

Current legal developments in residue analysis

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Pesticides – VO 396 - consolidated version

Regulation 2005/396 / EC on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Directive 91/414 / EEC of 23 February 2005, Official Journal of the European Union L 70, S.1 of 16 March 2005

Consolidated version- Status: 03 November 2017

02005R0396 — DE — 03 November 2017 — 027.001 — 1

3035 pages

Current legal developments

New Council Regulation on Organic Agriculture adopted

From 1 July 2021, new regulations on organic agriculture will apply in the EU

- The production rules are simplified and harmonized by abolishing a number of derogations.
- The control system is strengthened by stricter precautions and robust risk-based controls along the entire supply chain.
- Producers in non-EU countries must follow the same rules as producers in the EU.
- The scope of the organic farming rules will be extended to include a broader list of products (for example, salt, cork, beeswax, mate, grape leaves, palm hearts) and additional production rules (such as deer, rabbits and poultry).
- Certification is made easier for small farmers through a new system of group certification.
- There will be a more consistent approach to reducing the risk of unintentional pesticide contamination.
- Exceptions for production in confined beds in greenhouses will be gradually abolished.

<http://www.consilium.europa.eu/de/press/press-releases/2017/06/28/rules-organic-farming/>

Current legal developments(2)

Fipronil: results of follow-up monitoring published



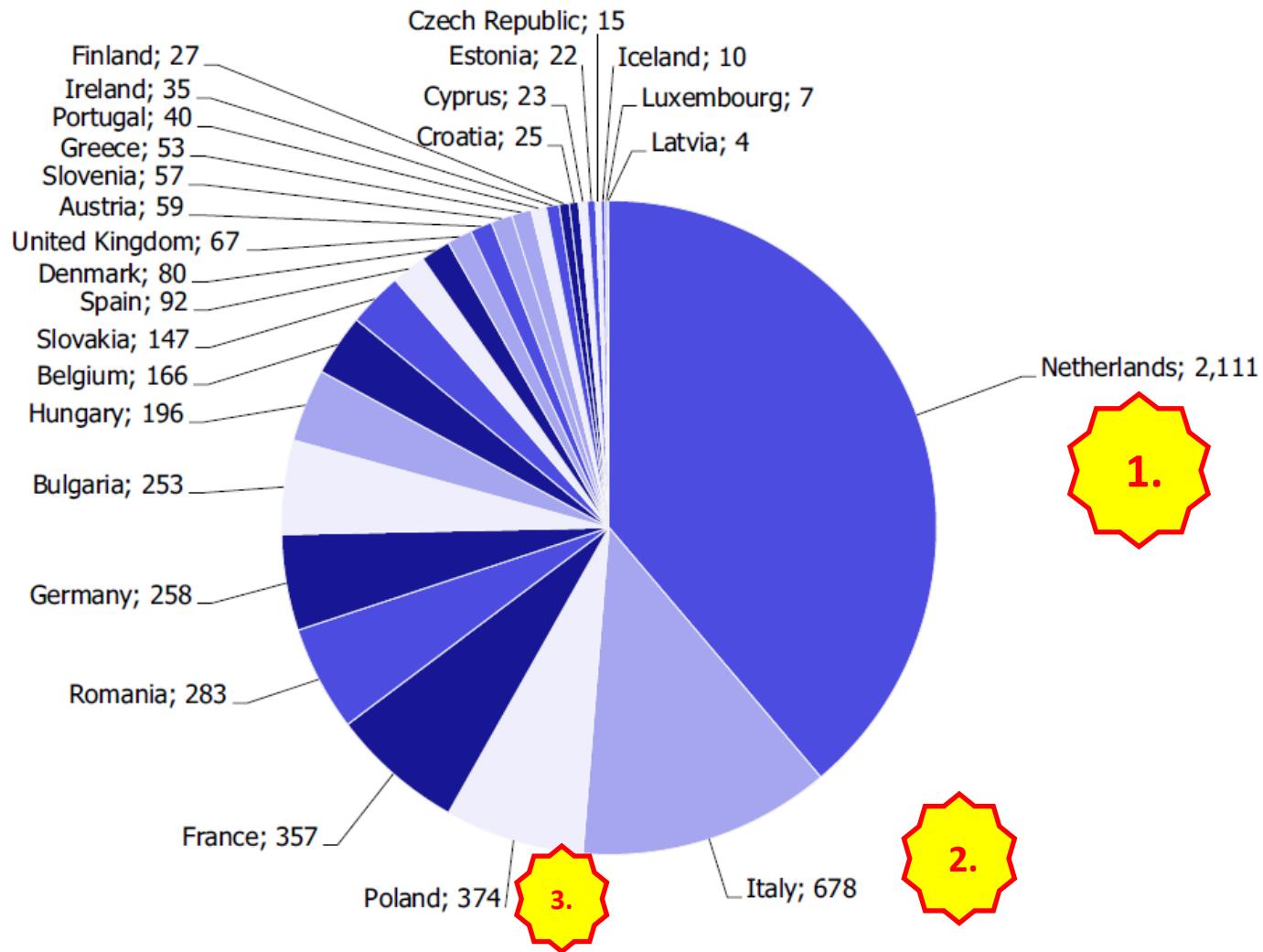
Parma, 3 May 2018

COMMUNICATIONS & EXTERNAL RELATIONS

UNDER EMBARGO until 03/05/2018 at 11.00 CET
NOT FOR FURTHER DISTRIBUTION

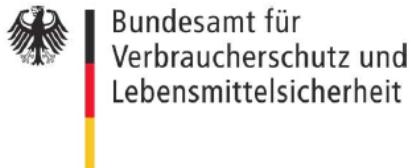
- **5.000** samples of eggs and chicken collected between 1 September and 30 November 2017
- **742** of the samples contained residues in quantities exceeding legal limits, almost all related to fipronil.
- The majority of exceedances were found in **suspect samples** – those derived from products or producers where illegal use was known or assumed
- Products with exceedances of legal limits originated from **eight Member States** – the Netherlands, Italy, Germany, Poland, Hungary, France, Slovenia, and Greece.
- The food products affected were mainly **unprocessed chicken eggs** and fat of laying hens.
Some exceedances were reported for **muscle** of laying hens and **egg powder**.

Fipronil - Number of samples analysed by Member States



SCIENTIFIC REPORT *Occurrence of residues of fipronil and other acaricides in chicken eggs and poultry muscle/fat* ; APPROVED: 18 April 2018 ; doi: 10.2903/j.efsa.2018.5164

