

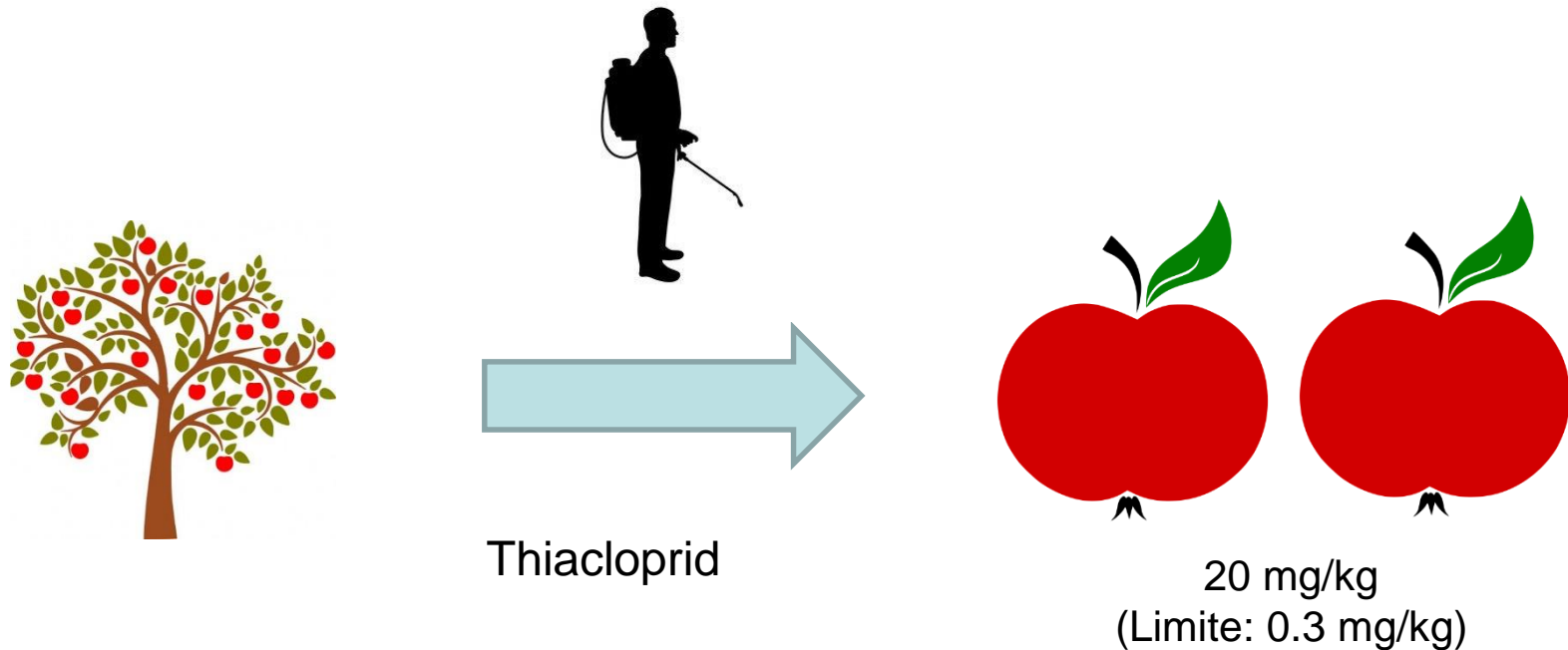
Démonstration pratique de l'évaluation des risques par l'autorité compétente

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Produit non-conforme: Y-a-t-il également un risque de sécurité alimentaire?

→ Evaluation de risque

- Pas de risque → Retrait de la vente
- Risque pour la santé → Rappel auprès du consommateur



- 1. **aRfD (dose de référence aiguë)**
- 2. TDI / **ADI** / UL (dose journalière tolérable)
- 3. TWI (PTWI) (dose hebdomadaire tolérable)
- 4. NOAEL, BMDL (No-observed adverse effect Level, Benchmark dose)

EFSA open Food tox:

<https://www.efsa.europa.eu/en/microstrategy/openfoodtox>

(last accessed on 04/06/2021)

- Dépassement de la valeur toxicologique:

➔ **Risque de sécurité alimentaire.**

- **Substances cancérogènes: application du principe ALARA.**



- Principe ALARA: « as low as reasonably achievable »
(substances cancérogènes)

→ MOE (margin of exposure)

- $MOE = \frac{BMDL}{Exposure}$ or $\frac{NOAEL}{Exposure}$
(dose d'un effet cancérogène)

- MOE > 10 000 = faible risque de cancer
- MOE < 10 000 un risque ne peut pas être exclu.



