

# The influence of industrial processing on residue levels present in raw materials

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European Pesticide Residue Workshop

May 25<sup>th</sup>, 2016

# Introductory remarks

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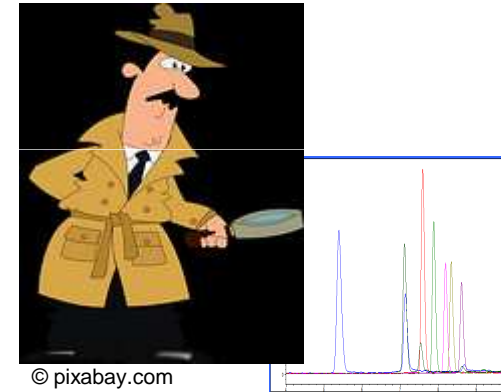
- Part of agricultural commodities are not eaten raw, but subject to processing operations prior to consumption
- Processing may modulate the pesticide residue level of commodities
- Quantitative scale of such an effect is described by 'processing factors'

$$\text{processing factor (Pf)} = \frac{\text{residue level in processed fraction } \left(\frac{\text{mg}}{\text{kg}}\right)}{\text{residue level in raw ingredient } \left(\frac{\text{mg}}{\text{kg}}\right)}$$

# Who is interested in processing factors ?

- **Food control services**

monitoring for compliance of pesticide residues in processed products against legal standards for the starting material (RAC)



- **Dietary Risk Assessors**

realistic estimate of dietary exposure of humans and livestock to pesticide residues in processed (by)products



# Guidance in place

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- Guideline on nature of the residue (qualitative manner)
  - OECD Guideline 507  
High temperature hydrolysis, simulating various conditions in pH, temperature regime
  
- Guideline/Guidance Document on magnitude of the residue (quantitative manner)
  - OECD Guideline 508
  - OECD Guidance Document ENV/JM/MONO(2008) on Magnitude of Pesticide Residues in Processed Commodities
    - Information on processing types and extrapolations
    - Simulation of processing steps on laboratory scale or (semi)technical scale representative of conditions *'usually used in practice'*

# Legal surroundings

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- Maximum residue limits for pesticides (MRL) in EU residue legislation are exclusively fixed for Raw Agricultural Products (RAC) in *Annex I to Regulation (EC) No 396/2005*
- *‘Where MRLs are not set out for processed and/or composite food or feed’* those MRLs of the RAC do apply *‘.. taking into account changes in the levels of pesticide residues caused by processing ..’*
- Legal requirement of article 20(2) of Regulation (EC) No 396/2005 of providing such processing information - *Annex VI* - has not yet been established

# Where to get information about processing factors ?

Full processing study reports are proprietary information, impeding to judge reliability and applicability of a specific published Pf figure, because of ...

- ↪ No insight in quality of underlying study
- ↪ lack in transparency on details of study design
- ↪ risk of misinterpretation due to inconsistent terms for processed food items

☞ Review of each individual processing study by scrutinizing against criteria of robustness and reliability (pre-defined by BfR)

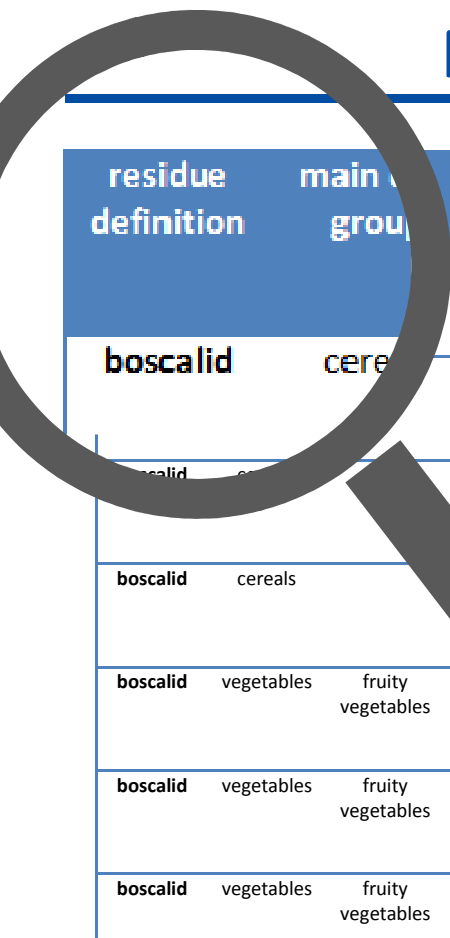


The resulting data compilation includes the stock of processing study reports (ca. 2600 on 193 actives) submitted in the framework of various regulatory procedures, amongst those ...

