



# Codex MRLs and EU risk assessment

**Hermine Reich**

Senior Scientific Officer

Unit on Plant Health and Pesticide Residues,

EFSA

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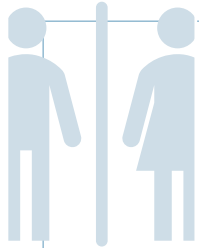
Introduction to EU legislation on pesticide residues in food

Process for implementation of CXLs in EU legislation

Assessment of Codex MRL proposals

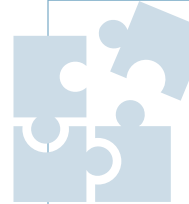
Reasons why CXLs are not implemented in EU legislation

Conclusions



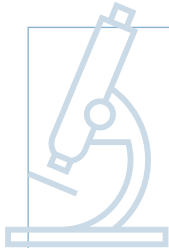
## Separation of risk assessment (RA) and risk management (RM)

- RM: Responsibility of European Commission and competent national authorities
- RA: Responsibility of EFSA and MS authorities responsible for scientific assessment



## Comprehensive legislation

- Specific MRLs: set as low as possible (ALARA principle)
- Default MRL of 0.01 mg/kg: if no specific MRLs established



## MRLs are based on scientific risk assessment

- The safety of a MRL must be demonstrated by data; minimum set of data defined in data requirements
- Burden of proof is with an applicant!
- MRLs may not pose an unacceptable risk to consumers
- Incomplete data may lead to MRL rejection if no clear conclusion on the safety of an MRL can be drawn



## Openness/Transparency/Non-discrimination

- Adapt to needs e.g. to address new use of pesticides
- All assessments are published
- Same rules for EU and non-EU products



**avoid trade barriers**

Common market-  
free movement of  
goods, respecting  
WTO agreement

**are protective for  
consumers**

No unacceptable  
consumer risk,  
exposure as low  
as possible

## EU MRLs

**give certainty for producers**

If pesticides are used  
according to label, food  
products are expected to  
comply with MRLs

**follow ALARA principle**

ALARA (as low as  
reasonably achievable)  
MRL based on GAP  
If no use of pesticide, MRL  
is set at LOQ

**precautionary principle**

Setting of technical zero-tolerance  
in case of missing data or  
unacceptable uncertainties

# Process to derive EU position on Codex MRL proposal

Publication of JMPR report



European Commission mandates EFSA to prepare comments on proposed Codex MRLs



EFSA assessment, consultation of Member States on draft comments



Discussion of EU position at risk management level  
(Council Working Parties, chaired by EU presidency)



Derivation of EU common position



Presentation of EU position in CCPR meeting

## Comments on proposed draft Codex MRLs to address the following aspects (1/2)

- Compilation of regulatory background information on active substances assessed by JMPR
  - Approval status of the active substance, reasons for non-approval
  - Previous assessments at EU level: MRL applications assessed by EFSA, EFSA conclusions and reasoned opinions on MRL applications or MRL review
  - Other relevant information, e.g. cut-off criteria, including endocrine disrupting properties.
- In case new toxicological reference values were proposed by JMPR
  - Comparison of the proposed reference values (ADI/ARfD) with agreed EU reference values
  - Toxicological data for components of the residue definition for risk assessment
  - Evaluation of the reasons for differences

## Comments on proposed draft Codex MRLs to address the following aspects (2/2)

- Comparison of EU MRLs/Codex MRL proposals
  - Are the residue definitions derived by JMPR comparable with the existing EU residue definitions? If different, what are the consequences?
  - Are the proposed draft Codex MRLs sufficiently supported by data (number of residue trials, residue trials representative for the GAP, metabolism data, processing studies, feeding studies, dietary burden calculations for livestock)?
- Are the proposed draft Codex MRLs safe for European consumers with regard to chronic, and where relevant, acute exposure?
  - Exposure calculations based on PRIMo rev. 3.1, including proposed Codex MRLs and the existing EU MRLs.
- EFSA Report on assessment of Codex MRL proposals is published in EFSA Journal

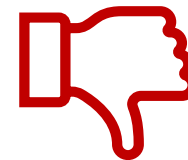
## Acute exposure



!

