
Root vegetables, subgroup of	Radishes	0213080	0.5	0.5	The CXL does not need to be adopted as the GB MRL is equivalent
Root vegetables, subgroup of	Salsifies	0213090	0.5	0.1	The CXL can be adopted as a GB MRL
Root vegetables, subgroup of	Swedes/rutabagas	0213100	0.5	0.09	The CXL can be adopted as a GB MRL
Root vegetables, subgroup of	Turnips	0213110	0.5	0.09	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
Root vegetables, subgroup of	Others - other root and tuber vegetables except sugar beet	0213990	0.5	0.02*	The CXL can be adopted as a GB MRL
Spinach	Spinaches	0252010	0.6	0.6	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 120. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

The STMR supporting the CXL for spinach is higher than the STMR supporting the GB MRL hence the STMR supporting the CXL has been used in the chronic exposure assessment.

Table 120 Summary of the consumer risk assessments for pyraclostrobin

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI is 32% of the ADI (infant)	No health effects due to chronic exposure are expected from the consumption of commodities treated with pyraclostrobin.
	EFSA	The highest IEDI is 32% of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest IESTI is 51.7% of the ARfD (infant/swedes)	No health effects due to acute exposure are expected from the consumption of commodities treated with pyraclostrobin.
	EFSA	The highest IESTI is 57% of the ARfD (Children/beetroots)	

Conclusions

The proposed draft CXLs for beetroots, horseradishes, parsnips, parsley roots/Hamburg roots parsley, salsifies, swedes/rutabagas, turnips and others are acceptable and a risk to consumers is unlikely.

The proposed draft CXLs for carrots, celeriacs/turnip rooted celeries, radishes and spinaches are lower than the GB MRLs in force.

2.38 Pyridate (315)

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

The JMPR assessed the active for the first time, and only for toxicology. Toxicological reference values were recommended by the JMPR.

As no CXLs are proposed at this time then no further consideration has been undertaken.

2.39 Pyrifluquinazon (316)

Pyrifluquinazon has never been considered for an approval in GB. Therefore, no specific MRLs have been established in the GB MRL Statutory Register and currently the default LOQ MRL of 0.01* mg/kg applies to all commodities.

The active was considered by the JMPR as a new active substance. The JMPR has made no recommendation for CXLs as a conclusion on the toxicological properties could not be reached on a number of metabolites found in products of animal origin. As no CXLs are proposed at this time then no further consideration has been undertaken.

2.40 Pyriofenone (310)

Pyriofenone is an approved active substance in GB. MRLs have been established in Part 3 of the GB MRL Statutory Register.

Pyriofenone was considered by the JMPR for new uses. Relevant background information is outlined in Tables 121 and 122.

Table 121 Toxicological reference values

	JMPR	GB	Units
ADI	0.09	0.07	mg/kg bw per day
ARfD	Not required	Not required	mg/kg bw

Table 122 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Pyriofenone	Pyriofenone	Yes
	Risk assessment	Pyriofenone	Pyriofenone	Yes
Livestock	Enforcement	Pyriofenone	Pyriofenone	Yes
	Risk assessment	Pyriofenone	Not required, considering the representative uses	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			(Provisionally: sum of pyriofenone and 2MDPM (free and conjugated) (ruminants only)	

2MDPM: (5-chloro-2-methoxy-4-methyl-3-pyridinyl)(3,4-dihydroxy-2-methoxy-6-methylphenyl)methanone

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

Whilst the JMPR and GB livestock residue definitions for enforcement and risk assessment are comparable, no residue definitions for products of poultry origin have been proposed in GB, however given that both the proposed draft CXLs and GB MRLs are set at the LOQ, this is not considered to affect the consideration of the proposed draft CXLs.

No definitive livestock residue definitions were set for the approval of the active substance; a provisional livestock residue definition for risk assessment to include metabolite 2MDPM (free and conjugated) was proposed (EFSA, 2013). Given the proposed draft CXLs are the same as the current GB MRLs, the livestock residue definition for risk assessment has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 123.

Table 123 CXL proposals for pyriofenone

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
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Eggs	Birds eggs	1030000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Mammalian fats (except milk fats)	All Mammalian species- fats	Various	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Milks	Milk	1020000	0.01*	0.01*	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	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry fats	Poultry - fats	1016020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry meat	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry, edible offal of	Poultry – Liver, kidney and edible	Various	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
	offals (other than liver and kidney)				

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

Consumer Risk Assessments

Dietary exposure assessments have not been undertaken as no CXLs are being recommended for adoption as GB MRLs.

Conclusions

The proposed draft CXLs are equivalent to the GB MRLs in force.

2.41 Pyriproxyfen (200)

Pyriproxyfen is an approved active substance in GB. MRLs have been established in Part 3 of the GB MRL Statutory Register.

Pyriproxyfen was considered by the JMPR for new uses. Relevant background information is outlined in Tables 124 and 125.

Table 124 Toxicological reference values

	JMPR	GB	Units
ADI	0.1	0.05	mg/kg bw per day
ARfD	Unnecessary	1	mg/kg bw

Table 125 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Pyriproxyfen	Pyriproxyfen (applicable to fruit and pulses/oilseeds crops – Foliar treatment)	Yes
	Risk assessment	Pyriproxyfen	Pyriproxyfen (applicable to fruit and pulses/oilseeds crops – Foliar treatment)	Yes
Livestock	Enforcement	Pyriproxyfen	Pyriproxyfen	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Pyriproxyfen	Pyriproxyfen	Yes

The residue definitions for plants for both risk assessment and enforcement are comparable between GB and the JMPR. However, the residue definitions for GB apply to fruit and pulses/oilseed crops only following a foliar application. The proposed draft CXL is for mango resulting from a foliar use.

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

The proposed draft CXLs and their consideration are outlined in Table 126.

Table 126 CXL proposals for pyriproxyfen

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Mango	Mangoes	0163030	0.02*	0.05*	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 no CXLs are being recommended for adoption as GB MRLs.

Conclusions

The proposed draft CXLs are lower than the GB MRLs in force.

2.42 Spirotetramat (234)

Spirotetramat is an approved active substance in GB. MRLs have been established in Part 3 of the GB MRL Statutory Register.

Spirotetramat was considered by the JMPR for new uses. Relevant background information is outlined in Tables 127 and 128.

Table 127 Toxicological reference values

	JMPR	GB	Units
ADI	0.05	0.05	mg/kg bw per day
ARfD	1	1	mg/kg bw

Table 128 Residue Definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Spirotetramat plus spirotetramat-enol, expressed as spirotetramat.	Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat	No
	Risk assessment	spirotetramat plus the metabolites enol, ketohydroxy, enol-glucoside, and monohydroxy, expressed as spirotetramat.	sum of spirotetramat, spirotetramat-enol, spirotetramat-enol-glucoside(Glc), spirotetramat-ketohydroxy and spirotetramat-monohydroxy, expressed as spirotetramat	Yes
Livestock	Enforcement	Spirotetramat and its metabolite spirotetramat enol expressed as spirotetramat	Spirotetramat and its metabolite spirotetramat enol expressed as spirotetramat	Yes

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
	Risk assessment	Spirotetramat and its metabolite spirotetramat enol expressed as spirotetramat	Sum of spirotetramat-enol and spirotetramat-enol-GA expressed as spirotetramat	No

enol metabolite (BYI08330-enol or spirotetramat-enol): 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one

ketohydroxy metabolite (BYI08330-ketohydroxy or spirotetramat-ketohydroxy): 3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione

enol-glucoside metabolite (BYI08330 enol-glucoside or spirotetramat-enol-GA): glucoside of 3-(2,5- dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat

monohydroxy metabolite (BYI08330-monohydroxy or spirotetramat-monohydroxy): cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one

The residue definitions for plants for risk assessment are comparable between GB and the JMPR. However, the residue definitions for plants for enforcement are not comparable. For GB, the residue definition for enforcement is the same as the residue definition for risk assessment. For the JMPR, the residue definition has been limited to spirotetramat plus spirotetramat-enol only.