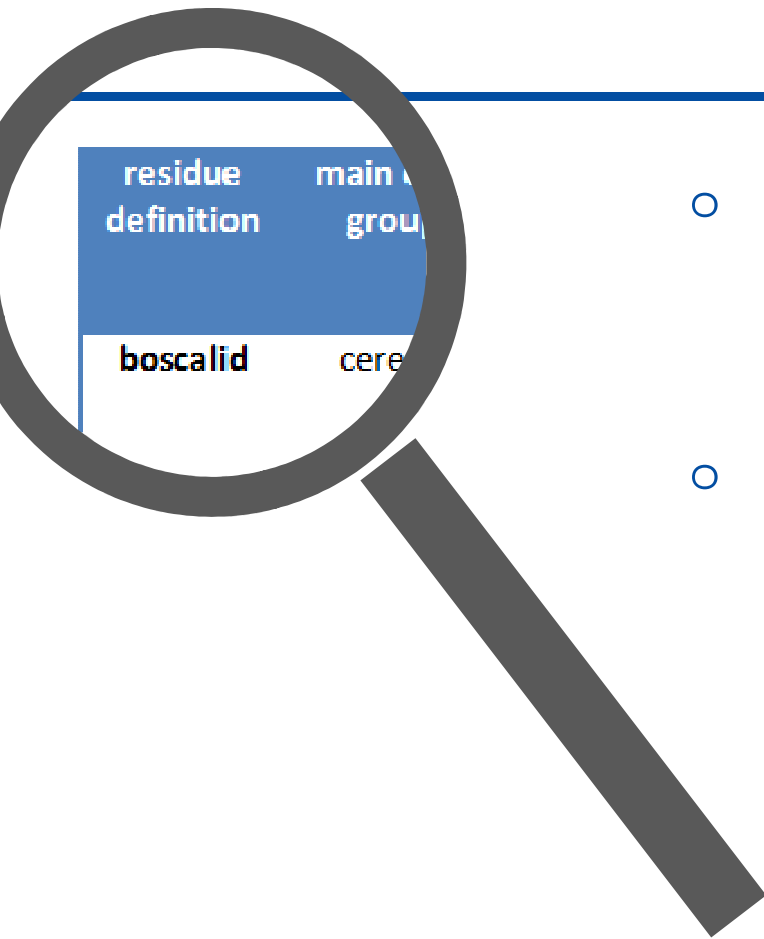
- approval of active substances (DAR, RAR)
- applications for setting of MRLs
- national PPP authorisations
- + data from food business operators on peel/pulp in citrus fruits

# New BfR database – elements of interest

residue definition	main group	commodity	processed matrix	OECD procedure code	individual Pf	median Pf	number of trials	acceptability of study	GLP	storage conditions	analytical method	procedural recovery	further comments	reference	EFSA regards	
<b>boscalid</b>	cereals	barley	pot/ pearl barley	XI	0.22 - 0.37	0.33	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		<a href="#">[2]</a>	EFSA Journal 2014;12(7):3799	
		barley	malt	V	0.37 - 0.58	0.49	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		<a href="#">[2]</a>	EFSA Journal 2014;12(7):3799	
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	barley	beer	V	0.01 - 0.02	0.02	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		<a href="#">[2]</a>	EFSA Journal 2014;12(7):3799		
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# Residue definition



- **residue definition for *monitoring*:**  
preferably simple marker amenable to MRM (e.g. *parent*),
  - fixed in Annexes II and III to Reg. (EC) No 396/2005
- **residue definition for *risk assessment*:**  
frequently encompassing further component(s) besides parent (metabolites, breakdown or reaction products)
  - not infrequently amended
  - no enacted legislation to look up for

The BfR data compilation is focusing on the **definition for monitoring** - with an option for future extension(s)

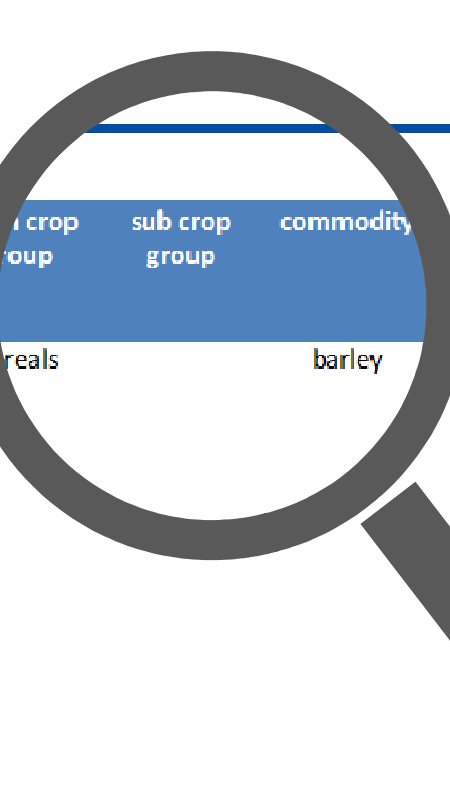
→ EFSA forthcoming grant call for drawing up a '*Database of processing types and processing factors compatible with the EFSA food classification and description system FoodEx 2*'



# New BfR database – elements of interest

residue definition	crop group	sub crop group	commodity	OECD procedure code	individual Pf	median Pf	number of trials	acceptability of study	GLP	storage conditions	analytical method	procedural recovery	further comments	reference	EFSA regards	
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boscalid	cereals		spring barley	V	0.53 - 1.10	0.93	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		<a href="#">[2]</a>	EFSA Journal 2014;12(7):3799	
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# Main/sub crop groups and commodities



