

**Validation of new
compounds included in the
Working Document**





EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and Feed Safety, Innovation
Pesticides and biocides

SANCO/12745/2013
25 – 26 November 2019 rev. 11(3)

Working document on pesticides to be considered for inclusion in the national control programmes to ensure compliance with maximum residue levels of pesticides residues in and on food of plant and animal origin.

This document has been conceived as a working document of the Commission Services. It does not represent the official position of the Commission. It does not intend to produce legally binding effects.

Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

WORKING DOCUMENT

Proposes pesticides to be included in

- EU Multi-Annual Control Programme (**EU-MACP**)
- National Control Programmes (**NCPs**) of the member states on a voluntary basis

Assessment of active substances

- **Occurrence** (EFSA's annual reporting data)
- **Toxicological** reference data
- Analytical **coverage** (survey by EURL-SRM)

Yearly updated

Public and available online

4. Pesticides to be considered for inclusion in National Control Programmes (NCP)

The substances are listed in alphabetical order, separately for commodities of plant origin and of animal origin and per category. Substances newly added to this version of the WD are indicated in white background, while older substances that were evaluated during the 2018 WG are in grey background.

4.1. Pesticides to be considered for analysis in products of plant origin (PO)

4.1.1. Frequent detections¹, MRL exceedances or RASFF notifications

<p>4-CPA (4-chlorophenoxyacetic acid) (Not approved) – PO Added: 10/2013</p> <p>Toxicity: no toxicological reference values available Method: MRM/SRM, Priority: 2B Evaluation: after 2 years (10/2020)</p> <ul style="list-style-type: none"> ✓ 0.03% findings (0.02% MRL exceedances) EFSA 2014 ✓ 0.03% findings (0.02% MRL exceedances) EFSA 2015 ✓ 0.02% findings (0.03% MRL exceedances) EFSA 2016 ✓ 0.02% findings (0.03% MRL exceedances) EFSA 2017 <p>18% labs and 29% MS analysed full RD in 2018. ⇒ Analytical coverage poor ⇒ Findings do not justify inclusion in EU MACP Especially relevant in zucchini, aubergines, melons, peanuts, soya and soya sprouts</p>	<p>Acclonifen – PO Added: 10/2019</p> <p>Toxicity: ADI = 0.07 mg/kg bw/day, ARfD NA Method: MRM, Priority: 2A Evaluation: after 1 year (10/2020)</p> <ul style="list-style-type: none"> ✓ 0.21% findings (0.00% MRL exceedances) EFSA 2015 ✓ 0.10% findings (0.01% MRL exceedances) EFSA 2016 ✓ 0.10% findings (0.01% MRL exceedances) EFSA 2017 <p>No data on analytical coverage. Frequently found in samples of the carrot family (carrot, coriander, parsley, parsnip) as well as in various other leafy vegetables</p>
<p>Bifenazate – PO Added: 10/2019</p> <p>Toxicity: ADI = 0.01 mg/kg bw/day, ARfD NA Method: MRM/SRM, Priority: 2A Evaluation: after 1 year (10/2021)</p> <ul style="list-style-type: none"> ✓ 0.24% findings (0.00% MRL exceedances) EFSA 2015 ✓ 0.30% findings (0.00% MRL exceedances) EFSA 2016 ✓ 0.56% findings (0.00% MRL exceedances) EFSA 2017 <p>7% labs and 23% MS analysed full RD in 2016 54% labs and 71% MS analysed full RD in 2017 10% labs and 25% MS analysed full RD in 2018 Occurs in oxidised or reduced form, depending on the commodity. An analytical method has been developed by the EURL-SRM and is published on EURL website (http://www.eurl-pesticides.eu/userfiles/file/EurlSRM/meth_Bifenazate_EurlSRM.pdf). Especially relevant for, green beans, sweet pepper, strawberries, tomato etc. grapes</p>	<p>Copper compounds – PO Added: 10/2019</p> <p>Toxicity: ADI = 0.15 mg/kg bw/day, ARfD NA Method: SRM, Priority: 2B Evaluation: after 2 years (10/2021)</p> <ul style="list-style-type: none"> ✓ 0.05% findings (66.74% MRL exceedances) EFSA 2015 ✓ 0.00% findings (66.22% MRL exceedances) EFSA 2016 ✓ 0.24% findings (79.81% MRL exceedances) EFSA 2017 <p>No data on analytical coverage.</p>
<p>Chloridazone (Not Approved) – PO Added: 10/2019</p> <p>Toxicity: ADI = 0.1 mg/kg bw/day, ARfD NA Method: SRM, Priority: 2A Evaluation: after 2 years (10/2021)</p> <ul style="list-style-type: none"> ✓ 1.02% findings EURL-SRM 2017-2019 ✓ 0.01% findings (0.00% MRL exceedances) EFSA 2016 ✓ 0.32% findings (0.00% MRL exceedances) EFSA 2017 <p>No data on analytical capability. Chloridazon-desphenyl (and therefore also the full residue definition of chloridazon) requires an SRM method (QuPe). All findings concern chloridazon desphenyl. Residue findings mainly concern leafy vegetables such as parsley, spinach and lettuce. In 75% of the positive findings residue levels exceeded 0.01 mg/kg. The isotopically labelled standard is not yet available</p>	<p>Cyantraniliprole – PO Added: 10/2019</p> <p>Toxicity: ADI = 0.01 mg/kg bw/day, ARfD NA Method: MRM, Priority: 1A Evaluation: after 1 year (10/2020)</p> <ul style="list-style-type: none"> ✓ 14.29% findings (0.00% MRL exceedances) EFSA 2015 ✓ 0.25% findings (0.00% MRL exceedances) EFSA 2016 ✓ 0.89% findings (0.00% MRL exceedances) EFSA 2017 <p>No data on analytical coverage. Mainly encountered in cherries, tomatoes and plums.</p>