The JMPR report has listed all the residue levels for each crop relating to the residue definition for risk assessment. As this is the same as the residue definition for enforcement in GB, then HSE has been able to estimate the GB MRLs that would be required for the proposed draft CXLs. These are outlined in table 129.

For livestock, the residue definitions for enforcement for GB and the JMPR are comparable. However, the residue definitions for risk assessment are different. As no CXLs are proposed for products of animal origin, this issue has not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 129.

Table 129 CXL proposals for spirotetramat

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	Residue levels for RD _{enf} in GB (mg/kg)	CXL for RD _{enf} in GB (mg/kg)	GB MRL (mg/kg)	Comment/ HSE recommendation on the CXL if accepted as a Codex food standard
Carrot	Carrots	0213020	0.04	<0.05(4), 0.059, 0.060, 0.07, and 0.1	0.15	0.1	The CXL can be adopted as a GB MRL
Strawberry	Strawberries	0152000	0.3	0.05, 0.06, 0.07, 0.08(2), 0.09 and 0.19(2)	0.4	0.4	The CXL does not need to be adopted as the GB MRL is equivalent
Sugar beet	Sugar beet roots	0900010	0.06	<0.05(5), 0.05, 0.051, 0.052, 0.053, 0.054, 0.055, 0.057(2), 0.06 and 0.072	0.15	0.1*	The CXL can be adopted as a GB MRL

RD_{enf} residue definition for enforcement

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 130. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 130 Summary of the consumer risk assessments for spirotetramat

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI was 34 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with spirotetramat
	EFSA	The highest IEDI was 29 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI was 0.7 % of the ARfD (Infants/carrot)	No health effects due to acute exposure are expected from the consumption of all other commodities treated with spirotetramat
	EFSA	The highest IESTI was 0.7 % of the ARfD (Children/carrot)	

Conclusions

The proposed draft CXLs for carrot and sugar beet are acceptable and a risk to consumers is unlikely.

The proposed draft CXL for strawberry is equivalent to the GB MRL in force.

2.43 Tebuconazole (189)

Tebuconazole is an approved active substance in GB. MRLs have been 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 131 and 132.

Table 131 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 132 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Tebuconazole	Tebuconazole	Yes
	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	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			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 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 TDMs. The JMPR evaluation does not include the levels of TDMs in the residues trials and therefore HSE is unable to perform consumer risk assessments for GB.

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 draft CXLs and their consideration are outlined in Table 133.

Table 133 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
Oranges, sweet, sour (including orange-like hybrids), subgroup of	Oranges	0110020	0.4	0.9	The residue definitions for risk assessment are not comparable and no data on TDMs is available. The CXL does not need to be adopted as the GB MRL is higher.
Mandarins, subgroup of	Mandarins	0110050	0.7	5	The residue definitions for risk assessment are not comparable and no data on TDMs is available. 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 no CXLs are being recommended for adoption as GB MRLs.

It is also noted that it would not be possible to conclude on the acceptability of the consumer risk assessments as data are not available for all the triazole derivative metabolites.

Conclusions

The proposed draft CXLs are lower than the GB MRLs in force.

It is also noted that proposed draft CXLs would not be acceptable as insufficient residues data are available for the triazole derivative metabolites.

2.44 Thiabendazole (065)

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

The JMPR considered new uses for the active substance. Relevant background information is outlined in Tables 134 and 135.

Table 134 Toxicological reference values

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

Table 135 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Thiabendazole	Thiabendazole	Yes
	Risk assessment	Thiabendazole	Post-harvest: Thiabendazole Pre-harvest and rotational crops:	Yes for post-harvest uses

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			1) Thiabendazole 2) total benzimidazole	
Livestock	Enforcement	sum of thiabendazole and 5-hydroxythiabendazole	Milk: sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole All other commodities: sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole	No for milk Yes for all other commodities
	Risk assessment	sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate	Milk: 1) sum of thiabendazole, 5-OH-thiabendazole and its sulfate conjugate, expressed as thiabendazole	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			2) total benzimidazole All other commodities: 1) sum of thiabendazole and 5-OH-thiabendazole, expressed as thiabendazole 2) total benzimidazole	

The residue definitions for plants for enforcement are comparable between GB and the JMPR. For risk assessment, the residue definitions are comparable for post-harvest uses. For pre-harvest uses and rotational crops the residue definition for GB also includes benzimidazole. However, substantive CXLs have only been proposed for post-harvest uses (mango and sweet potato). The proposed draft CXLs for pre-harvest uses are all at the LOQ of 0.01* mg/kg and as the GB MRLs are equivalent or higher 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 draft CXLs and their consideration are outlined in Table 136.

Table 136 CXL proposals for thiabendazole

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
Beans with pods	Beans (with pods)	0260010	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
Beans without pods	Beans (without pods)	0260020	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Dry beans, subgroup of	Beans	0300010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Dry beans, subgroup of	Soyabeans	0401070	0.01*	0.02	The CXL does not need to be adopted as the GB MRL is higher
Dry peas, subgroup of	Peas	0300030	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Mango	Mangoes	0163030	7	0.01*	A specific application to raise the GB MRL to the same level is under evaluation. The CXL has not been considered further in this assessment.
Peas with pods	Peas (with pods)	0260030	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent.
Peas without pods	Peas (without pods)	0260040	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Sweet potato	Sweet potatoes	0212020	9	0.01*	An acute intake concern was identified. The CXL should not be adopted as a GB MRL.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 137. The outputs from the UK models and PRIMo can be seen in annexes 1-4.

Table 137 Summary of the consumer risk assessments for thiabendazole

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI was 79 % of the ADI (infant and toddler) – using consumption data for potatoes for sweet potatoes The highest NEDI was 48 % of the ADI (toddler) – using consumption data for yams for sweet potatoes	No health effects due to chronic exposure are expected from the consumption of commodities treated with thiabendazole
	EFSA	The highest IEDI was 51 % of the ADI (NL toddler)	
Acute exposure assessment	UK	The highest NESTI for sweet potatoes was: 741 % of the ARfD (toddler) – using consumption data for potato 304 % of the ARfD (toddler) – using consumption data for yams	An acute intake concern has been identified for sweet potatoes
	EFSA	The next highest IESTI was 351 % of the ARfD (Children/ boiled sweet potatoes)	

Conclusions

The proposed draft CXL for sweet potatoes is not acceptable as it leads to dietary intakes that exceed the ARfD.

The proposed draft CXL for mangoes has not been considered as a specific application to HSE to raise the GB MRL has been received.

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

2.45 Tolclofos-methyl (191)

Tolclofos-methyl is an approved active substance in GB. MRLs have been established in Part 2 of the GB MRL Statutory Register.

The JMPR assessment was a periodic review of tolclofos-methyl. Relevant background information is outlined in Tables 138 and 139.