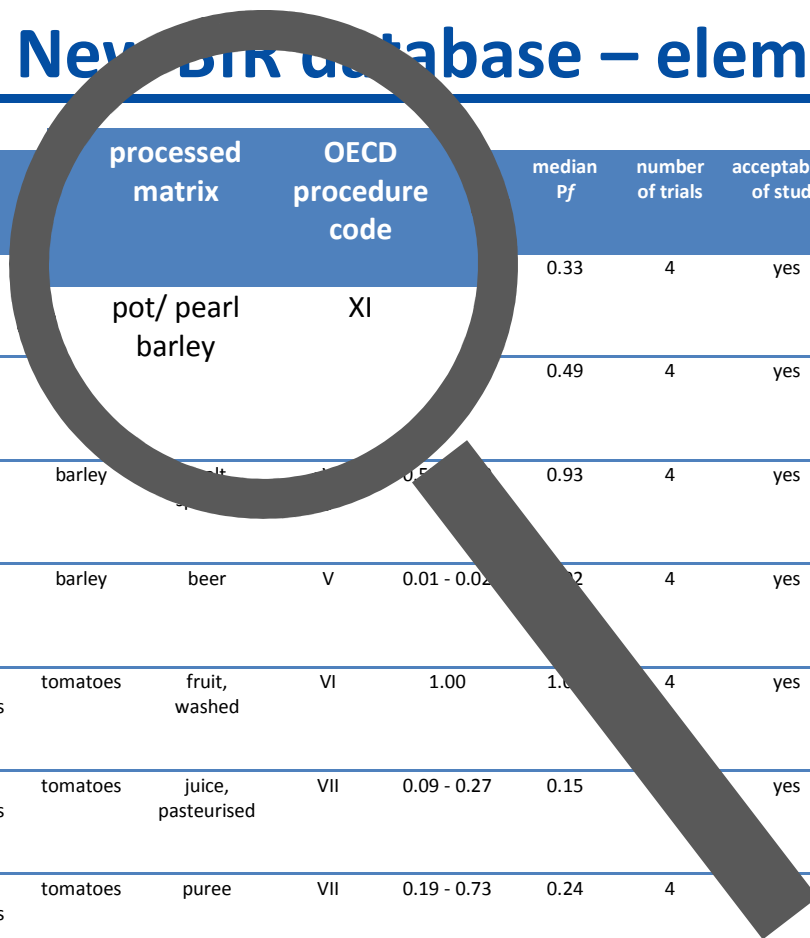
main crop group	sub crop group	commodity
cereals		barley

- Alignment of RACs to those food categories of Annex I to Reg. (EC) No 396/2005
- Standardization of terminology in case of diverging terms employed for identical RACs  
e.g. 'canola seed' was replaced by 'rape seed'  
e.g. 'corn' (AE) was replaced by 'maize' (BE)
- Distinction between red and white varieties for vinification

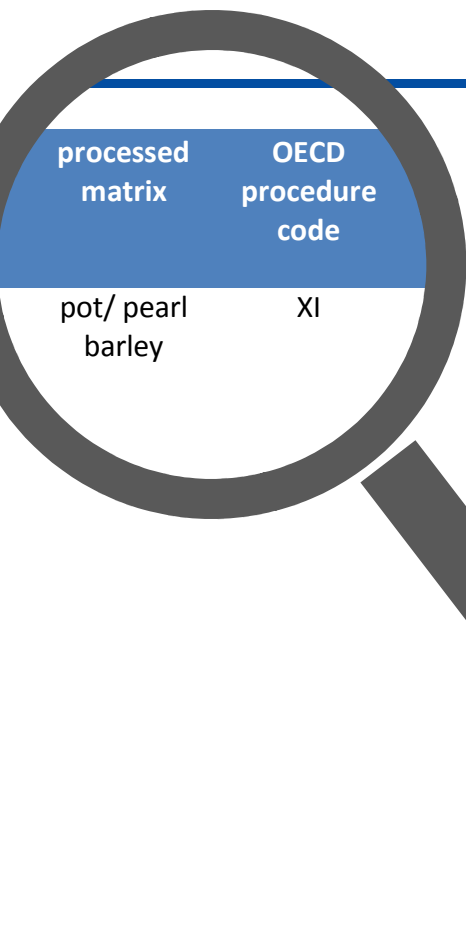
Main crop group	Sub crop group	Commodity
fruits	citrus fruits	grapefruit lemons limes mandarins oranges
	pome fruits	apples pears
	stone fruits	apricots cherries peaches plums
	berries and small fruits	grapes, red grapes, white black currants strawberries

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# Matrices and matrix grouping

