



# *Pesticide Regulation in EU and EU's double standards*

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ENSSER, Berlin 7<sup>th</sup> May 2019



- EU pesticide authorisation system – theory and reality
- Maximum Residue Limits & EU's double standards
- Lobbying against EU law



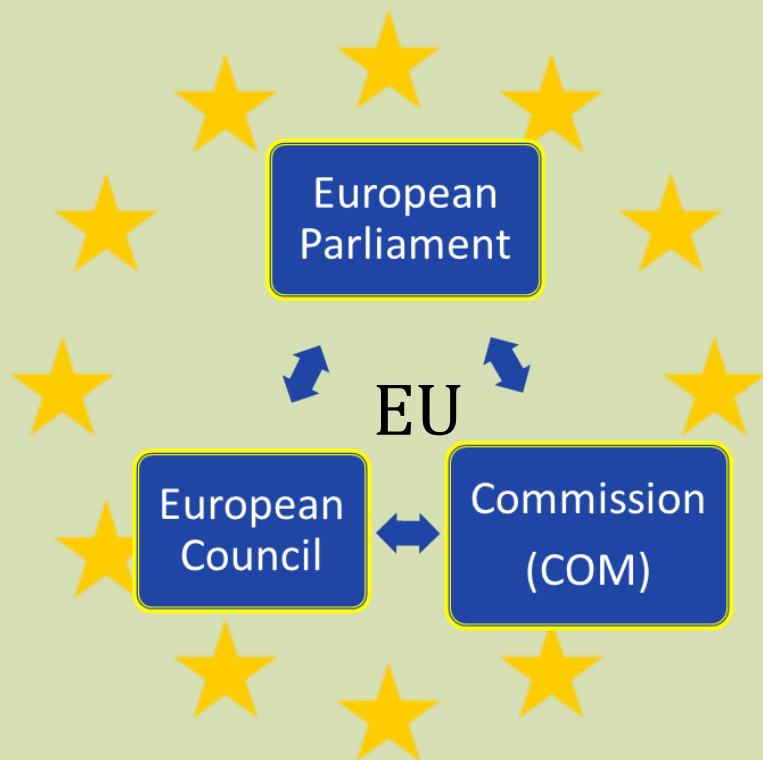
*“The EU pesticides and biocides legislations are the strictest and most protective in the world. They are based on sound assessments and robust, extensive data requirements”*

Commissioner Vytenis Andriukaitis  
Directorate General for Health and Food Safety  
June 2016, European Parliament hearing on EDCs

# Legal requirements - pesticides



## Plant Protection Product Regulation (PPPR) 1107/2009:



- High level of protection for ALL
  - Humans, animals, environment
- Protect the vulnerable
  - Pregnant women, children, babies
- Apply the precautionary principle
- Consider active substances, products and residues (food & environment)
- Consider mixture effects (cocktails)

Mutagens, Carcinogens, Toxic  
to Reproduction, Endocrine  
Disruptors, PBTs



Hazards

# Legal requirements - pesticides



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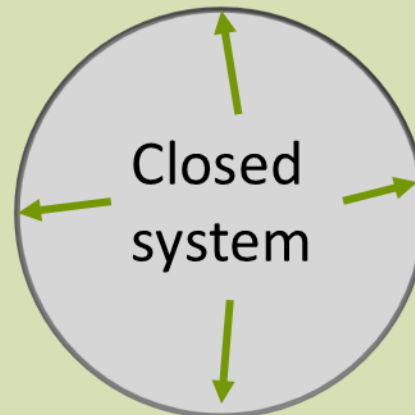


Hazards

“Hazard-based  
cut-offs”



Derogations/exceptions:  
E.g. (Carcin + Reprotox + EDCs)  
→ **negligible exposure**



Residues < LOD



- Precautionary principle ✖
- Inadequate, insufficient regulatory tests – data gaps
- Adverse effects dismissed for “unscientific” reasons
- Academic scientific literature ✖
- Harmful pesticides continue to be authorised without restrictions or monitoring
- EDCs high burden of proof
- Safety testing is done by the industry
- Studies are “private” and poorly reported
- Conflicts of interest in the whole process
- Products are not assessed for chronic effects
- Mixtures are not assessed ✖