Table 138 Toxicological reference values

	JMPR	GB	Units
ADI	0.07	0.064	mg/kg bw per day
ARfD	N/A	0.14	mg/kg bw

Table 139 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Tolclofos-methyl	Tolclofos-methyl	Yes
	Risk assessment	Sum of tolclofos-methyl, ph-CH ₃ (incl. conjugates), TMCH ₂ OH (incl. conjugates), DM-TM-CH ₂ OH) and DM-TM, expressed as tolclofos-methyl.	Root and tuber crops (Potato) for tuber treatment: Tolclofos-methyl and DM-TM-CH ₂ OH expressed as tolclofos-methyl. Leafy crops (Lettuce) for soil treatment:	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
			• tolclofos-methyl • TM-CH₂OH-conjugate • ph-CH₃-conjugate (Provisional)	
Livestock	Enforcement	Tolclofos-methyl	Tolclofos-methyl	Yes
	Risk assessment	Sum of tolclofos-methyl and 3,5-dichloro-4-hydroxybenzoic acid (ph-COOH), expressed as tolclofos-methyl	Tolclofos-methyl and ph-COOH, expressed as tolclofos-methyl. Finalisation of the residue definition for risk assessment in animal is pending on the recalculation of dietary burden upon finalization of the residue definition for risk assessment of feed items.	Yes

DM-TM-CH₂OH: O-methyl O-hydrogen O-[2,6-dichloro-4-(hydroxymethyl)phenyl] phosphorothioate

ph-CH₃: 2,6-dichloro-4-methylphenol

TM-CH₂OH: O,O-dimethyl O-[2,6-dichloro-4-(hydroxymethyl)phenyl] phosphorothioate

DM-TM: O-methyl O-hydrogen O-(2,6-dichloro-4-methylphenyl) phosphorothioate

ph-COOH: 3,5-dichloro-4-hydroxybenzoic acid

The residue definitions for plants and animals for enforcement are comparable between GB and the JMPR. The residue definitions for risk assessment in livestock are comparable. Although the residue definition for risk assessment may need to be reconsidered based on the recalculation of the livestock dietary burden.

The residue definitions for risk assessment in plants are not comparable between GB and the JMPR. This is considered further under Table 140.

The proposed draft CXLs and their consideration are outlined in Table 140.

Table 140 CXL proposals for tolclofos-methyl

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Leafy greens except spinach, purslane and chard	Lettuces	0251020	0.7	2	The CXL does not need to be adopted as the GB MRL is higher
Leafy greens except spinach, purslane and chard	Escarole/ broad leaved endive	0251030	0.7	0.9	The CXL does not need to be adopted as the GB MRL is higher
Leafy greens except spinach, purslane and chard	Grape leaves and similar species	0253000	0.7	0.01*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Leafy greens except spinach, purslane and chard	Chervil	0256010	0.7	0.02*	The residue definitions are not compatible between GB and the JMPR. The

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
					CXL should not be adopted as a GB MRL.
Leafy greens except spinach, purslane and chard	Celery leaves	0256030	0.7	0.02*	The residue definitions are not compatible between GB and the JMPR. The CXL should not be adopted as a GB MRL.
Potato	Potatoes	0211000	0.3	0.2	An acute intake concern has been identified. The CXL should not be adopted as a GB MRL.
Products of animal origin	Products of animal origin	various	0.01	0.01	The CXLs do not need to be adopted as the GB MRLs are equivalent

With regards to root and tuber crops, additional metabolites are included in the JMPR residue definition for risk assessment and the GB definition was only set on the basis of a tuber treatment. Specifically, for the approval of the active substance, the GB active substance register states that when authorising uses *'the risk to consumers, in particular the potential risk from metabolite DM-TM-CH₂OH in potatoes, must be taken into account'*.

The GAP considered by the JMPR was for a tuber treatment and therefore the GB residue definition covers this. A conversion factor for enforcement to risk assessment for the GB residue definitions has not been agreed, however a tentative conversion factor based upon the potato metabolism data was summarised in the EFSA Conclusion on the active substance renewal (EFSA, 2018) and used to perform a provisional consumer risk assessment. A ratio of 1:4 between the parent and DM-TM-CH₂OH was used and a molecular weight conversion factor of 0.99. This conversion factor is applicable to the GAP considered by the JMPR and therefore these factors were applied to the STMR and HR values of tolclofos-methyl from the residue field trials on potato supporting the proposed draft CXL. The values are summarised in table 141.

Table 141 Calculation of the STMRs and HR in accordance with the GB RD-RA

Endpoint	Tolclofos-methyl residues (mg/kg)	Calculated residue as Tolclofos-methyl and DM-TM-CH ₂ OH expressed as tolclofos-methyl
STMR	0.01	0.05
HR	0.21	1.04**

** Residue = ((0.21 mg/kg x 4) x 0.99) + 0.21 mg/kg

= 1.04 mg/kg

For the proposed draft CXL for leafy greens, it is noted that the current approval in GB is restricted to uses on ornamentals and potatoes only. For the latest approval the following was concluded:

EFSA concluded that, for the time being, the consumer risk assessment could not be finalised, in view of the outstanding data to finalise the toxicological assessment of the metabolites TM-CH₂OH conjugate and ph-CH₃ conjugate (2,6-dichloro-4-methylphenol conjugate), which are part of the residue definition for risk assessment applicable to the use on lettuce,².

In the absence of the toxicological data or data to confirm that the residue levels for these metabolites are < 0.01 mg/kg then a consideration of the proposed draft CXLs is not possible for leafy crops. It is noted that in the JMPR assessment that residues data for these metabolites were not available. A conversion factor was applied to the residue levels of tolclofos-methyl with the available metabolism data indicating that positive residues will be obtained for the metabolites.

For the range of products of animal origin listed above, the GB MRLs are the same as the proposed draft CXLs. Therefore, no further consideration of these CXLs has been made. It should be noted that the STMRs supporting these CXLs are lower than the STMRs supporting the current GB MRLs for these commodities, despite the differences in residue definition.

Consumer Risk Assessments

The outcome of the consumer risk assessments are summarised in Table 142. The outputs from PRIMo and the UK models can be seen in annexes 1-4.

² [Review report \(renewal\) - SANTE/11272/2018 Rev.4 21 May 2019](#)

Table 142 Summary of the consumer risk assessments for tolclofos-methyl

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDIs was 5% of the ADI (infant, vegetarian and elderly own home))	No health effects due to chronic exposure are expected from the consumption of commodities treated with tolclofos-methyl
	EFSA	The highest IEDI was 3% of the ADI (GEMS/ food G11)	
Acute exposure assessment	UK	The highest NESTI was 114 % of the ARfD (infant/potato)	An acute intake concern has been identified for potatoes
	EFSA	The highest IESTI was 114% of the ARfD for potatoes (children/potatoes)	

Conclusions

The proposed draft CXL for products of animal origin are equivalent to the GB MRLs in force.

The proposed draft CXL for Leafy greens (except spinach, purslane and chard) cannot be considered further as the residue definitions for GB do not currently cover leafy crops and additional toxicological data are required.

The proposed draft CXL for potatoes is not acceptable as it leads to dietary intakes that exceed the ARfD.

2.46 Tolfenpyrad (269)

Toflenpyrad has never been considered for an approval in GB. Therefore, no specific MRLs have been established in the GB MRL Statutory Register and currently the default LOQ MRL of 0.01* mg/kg applies to all commodities.

Tolfenpyrad was considered by the JMPR for new uses. Relevant background information is outlined in Tables 143 and 144.

Table 143 Toxicological Reference Values

	JMPR	GB	Units
ADI	0.006	N/A	mg/kg bw per day
ARfD	0.01	N/A	mg/kg bw

N/A = Not applicable. The active has not been considered in GB.

Table 144 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Tolfenpyrad	N/A	N/A
	Risk assessment	Tolfenpyrad	N/A	N/A
Livestock	Enforcement	sum of tolfenpyrad and PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl] phenoxy] benzoic acid; free and conjugated) and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonyl aminomethyl] phenoxy] benzoic acid; released with alkaline hydrolysis) expressed as tolfenpyrad.	N/A	N/A
	Risk assessment	sum of tolfenpyrad and PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl] phenoxy] benzoic acid; free and conjugated) and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-	N/A	N/A

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		yl]carbonyl aminomethyl] phenoxy] benzoic acid; released with alkaline hydrolysis) expressed as tolfenpyrad.		