Outils par l'EFSA pour l'évaluation des risques

<https://www.efsa.europa.eu/fr/science/tools-and-resources>

(last accessed on 04/06/2021)

- **Pesticides:** EFSA Primo tool rev 3.1

<https://www.efsa.europa.eu/de/applications/pesticides/tools>

(last accessed on 04/06/2021)

Contaminants: EFSA Race Tool: Rapid assessment of of chemical exposure

Demande d'accès : servicedesk@efsa.europa.eu

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- Active substances
- Food products
- **Pesticide residues**

Pesticide residue(s) and maximum residue levels (mg/kg)

Back to search Export history

2 products selected Filter results ...

Code number	Products to which MRLs apply	Thiacloprid ⁱ Reg. (EU) 2019/50 applicable	Thiacloprid ⁱ Reg. (EU) 2016/1355 previous
0130010	● Apples	0.3	0.3
0130020	● Pears	0.3	0.3

Category |
 Group |
 Sub-group |
 Main product |
 Others |
 Clickable footnotes |
 * Indicates lower limit of analytical determination

https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en
(last accessed on 04/06/2021)



EFSA Primo Model (rev 3.1, Stand 04.06.2021)

Onglet: Input values

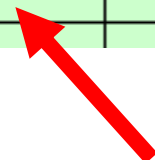
Active substance:		Thiacloprid		
ADI (value, unit, source, year of assessment)		0.1	mg/kg bw per day	
ARfD (value, unit, source, year of assessment)		0.5	mg/kg bw	
Residue definition:	enforcement / plants (unprocessed)			
Residue definition:	enforcement / animals (unprocessed)			
Residue definition:	risk assessment / plants (unprocessed)			
Residue definition:	risk assessment / animals (unprocessed)			
Normal mode	input table below (i.e. MRL, HR an	Comments		

<https://www.efsa.europa.eu/de/applications/pesticides/tools>



Onglet: Input values

Level	Code no.	Commodity or group of commodities to which the MRLs apply	Source / type of MRL	MRL / proposed MRL / CXL (mg/kg)	LOQ
4	130010	Apples		20.000	
4	162050	Star apples/cainitos			
4	163050	Graate apples/nomegranates			



Exemple: 20 mg/kg thiacloprid dans des pommes.

Pour l'évaluation de risque, apart la teneur en teneur en pesticide par kg de denrée alimentaire, les données de consommation sont également requises.

→ Données de consommation sont intégrées dans l'outil EFSA Primo

→ <https://data.europa.eu/euodp/de/data/dataset/the-efsa-comprehensive-european-food-consumption-database>



Show results for all crops									
Unprocessed commodities	Results for children No. of commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No. of commodities for which ARfD/ADI is exceeded (IESTI):				
	1				1				
	IESTI				IESTI				
	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
431%	Apples	20 / 20	2156	112%	Apples	20 / 20	561		

Dépassement de la dose de reference aigue (aRfD) (par un facteur de 4.3) pour les pommes (Résultats <100 % de la ARfD peuvent être considérés comme sans risque)

Processed commodities	Results for children No of processed commodities for which ARfD/ADI is exceeded (IESTI):				Results for adults No of processed commodities for which ARfD/ADI is exceeded (IESTI):				
	1				1				
	IESTI				IESTI				
	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)	
217%	Apples / juice	20 / 20	1083	133%	Apples / juice	20 / 20	667		
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	

Produits dérivés (jus): Dépassement de la dose de reference toxicologique par un facteur de 2.2.