# Shortfalls and solutions of RA system



A WHITE PAPER

## ENSURING A HIGHER LEVEL OF PROTECTION FROM PESTICIDES IN EUROPE

THE PROBLEMS WITH CURRENT PESTICIDE RISK ASSESSMENT PROCEDURES IN THE EU – AND PROPOSED SOLUTIONS

Prepared for 'Citizens for Science in Pesticide Regulation'  
A European Coalition – 2018



<https://citizens4pesticidereform.eu/>



## Facts – number of pesticides increasing

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### 492 active substances approved 2009-2018

- **142 renewed** or first time approved
  - 8 candidates for substitution
  - 12 low-risk
- 40 no longer approved
  - **Just 15 non-approvals**
  - 18 withdrawn by applicant
  - 7 withdrawn for data gaps





# Facts – Approved active substances

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- 11 toxic to reproduction
- 140 acutely toxic to aquatic organisms
- 5 classified as EDC
- 34 two PBT criteria
- Several pesticides are misclassified

*Is this  
really the  
most  
protective  
system?*



# MRL regulation (396/2005)

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*“This Regulation establishes... the need to ensure a high level of consumer protection ... relating to maximum levels of pesticide residues in or on food and feed of plant and animal origin”.*

Consumers’  
and animal  
health in EU

*All parties can send an MRL application*

Risk-based

*Not applied for exported food*

*Import tolerance ----> trade*

# Procedure – setting MRLs in EU



Application  
MRL

Good  
agricultural  
practice



- 330 food products
- 1100 pesticides (EU and non EU)
- No application <LOD or 0.01 mg/kg



# Control of MRLs in EU

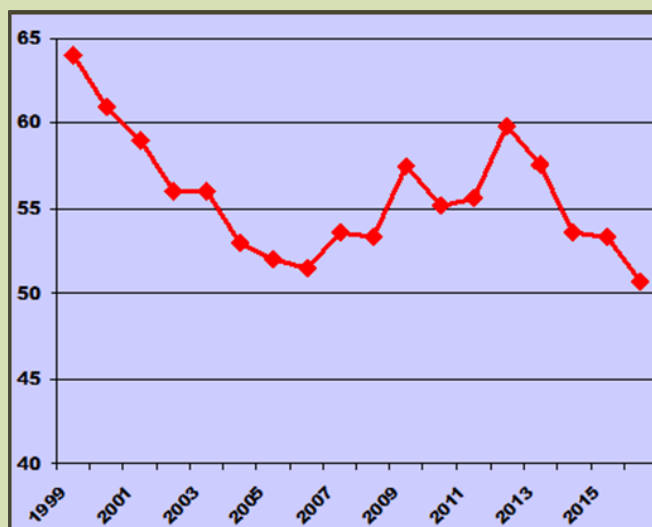


## Pesticide residues in food



- 84,650 samples for 791 pesticides
- 67% from EU, 27% non-EU, 6% unknown
- 96.2 % within MRL, 53.8% <LOD