N/A = Not applicable. The active has not been considered in GB.

The proposed draft CXLs and their consideration are outlined in Table 145.

Table 145 CXL proposals for tolfenpyrad

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
Bulb onion, subgroup of	Garlic	0220010	0.09	0.01*	The CXL can be adopted as a GB MRL
Bulb onion, subgroup of	Onions	0220020	0.09	0.01*	The CXL can be adopted as a GB MRL
Bulb onion, subgroup of	Shallots	0220030	0.09	0.01*	The CXL can be adopted as a GB MRL
Edible offal (mammalian) †	All mammalian species – liver, kidney and edible offals	various	0.4	0.01*	The CXL can be adopted as a GB MRL
Eggs	Birds eggs	1030000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Eggplants, subgroup of	Aubergines/ eggplants	0231030	0.7	0.01*	An acute intake concern has been identified. The JMPR also noted a public health concern.
Lemons and limes (including citron), subgroup of	Lemons	0110030	0.9	0.01*	An acute intake concern has been identified. The CXL should not be adopted as a GB MRL.
Lemons and limes (including	Limes	0110040	0.9	0.01*	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
citron), subgroup of					
Lemons and limes (including citron), subgroup of	Kumquats	0161040	0.9	0.01*	The CXL can be adopted as a GB MRL
Mandarins, subgroup of	Mandarins	0110050	0.9	0.01*	An acute intake concern has been identified. The CXL should not be adopted as a GB MRL.
Oranges, sweet, sour (including orange-like hybrids), subgroup of	Oranges	0110020	0.6	0.01*	An acute intake concern has been identified. The CXL should not be adopted as a GB MRL
Peppers, subgroup of, excluding okra, martynia and roselle	Sweet peppers/bell peppers	0231020	0.5	0.01*	An acute intake concern has been identified. The CXL should not be adopted as a GB MRL.
Pummelo and grapefruits (including shaddock-like hybrids, among other	Grapefruits	0110010	0.6	0.01*	An acute 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
grapefruits), subgroup of					
Milks	Milk	1020000	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Mammalian fats (except milk fats) †	All Mammalian species- fats	Various	0.01*	0.01*	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	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Poultry, 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
Poultry meat	Poultry - muscle	1016010	0.01*	0.01*	The CXL does not need to be adopted as the GB MRL is equivalent
Tomatoes, subgroup of	Tomatoes	0231010	0.7	0.01*	An acute intake concern has been identified. The JMPR also noted a public health concern.

† 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 146. The outputs from PRIMo and the UK models can be seen in annexes 1-4.

Table 146 Summary of the consumer risk assessments for tolfenpyrad

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI was 41% of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with tolfenpyrad
	EFSA	The highest IEDI was 33 % of the ADI (NL toddler)	
Acute exposure assessment	UK	There are exceedances of the ARfD for a range of crops. The highest NESTI was 464 % of the ARfD (infant/oranges).	An acute intake concern has been identified for grapefruits, lemons, mandarins, oranges, tomatoes, peppers and aubergines. No health effects due to acute exposure are expected from the consumption of all other commodities treated with tolfenpyrad.
	EFSA	There are exceedances of the ARfD for a range of crops. The highest IESTI was 464 % of the ARfD (Children/oranges).	

Conclusions

The proposed draft CXLs for limes, kumquats, garlic, onions, shallots and edible offals (mammalian) are acceptable and a risk to consumers is unlikely.

A public health concern has been identified by the JMPR for the proposed draft CXLs for tomatoes, subgroup of, and aubergines, subgroup of.

The proposed draft CXLs for oranges, mandarins, lemons, grapefruits and peppers are not acceptable as they lead to dietary intakes that exceed the ARfD.

The proposed draft CXLs for milks, mammalian fats (except milk fats), Meat (from mammals other than marine mammals), poultry, edible offal of, eggs and poultry meat are equivalent to the GB MRLs in force.

2.47 Triflumuron (317)

Triflumuron is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register. The majority of MRLs are set at the LOQ, with substantive MRLs in force for pome fruits and stone fruits.

The active was considered by the JMPR as a new active substance. The JMPR has made no recommendation for CXLs as a conclusion could not be reached on the toxicological properties of a metabolite found in commodities of plant and animal origin.

With regards to plants, the metabolite in question (M01, 2-chlorobenzamide) arose in soya beans and rotational crops which is not relevant to the current MRLs in force for pome and stone fruits. The metabolite also arose in products of animal origin. Pome fruit (apple pomace) may be fed to livestock. However, the available livestock metabolism data demonstrate that significant residues in products of animal origin are not expected from the use on pome fruits.

Conclusions

HSE recommends that no further consideration on the MRLs in force in GB is required as a result of the JMPR assessment. However, any requests to set new MRLs may require a further consideration of the toxicological properties of metabolite M01.

2.48 Valifenalate (318)

Valifenalate is an approved active substance in GB. MRLs have been established in Part 2 of the GB MRL Statutory Register.

Valifenalate was considered by the JMPR as a new active substance. Relevant background information is outlined in Tables 147 and 148.

Table 147 Toxicological reference values

	JMPR	GB	Units
ADI	0.2	0.07	mg/kg bw per day
ARfD	N/A	N/A	mg/kg bw

Table 148 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Valifenalate	Valifenalate	Yes
	Risk assessment	Valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), expressed as valifenalate.	Valifenalate	No
Livestock	Enforcement	Valifenalate	Valifenalate	Yes
	Risk assessment	Valifenalate and 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid (valifenalate-acid), expressed as valifenalate.	Valifenalate and its metabolite IR5839 (valifenalate-acid)	Yes

Metabolite IR5839 (valifenalate-acid): 3-(4-chlorophenyl)-3-[[N-(isopropoxycarbonyl)-L-valyl]amino]propionic acid

The residue definitions for plants for enforcement are comparable between GB and the JMPR. The JMPR residue definition for risk assessment for plants contains an additional metabolite and is therefore more extensive. As such, the residue levels used from the JMPR for the dietary exposure assessment will overestimate the exposure compared to the GB residue definitions.

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

The proposed draft CXLs and their consideration are outlined in Table 149.

Table 149 CXL proposals for valifenalate

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Eggplant	Aubergines/ Eggplant	231030	0.4	0.8	The CXL does not need to be adopted as the GB MRL is higher
Grapes	Grapes	0151000	0.3	0.2	The CXL can be adopted as a GB MRL
Onion, bulb	Onions	0220020	0.5	0.5	The CXL does not need to be adopted as the GB MRL is equivalent
Shallot	Shallots	0220030	0.5	0.5	The CXL does not need to be adopted as the GB MRL is equivalent
Tomato	Tomatoes	0231010	0.4	0.8	The CXL does not need to be adopted as the GB MRL is higher
CXLs for POAO	GB MRLs for POAO	Various	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 150. The outputs from PRIMo and the UK models can be seen in annexes 1-4.

Table 150 Summary of the consumer risk assessments for valifenalate

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	The highest NEDI was 14 % of the ADI (toddler)	No health effects due to chronic exposure are expected from the consumption of commodities treated with valifenalate
	EFSA	The highest IEDI was 8 % of the ADI (ES Adult).	
Acute exposure assessment	UK	The active is not acutely toxic and an ARfD has not been allocated	
	EFSA		

Conclusions

The proposed draft CXL for grapes is acceptable and a risk to consumers is unlikely.

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

2.49 MRLs for Spices

The JMPR conducted a review of monitoring data to derive CXLs on spices for acetamiprid and carbendazim.