¹ SRM-compounds are typically analysed on specific commodities so their detection frequencies are typically higher than if they would have been analysed randomly.

WORKING DOCUMENT

Categorisation of the pesticides

- Frequent **detections**, **MRL** exceedances or **RASFF** notifications
- **Recent approvals**
- Substances showing a high **toxicity**
- **Art. 12** priority list

Priority

Based on a combination of

Analytical method

- MRM (priority **1**)
- SRM (priority **2**)

Toxicity

- ADI or ARfD ≤ 0.1 (priority **A**)
- ADI and ARfD > 0.1 (priority **B**)

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WORKING DOCUMENT

New MRM-amenable compounds (SANCO 12745/2013, rev. 11-3, November 2019)

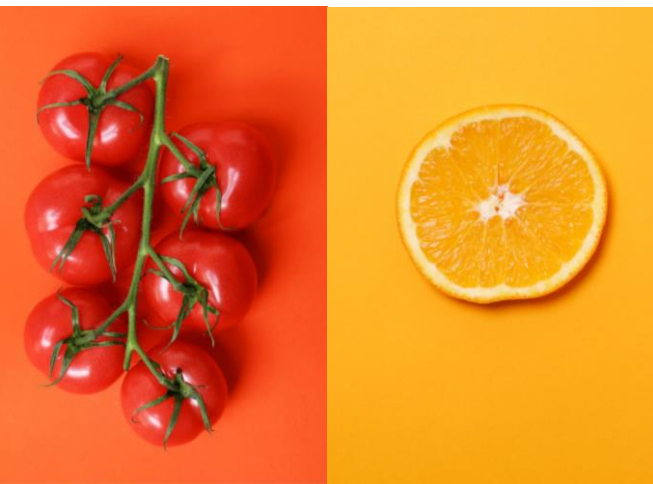
Priority	Name
1-A	– Aclonifen
2-A	– Bifenazate
1-A	– Cyantraniliprole
1-B	– Florpyrauxyfen benzyl
1-B	– Flutianil
1-A	– Isofetamid
2-A	– Isoxaflutole
1-A	– Mefentrifluconazole
1-A	– Mercury compounds
1-A	– Metaflumizone*
1-A	– Triflumizole
2-B	– Trinexapac

COMMERCIAL AVAILABILITY



Name	CAS number	SIGMA ALDRICH (MERCK)		LGC STANDARDS	
		Price (€)	Amount (mg)	Price (€)	Amount (mg)
Aclonifen	74070-46-5	46.80	50	46.80	250
Cyantraniliprole	736994-63-1	91.20	25	90.90	25
Flutianil	958647-10-4	-	-	127.80	10
Isofetamid	875915-78-9	-	-	135.00	25
Mefentrifluconazole	1417782-03-6	-	-	95.40	25
Triflumizole	68694-11-1	89.50	100	69.30	100

METHODOLOGY



5 replicates (tomato, orange)
spiked with **0.010 mg/kg**
(mix of WD compounds)

QuEChERS
extraction
method

Recoveries
Repeatability



Matrix-matched
calibration curves

Concentrations (mg/kg):

0.005	0.100
0.010	0.200
0.020	0.500

Linearity
Matrix effect



Agilent 1290 Infinity **LC System**
Agilent 6490A **LC/MS Triple Quad**

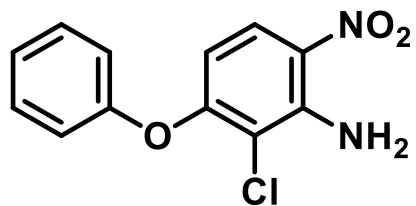


Agilent Intuvo 9000 **GC System**
Agilent 7010B **GC/MS Triple Quad**



https://www.youtube.com/watch?v=WqsqINRsYck&feature=youtu.be&ab_channel=D%C3%ADaz-Galiano

Aclonifen



Chemical Formula: $C_{12}H_9ClN_2O_3$
Exact Mass: 264,03



Nitrophenyl ether



Herbicide frequently found in samples of the carrot family as well as in other leafy vegetables (2015 to 2017)