List of authorized plant protection products in Germany



Übersichtsliste (April 2018)

Übersichtsliste

 Übersichtsliste (April 2018) (pdf, 4 MB, nicht barrierefrei)

**Liste der zugelassenen Pflanzenschutzmittel in Deutschland
mit Informationen über beendete Zulassungen**

Stand: April 2018

**List of Authorised Plant Protection Products in Germany
with Information on Terminated Authorisations**

http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/psm_uebersichtsliste.pdf?

Last changes (1):

COMMISSION REGULATION (EU) 2018/687 of 4 May 2018

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council regarding maximum residue levels for acibenzolar-S-methyl, benzovindiflupyr, bifenthrin, bixafen, chlorantraniliprole, deltamethrin, flonicamid, fluazifop-P, isofetamid, metrafenone, pendimethalin and teflubenzuron in or on certain products

COMMISSION REGULATION (EU) 2018/686 of 4 May 2018

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council regarding maximum residue levels for chlorpyrifos, chlorpyrifos-methyl and triclopyr in or on certain products

COMMISSION REGULATION (EU) 2018/685 of 3 May 2018

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council regarding maximum residue levels for abamectin, beer, fluopyram, fluxapyroxad, maleic hydrazide, mustard seeds powder and tefluthrin in or on certain products

COMMISSION REGULATION (EU) 2018/62 of 17 January 2018

replacing **Annex I** in COMMISSION REGULATION (EU) 396/2005

Last Changes (2):

COMMISSION REGULATION (EU) 2018/78 of 16 January 2018

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council regarding maximum residue levels for 2-phenylphenol, bensulfuron-methyl, dimethachlor and lufenuron in or on certain products

COMMISSION REGULATION (EU) 2018/73 of 16 January 2018

amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council regarding maximum residue levels for mercury compounds in or on certain products

COMMISSION REGULATION (EU) 2018/70 of 16 January 2018

amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council regarding maximum residue levels for ametoctradin, chlorpyrifos-methyl, cyproconazole, difenoconazole, fluazinam, flutriafol, prohexadion and sodium chloride in or on certain products

Last Changes:

REGULATION (EU) 2017/625 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2017

on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

Organic agriculture

Authorized pesticides

selection for organic agriculture on the COMMISSION REGULATION (EU) 834/2007

Plant protection products in organic agriculture

Authorised substances

The Annex II REGULATION (EC) 889/2008 contains a positive list of all active substances which may be included in the pesticides used. Substances that are not listed may not be used.