*Fruits and vegetables in EU shops with no pesticide residues*

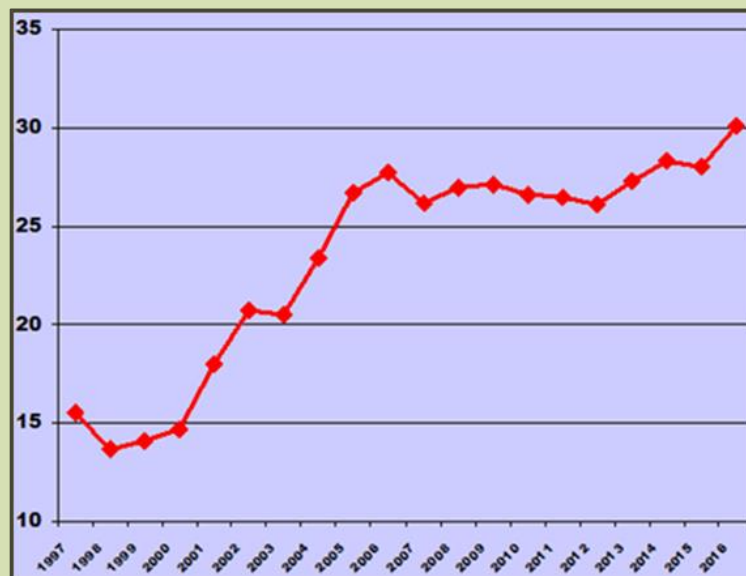


# Control of MRLs in EU



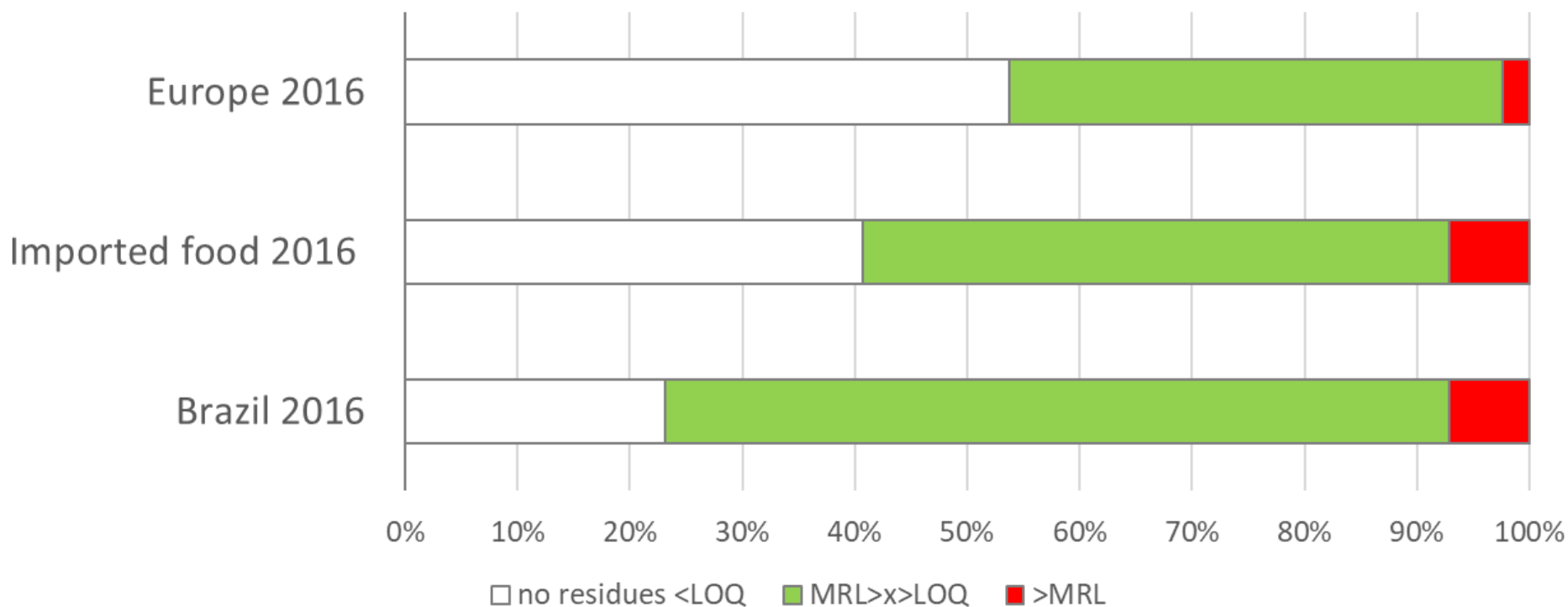
EU samples with  
**multiple residues: 30%**

*Gooseberries 85.7%*  
*Grapefruits 73.1 %*  
*Grapes 68.1%*  
*Strawberries 65.4 %*