Moderate to high persistence in soil and water



Low mammalian toxicity, can **bioaccumulate**. **Toxic** to aquatic organisms

Polarity

Log P 4.37

Volatility

Vapour pressure
(20 °C, mPa) 0.016

Solubility (mg/L)

Water	1.4
Methanol	49200
Acetone	730000
Toluene	442000
Acetonitrile	> 1300



Recommended

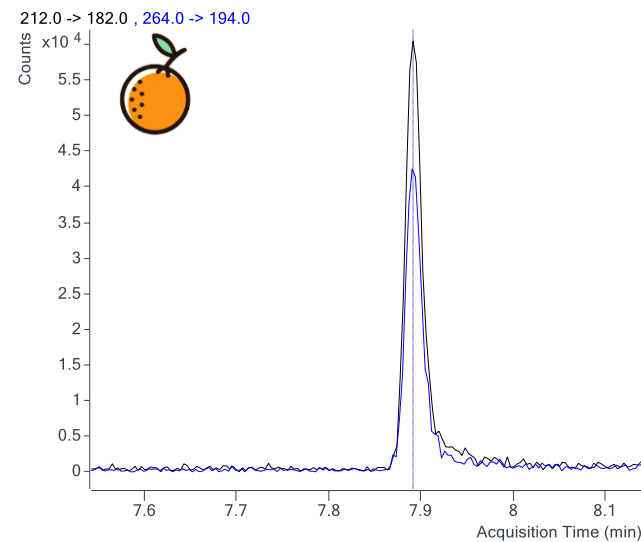
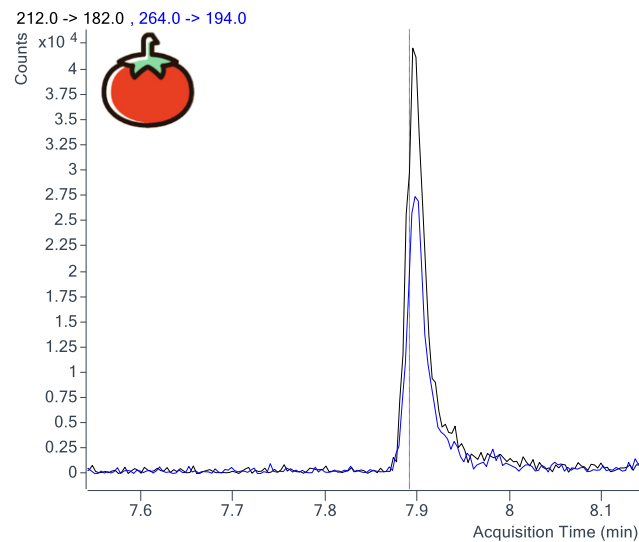


Aclonifen

Validation data (GC; 0.010 mg/kg)

	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
Tomato	86	4	0.005 - 0.200	98
Orange	104	9	0.005 - 0.200	

Chromatograms (0.010 mg/kg)

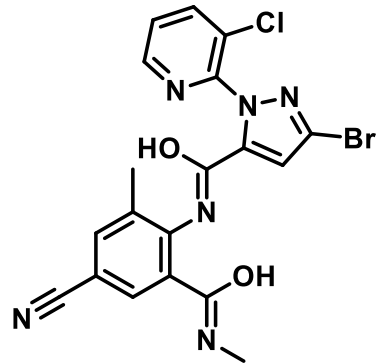


Selected Transitions (GC)

212.0 - 182.0
264.0 - 194.0



Cyantraniliprole



Chemical Formula: $C_{19}H_{14}BrClN_6O_2$
Exact Mass: 472,0050



Diamide



Insecticide mainly found in cherries, tomatoes and plums (up to 14.3 % findings by EFSA monitorings in 2015)



Not expected to be persistent in soil nor water



Low mammalian toxicity, low potential to bioaccumulate. Highly toxic to **honeybees**, **earthworms** and **aquatic species**

Polarity

Log P 2.02

Volatility

Vapour pressure

(20 °C, mPa) $5 \cdot 10^{-13}$

Decomposes at high temperature

Solubility (mg/L)