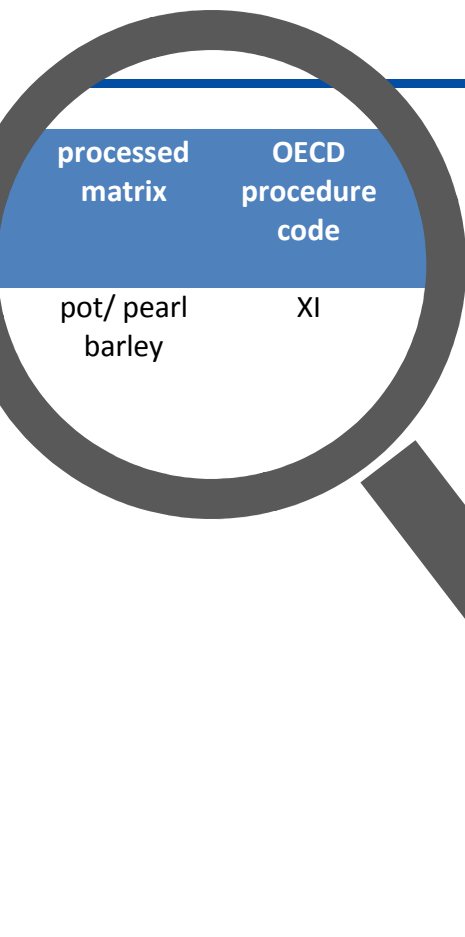


processed matrix	OECD procedure code
pot/ pearl barley	XI

- Nomenclature of processed fractions (matrix) are found different in different studies  
e.g. *'spent grain'* and *'brewer's grain'*  
e.g. *'young beer'*, *'cooled beer'* and simply *'beer'* were combined into a common matrix term *'beer'*

Altogether,  
*ca.* 800 denotations for processed fractions housed by the inventory were narrowed down into a total of 175 consolidated descriptors

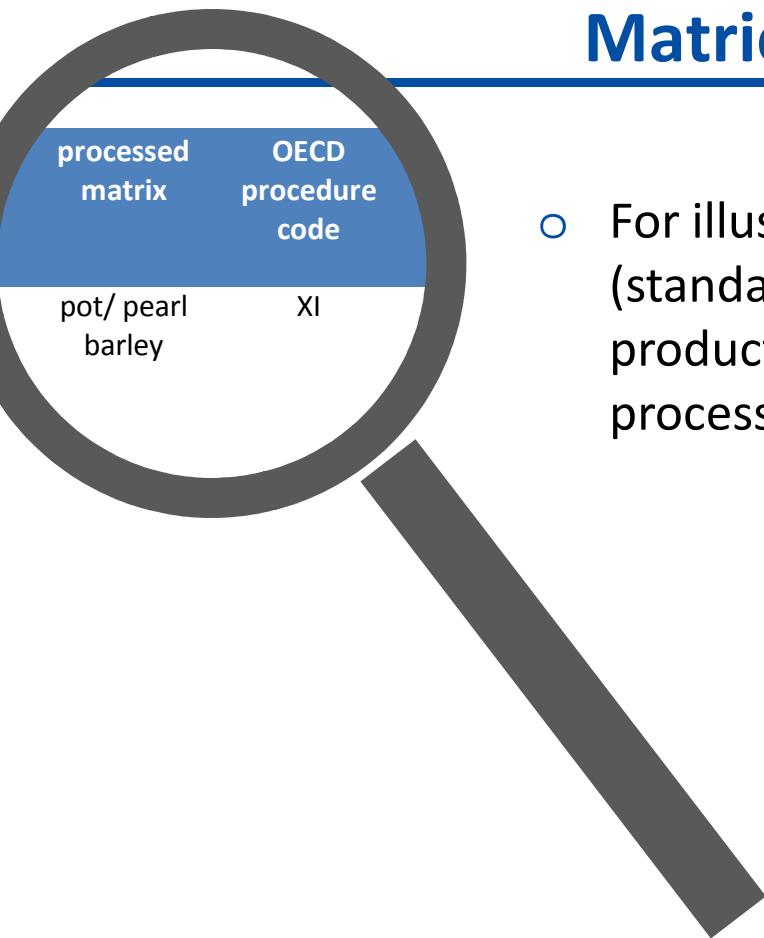
# Matrices and matrices grouping



- To unequivocally classify the processing type each processing operation was assigned one of the processing codes outlined in OECD Guidance Document ENV/JM/MONO(2008)23

I	distribution in the edible/ non edible portion
II	preparation of fruit juice
III	preparation of canned fruit
IV	preparation of other fruit products
V	preparation of alcoholic beverages (fermentation, distillation)
VI	cooking vegetables, pulses and grains in water (including steaming)
VII	preparation of vegetable juice
VIII	preparation of canned vegetable
IX	miscellaneous preparation of other vegetable products
X	preparation of oil (extraction, pressing, milling in case of maize) Xa belongs to extraction, Xb belongs to pressing, Xc belongs to maize milling
XI	distribution on milling
XII	preparation of sugar
XIII	infusions and extractions
XIV	silage production
XV	processing of products of animal origin including preparation of meat and fish (poaching, frying, baking, boiling)
XVI	dehydration
XVII	fermentation of soybeans, rice and others (except alcoholic beverages)
XVIII	microwaving vegetable
XIX	pickling

# Matrices and matrices grouping



- For illustrative assistance a total of 34 processing maps (standardized flow charts) were drawn up, showing affiliated products and co-products which may be yielded from a processed commodity

