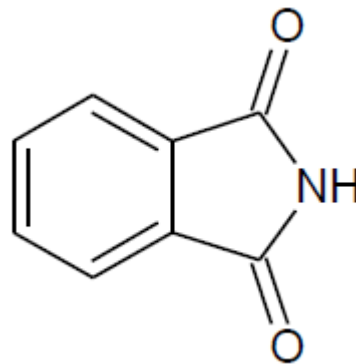


Phthalimide

Sources, Relevance and Consequences



HiPP Today

One of the leading producers of baby food in Europe

- 8 company-owned production sites
- About 3,500 employees* within the HiPP Group
- Sales of HiPP Group = approx. 1,000 mio € (2019) (50 % of it internationally)



One of the world's largest processor of organically produced raw materials

- More than 60 years of experience in organic farming
- Approx. 8,000 farmers
- Approx. 80,000 hectares of organic farmland
- Processing more than 160,000 tons of organic raw materials per year

Residue Testing @ HiPP 2019

- QuEChERS & S19 based multi methods
- Various single residue methods (glyphosate, CS₂, ethephone etc.)
- 6,193 samples
- 5,326 analyzed internally
- Own accredited laboratory
- Staffed with 30 technicians and food chemists

Phthalimide - Development

- Metabolite & breakdown product of folpet (and phosmet (!))
- Folpet: approved fungicide with authorisations in almost every EU MS
- EFSA included phthalimide in its risk assessment of folpet & recommended to change the residue definition accordingly (EFSA Journal 2011;9(9):2391, 40 pp.)
- COM Regulation (EU) 2016/156: „folpet“ -> „Sum of folpet and phthalimide, expressed as folpet“

Phthalimide - Development

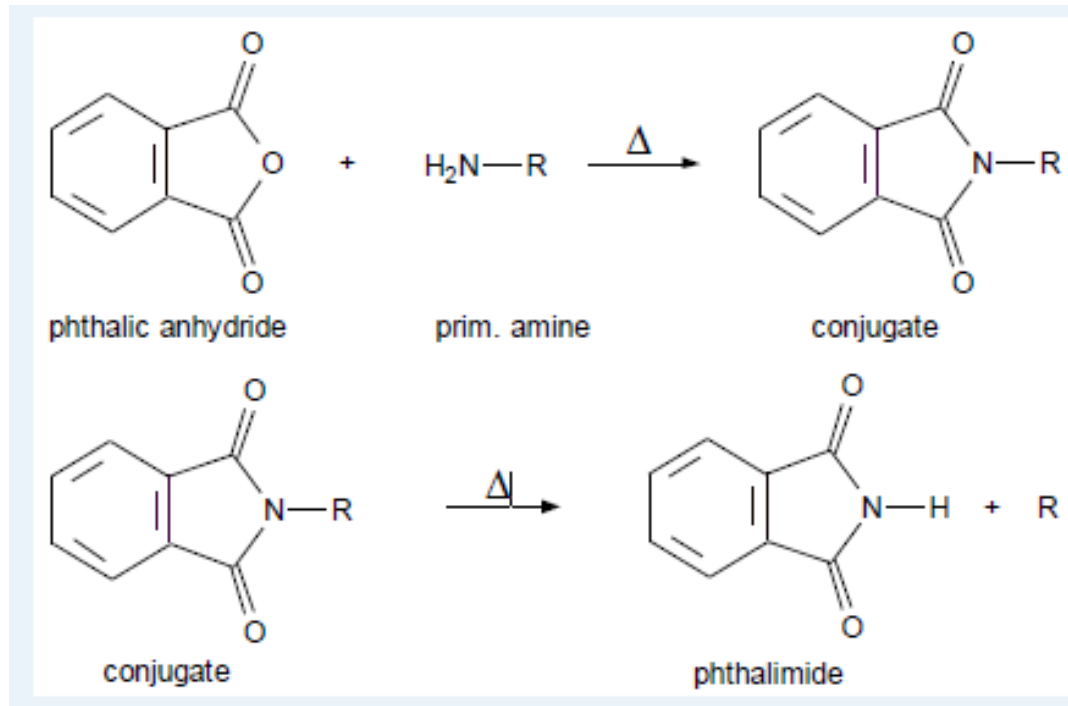
- Laboratories started to include phthalimide in their multi residue methods
- ⇒ Findings of „folpet (sum)“ increased rapidly
- ⇒ Root cause analysis: findings of phthalimide are not plausible with respect to use of folpet
- ⇒ Analytical investigation on the possible formation of phthalimide in analytical processes started

Phthalimide - Source

„Phthalimide can be (I) a **metabolite** of folpet or phosmet, (II) **reaction product** of folpet during GC injection, (III) an **artefact** resulting from thermic reaction of the ubiquitously occurring phthalic anhydride with primary amino compounds of the matrix either in GC-injector or (IV) of **process-induced origin** especially in dried products.“