Water 14.2

Methanol 4730

Acetone 6540

Toluene 576

Acetonitrile > 1100



Recommended

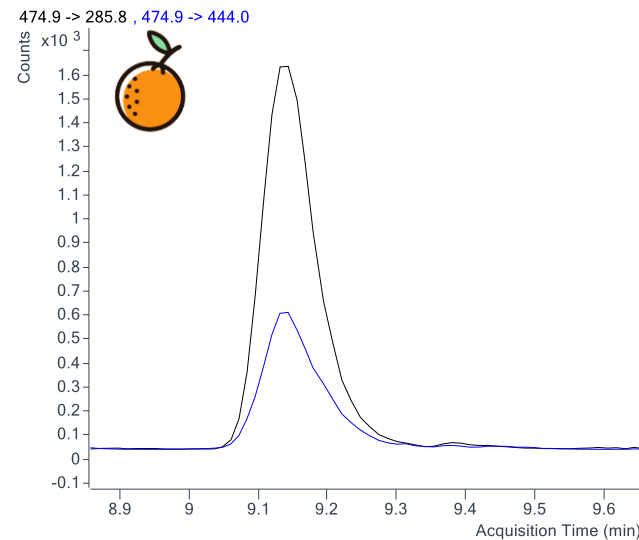
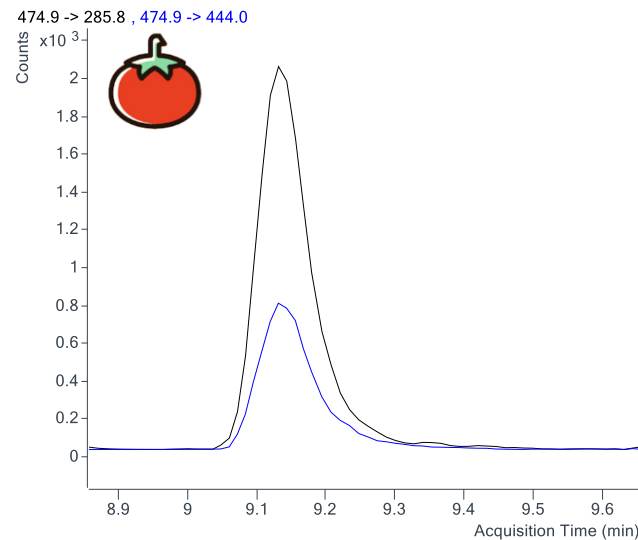


Cyantraniliprole

Validation data (LC; 0.010 mg/kg)

	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
Tomato	91	10	0.005 - 0.500	-21
Orange	82	6	0.005 - 0.500	

Chromatograms (0.010 mg/kg)

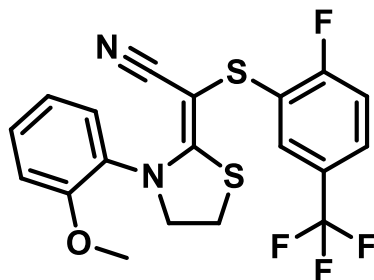


Selected Transitions (LC)

474.9 - 285.8
474.9 - 444.0



Flutianil



Chemical Formula: $C_{19}H_{14}F_4N_2OS_2$

Exact Mass: 426,0484



Thiazolidine



Fungicide (recently approved substance)



Persistent in **soil** but not in water



Low mammalian toxicity, but there are **concerns** regarding effects on **reproduction** and **carcinogenicity**

Polarity

Log P 3.1

Volatility

Vapour pressure
(20 °C, mPa) $2 \cdot 10^{-4}$

Solubility (mg/L)

Water	0.1
Methanol	56200
Acetone	66400
Toluene	11200
Acetonitrile	> 1100



Flutianil

Recommended



Validation data (LC; 0.010 mg/kg)

Validation data (GC; 0.010 mg/kg)

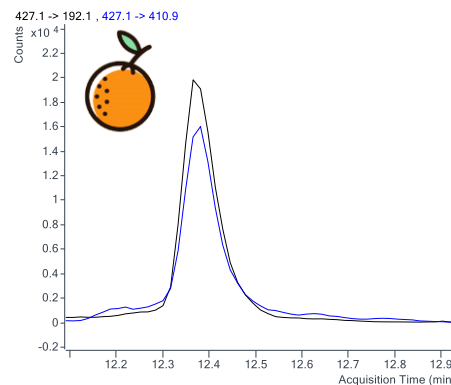
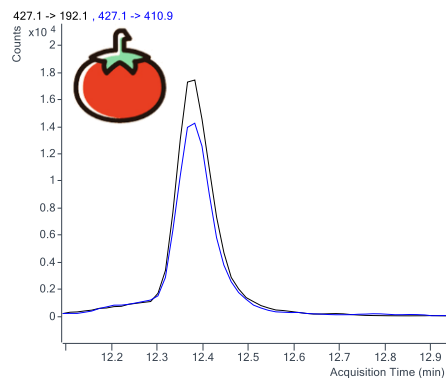
	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
Tomato	92	8	0.005 - 0.500	-24	89	5	0.005 - 0.200	48
Orange	81	8	0.005 - 0.200		98	14	0.005 - 0.200	

Chromatograms (0.010 mg/kg)

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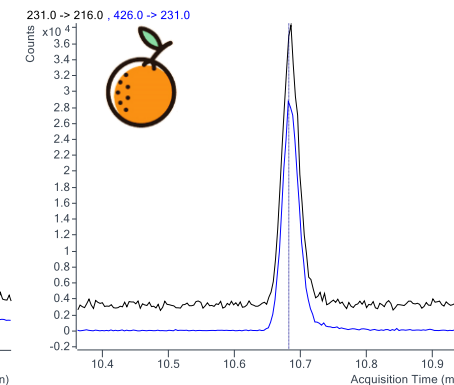
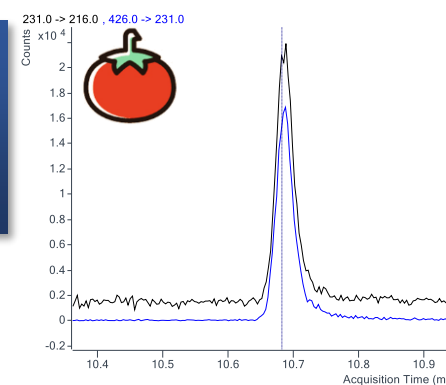
Selected
Transitions
(LC)