Pesticides — plant protection products as referred to in Article 5(1)

Authorised plant protection products

The Federal Office of Consumer Protection and Food Safety (BVL) prepares a quarterly overview of approved plant protection products that may be used in organic agriculture. The selection is based on Regulation (EC) No 834/2007.

Authroised plant protection substances for the organic agriculture –

Selection of the Regulation (EG) Nr. 834/2007 (PDF-file)

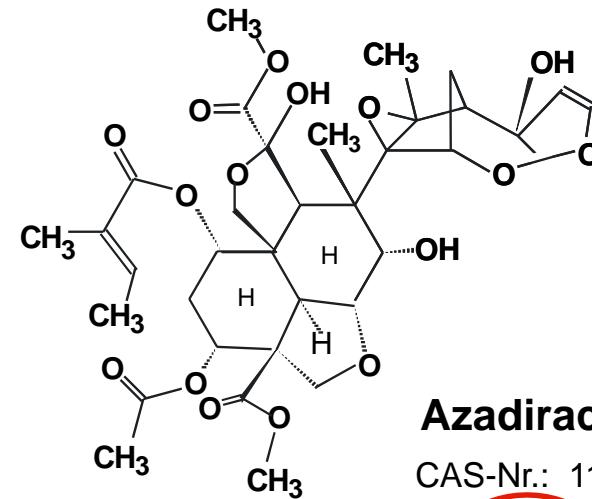
- | | |
|-------------------------------|----------------------------|
| 6.3.1: Beeswax | 6.3.11: Neem |
| 6.3.2: Gelatin | 6.3.12: Paraffin oil |
| 6.3.3: Hydrolysed protein | 6.3.13: vegetable oils |
| 6.3.4: Kalialauna | 6.3.14: Pyrethrin |
| 6.3.5: Potassium permanganate | 6.3.15: Quartz sand |
| 6.3.6: Kaolin | 6.3.16: Quassia Bitterwood |
| 6.3.7: Diatomaceous earth | 6.3.17: Rotenone |
| 6.3.8: Copper | 6.3.18: Soft soap |
| 6.3.9: laminarin | 6.3.19: Sulfur |
| 6.3.10: Lecithin | 6.3.20: Spinosad |

Neem leaf extract NeemAzal

Composition

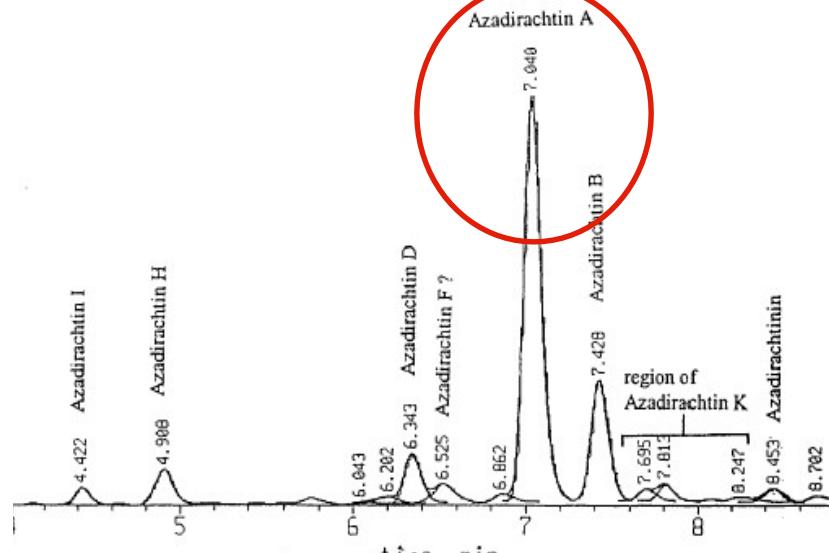
Tabelle 1: Analytische Ergebnisse zur Zusammensetzung von NeemAzal.