Acetamiprid

Acetamiprid is an approved active substance in GB. MRLs are established in Part 2 of the GB MRL Statutory Register. Relevant background information is outlined in Tables 151 and 152.

Table 151 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 152 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 metabolite IM-2-1 (N-desmethyl-acetamiprid), expressed as acetamiprid	Yes
	Risk assessment	Sum of acetamiprid and N-desmethyl-acetamiprid,	Sum of acetamiprid and metabolite IM-2-1 (N-desmethyl-acetamiprid),	Yes

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

The proposed draft CXLs and their consideration are outlined in Table 153.

Table 153 CXL proposals

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Spices, seeds, subgroup of	Seed spices	0810000	2	0.05*	The CXL can be adopted in GB

Consumer risk assessments

The outcome of the consumer risk assessments are summarised in Table 154. The outputs from PRIMo can be seen in annexes 2 and 4.

Table 154 Summary of the consumer risk assessments for acetamiprid

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	No UK consumption data for spices	No health effects due to chronic exposure are expected from the consumption of seed spices treated with acetamiprid.
	EFSA	The highest IEDI is 19% of the ADI (NL toddler)	
Acute exposure assessment	UK	No UK consumption data for spices	No health effects due to acute exposure are expected from the consumption of seed spices treated with acetamiprid
	EFSA	The highest IESTI is 2% of the ARfD (children/ fennel seed)	

Conclusions

The proposed draft CXL for seed spices is acceptable and a risk to consumers is unlikely.

Carbendazim

Carbendazim is not an approved active substance in GB. The approval expired on 30 November 2014. MRLs are established in Part 2 of the GB MRL Statutory Register.

The JMPR conducted a review of monitoring data to derive CXLs on spices for the active substance. Relevant background information is outlined in Tables 155 and 156.

Table 155 Toxicological Reference Values

	JMPR	GB	Units
ADI	0.03	0.02	mg/kg bw per day
ARfD	0.1	0.02	mg/kg bw

Table 156 Residue definitions

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
Plants	Enforcement	Sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim	Sum of benomyl and carbendazim expressed as carbendazim	No
	Risk assessment	Sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim	Carbendazim	No
Livestock	Enforcement	Sum of benomyl, carbendazim	Carbendazim and thiophanate-methyl,	No

Commodity	Residue definition type	JMPR	GB	Are the residue definitions comparable
		and thiophanate-methyl, expressed as carbendazim	expressed as carbendazim	
	Risk assessment	Sum of benomyl, carbendazim and thiophanate-methyl, expressed as carbendazim	Milk: Sum of carbendazim, 4- and 5-OH-carbendazim, calculated as carbendazim Other animal matrices: Sum of carbendazim and 5-OH carbendazim, expressed as carbendazim	No

The plant residue definitions for risk assessment and enforcement are not comparable between GB and JMPR. However, as the JMPR residue definitions are more extensive, the GB MRL required would be equivalent to, or lower than, the proposed draft CXL; hence the proposed CXL have been take forward for assessment.

It should be noted that thiophanate-methyl and benomyl are active substances. The approval for thiophanate-methyl expired on 19 October 2020. Benomyl was not supported for an approval in GB. Different toxicological reference values have been established for thiophanate-methyl and therefore in GB this is determined separately rather than as a sum along with carbendazim. The metabolism of thiophanate-methyl in plants involves the cyclisation of the molecule to form carbendazim. However, the metabolism of carbendazim does not result in thiophanate-methyl being formed. Therefore, a GB specific assessment of the dietary exposure to thiophanate-methyl is not required for the assessment of the proposed draft CXL. Benomyl is not an approved active substance in GB and no import tolerances have been established. Therefore, it was recommended previously (EFSA, 2014) that this was removed from the residue definition for enforcement.

The livestock residue definitions for enforcement and risk assessment are different. As no CXLs are proposed on products of animal origin, these differences have not been considered further.

The proposed draft CXLs and their consideration are outlined in Table 157.

Table 157 CXL proposals

Codex commodity description	GB commodity description	GB commodity code	CXL (mg/kg)	GB MRL (mg/kg)	Comment
Spices, seeds, subgroup of	Seed spices	0810000	5	0.1*	The CXL can be adopted as a GB MRL

Consumer risk assessments

The outcome of the consumer risk assessments are summarised in Table 158. The outputs from PRIMo can be seen in annexes 2 and 4.

Table 158 Summary of the consumer risk assessments for carbendazim

Dietary exposure assessment	Model	Outcome	Comment
Chronic exposure assessment	UK	No UK consumption data for spices	No health effects due to chronic exposure are expected from the consumption of seed spices treated with carbendazim
	EFSA	The highest IEDI is 61 % of the ADI (NL toddler)	
Acute exposure assessment	UK	No UK consumption data for spices	No health effects due to acute exposure are expected from the consumption of seed spices treated with carbendazim
	EFSA	The highest IESTI is 2 % of the ARfD (children/fennel seeds)	

Conclusions

The proposed draft CXLs for seed spices is acceptable and a risk to consumers is unlikely.

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 for the proposed draft CXLs only 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 EFSA 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 ie 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 EFSA PRIMo are outlined in annexes 1 - 4 which have been published separately.

Consumption data

For the commodities outlined below in the first column, the available consumption data is limited in the UK models. Therefore, the commodities outlined in the second column have been used to ensure that appropriate consumption values are used in the consumer risk assessments.

Commodity	Consumption data used in the UK models
Blueberries, rose hips, elderberries, guelder rose	Blackberries and raspberries
Coriander, dill	Parsley
Cardoons	Celeries, fennels and rhubarb
Escaroles	Lettuce
Guava	Peach
Kale	Head cabbage
Kumquats	Lemons and limes
Loquats/Japanese medlars	Apples and pears
Shallots	Bulb onion
Sugar cane	Refined sugar
Sweet potatoes	Potatoes and yams

For ginseng there is no chronic consumption data, but dietary exposure is expected to be low. For the acute risk assessment, the consumption data from PRIMo has been used and no health effects due to acute exposure are expected for the proposed draft CXLs.

For coffee beans and spices, there are no consumption data in the UK model and the consumption data from PRIMo have been used. The consumption levels would have no impact on the UK approach to the chronic risk assessment as these commodities are not the main contribution to the overall chronic exposure.

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 52nd session of the CCPR.

The competent authority recommends the adoption of CXLs for afidopyropen, azoxystrobin, benzovindiflupyr, boscalid, cypermethrin, cyprodinil, flupyradiflurone (and difluoroacetic acid (DFA)), fluxapyroxad, fosetyl, glyphosate, isofetamid, mandestrobin, penthiopyrad, pyraclostrobin, spirotetramat, tolfenpyrad, valifenalate and MRLs for spices (acetamiprid and carbendazim).

For CXLs that are recommended for adoption as GB MRLs the competent authority 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.

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

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 proposed draft CXL for dicamba/cotton seed is not recommended for adoption as the authorisation considered by the JMPR is for a GM variety of cotton that is not currently approved in GB.

For pydiflumetofen, the competent authority recommends that the CXLs are not adopted

For all other proposed draft CXLs not recommended for adoption in GB the competent authority identified the following issues

- The residue data supporting the JMPR assessment were not compatible with the residue definitions in force in GB; and/or
- Exceedances of the GB toxicological reference values; and/or
- The latest approval assessment for the active substance identified concerns for human health

For these proposed draft CXLs as the required level of protection has not been met, HSE recommends that these CXLs are not adopted as GB MRLs.

A summary of the recommendations for each active substance are outlined in Table 159. The CXLs recommended by the Competent Authority for adoption as GB MRLs are outlined in Table 160. These CXLs should only be adopted as GB MRLs if they are established as Codex Food Standards.