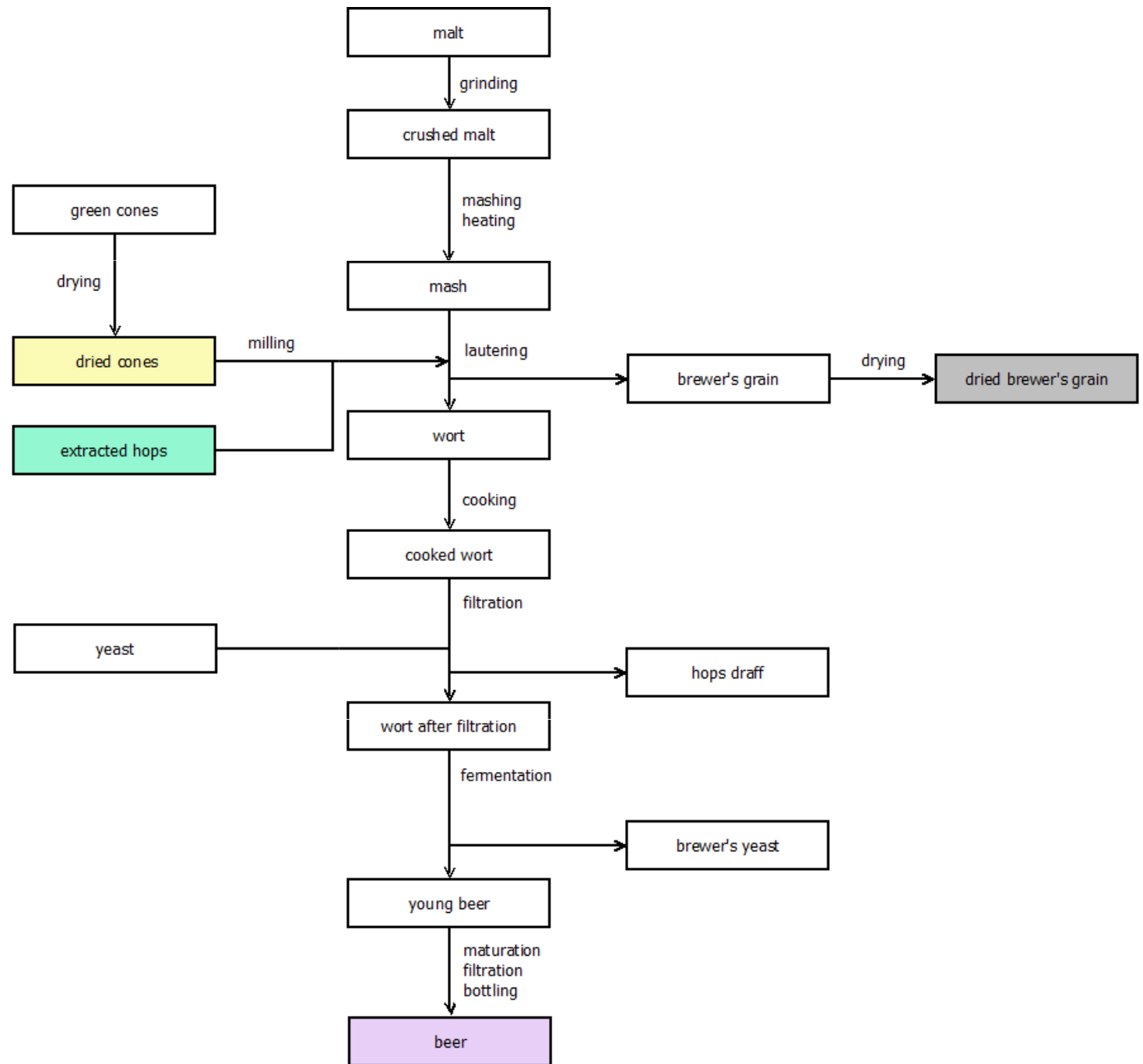
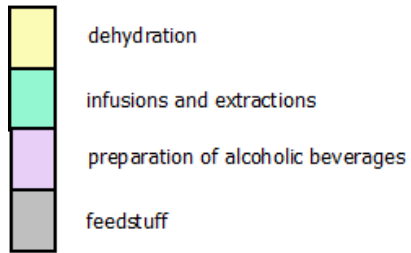