427.1 - 192.1
427.1 - 410.9

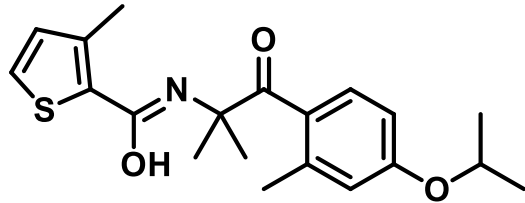


Selected
Transitions
(GC)

231.0 - 216.0
426.0 - 231.0



Isofetamid



Chemical Formula: $C_{20}H_{25}NO_3S$
Exact Mass: 359,1555



Amide



Fungicide (recently approved substance)



Moderately persistent in soil and water



Low mammalian toxicity, moderate toxicity for **aquatic organisms, honeybees** and **earthworms**

Polarity

Log P 2.5

Volatility

Vapour pressure
(20 °C, mPa) $4 \cdot 10^{-4}$

Solubility (mg/L)

Water	5.3
Acetone	250000
Ethyl acetate	250000
Acetonitrile	> 1100

Isofetamid

Recommended



Validation data (LC; 0.010 mg/kg)

Validation data (GC; 0.010 mg/kg)

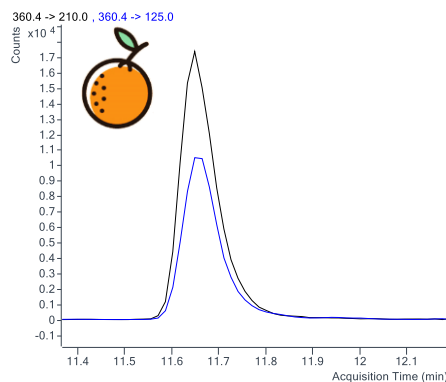
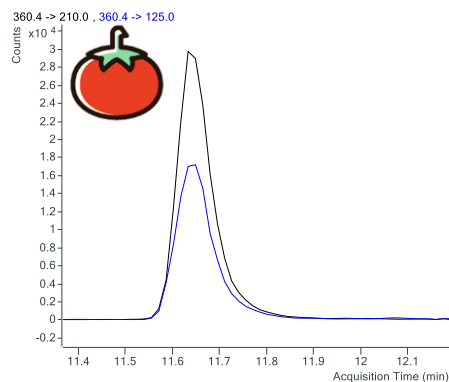
	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
Tomato	87	8	0.005 - 0.500	-31	76	4	0.005 - 0.200	51
Orange	72	6	0.005 - 0.500		95	12	0.005 - 0.200	

Chromatograms (0.010 mg/kg)

Chromatograms (0.010 mg/kg)

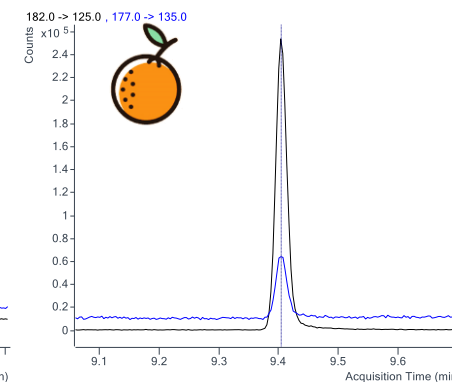
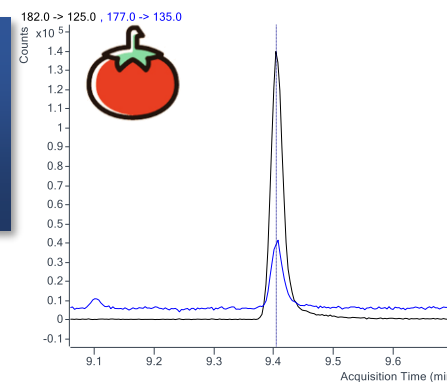
Selected
Transitions
(LC)

360.4 - 210.0
360.4 - 125.0

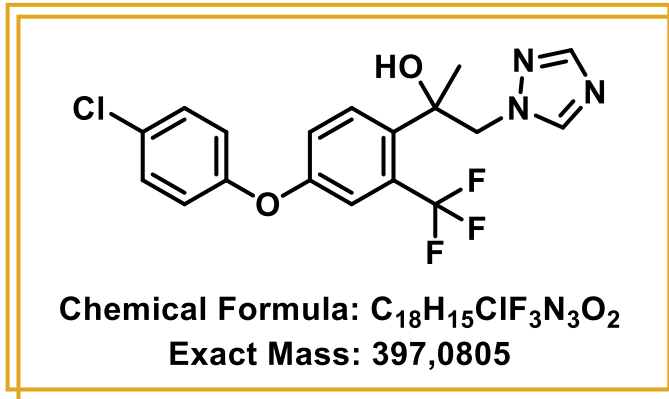


Selected
Transitions
(GC)