Table 159 The recommendations of HSE for each active substance

Active substance (JMPR number)	Recommendation	Explanation
Acetochlor (280)	The proposed draft CXLs should not be adopted as GB MRLs	The active substance is non-approved in GB. Harmful effects on human health cannot be excluded.
Afidopyropen (312)	The proposed draft CXLs, except the CXL for leaves of brassicacea, can be adopted as GB MRLs.	The proposed draft CXL for leaves of brassicacea results in intakes that exceed the ARfD and hence a risk to consumers cannot be excluded. The proposed draft CXLs for all other commodities are acceptable and a risk to consumers is unlikely.
Azoxystrobin (229)	The proposed draft CXL for guava can be adopted as a GB MRL.	A risk to consumers is unlikely.
Benzovindiflupyr (261)	The proposed draft CXLs can be adopted as GB MRLs.	A risk to consumers is unlikely.
Bifenthrin (178)	A public health concern was identified by the JMPR for the MRL for strawberries and therefore this proposed draft CXL will not be adopted as a food standard.	Harmful effects on human health cannot be excluded.
Boscalid (221)	The proposed CXLs for apricots, peaches, plums and apples are all equivalent to or lower than the GB MRLs in force. All other proposed CXLs can be adopted as GB MRLs.	For the CXLs that can be adopted a risk to consumers is unlikely.

Active substance (JMPR number)	Recommendation	Explanation
Buprofezin (173)	The proposed draft CXLs for products of animal origin are equivalent to the GB MRLs. The proposed draft CXL for tree nuts should not be adopted as a GB MRL.	The active substance approval is restricted to uses on non-edible crops only due to the formation of aniline on processing of treated foods. Harmful effects on human health cannot be excluded. To establish toxicological reference values for aniline in GB the new data evaluated by the JMPR would need to be assessed and a review undertaken on all available information.
Chlorantraniliprole (263)	The proposed draft CXL for beans (pulse), pea (pulse) and palm fruits are equivalent to the GB MRLs.	N/A.
Chlorothalonil (081)	The proposed draft CXL for cranberries should not be adopted as a GB MRL.	Harmful effects on human health cannot be excluded. The GB residue definitions for risk assessment for plants contain additional metabolites and toxicological reference values could not be established for all these metabolites. A conclusion on the genotoxicity, of some of the metabolites that consumers will be exposed to, cannot be reached.
Clethodim (187)	The JMPR did not recommend any MRLs.	N/A
Cyclaniliprole (207)	The proposed draft CXLs should not be adopted as GB MRLs.	A risk to consumers cannot be excluded. Additional information is required on the

Active substance (JMPR number)	Recommendation	Explanation
		toxicity of metabolites that consumers will be exposed to and on the magnitude of the residue levels in processed fractions
Cypermethrin (118)	The proposed draft CXL for ginseng can be adopted as a GB MRL.	A risk to consumers is unlikely.
Cyprodinil (207)	The proposed draft CXL for soya bean can be adopted as a GB MRL.	A risk to consumers is unlikely.
Dicamba (240)	The proposed draft CXLs for GM maize and soyabeans are equivalent to or lower than the GB MRLs in force. The proposed draft CXL for GM cotton seeds should not be adopted as a GB MRL.	The GM cotton seed variety is not approved in GB so the CXL should not be adopted.
Dimethoate (027)	The JMPR did not recommend any MRLs.	N/A
Fenazaquin (297)	The proposed draft CXL for almonds and products of animal origin are equivalent to the GB MRLs. The proposed draft CXL for other tree nuts, except coconut, should not be adopted as a GB MRL.	The residue trials did not include a metabolite that is part of the residue definition for risk assessment in GB. It is therefore not possible to conclude on the consumer risk assessment.
Flonicamid (282)	The proposed draft CXLs should not be adopted as GB MRLs.	The proposed CXLs are not acceptable as the residue trials did not include the metabolites TFNA and TFNG. Therefore, it is not possible to calculate the GB MRLs and complete the consumer exposure assessment.

Active substance (JMPR number)	Recommendation	Explanation
Fluazifop-P-butyl (238)	The proposed draft CXLs should not be adopted as GB MRLs.	A risk to consumers cannot be excluded. The chronic intakes exceed the ADI. For strawberries intakes exceeding the ARfD were observed.
Fluensulfone (265)	The proposed draft CXLs should not be adopted.	The active has not been considered for approval in GB. HSE has undertaken an IT assessment and it was not possible to establish residue definitions.
Flupyradifurone (285)	The proposed draft CXL for cacao beans and the MRL calculated for DFA are lower than the GB MRLs in force. The proposed draft CXLs for all other commodities can be adopted as GB MRLs.	For the CXLs that can be adopted a risk to consumers is unlikely.
Fluxapyroxad (256)	The proposed draft CXLs can be adopted as GB MRLs.	A risk to consumers is unlikely.
Fosetyl-Al (302)	The proposed draft CXLs for kiwi and coffee bean are lower than the GB MRLs in force. The proposed draft CXLs for all other commodities should be adopted as GB MRLs.	For the CXLs that can be adopted a risk to consumers is unlikely.
Glyphosate (158)	The proposed draft CXL for peas is equivalent to the GB MRL in force. The proposed draft CXL for beans should be adopted as a GB MRL.	For the CXL for beans a risk to consumers is unlikely.
Isofetamid (290)	The proposed draft CXLs should be adopted as GB MRLs.	A risk to consumers is unlikely.

Active substance (JMPR number)	Recommendation	Explanation
Kresoxim-methyl (199)	The proposed draft CXL is lower than the GB MRL in force.	N/A
Mandestrobin (307)	The proposed draft CXLs for products of animal origin are lower than the GB MRLs in force. The proposed draft CXLs for grape and strawberries can be adopted as GB MRLs. The proposed draft CXL for oilseed rape should not be adopted.	For oilseed rape, the residue definitions are not comparable between the JMPR and GB and a conversion factor cannot be established. For the CXLs that can be adopted a risk to consumers is unlikely.
Mesotrione (277)	The proposed draft CXLs are equivalent to the GB MRLs in force.	N/A
Metaflumizone (236)	The proposed draft CXLs should not be adopted.	A risk to consumers cannot be excluded as the chronic intakes exceed the ADI and the acute intakes for table grapes and oranges exceed the ARfD.
Metconazole (313)	The proposed draft CXLs should not be adopted as GB MRLs.	Insufficient residues data are available on the triazole derivative metabolites and therefore it is not possible to undertake a complete consumer exposure assessment.
Methoprene (147)	The proposed draft CXL for peanuts should not be adopted as a GB MRL.	The proposed CXL is based on the peanut with its shell. The GB MRL should be set on the unshelled nut. In addition, a risk to consumers cannot be

Active substance (JMPR number)	Recommendation	Explanation
		excluded as the intakes exceeded the ADI.
Pendimethalin (292)	The proposed draft CXLs are equivalent to or lower than the GB MRLs in force.	N/A
Penthiopyrad (253)	The proposed draft CXLs can be adopted as GB MRLs.	A risk to consumers is unlikely.
Picoxystrobin (258)	The proposed draft CXLs should not be adopted as GB MRLs.	The active substance is non-approved in GB. Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of picoxystrobin occurring in food. Consequently, the required level of protection has not been met.
Propiconazole (160)	The proposed draft CXLs should not be adopted as GB MRLs.	The active substance is non-approved in GB. Based on the risk assessment conducted in the renewal assessment, HSE concludes that harmful effects on human health cannot be excluded for residues of propiconazole occurring in food. Consequently, the required level of protection has not been met.
Pydiflumetofen (309)	The proposed draft CXLs should not be adopted as GB MRLs.	The active substance is currently being evaluated as a new active substance for approval in GB. In addition, an import tolerance application has been submitted.