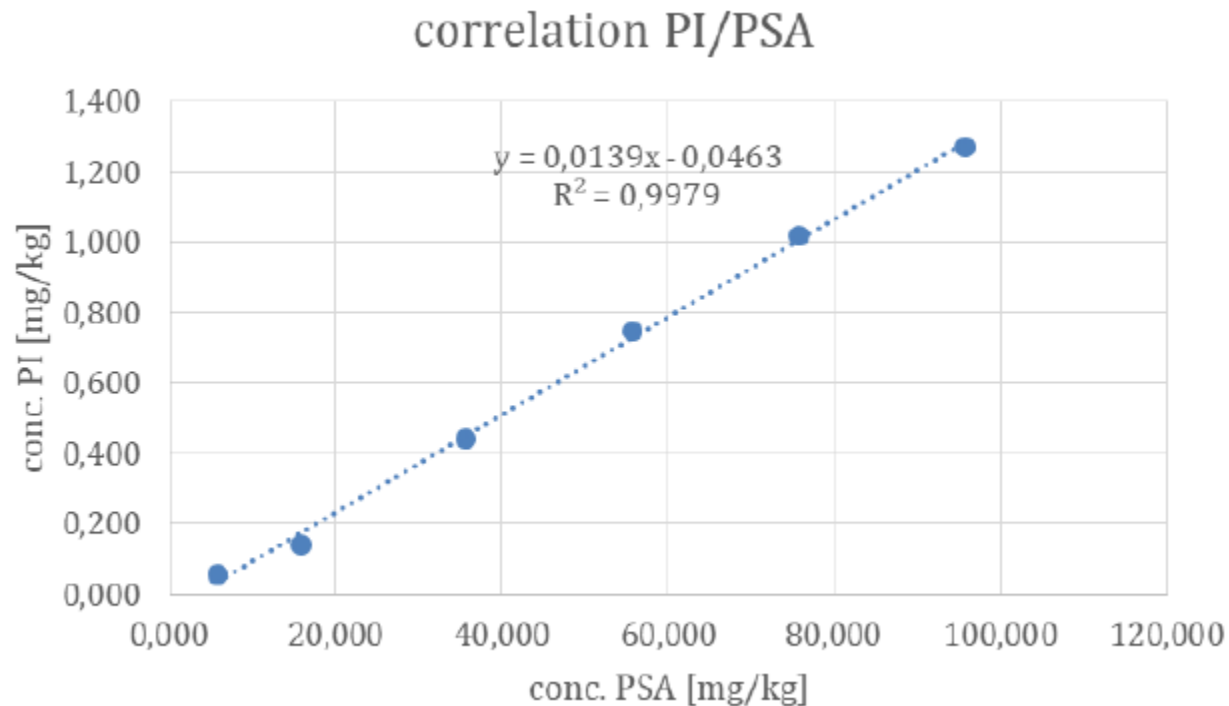
Nitsopoulos et.al., EPRW 2018, award-winning [poster](#)

Phthalimide - Source



Nitsopoulos et.al., EPRW 2018

Phthalimide - Source



Dried parsley, spiked with phthalic anhydrid (PSA)
Nitsopoulos et.al., EPRW 2018

Phthalimide - Source

**Analytical method, avoiding the artefact:
LC-(APCI)MS/MS**

- Not common in routine laboratories
- LOQ higher than in routine GC-MS/MS (personal observation)
- Only suitable for fresh products (without thermal treatment in advance)

Phthalimide - Relevance

HiPP's data: Results from organic fruits

samples	532	
positive on phtalimide	197	37 %
folpet (sum) > 10 ppb	197	37 %
folpet (sum) > 20 ppb	113	21 %
positive on folpet (as such)	0	0 %

Phthalimide - Relevance

Publications:

Formation of phthalimide as an artefact in analysis

- [Nitsopoulos](#) et.al., EPRW 2018
- [Romanotto](#) et.al., RAFA 2017

Phthalimide - Relevance

Publications:

Evaluation of phthalimide residues in (organic) food:

- German Pesticides WG, [position paper 2016](#)
- EU Reference Laboratory SRM, [Analytical Observation Report](#), 2017
- Relana Quality Circle, [position paper 2017](#)
- BNN, [Interpretation aid for Orientation Values](#)

Phthalimide – Consequences

Key messages for evaluation of phthalimide residues in (organic) food:

- Enforcement, based on findings of phthalimide alone, is not possible
- Lack of legal certainty for the official enforcement of MRLs for folpet in its actual residue definition

Phthalimide - Consequences

A real issue:

Blocking of **peach flakes** and products made thereof by our control body in an eastern europe country

⇒ **27 ppb phthalimide**, analysed by ourselves and documented in our data system

Competent Authority & Control Body:

- No knowledge about phthalimide and its possible sources
- Zero tolerance is needed due to consumer's expectations
- Concentration factors shall not be applied

Almost 8 weeks needed for solving this issue

Phthalimide - Conclusions

- Phthalimide is not a suitable parameter to monitor compliance of (organic) food with respect to use of folpet
- Residue definition should be „folpet“ only
- Phthalimide findings alone should not be prosecuted due to lack of legal certainty

... to be discussed ...



Das Beste aus der Natur. Das Beste für die Natur.

Thank you for your Attention!

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