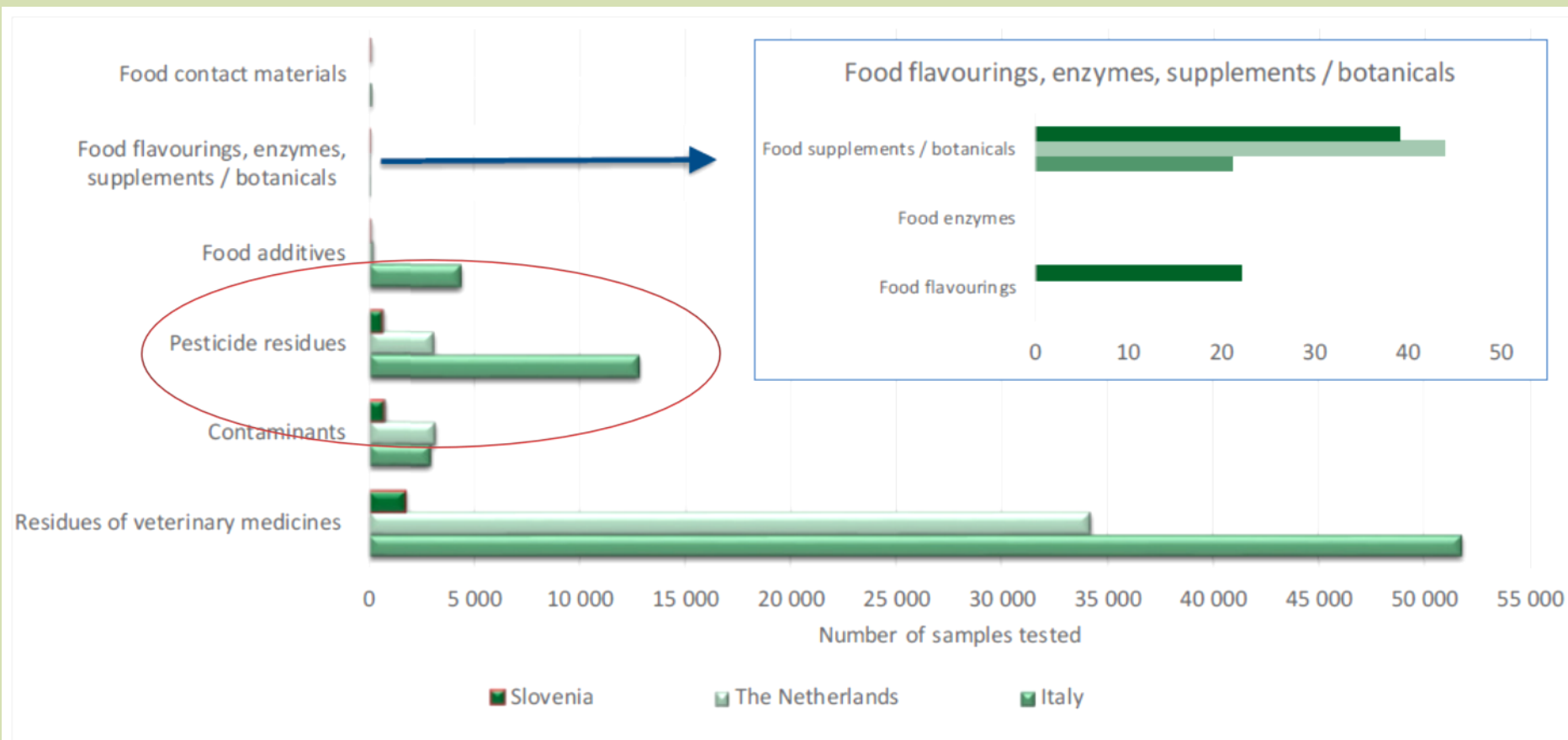




# Comparing MRLs in food EU/imported



# Uneven control in EU countries



*Reminder: Applications are done on Member States and Member States send out the samples for monitoring*



# MRLs for non-approved pesticides



1. Approval rejected – high toxicity
2. Not used – no request for EU approval

**If not detected = no problem**

If MRL not safe:  
Default value  
0.01 mg/kg or  
LOD



Not included in  
Annex II or III  
of MRL Reg.