Substanz	Durchschnittlicher Gehalt in NeemAzal (Gewichts-%)
Azadirachtine:	
Azadirachtin A	34
Azadirachtin B	5.5
Azadirachtin D	2.1
Azadirachtin E	≤ 1
Azadirachtin F	≤ 1
Azadirachtin G	≤ 1
Azadirachtin H	2.3
Azadirachtin I	0.8
Azadirachtin K und andere Azadirachtine	≤ 2
Azadirachtinin	2
Summe der Azadirachtine:	51,7
Andere Limonoide:	
Salannin	3
Nimbin	0.7
Desacetyl-salannin	0.7
Desacetyl-nimbin	0.5
6-O-Acetylnimbandiol	≤ 1
Summe anderer Limonoide:	5,9
Gesamtsumme aller Limonoide:	<u>57,6</u>



Azadirachtin

CAS-Nr.: 11141-17-6



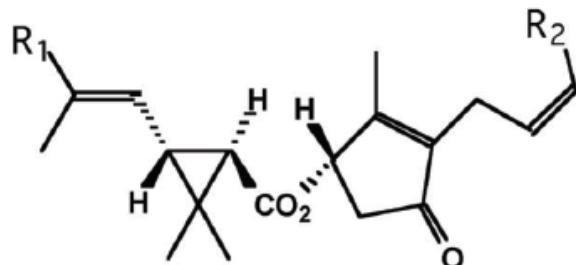
Chromatogram section of NeemAzal.

= 1 % AzA in 1 L NeemAzal-T/S

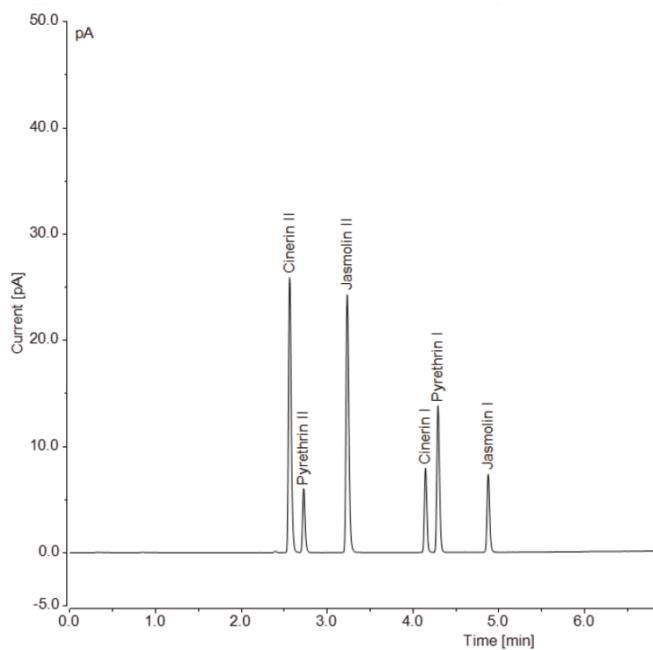
Pyrethrum

Origin: chrysanthemums

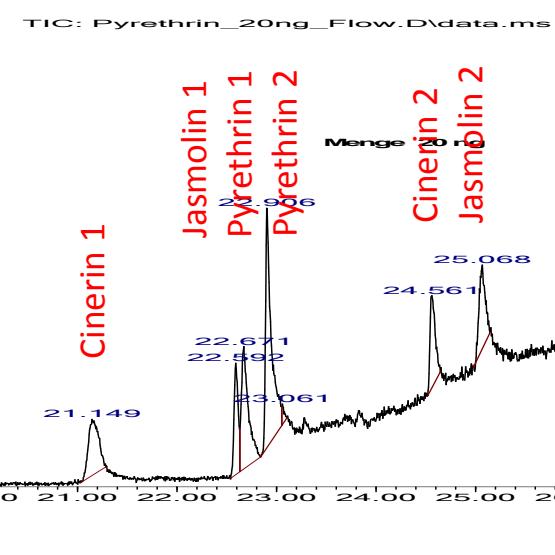
Pyrethrum is obtained from the flowers of chrysanthemum species by pulverization or extraction poisonous for all insect species.