Active substance (JMPR number)	Recommendation	Explanation
Pyflubumide (314)	The JMPR has identified a public health concern for the proposed CXLs.	N/A
Pyraclostrobin (210)	The proposed draft CXLs for carrots, celeriacs/turnip rooted celeries, radishes and spinaches are lower than the GB MRLs in force. The proposed draft CXLs for all other commodities can be adopted as GB MRLs.	For the CXLs that can be adopted a risk to consumers is unlikely.
Pyridate (315)	The JMPR only undertook a toxicological assessment and no CXLs have been proposed at this time.	N/A
Pyriproxyfen (200)	No CXLs have been proposed by the JMPR as a conclusion on the toxicological properties of a number of metabolites found in products of animal origin could not be established.	N/A
Pyriproxyfen (200)	The proposed draft CXLs are equivalent to the GB MRLs in force.	N/A
Pyriproxyfen (200)	The proposed CXL is lower than the GB MRL in force.	N/A
Spirotetramat (234)	The proposed draft CXL for strawberry is equivalent to the GB MRL in force. The proposed draft CXLs for carrot and sugar beet can be adopted as GB MRLs.	For the CXLs that can be adopted a risk to consumers is unlikely.

Active substance (JMPR number)	Recommendation	Explanation
Tebuconazole (189)	The proposed draft CXLs should not be adopted as GB MRLs.	Insufficient residues data are available on the triazole derivative metabolites and therefore it is not possible to undertake a complete consumer exposure assessment.
Thiabendazole (065)	The proposed draft CXL for sweet potatoes should not be adopted as a GB MRL. The proposed draft CXL for mangoes has not been considered as a specific application for a GB MRL has been received. The proposed draft CXLs for all other commodities are equivalent to or lower than the GB MRLs in force.	For sweet potatoes, a risk to consumers cannot be excluded as intakes exceeding the ARfD were observed.
Triflumuron (317)	The JMPR made no recommendations for CXLs as a conclusion on the toxicological properties of a metabolite could not be established.	N/A
Tolclofos-methyl (191)	The proposed draft CXL for potatoes should not be adopted. The proposed draft CXLs for products of animal origin are equivalent to or lower than the GB MRLs in force. The proposed draft CXL for Leafy greens (except spinach, purslane and chard) cannot be considered further	For potatoes a risk to consumers cannot be excluded as intakes exceeding the ARfD were observed. For leafy crops, the GB residue definitions do not cover leafy crops and additional tox data are required.

Active substance (JMPR number)	Recommendation	Explanation
	as the residue definitions for GB do not cover leafy crops and additional tox data are required.	
Tolfenpyrad (269)	The proposed draft CXLs for limes, kumquats, garlic, onions, shallots and edible offals (mammalian) can be adopted as GB MRLs. The JMPR report has highlighted a public health concern for the CXLs for tomatoes, subgroup of, and aubergines, subgroup of. The proposed draft CXLs for oranges, mandarins, lemons, grapefruits and peppers are not acceptable as they lead to dietary intakes that exceed the ARfD. The proposed draft CXLs for milks, mammalian fats (except milk fats), meat (from mammals) other than marine mammals), poultry, edible offal of, eggs and poultry meat are equivalent to the GB MRLs in force.	For the CXLs that can be adopted a risk to consumers is unlikely. A risk to consumers cannot be excluded for tomatoes, aubergine, oranges, mandarins, lemons, grapefruits and peppers. Intakes exceeding the ARfD were observed.
Valifenalate (318)	The proposed draft CXL for grapes can be adopted as a GB MRL. The proposed draft CXLs for all other commodities are equivalent to or lower than the GB MRLs in force	For grapes a risk to consumers is unlikely.

Active substance (JMPR number)	Recommendation	Explanation
MRLs for Spices	Acetamiprid The proposed draft CXL can be adopted as a GB MRL. Carbendazim The proposed draft CXL can be adopted as a GB MRL.	A risk to consumers is unlikely.

Table 160 CXLs recommended by HSE 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 plant origin: acetamiprid				
	0810000	Seed spices	0.05*	2
Afidopyropen (312)				
Enforcement residue definition for products of plant origin: afidopyropen				
	0110000	Citrus fruits	0.01*	0.15
	0120000	Tree nuts	0.01*	0.01*
	0130000	Pome fruits	0.01*	0.03
	0140010	Apricots	0.01*	0.015
	0140020	Cherries (sweet)	0.01*	0.03
	0140030	Peaches	0.01*	0.015
	0140040	Plums	0.01*	0.01*
	0161040	Kumquats	0.01*	0.15
	0211000	Potatoes	0.01*	0.01*
	0212000	Tropical root and tuber vegetables	0.01*	0.01*
	0213040	Horseradishes	0.01*	0.01*
	0231010	Tomatoes	0.01*	0.15
	0231020	Sweet peppers/bell peppers	0.01*	0.1
	0231030	Aubergines/eggplants	0.01*	0.15
	0232010	Cucumbers	0.01*	0.7
	0232030	Courgettes	0.01*	0.07
	0233300	Cucurbits with inedible peel	0.01*	0.05

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	0241000	Flowering brassicas	0.01*	0.4
	0243020	Head cabbages	0.01*	0.5
	0251020	Lettuces	0.01*	2
	0251030	Escarole/ broad leaved endive	0.01*	2
	0252000	Spinaches and similar leaves	0.01*	2
	0253000	Grape leaves and similar species	0.01*	2
	0256010	Chervil	0.01*	2
	0256030	Celery leaves	0.01*	5
	0256040	Parsley	0.01*	5
	0270020	Cardoons	0.01*	3
	0270030	Celeries	0.01*	3
	0270040	Florence fennels	0.01*	3
	0270070	Rhubarbs	0.01*	3
	0401070	Soyabeans	0.01*	0.01*
	0401090	Cotton seeds	0.01*	0.08
	0840030	Turmeric/curcuma	0.01*	0.01*
Enforcement residue definition for products of animal origin: afidopyropen				
	1016010	Poultry - muscle	0.01*	0.01*
	1016020	Poultry - fats	0.01*	0.01*
	1020000	Milk	0.01*	0.001*
	1030000	Birds eggs	0.01*	0.01*
	Various	All mammalian species - liver, kidney and edible offals	0.01*	0.2

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	Various	All Mammalian species- fats	0.01*	0.01*
	Various	All Mammalian species - muscle	0.01*	0.01*
	Various	Poultry - Liver, kidney and edible offals (other than liver and kidney)	0.01*	0.01*
Azoxystrobin				
Enforcement residue definition for products of plant origin: azoxystrobin				
	0163070	Guavas	0.01*	0.2
Benzovindiflupyr				
Enforcement residue definition for products of plant origin: benzovindiflupyr				
	0220010	Garlic	0.01*	0.02
	0220020	Onions	0.01*	0.02
	0220030	Shallots	0.01*	0.02
	0900020	Sugar canes	0.04	0.4
Boscalid				
Enforcement residue definition for products of plant origin: boscalid				
	0130020	Pears	1.5	2
	0130030	Quinces	1.5	2
	0130040	Medlars	0.01*	2
	0130050	Loquats/ Japanese medlars	0.01*	2
	0130990	Others - pome fruits	0.01*	2
	0140020	Cherries (sweet)	4	5
	0163030	Mangoes	0.01*	2
	0610000	Teas	0.01*	40