**How to include  
in Annexes?**



Application,  
import  
tolerance,  
Codex

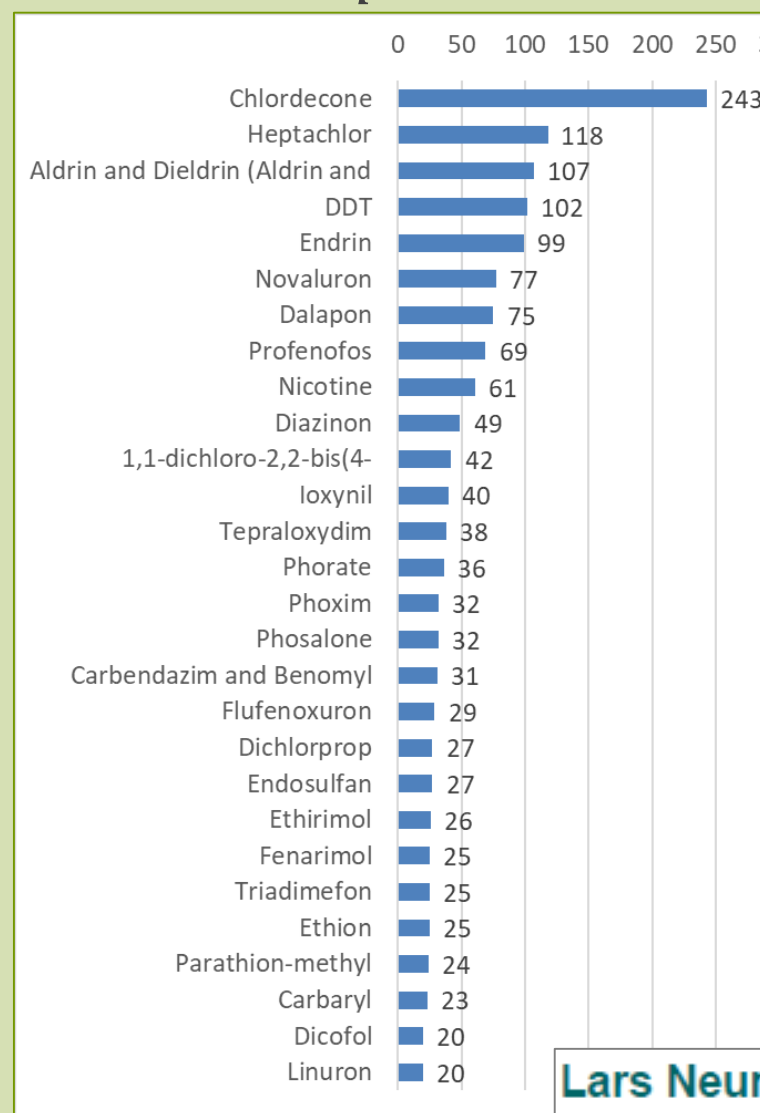
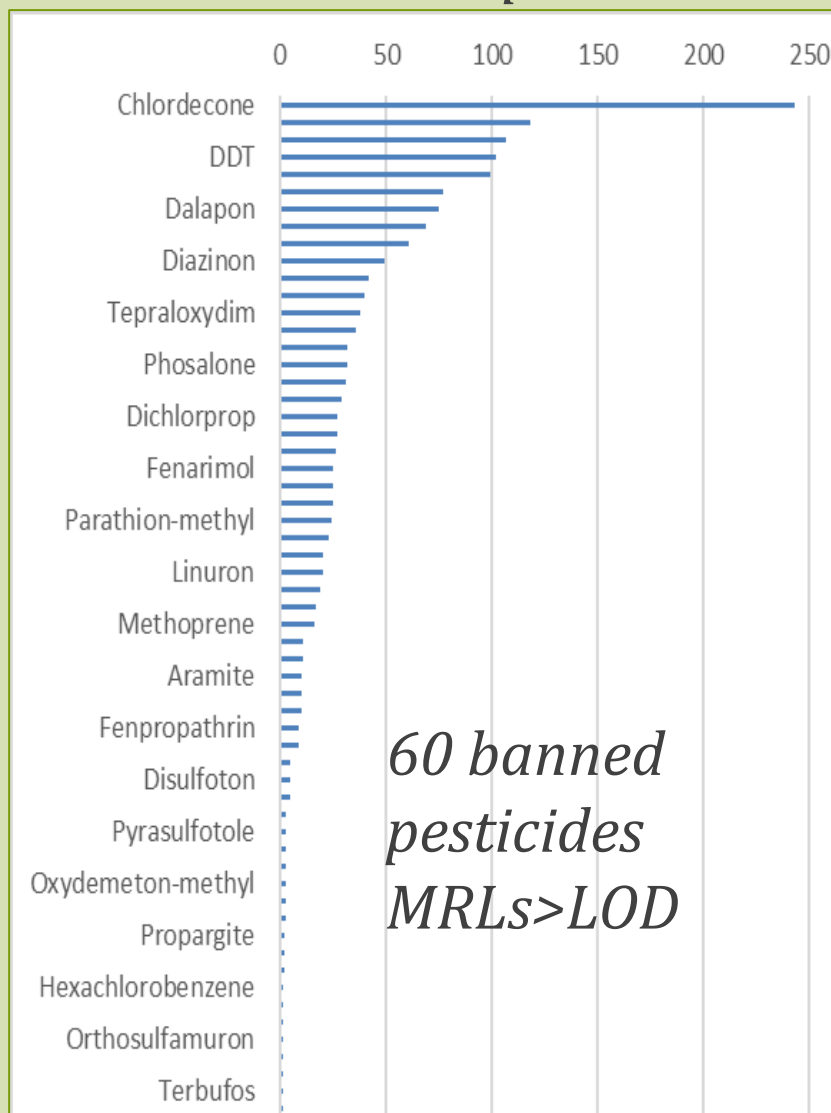
MRL for all banned pesticides should be  
LOD, right?