	R1	R2
Cinerin I	CH ₃	CH ₃
Cinerin II	CO ₂ CH ₃	CH ₃
Pyrethrin I	CH ₃	CH=CH ₂
Pyrethrin II	CO ₂ CH ₃	CH=CH ₂
Jasmolin I	CH ₃	CH ₂ CH ₃
Jasmolin II	CO ₂ CH ₃	CH ₂ CH ₃



UHPLC/DAD: C18 1.5 µm, 2.1 × 100 mm



Wiki: *Tanacetum cinerariifolium*



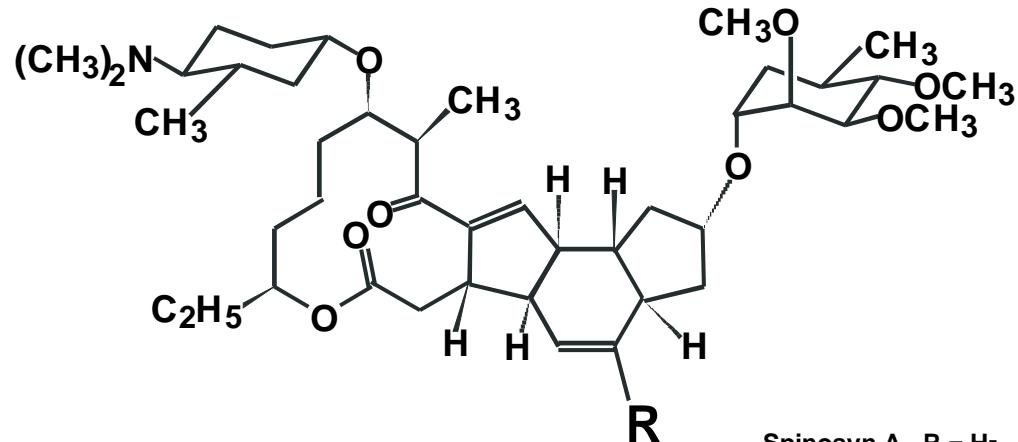
Wiki: *Chrysanthemum japonense*

Spinosad

Origin

soil bacterium

Saccharopolyspora spinosa
is obtained by fermentation



Spinosad

CAS-Nr.: 168316-95-8

Spinosyn A, R = H-
Spinosyn D, R = CH₃-

Insecticide

- ✗ Affects the neuronal activity in the nervous system of the harmful organisms.
- ✗ The effect begins already a few hours after the treatment and leads to a complete, irreversible paralysis of the pest.
- ✗ The uptake of the active substance "spinosad" takes place by feeding activities as well as by contact with the active substance.
- ✗ Bee-harming B1
- ✗ Very toxic to aquatic organisms

Not (anymore) approved active ingredients (6)

Active substance	
Orthosulfamuron	Non-approval of the active substance
Picoxystrobin	Not renewal of the approval Grace period: 03.11.2018 Was approved in Germany
Tallölpech (Repellent)	Expiration of approval Grace period: 14.10.2018 Was approved in Germany
Tallöl roh (Repellent)	Expiration of approval Grace period: 14.10.2018 No approvals in DE
Tricyclazole	No approvals in DE

Source: BVL - Dr. Helke Franz March 2018

New active substances approved in the EU (7)

not included in authorized plant protection products in Germany

Active Substance	Substance class	AWG (EFSA)	Method (EFSA)	Methode EURL Data pool	Approved	Approved in the EU
1,4-Dimethylnaphthalene	growth regulator	potatoe	GC-MS (QuEChERS)	-	01.07.2014	AT, BE, NL
Acibenzolar-S-methyl (Benzothiadiazole)	plant activator	stone fruits, tomato	LC-MS/MS	QuEChERS	01.11.2001	BE, CZ, EL, ES, FR, IT, PT, UK
Ascorbic acid	fungicide	potatoe tomato	No MRL	-	01.07.2014	NL
Azimsulfuron	herbicide	rice	LC-MS/MS	QuEChERS	01.10.1999 renewed: 01.01.2012	EL, ES, FR, HU, IT, PT, RO
Benzovindiflupyr Approved in Germany	insecticide	grain	LC-MS/MS QuEChERS	(QuEChERS)	02.03.2016	AT, BE, DE, EE, ES, FI, FR, HR, HU, IE, LT, LU, LV, NL, PL, RO, SE, SI, UK
Bispyribac	herbicide	rice	LC-MS/MS	QuEChERS	01.08.2011	BG, EL, ES, IT, PT, RO
Cerevisane	resistance inductor	lettuce	No MRL	-	23.04.2015	
Chromafenozide	insecticide	stone fruits, grapes	HPLC-DAD	QuEChERS, (QuOil)	01.04.2015	