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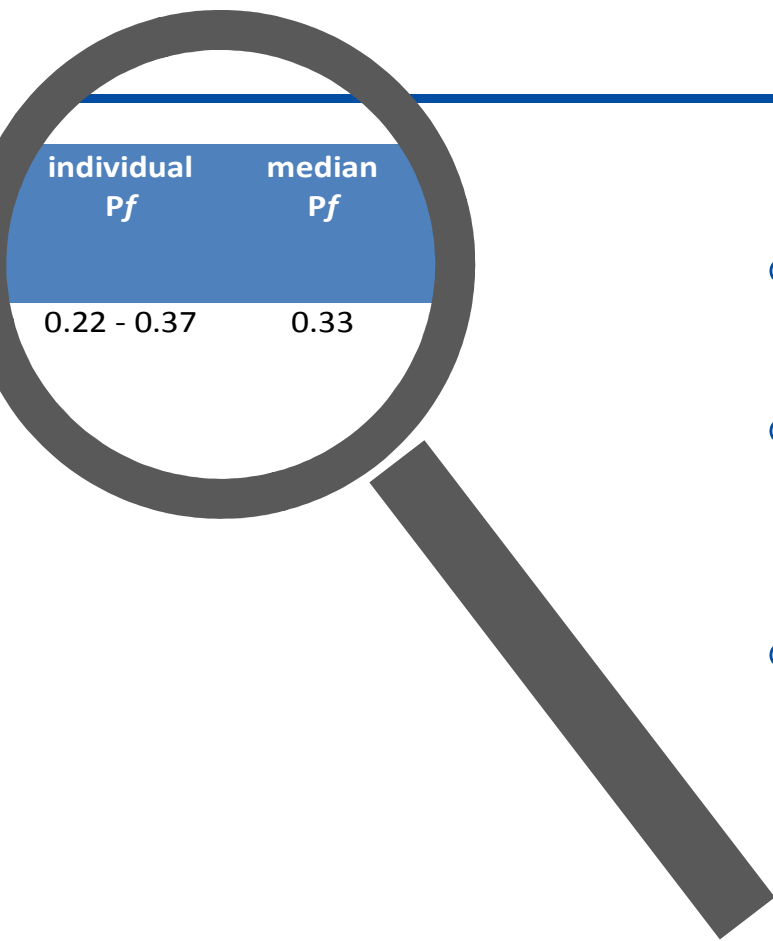


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# Processing factors

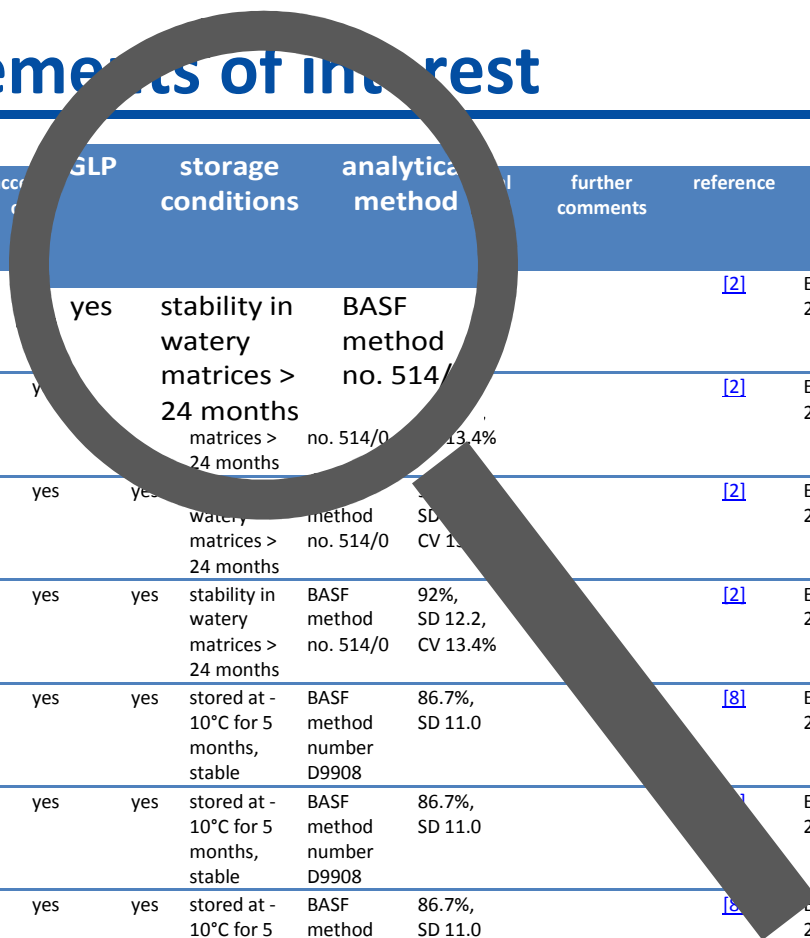


- range of *Pf* - in case of replicate trials in a single study
- median *Pf* - in case of more than one processing factor been specified for a processed fraction in the study
- number of replicates in a study per processed fraction

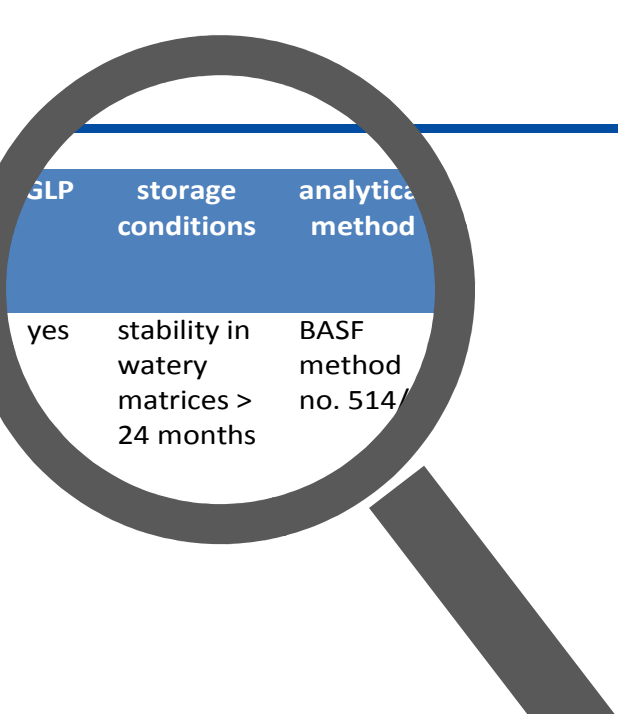
The data pool is currently populated with about 6300 median *Pf* values