EFSA Race tool

INDEX X

Summary of your selections

- 1 Substance
- 2 Select Food

1. Choose the substance

Choose the substance
This prompt allows only one selection.

Search for: ochratoxin Match case

Available:

- Ochratoxins:
- Ochratoxin B:56-41-7:C[C@H](N)C(=O)O

Selected:

- Ochratoxin A:303-47-9:C[C@@H]1CC2=C(C=C(C(=O)O)O)C(=O)N[C@@H](CC3=CC=CC=C3)C(=O)OCl

1 - 3 of 3

2. Select Food

Qualify on the attributes of the Hierarchy for Rasff Exposure hierarchy.
This prompt requires at least one condition.

Search for: Match case


Available:

- Seed spices
- Fruit spices
 - Foodex2 Item L4
 - Peppercorn (black, green and white) and similar-**
 - Other fruit spices
 - Sichuan pepper fruit and similar-
 - Caraway fruit and similar-
 - Cardamom fruit and similar-
 - Vanilla and similar-
 - Tamarind and similar-
 - Juniper berry and similar-
 - Allspice fruit and similar-

Selected:

- Foodex2 Item L4 **Select In List Peppercorn (black, green and white) and similar-**

Run Document Cancel



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Chemical Contaminants Risk Evaluation - Exposure

Risk Evaluation - Name:

User Reference:

Food description

Peppercorn (black, green and white) and similar - - Number of Consumers: 196590

Contaminant

Substance Name: Ochratoxin A

CAS Number: 303-47-9

Smiles Notation: C[C@@H]1CC2=C(C=C(C(=C2C(=O)O1)O)C(=O)N[C@@H](CC3=CC=CC=C3)C(=O)O)Cl

[Register Analysis](#)



Select your risk evaluation

OTA in spices

Please consider that if your web browser language is not set to English you might experience issues leading to flawed results which are expected.

Dietary data from the UK were included in RACE when the UK was a member of the European Union.

Risk evaluation description

Risk Evaluation:

OTA in spices

User Reference:

DZ

Food description

Peppercorn (black, green and white) and similar-

Contaminant

Substance Name: Ochratoxin A

Substance CAS: 303-47-9

Substance SMILES:

C[C@@H]1CC2=C(C=C(C(=C2C(=O)O1)O)C(=O)N[C@@H](CC3=CC=CC=C3)C(=O)O)Cl

Insert new analysis

delete analysis

Analytical value	Analytical value unit
<input type="text"/>	Microgram/kilogram
Reference point acute value	Reference point type acute
<input type="text"/>	ARfD
Reference point chronic value	Unit acute
<input type="text"/>	g/kg bw
	Reference point type chronic
	BMDL (G)
	Unit chronic
	mg/kg bw/day
	source of reference point
	<input type="text"/>

In order to generate your analysis please insert a new analysis or use the input mask and then click on update analysis values

Update analysis values



Risk evaluation description

Insert new analysis **delete analysis**

Analytical value

Analytical value unit
Microgram/kilogram

Reference point acute value

Reference point type acute
ARfD

Unit acute
g/kg bw

Reference point chronic value

Reference point type chronic
TWI

Unit chronic
ng/kg bw/week

source of reference point

Update analysis values

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Risk evaluation description

Insert new analysis **print excel analysis** **delete analysis**

Analytical value <input type="text" value="200"/>	Analytical value unit <input type="text" value="Microgram/kilogram"/>
Reference point acute value <input type="text" value="999999"/>	Reference point type acute <input type="text" value="ARfD"/> Unit acute <input type="text" value="g/kg bw"/>
Reference point chronic value <input type="text" value="120"/>	Reference point type chronic <input type="text" value="TWI"/> Unit chronic <input type="text" value="ng/kg bw/week"/>
source of reference point <input type="text"/>	