Source: BVL - Dr. Helke Franz March 2018

New active substances approved in the EU (8)

not included in authorized plant protection products in Germany

Active Substance	Substance class	AWG (EFSA)	Method (EFSA)	Methode EURL Data pool	Approved	Approved in the EU
COS-OGA	resistance inductor	cucurbits	No MRL	-	22.04.2015	AT, BE, CY, EL, ES, FR, IT, NL, PL, PT
Cyantraniliprole (Notfallzulassung in DE)	insecticide	fruits, vegetables	LC-MS/MS S19	-	14.09.2016	HU, IE, PL, RO, UK
Cyflumetofen	acarizide	ornamental plants	-	QuEChERS	01.06.2013	BE, NL
Cyhalofop-butyl	herbicide	rice	LC-MS/MS	QuEChERS (GC, LC)	01.10.2002	EL, ES, FR, IT, PT
Disodium phosphonate	fungicide	grapes	LC-MS/MS	QuPPe (Phosphorous acid)	01.02.2014	FR, IT, PT
Emamectin	insecticide	fruits, vegetables	LC-LC-MS/MS	QuEChERS	01.05.2014	BE, BG, CY, EL, ES, FR, HR, HU, IT, NL, PL, PT, RO, SI
Etoxazole	insecticide	fruits, vegetables	GC-MS/MS, GC-PND	QuEChERS, (QuOil), (ChemElut) (GC, LC)	01.06.2005	AT, BE, CY, EL, ES, FR, HR, HU, IE, IT, NL, PL, PT, SI, UK
Eugenol	fungicide	herbs	No MRL	-	01.12.2013	EL
FEN 560 (Fenugreek seed powder = Bockshornkleesamen-pulver)	insecticide	grapes	No MRL	-	01.11.2010	FR, IT
Flubendiamide	insecticide	fruits, vegetables rice, maize	LC-MS/MS	(QuEChERS, QuOil (GC))	01.09.2014	CY, EL, ES, NL

Source: BVL - Dr. Helke Franz March 2018

New active substances approved in the EU (9)

not included in authorized plant protection products in Germany

Active Substance	Substance class	AWG (EFSA)	Method (EFSA)	Methode EURL Data pool	Approved	Approved in the EU
Flumetralin	Growth regulator	tobacco	GC-MS	(QuEChERS, QuOil (GC))	11.12.2015	
Flupyradifurone Zwei RD vorgeschlagen: Flupyradifurone (Anwendung) Difluoroessigsäure (DFA) (Nachbau)	insecticide	fruits, vegetables, hops	LC-MS/MS	(QuEChERS)	09.12.2015	
Forchlorfenuron	growth regulator	grapes	LC-MS/MS	QuEChERS, (QuOil)	01.04.2006	CY, EL, ES, FR, IT, PT
Geraniol	fungicide	grapes	No MRL	-	01.12.2013	CY, EL, ES, IT, MT, PT
Halauxifen-methyl	herbicide	grain	LC-MS/MS QuEChERS	-	05.08.2015	
Halosulfuron methyl (Notfallzulassung in DE)	herbicide	rice	LC-MS/MS (dried)	QuEChERS	01.10.2013	EL, ES, FR, IT
Heptamaloxylglucan	growth regulator	grapes	No MRL	-	01.06.2010	FR
Ipcconazole Approved in Germany	fungicide	grain	LC-MS/MS S19	(QuEChERS)	01.09.2014	AT, BE, BG, CZ, FR, HU, IT, PL, RO, SK, UK
Isofetamid	fungicide	fruits, vegetables	LC-MS/MS	-	15.09.2016	
Laminarin	growth regulator	grain	No MRL	-	01.04.2005	BE, DK, EL, ES, FR, NL, PL, PT, UK

Source: BVL - Dr. Helke Franz March 2018

New active substances approved in the EU (10) not included in authorized plant protection products in Germany