# MRLs in food for banned pesticides (110)



*Food items where pesticide MRL > LOD*

*Top 30*



## MRLs for banned pesticides - example



### Carbendazim – fungicide, banned in 2014

EFSA 2010 assessment:

- Mutagenic - humans
- Liver tumours in animal experiments
- Infertility in male rats, decrease sperm counts, testicular atrophy, absence of spermatogenesis
- Teratogen in rabbits & rats
- Very toxic to aquatic life



**MRLs > 10-200 x LOD permitted in 31 products**

**2.9% EU food**

# MRLs for authorised but hazardous pesticides




## **Glyphosate –herbicide, reapproved in 2017 for 5 years**

- Probable carcinogen for humans (IARC/WHO, 2015)
  - Humans, animals, genotoxicity
  - Skeletal deformities, teratogenesis
  - Reduced fertility, abnormal sperm morphology/counts, interfering with steroid synthesis
  - Chronic toxicity for aquatic organisms, high health risk for birds
- EU – no human health risk!
  - 60% increase in ADI 0.3 mg/kg → 0.5 mg/kg

**3% EU food**



## Against hazard cut-off criteria in import tolerances

 Ref. Ares(2018)5236296 - 27/07/2018

**BTO 10/07/2017 – Meeting between Commissioner Andriukaitis and representatives of Bayer and Syngenta**

Participants:

- Commissioner Andriukaitis, Nahtalie Chaze (Cabinet), [REDACTED] (SANTE [REDACTED])

- Bayer: [REDACTED]  
[REDACTED]

Syngenta: [REDACTED]

The meeting took place on request of Bayer and Syngenta to discuss their concerns about the impact of the Commission's interpretation of regulations governing the agro-chemical sector in the EU, in particular related to endocrine disruptors, neonicotinoids and import tolerances.

The industry representatives expressed their views regarding the need to conduct risk assessments for the setting of MRLs also for substances that are not approved in the EU due to their meeting the cut-off criteria in the pesticides Regulation and cautioned against setting too low MRLs as this would favour the development of mycotoxins. The Commissioner explained that if substances meet the cut-off criteria, accepting MRLs higher than the limit of detection would constitute unacceptable risks to human health.



syngenta International AG  
Schwarzwaldallee 215  
CH-4002 Basel



Bayer Crop Science AG  
Alfred-Nobel-Strasse 50  
D-40789 Monheim



BASF SE  
Agricultural Center Limburgerhof  
D-67117 Limburgerhof



Mr Daniel Calleja Crespo  
Director General  
DG Enterprise and Industry  
EUROPEAN COMMISSION  
200, rue de la Loi  
1049 Brussels

Dear Mr. Commissioner,

We would like to draw your attention to the urgent issue of regulating endocrine disruptors that your Directorate General is currently dealing with. If the criteria for the identification of Endocrine Disruptors are not drafted carefully and proportionately, many pesticide active substances might unnecessarily face strong regulatory consequences, i.e. restriction or ban. This will ultimately decrease the competitiveness of European farmers and food producing industry, and adversely impact on international trade. Furthermore it will increase the risk of our very capital intensive research & development to a degree that agrochemical research and development may no longer be sustainable in Europe in the future. Therefore, we would like to ask for your support to ensure that the final criteria are based on sound scientific principles in order to enable an appropriate and balanced assessment of the endocrine disrupting potential of our active substances.

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disrupting potential of our active substances.

# Recommendations

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- Stop exportation of banned pesticides based on human health and environment concerns on exporting country
- Zero tolerance in food for banned pesticides
- Reform the risk assessment procedure
- Replace pesticides with agroecology





*Thank you!*

*Lets work together towards a healthier future*