Update analysis values

Evaluation des risques: Contaminants - Résultats



Rasff analysis	RP Type	Food description	Survey's country	Survey	Population group	Number of consumers	Number of subjects	Mean exp	Median exp	95 exp	Exposure unit	Output Mean	Output Median	Output 95	Output Unit	Percentile reliability allowed
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Austria	Austrian Study on Nutritional Status 2010-12 - Children	Other children	107	128	57.846	42.446	146.586 g/kg bw/week		48.205	35.371	122.155		%
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Belgium	Regional Flanders	Other children	57	625	4 350.178	3 111.111	15 400.000 g/kg bw/week		3 625.149	2 592.593	12 833.333		% stically robust'
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Bulgaria	NUTRICHILD	Other children	353	433	84.830	67.742	197.273 g/kg bw/week		70.692	56.452	164.394		%
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Czech Republic	Czech National Food Consumption Survey	Other children	352	389	38.222	29.289	101.587 g/kg bw/week		31.852	24.408	84.656		%
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Germany	Consumption Survey of Food Intake among Infants and Young Children	Other children	222	293	37.463	17.579	154.583 g/kg bw/week		31.220	14.649	128.819		%
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Germany	Eating Study as a KIGGS Module (EskIMo)	Other children	632	835	61.623	34.708	206.081 g/kg bw/week		51.353	28.923	171.734		%
OTA in spices	Tolerable Weekly Intake (including provisional and temporary)	Peppercorn (black, green and white) and similar-	Denmark	The Danish National Dietary survey 2005-2008	Other children	174	298	24.880	17.506	66.198 g/kg bw/week		20.734	14.589	55.165		%

Avantage: Intégration de la base de données européenne de consommation:

<https://data.europa.eu/euodp/de/data/dataset/the-efsa-comprehensive-european-food-consumption-database>

Document d'évaluation de risque interne



Les champs D9 et E9, D11 et E11 ainsi que D12 doivent être remplis obligatoirement!

Only cells in green can be changed!

Link to tox. Value		Link to consumption data	
EFSA 2020			

INPUT

Substance	Nickel	
Tox reference value	13	µg/kg bw
Type of tox reference	TDI (mg/kg bw)	0.013
Concentration of substance	5	mg/kg
Consumption of the food (g/day)	50	

important to select unit !

Substance	TDI (mg/kg bw)	Concentration substance (mg/kg)	Consumption (g/day)	Children (10 kg)	Adults (60 kg)
Nickel	0.013	5	50	0.13	0.78

Consumption g/day	Exposure (mg)	% Tox. Ref (children)	% Tox. Ref (adults)
50	0.25	192.3	32.1
5	0.03	19	3
10	0.05	38	6
15	0.08	58	10
20	0.10	77	13
25	0.13	96	16
30	0.15	115	19

Indication of the consumption (in grams/day) at which the toxicological reference value will be exceeded.

100% Tox. Ref Children	100% Tox. Ref Adults
26	156

Consumption in grams

Évaluation de risque rapide. Pas d'intégration automatique des données de consommation européennes, mais la quantité qu'on peut consommer sans risque de santé est facilement visible.



EFSA comprehensive European food consumption database:

Ressourcen	
↓ HERUNTERLADEN	1. <i>Chronic food consumption statistics – all subjects (g/day)</i> EXCEL XLS
↓ HERUNTERLADEN	2. <i>Chronic food consumption statistics – all subjects (g/kg bw per day)</i> EXCEL XLS
↓ HERUNTERLADEN	3. <i>Chronic food consumption statistics – consumers only (g/day)</i> EXCEL XLS
↓ HERUNTERLADEN	4. <i>Chronic food consumption statistics – consumers only (g/kg bw per day)</i> EXCEL XLS
↓ HERUNTERLADEN	5. <i>Acute food consumption statistics – all days (g/day)</i> EXCEL XLS
↓ HERUNTERLADEN	6. <i>Acute food consumption statistics – all days – (g/kg bw per day)</i> EXCEL XLS
↓ HERUNTERLADEN	7. <i>Acute food consumption statistics – consuming days only (g/day)</i> EXCEL XLS
↓ HERUNTERLADEN	8. <i>Acute food consumption statistics – consuming days only (g/kg bw per day)</i> EXCEL XLS
↓ HERUNTERLADEN	9. <i>Full dataset</i> CSV

<https://data.europa.eu/euodp/de/data/dataset/the-efsa-comprehensive-european-food-consumption-database>



Merci pour votre attention!



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