182.0 - 125.0
177.0 - 135.0



Mefentrifluconazole



Triazole



Fungicide (recently approved substance)



No persistent in soil nor water



Low mammalian toxicity

Polarity

Log P 3.4

Volatility

Vapour pressure

(20 °C, mPa) $3 \cdot 10^{-3}$

Decomposes at high temperature

Solubility (mg/L)

Water	0.8
Acetone	93200
Ethyl acetate	116200
Acetonitrile	> 1200

Recommended

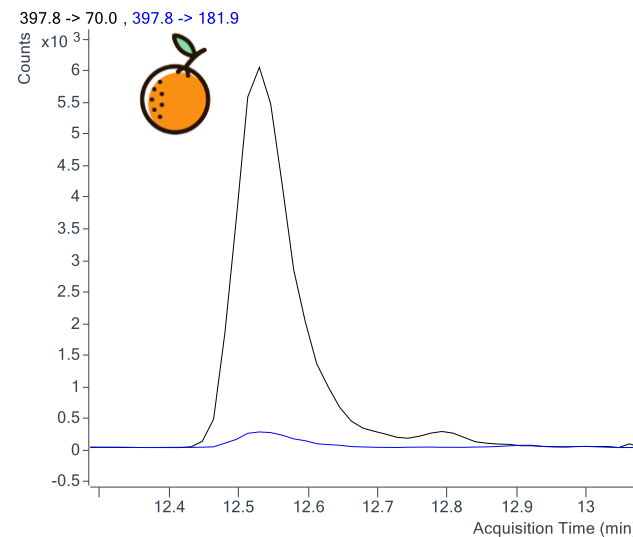
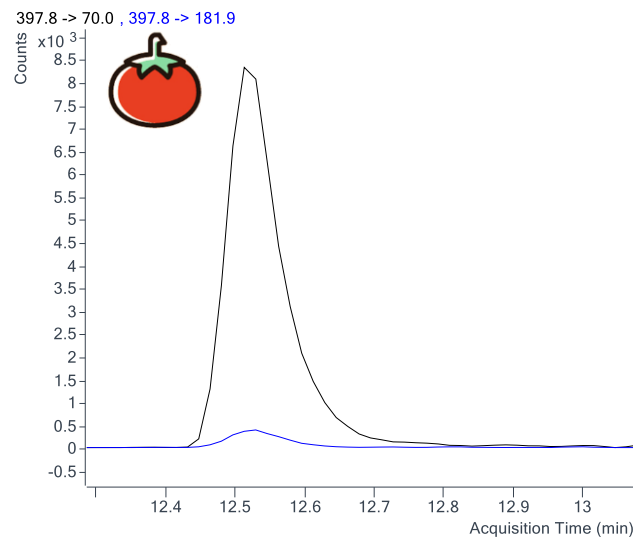


Mefentrifluconazole

Validation data (LC; 0.010 mg/kg)

	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
Tomato	88	12	0.005 - 0.500	-23
Orange	84	10	0.005 - 0.500	

Chromatograms (0.010 mg/kg)

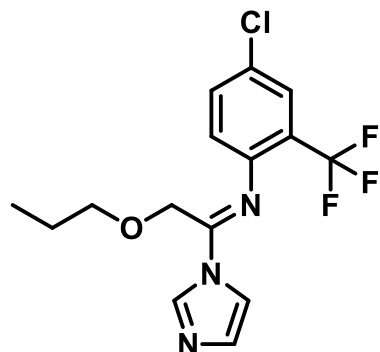


Selected Transitions (LC)

397.8 - 70.0
397.8 - 181.9

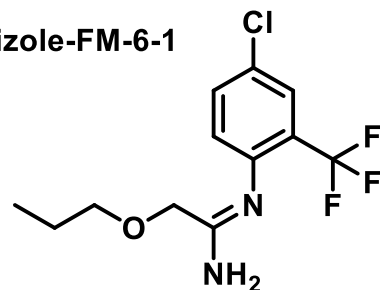


Triflumizole



Chemical Formula: $C_{15}H_{15}ClF_3N_3O$
Exact Mass: 345,0856

Triflumizole-FM-6-1



Chemical Formula: $C_{12}H_{14}ClF_3N_2O$
Exact Mass: 294,07



Residue definition Triflumizole and metabolite FM-6-1, expressed as triflumizole



Imidazole



Fungicide frequently detected in grapes (up to 6 % samples between 2015 and 2017) and cucumber (up to 17% samples)



No persistent in soil nor water



Moderate **mammalian toxicity**, also to **aquatic species** and **honeybees**

Polarity

Log P 4.77

Volatility

Vapour pressure
(20 °C, mPa) 0.191

Decomposes at high temperature

Solubility (mg/L)