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<b>boscalid</b>	cereals		barley	pot/ pearl barley	XI	0.22 - 0.37	0.33	4		yes	stability in watery matrices > 24 months	BASF method no. 514/0				[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	cereals		barley	malt	V	0.37 - 0.58	0.49	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	13.4%			[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	cereals		barley	malt sprouts	V	0.53 - 1.10	0.93	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	SD 11.0	CV 13.4%		[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	cereals		barley	beer	V	0.01 - 0.02	0.02	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%			[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	fruit, washed	VI	1.00	1.00	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0			[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	juice, pasteurised	VII	0.09 - 0.27	0.15	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0			[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	puree	VII	0.19 - 0.73	0.24	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0			[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	paste	VII	0.53 - 2.24	0.73	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0			[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	fruit, peeled	VI	0.03 - 0.07	0.05	3	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0			[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	fruit, canned	VIII	0.03 - 0.12	0.05	3	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0			[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	fruits	pome fruits	apples	fruit, washed	IV	0.4 - 1.00	0.65	4	yes	yes	stored at -18°C for 5 months	BASF method no. 445/0	92.1%, SD 10.9, CV 11.8%			[16]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	fruits	pome fruits	apples	pomace, wet	II	5.8 - 8.2	6.55	4	yes	yes	stored at -18°C for 5 months	BASF method no. 445/0	92.1%, SD 10.9, CV 11.8%			[16]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	fruits	pome fruits	apples	juice	II	0.05 - 0.10	0.08	4	yes	yes	stored at -18°C for 5 months	BASF method	92.1%, SD 10.9,			[16]	EFSA Journal 2014;12(7):3799



# 'Eligibility' criteria



GLP	storage conditions	analytical method
yes	stability in watery matrices > 24 months	BASF method no. 514/

- processing factors used in either risk assessment or enforcement of legal standards should comply with a minimum of quality criteria, as regulatory decisions may largely depend on that piece of information.
- the following requirements should be adequately satisfied as a prerequisite for acceptability and reliability of study results

## Acceptability of a study

all criteria satisfactory addressed .....



*acceptable*

one of key criteria not fulfilled .....



*indicative*

more than one criterion not fulfilled ..