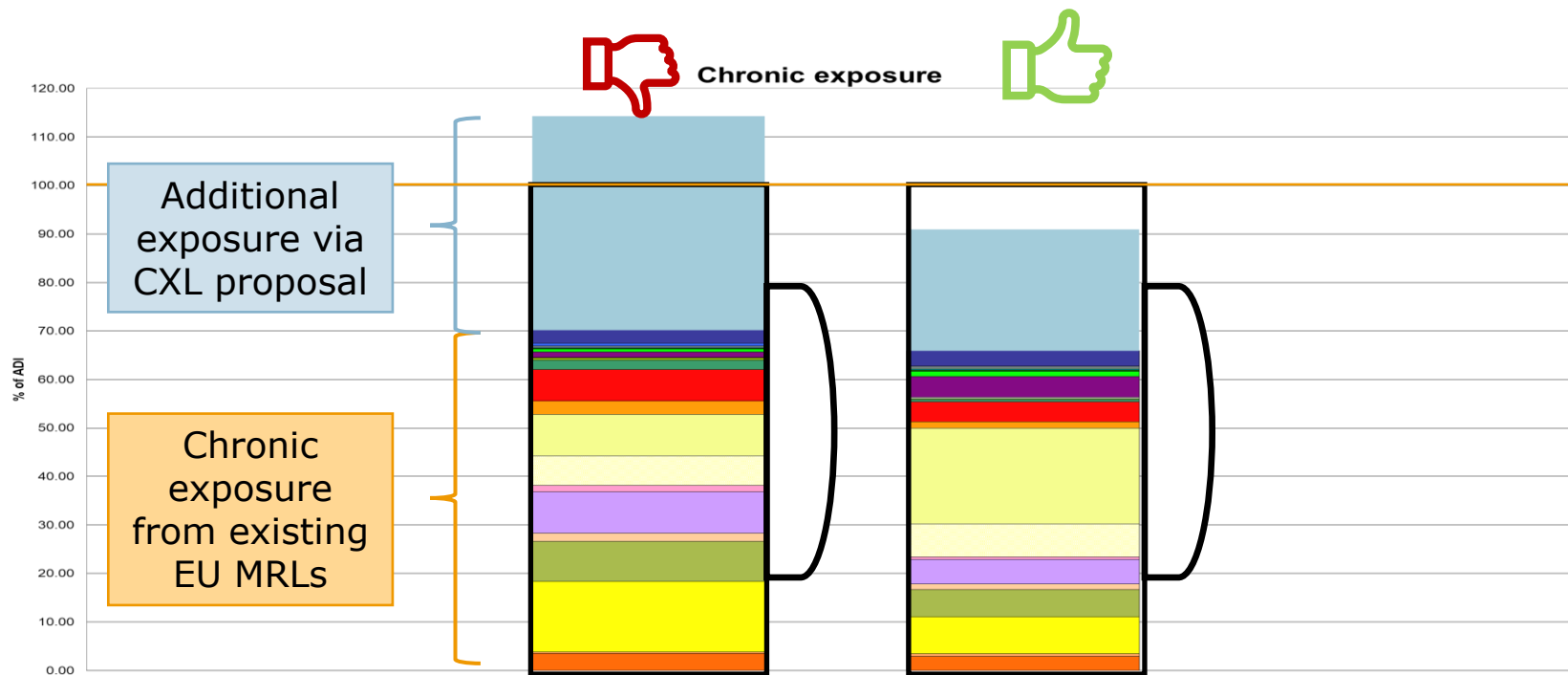
For the risk assessment, residues in the edible part of the crop are considered (e.g. banana without peel)

MRL is set for the whole product (e.g. banana incl. the peel)





# Chronic risk assessment: risk cup concept



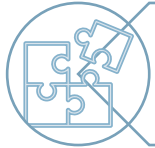
Oranges	Mandarins	Apples	Pears	Peaches	Table grapes	Strawberries
Bananas	Potatoes	Carrots	Tomatoes	Peppers	Aubergines (egg plants)	Cucumbers
Cauliflower	Head cabbage	Lettuce	Spinach	Beans (without pods)	Peas (without pods)	Leek
Oats	Rice	Rye	Wheat	CXL proposal for kale		

# Reasons for EU reservations (1/2)



## Ongoing evaluation of the a.s. in the EU

- depending on the outcome of EU assessment, CXLs may be implemented at a later stage



## JMPR residue definition (RD) is not compatible with EU RD

- e.g. in EU RD additional metabolites are included



## Residue definition derived by JMPR is not acceptable

- e.g. toxicological relevant compounds are not included in the RD derived by JMPR



## MRL is higher than necessary

- due to different policy on setting group MRLs, extrapolation rules were not respected