Water	10.5
Methanol	496000
Acetone	1440000
Toluene	1486000
Acetonitrile	> 1100



Triflumizole

LC

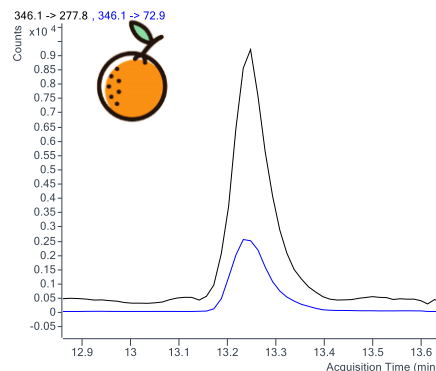
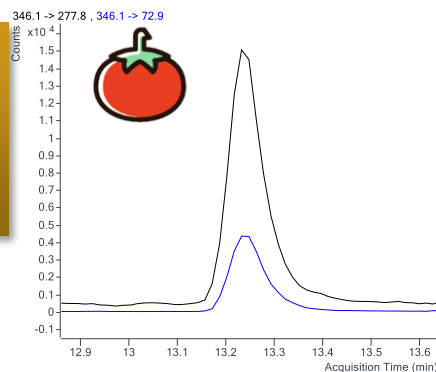
Validation data for triflumizole (LC)

	Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
Tomato	87	9	0.005 - 0.500	-20
Orange	51	11	0.005 - 0.500	

Chromatograms (0.010 mg/kg)

Selected Transitions (triflumizole)

346.1 - 277.8
346.1 - 72.9

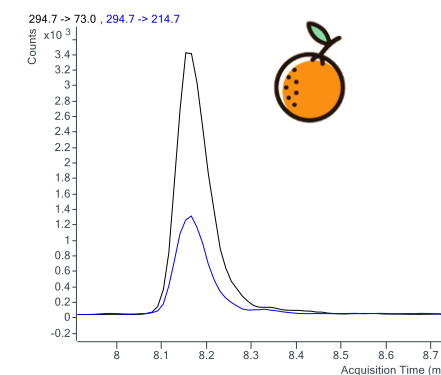
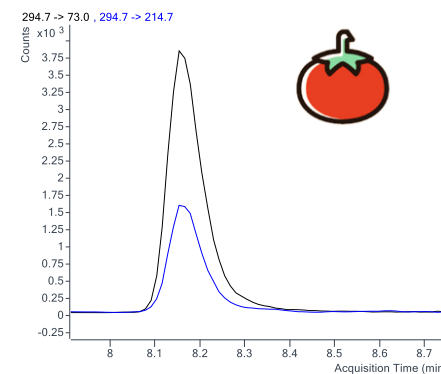


Triflumizole-FM-6-1

Validation data for triflumizole-FM-6-1 (LC)

Recovery (%)	RSD (%)	Linearity	Matrix effect (%)
82	15	0.005 - 0.200	-23
86	11	0.005 - 0.200	

Chromatograms (0.010 mg/kg)



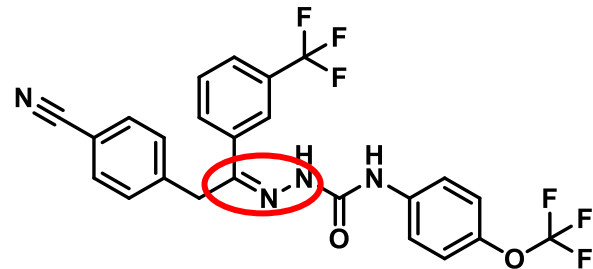
Selected transitions (triflumizole-FM-6-1)

294.7 - 73.0

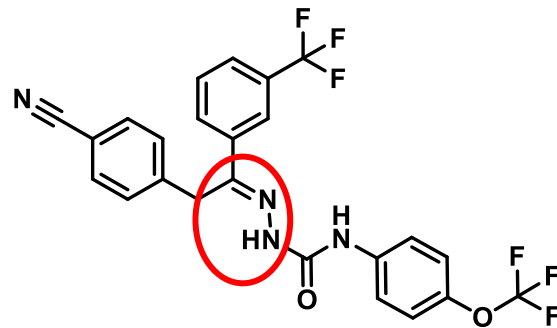
294.7 - 214.7

Metaflumizone

Z-isomer



E-isomer



Chemical Formula: $C_{24}H_{16}F_6N_4O_2$
Exact Mass: 506,12



Residue definition Metaflumizone (sum of *E*- and *Z*- isomers)



Semicarbazone
(two isomeric forms)



Insecticide mainly found in tomato and pepper (up to 8 % samples between 2016 and 2017)



Persistent in soil and water



Low mammalian toxicity, but high potential for **bioaccumulation**.
Low to moderate toxicity to **aquatic species, honeybees** and **earthworms**.