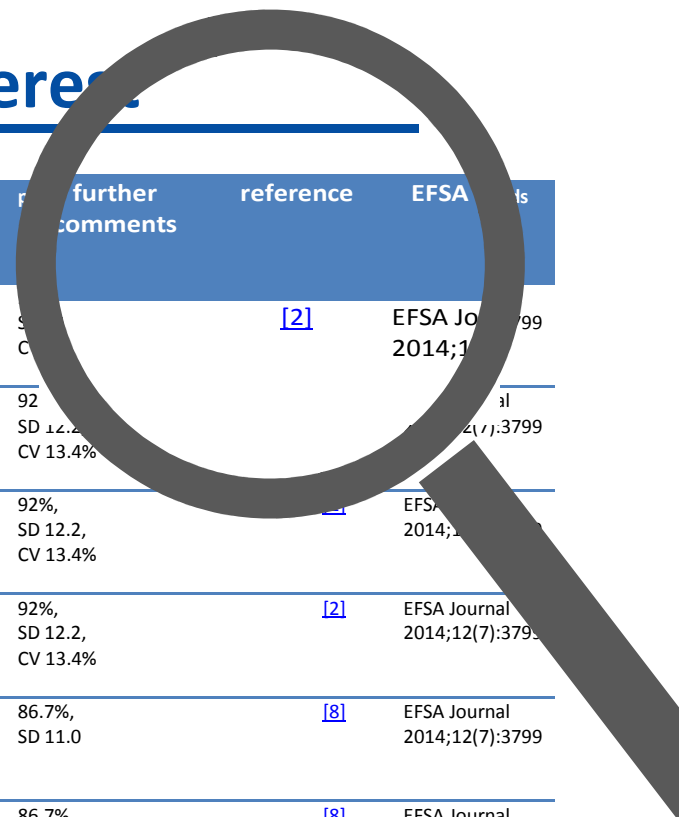


*nonsatisfying*

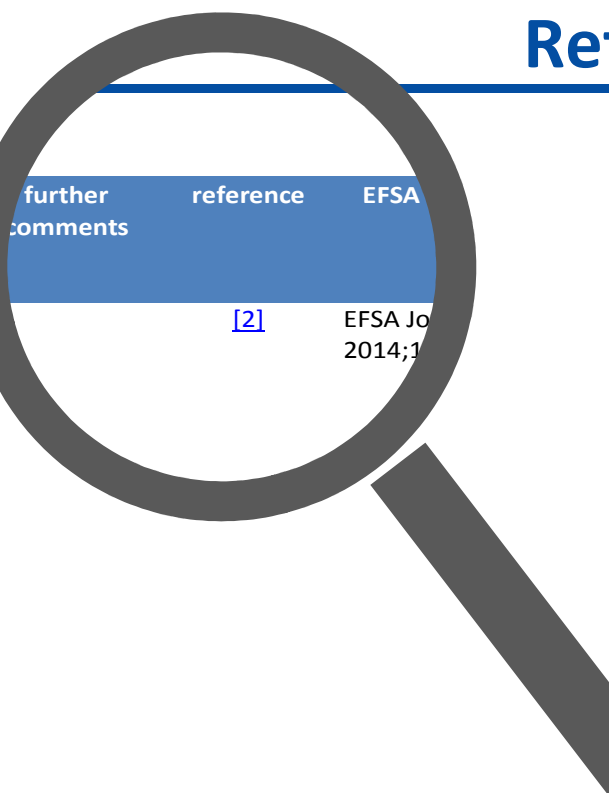
out of the *ca.* 6300 factors  
*ca.* 2700 were tagged fully  
'*acceptable*',  
performance of a *ca.* 11 %  
share is earmarked as  
'*nonsatisfying*'

# New BfR database – elements of interest

residue definition	main crop group	sub crop group	commodity	processed matrix	OECD procedure code	individual Pf	median Pf	number of trials	acceptability of study	GLP	storage conditions	analytical method	stability	further comments	reference	EFSA Journal
<b>boscalid</b>	cereals		barley	pot/ pearl barley	XI	0.22 - 0.37	0.33	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	cereals		barley	malt	V	0.37 - 0.58	0.49	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	cereals		barley	malt sprouts	V	0.53 - 1.10	0.93	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	cereals		barley	beer	V	0.01 - 0.02	0.02	4	yes	yes	stability in watery matrices > 24 months	BASF method no. 514/0	92%, SD 12.2, CV 13.4%		[2]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	fruit, washed	VI	1.00	1.00	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0		[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	juice, pasteurised	VII	0.09 - 0.27	0.15	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0		[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	puree	VII	0.19 - 0.73	0.24	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0		[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	paste	VII	0.53 - 2.24	0.73	4	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0		[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	fruit, peeled	VI	0.03 - 0.07	0.05	3	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0		[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	vegetables	fruity vegetables	tomatoes	fruit, canned	VIII	0.03 - 0.12	0.05	3	yes	yes	stored at -10°C for 5 months, stable	BASF method number D9908	86.7%, SD 11.0		[8]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	fruits	pome fruits	apples	fruit, washed	IV	0.4 - 1.00	0.65	4	yes	yes	stored at -18°C for 5 months	BASF method no. 445/0	92.1%, SD 10.9, CV 11.8%		[16]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	fruits	pome fruits	apples	pomace, wet	II	5.8 - 8.2	6.55	4	yes	yes	stored at -18°C for 5 months	BASF method no. 445/0	92.1%, SD 10.9, CV 11.8%		[16]	EFSA Journal 2014;12(7):3799
<b>boscalid</b>	fruits	pome fruits	apples	juice	II	0.05 - 0.10	0.08	4	yes	yes	stored at -18°C for 5 months	BASF method	92.1%, SD 10.9,		[16]	EFSA Journal 2014;12(7):3799



# References and further information



- **References**

bibliographic information on studies

- **EFSA evaluations**

indicates whether there is a Reasoned Opinion available on the review of existing MRLs for the active substance

- **Further Comments**

miscellaneous information, e.g. on ...

- metabolites / isomers
- residue in RAC < LOQ (ca. 900 in 6300 factors)
- deviations from the published analytical method
- particularities of processing conditions
- any other irregularities

# Persisting limitations and uncertainties

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- Limited to simply processed commodities (basically staple food)
- Uncertainties about representativeness of processing procedures
- Laboratory scale vs. industry scale
  - ↳ can there an 1:1 extrapolation be assumed?
- Lacking of important details in study reports
  - e.g. duration of fermentation (winemaking)
  - e.g. thickness of removed peel (potatoes)
  - e.g. extraction procedures (oil processing)
  - e.g. ratio of pulp/juice (apple juice)
- Inconsistencies of matrix terms
  - e.g. flour types
  - e.g. beer brewing
  - e.g. vinification (production modes of rosé wines)

**The liability lies solely with the user of the information !**

# 'Take home messages'

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- The outcome of the data gathering project provides for comprehensive, customized search capabilities across a huge number of processing factors - along with information on key parameters of underlying studies
- The added value promotes confidence and allows for building of more robust decisions on whether processed food has been manufactured in compliance with legal standards
- The database is accessible to the general public (BfR homepage)
- Publication of the project description in a scientific journal is underway
- It is intended to future develop the database by
  - populating with input from upcoming new processing studies
  - creating new features for data users
  - foster co-operations and partnerships with other scientific institutions



***Thank you for your kind attention***

... and many thanks to my colleague, Rebekka Scholz,  
having undertaken all of the complex compilation work !

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