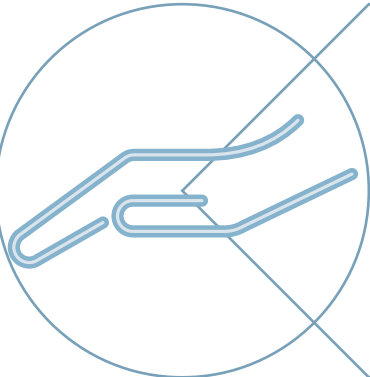
## Commodities do not comply with the EU crop description

- rice: EU sets MRL for husked rice; CXL for GC 0649 (rice) refers to rice with husks



## Data gaps in the dossier supporting Codex MRL, e.g.

- Lack of information on general toxicity of a.s. or of relevant metabolites
- Insufficient evidence to demonstrate the absence of genotoxicity of a.s./metabolites
- Insufficient data on plant metabolism or formation of degradation products under processing conditions
- Number of residue trials not compliant with the minimum number of studies defined in FAO manual



## EFSA identifies possible consumer health risks

- EU risk cup is already full: no new MRLs can be added, unless other EU MRLs are lowered
- Risk identified using EU ADI/ARfD in risk assessment
- Different consumption data used in EU risk assessment (PRIMo rev. 3.1)
- Different variability factor used in EU (acute risk assessment, IESTI case 2a and 2b)

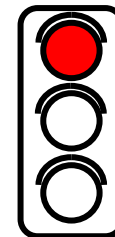
EU supports advancement of CXLs

- Codex MRLs are implemented in EU legislation, translated to the corresponding EU food classification



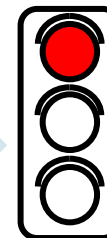
EU opposes the advancement

- Jmpr identified a possible consumer health concern
- No advancement of Codex MRL proposal



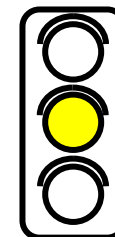
EU introduces a reservation in CCPR

- CXLs will not be implemented in EU legislation; implementation postponed (see next slide),
- Codex MRL will advance in step procedure



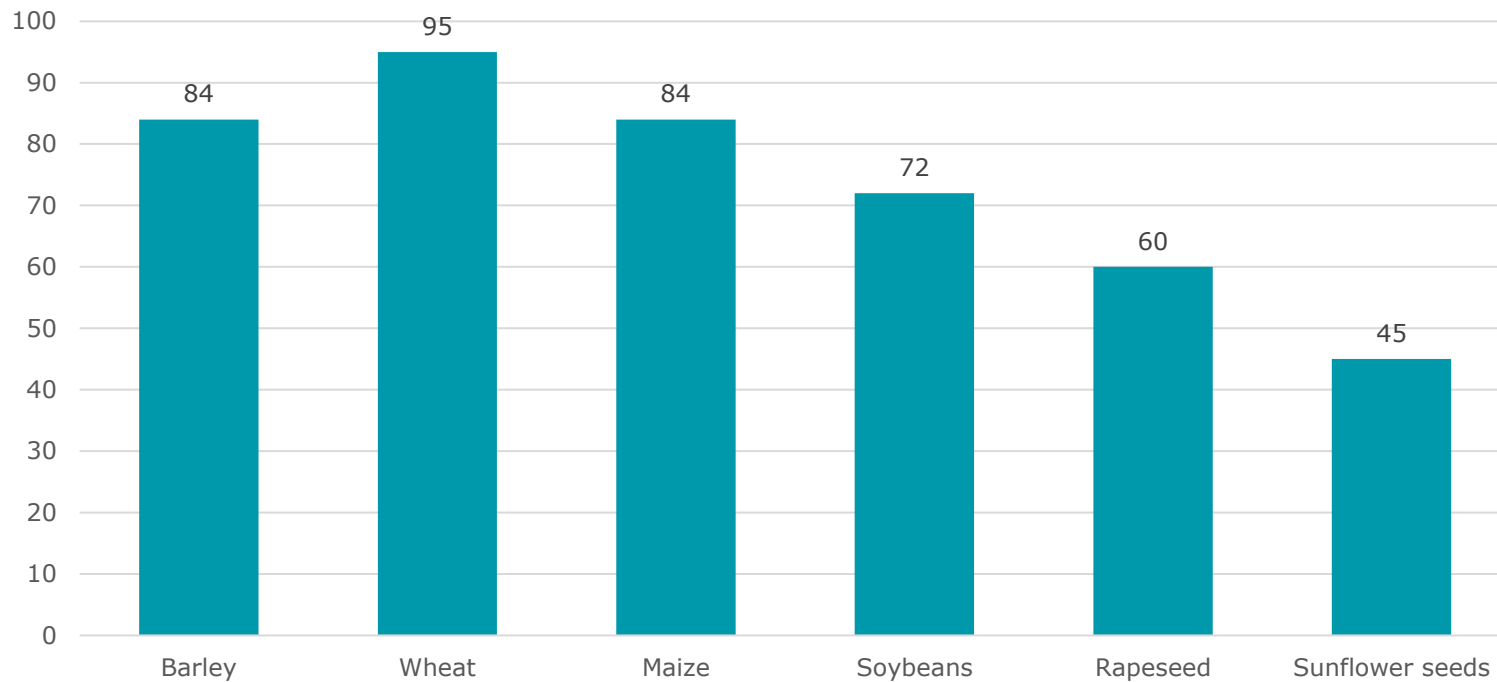
EU provides comments on Jmpr assessments