Polarity

Log P 4.06

Volatility

Vapour pressure

(20 °C, mPa) $2 \cdot 10^{-08}$

Decomposes at high temperature

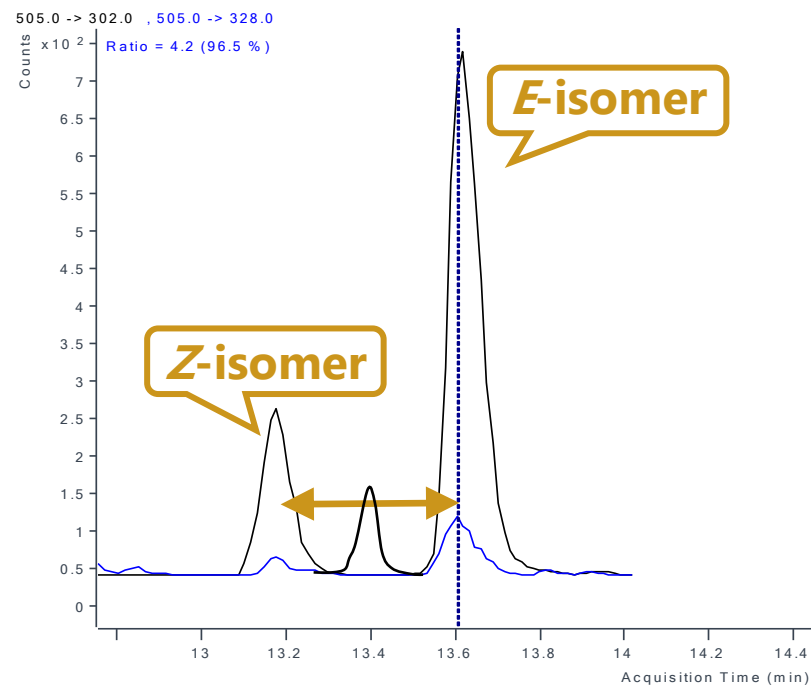
Solubility (mg/L)

Water	0.0018
Methanol	14100
Acetone	153300
Toluene	4000
Acetonitrile	> 1200

Metaflumizone

LC

Chromatogram (0.010 mg/kg in tomato)



Selected
transitions
(LC)

505.0 - 302.0

505.0 - 328.0

Different behaviour of the isomers

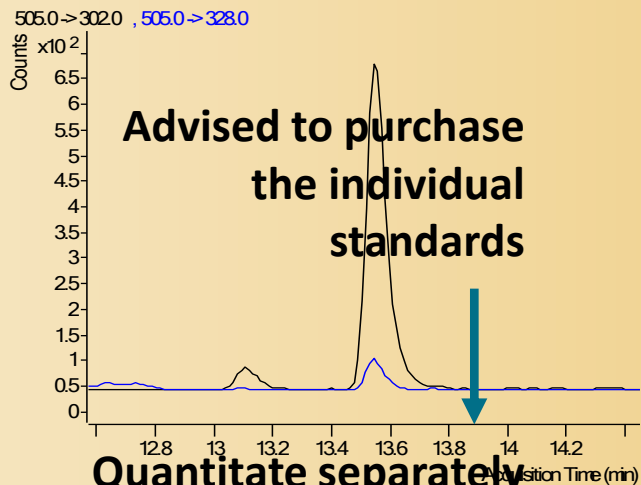
E-isomer usually shows a higher sensitivity

Two separated peaks (about 0.4 minutes difference)

- Make sure to either analyse them separately (different chromatograms) OR to have a wide acquisition window
- Possible matrix interferences between both peaks

The concentration corresponds to the sum of isomers

Check the ratio of the isomers in the certificate of analysis



Advised to purchase the individual standards

Quantitate separately and report the sum of concentrations

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(E)-Metaflumizone

Synonyms: (2E)-2-[2-(4-Cyanophenyl)-1-[3-(trifluoromethyl)phenyl]ethylidene]-N-[4-(trifluo... Show more

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(Z)-Metaflumizone

Synonyms: Hydrazinecarboxamide, 2-[2-(4-cyanophenyl)-1-[3-(trifluoromethyl)phenyl]ethylide... Show more

CONCLUSIONS

Compound	LC			GC		
	Recovery in tomato (RSD) (%)	Recovery in orange (RSD) (%)	Matrix effect in orange (%)	Recovery in tomato (RSD) (%)	Recovery in orange (RSD) (%)	Matrix effect in orange (%)
Aclonifen				86 (4)	104 (10)	98
Cyantraniliprole	91 (10)	82 (6)	-21			
Flutianil	92 (8)	81 (8)	-24	79 (5)	98 (14)	48
Isofetamid	87 (8)	72 (6)	-31	76 (4)	95 (12)	51
Mefentrifluconazole	88 (12)	84 (10)	-23			
Triflumizone	87 (9)	51 (11)	-20			
Triflumizole-amino	82 (15)	86 (11)	-23			

Most compounds newly included in the Working Document (rev. 11-3, November 2019) can be easily analysed by routine **multiresidue methods**

These compounds are likely to be soon included in the **EU-MACP**

Your turn!

Do you usually optimize the compounds published in the Working Document in your multiresidue methods?

Do you have experience with any of these compounds?

Is there any comment/issue/question that you would like to discuss?





Thank you for your attention