Active Substance	Substance class	AWG (EFSA)	Method (EFSA)	Methode EURL Data pool	Approved	Approved in the EU
Maltodextrin	insecticide	fruits, cabbage	No MRL	-	01.10.2013	BE, ES, FR, IE, NL, UK
Mandestrobin Approved in Germany	fungicide	rapeseed	GC-MS, S19 LC-MS/MS, QuEChERS	-	09.12.2015	AT, DE
Meptyldinocap	fungicide	grapes	LC-MS/MS, GC-ECD	QuEChERS (LC, GC)	01.04.2015	AT, CZ, EL, ES, FR, HR, HU, IT, MT, PT, RO, SI, SK, UK
Metobromuron (Notfallzulassung in DE)	herbizid	potatoe	LC-MS/MS, QuEChERS	QuEChERS, (QuOil), (ChemElut)	01.01.2015	AT, BE, CZ, EE, FR, IE, LU, NL, PL, RO, UK (war bis 2004 in DE zugelassen)
Orange oil Approved in Germany	insecticide	tomatoe	No MRL	-	01.05.2014	BE, CY, FR, IT, RO
Oxasulfuron	herbicide	soy beans	LC-MS, S19	(QuEChERS)	01.07.2003	HR, IT
Oxathiapiprolin	herbicide	grapes, vegetables, potatoe	LC-MS/MS S19	(QuEChERS)	03.03.2017	BE, IE, UK
Penflufen Approved in Germany	fungicide	Potatoe	LC-MS/MS	(QuEChERS) (LC, GC)	01.02.2014	CZ, FI, NL, PL, UK
Penthiopyrad	fungicide	stone fruit, grain, vegetables	LC-MS/MS S19	(QuEChERS) (LC, GC)	01.05.2014	AT, CZ, EE, EL, FR, HU, IE, IT, MT, NL, PL, PT, RO, SK, UK
Profoxydim	herbicide	rice	(GC-MS, Common moiety method)	(QuEChERS)	01.08.2011	EL, ES, IT, PT

Source: BVL - Dr. Helke Franz March 2018

G. Kempe | Eurofins Symposium "25 Jahre Rückstandsanalytik" | June 2018

New active substances approved in the EU (11)

not included in authorized plant protection products in Germany

Active Substance	Substance class	AWG (EFSA)	Method (EFSA)	Methode EURL Data pool	Approved	Approved in the EU
Pyridalyl	insecticide	vegetables	GC-MS, S19	(QuEChERS) (QuOil) (LC,GC)	01.07.2014	NL
Pyriofenone Approved in Germany	fungicide	grain, grapes	LC-MS/MS	-	01.02.2014	AT, BE, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, UK
Rescalure	insecticide	citrus fruits	No MRL	-	18.12.2015	ES, PT
S-Abscisic acid (S-scisinsäure)	growth regulator	grapes, tomatoe	(LC-MS/MS, No method for food) No MRL	(QuEChERS)	01.07.2014	EL, ES, IT
Sedaxane	fungicide	grain	LC-MS/MS, QuEChERS	(QuEChERS)	01.02.2014	AT, BE, CY, CZ, EE, EL, FI, FR, HU, IT, LT, LU, LV, NL, PL, RO, SE, UK
Sodium silver thiosulphate	growth regulator	ornamental plants	No MRL	-	01.05.2014	NL
Spinetoram	insecticide	grapes, fruits	LC-MS/MS	QuEChERS	01.07.2014	CY, EL, ES, FR, HR, PT, SI
Spiromesifen	acaricide Insecticide	fruits, vegetables	LC-MS/MS (S19)	(QuEChERS) (LC, GC)	01.10.2013	BE, CY, EL, ES, FR, IE, IT, LU, MT, NL, UK
Sulfoxaflor	insecticide	fruits,grain	LC-MS/MS	(QuEChERS)	18.08.2015	EL, IE
Terpenoid blend QRD-460	insecticide	vegetables	No MRL		10.08.2015	
Thymol	fungicide	grapes	No MRL	-	01.12.2013	CY, EL, ES, FR, IT, MT, PTEL