- EU shares observations or proposals for corrections

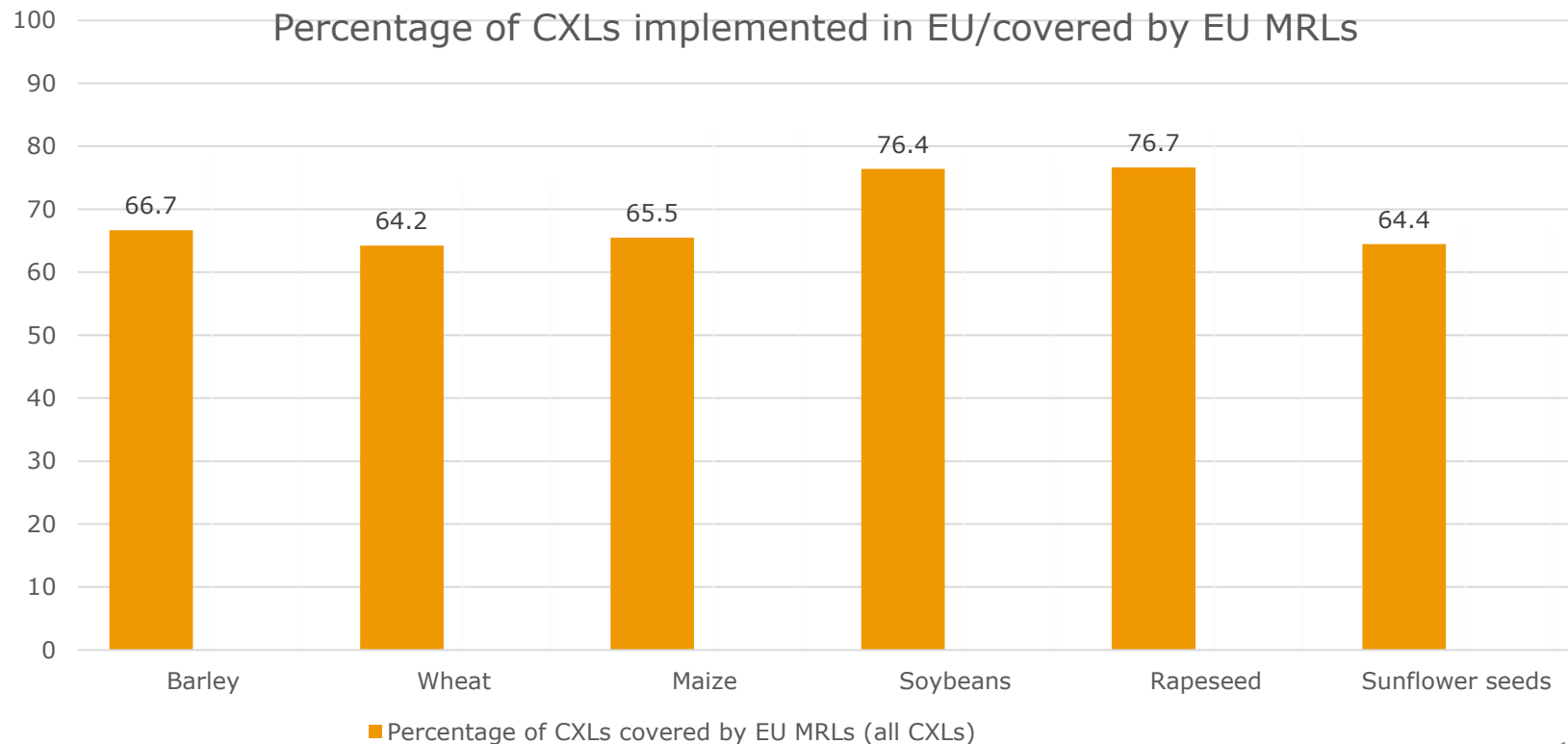


## Example: cereals, oilseeds

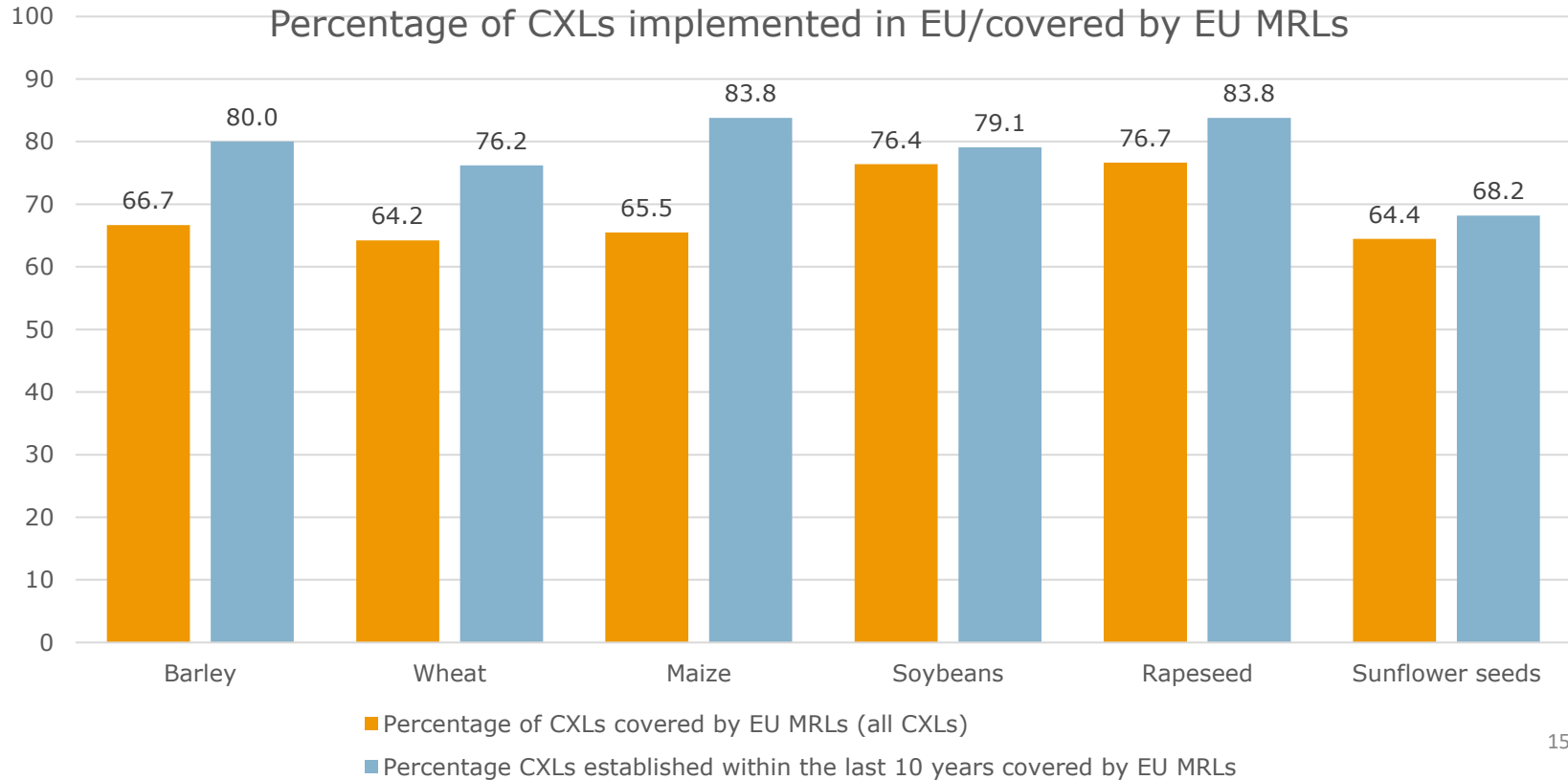
Number of Codex MRLs



## Example: cereals, oilseeds



## Example: cereals, oilseeds





# Conclusions

Well established process to decide whether CXLs can be taken over in EU legislation

Scientific assessment of EFSA serves as a basis to decide on EU position in CCPR

CXLs, for which EU supports advancement in CCPR/CAC, are implemented in EU legislation

CXLs implemented in EU legislation comply with the same scientific standards and policy principles as other EU MRLs

Open EU MRL legislation: Depending on the reasons for not implementing the CXLs, application for setting an import tolerance should be considered