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
Carbendazim				
Enforcement residue definition for products of plant origin: sum of benomyl and carbendazim expressed as carbendazim				
	0810000	Seed spices	0.1*	5
Cypermethrin				
Enforcement residue definition for products of plant origin: cypermethrin including other mixtures of constituent isomers (sum of isomers)				
	0633020	Ginseng	0.1*	0.15
Cyprodinil				
Enforcement residue definition for products of plant origin: cyprodinil				
	0401070	soyabeans	0.02*	0.3
Flupyradifurone				
Enforcement residue definition for products of plant origin: flupyradifurone				
	0153010	Blackberries	1.5	6
	0153020	Dewberries	0.01*	6
	0153030	Raspberries (red and yellow)	1.5	6
	0153990	Other cane berries	0.01*	6
	0163010	Avocados	0.01*	0.6
	0620000	Coffee beans	0.05*	0.9
	0700000	Hops	4	10
Difluoroacetic acid (DFA, from the use of flupyradifurone)				
Enforcement residue definition for products of plant origin: difluoroacetic acid				
	0153010	Blackberries	0.07	0.1
	0153020	Dewberries	0.02*	0.1

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	0153030	Raspberries (red and yellow)	0.07	0.1
	0153990	Other cane berries	0.02*	0.1
	0163010	Avocados	0.02*	0.15
	0620000	Coffee beans	0.1*	0.3
	0700000	Hops	0.3	3
Fluxapyroxad				
Enforcement residue definition for products of plant origin: fluxapyroxad				
	0110010	Grapefruits	0.3	0.6
	0110020	Oranges	0.3	1.5
	0110030	Lemons	0.01*	1
	0110040	Limes	0.01*	1
	0110050	Mandarins	0.01*	1
	0161040	Kumquats	0.01*	1
Fosetyl				
Enforcement residue definition for products of plant origin: sum of fosetyl, phosphonic acid and their salts, expressed as fosetyl				
	0162010	Kiwi fruits (green, red and yellow)	150	200
	0620000	Coffee beans	5*	40
Glyphosate				
Enforcement residue definition for products of plant origin: glyphosate				
	0300010	Beans	2	15
Isofetamid				
Enforcement residue definition for products of plant origin: isofetamid				
	0154010	Blueberries	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*	4
	0154040	Gooseberries (green, red and yellow)	0.01*	4
	0154050	Rose hips	0.01*	4
	0300010	Beans	0.01*	0.09
	0300030	Peas	0.01*	0.09
Mandestrobin				
Enforcement residue definition for products of plant origin: mandestrobin				
	0151000	Grapes	0.01*	5
	0152000	Strawberries	0.01*	3
Penthiopyrad				
Enforcement residue definition for products of plant origin: penthiopyrad				
	0153010	Blackberries	0.01*	10
	0153020	Dewberries	0.01*	10
	0153030	Raspberries (red and yellow)	0.01*	10
	0153990	Other cane berries	0.01*	10
	0154010	Blueberries	0.01*	7
	0154030	Currants (black, red and white)	0.01*	7
	0154040	Gooseberries (green, red and yellow)	0.01*	7
	0154050	Rose hips	0.01*	7
	0154080	Elderberries	0.01*	7
Pyraclostrobin				
Enforcement residue definition for products of plant origin: pyraclostrobin				

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	0213010	Beetroots	0.1	0.5
	0213040	Horseradishes	0.3	0.5
	0213060	Parsnips	0.3	0.5
	0213070	Parsley roots/Hamburg roots parsley	0.1	0.5
	0213090	Salsifies	0.1	0.5
	0213100	Swedes/rutabagas	0.09	0.5
	0213110	Turnips	0.09	0.5
	0213990	Others - other root and tuber vegetables except sugar beet	0.02*	0.5
Spirotetramat				
Enforcement residue definition for products of plant origin: sum spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat				
	0213020	Carrots	0.1	0.15
	0900010	Sugar beet roots	0.1*	0.15
Tolfenpyrad				
Enforcement residue definition for products of plant origin: tolfenpyrad				
	0110040	Limes	0.01*	0.9
	0161040	Kumquats	0.01*	0.9
	0220010	Garlic	0.01*	0.09
	0220020	Onions	0.01*	0.09
	0220030	Shallots	0.01*	0.09
Enforcement residue definition for products of animal origin: sum of tolfenpyrad and PT-CA (4-[4-[(4-chloro-3-ethyl-1-methylpyrazol-5-yl)carbonylaminomethyl] phenoxy] benzoic acid; free and conjugated) and OH-PT-CA (4-[4-[[4-chloro-3-(1-hydroxyethyl)-1-methylpyrazol-5-yl]carbonyl aminomethyl] phenoxy] benzoic acid; released with alkaline hydrolysis) expressed as tolfenpyrad				

Active substance	Product code	Product	Existing GB MRL (mg/kg)	CXL recommended for adoption (mg/kg)
	various	All mammalian species - liver, kidney and edible offals	0.01*	0.4
Valifenalate				
Enforcement residue definition for products of plant origin: valifenalate				
	0151000	Grapes	0.2	0.3

† The CXLs should only be adopted once accepted as Coded Food Standards

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Abbreviations

Acute_consumer_ver1.2 UK consumer model for acute dietary intake assessments

ADI acceptable daily intake

ADME absorption, distribution, metabolism and excretion

ALARA Principle as low as reasonably achievable

Animal model 2017 EFSA model used to calculate the dietary burden of livestock using the OECD feeding studies

ARfD acute reference dose

a.s. active substance

BBCH growth stages of mono- and dicotyledonous plants

bw body weight

CA Competent authority

Chronic_consumer_ver1.1 UK consumer model for chronic dietary intake assessments

CCPR Codex Committee on Pesticide Residues

CRD Chemicals Regulation Division of the HSE

CXL Codex maximum residue level

DA Devolved Administrations

DAR draft assessment report

DAT days after treatment

Defra Department of Environment, Food and Rural Affairs

DT90 period required for 90% dissipation (define method of estimation)

DT 50 period required for 50 % dissipation (define method of estimation)

FAO Food and Agriculture Organization of the United Nations

GAP Good Agricultural Practice

GB Great Britain

HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry

HPLC-UVd high-performance liquid chromatography with ultraviolet detector

HR highest residue

HSE Health and Safety Executive

IEDI international estimated daily intake

IENTI international estimated short-term intake

ISO International Organisation for Standardisation

IUPAC International Union of Pure and Applied Chemistry

JMPR Joint FAO/WHO Meeting on Pesticide Residues

LOD limit of detection or limit of determination (should be defined)

LOQ limit of quantification

MRL maximum residue level

NEDI national estimated daily intake

NESTI national estimated short-term intake

NRL National reference laboratory

OECD Organisation for Economic Co-operation and Development

PBI plant-back interval

PHI preharvest interval

POAO products of animal origin

PRIMo (EFSA) Pesticide Residues Intake Model

QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)

RA risk assessment

RAR Renewal Assessment Report

RD residue definition

RD-enf residue definition for enforcement (also referred to as RD-Mo ie residue definition for monitoring)

RD-RA residue definition for risk assessment

RTI re-treatment interval

SC suspension concentrate

STMR supervised trials median residue

TCC Threshold of toxicological concern

TRR total radioactive residue

WG water-dispersible granule

WHO World Health Organization

Annexes

Annex 1: Chronic risk assessments undertaken using UK model version 1.1

Annex 2: Chronic risk assessments undertaken using EFSA PRIMo rev 3.1

Annex 3: Acute risk assessments undertaken using UK model version 1.2

Annex 4: Acute risk assessments undertaken using EFSA PRIMo rev 3.1

Annexes 1 - 4 contain the outputs from the consumer risk assessments. These have been published separately and are available here for the 52nd Session of the CCPR 2021: [GB Codex MRL List](#)