Source: BVL - Dr. Helke Franz March 2018

New active substances - in progress in the EU (12)

not included in authorized plant protection products in Germany

Active substance	Substance class	MRL fixed ¹⁾	Approved in the EU
ABE IT56 (Hefe-Extrakt)	fungicide		
Aluminium potassium sulphate dodecahydrate	bactericide		
Beta-Cypermethrin nicht genehmigt	insecticide	J ²⁾	
Cyclaniliprole nicht genehmigt	insecticide		
Dimethyl disulphide	fungicide nematicide		
Ethametsulfuron	herbicide	J	CZ, HU, IE, PL, RO, SK
Fenpicoxamid (vormals Lyserphenvalpyr)	fungicide		
Ferric pyrophosphate	molluscicide		

- 1) Member States have agreed that an authorization may be granted if the standard value of Article 18 (1) (b) (normally 0.01 mg / kg) can be met and no risk to the consumer from residues of this magnitude results. "
- 2) 2) MRL fixed for cypermethrin (sum of isomers)

Source: BVL - Dr. Helke Franz March 2018

New active substances - in progress in the EU (13)

not included in authorized plant protection products in Germany

Active substance	Substance class	MRL fixed ¹⁾	Approved in the EU
Florpyrauxifen benzyl	herbicide		
Flutianil	fungicide	J	
Mefentrifluconazole	fungicide		
Napropamide-M	herbicide		Napropamide is included in authorized plant protection products in Germany
Orthosulfamuron nicht genehmigt	herbicide	J	ES, IT
Oxathiapiprolin genehmigter Wirkstoff	fungicide		
Propanil	herbicide		
Pydiflumetofen	fungicide		
Tolpyralate	herbicide		
Tricyclazole nicht genehmigt	fungicide	J	

Source: BVL - Dr. Helke Franz March 2018

Thank you for your attention

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(Landesuntersuchungsanstalt für das Gesundheits- und
Veterinärwesen - LUA) of the Free State of Saxony

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GESELLSCHAFT DEUTSCHER CHEMIKER

Einladung



GESELLSCHAFT DEUTSCHER CHEMIKER

Neue analytische Methoden und rechtliche Vorgaben in der Pestizidanalytik

Analytische und rechtliche Aspekte bei der Beurteilung von Rückständen aus der Anwendung von Pestiziden

Dr. Günther Kempe

- Anforderungen des Einzelhandels an die Analytik und die EUVO 396/2005
- Messunsicherheit bei geringen Gehalten
- Rückstände in Bio Lebensmitteln
- Highlights von der EWPRW 2018
- QuEChERS modifiziert für fettreiche tierische Matrix
- Anthrachinon und Nikotin in Tee



656/18

25. September 2018 · Frankfurt am Main



Anerkannt mit 12 Punkten
www.zefo.org

LEITUNG



Dr. Günther Kempe

Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen
Fachgebietsleiter PWS
Chemnitz

Dr. Günther Kempe ist seit 1981 am Bezirks-Hygiene-Institut Chemnitz und dort seit mehr als 30 Jahren Fachgebietsleiter Lebensmitteltoxikologie. Zu dem ist er seit 1991 als Fachgebietsleiter für Pestizide und organische Rückstände an der Landesuntersuchungsanstalt für das Gesundheits- und Veterinärwesen Sachsen in verschiedenen Bereichen der Rückstandsanalytik tätig.

Seine analytischen Schwerpunkte liegen in der Gaschromatographie, LC-MS/MS und GC-MS/MS. Dr. Kempe ist bzw. war Mitglied in diversen Arbeitsgruppen des DIN, BVL bzw. BfR, Obmann der AG Pestizide der GDCh, sowie Vorsitzender der „BfR-Kommission für Pflanzenschutzmittel und ihre Rückstände“. Seit mehr als 15 Jahren organisiert und leitet er den GDCh- Kurs „Neue analytische Methoden und rechtliche Vorgaben in der Pestizidanalytik“ der AG Pestizide.

REFERENTEN

Dr. Lutz Alder	Berlin
Dr. Birgit Christall	BLL, Berlin
LC Andreas Hentschel	Institut Kirchhoff, Berlin
Dr. Karsten Hohgardt	BVL
Dr. Günther Kempe (siehe Leitung)	LUA Sachsen, Chemnitz
Dr. Jürgen Kuballa	GALAB Hamburg
Silja Laufer	CVUA Freiburg
Dr. Anna Romanotto	PICA Berlin