



Setting Pesticide MRLs in food in the EU

General Principles and Procedures

Informative session for third countries

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*Health and
Food Safety*

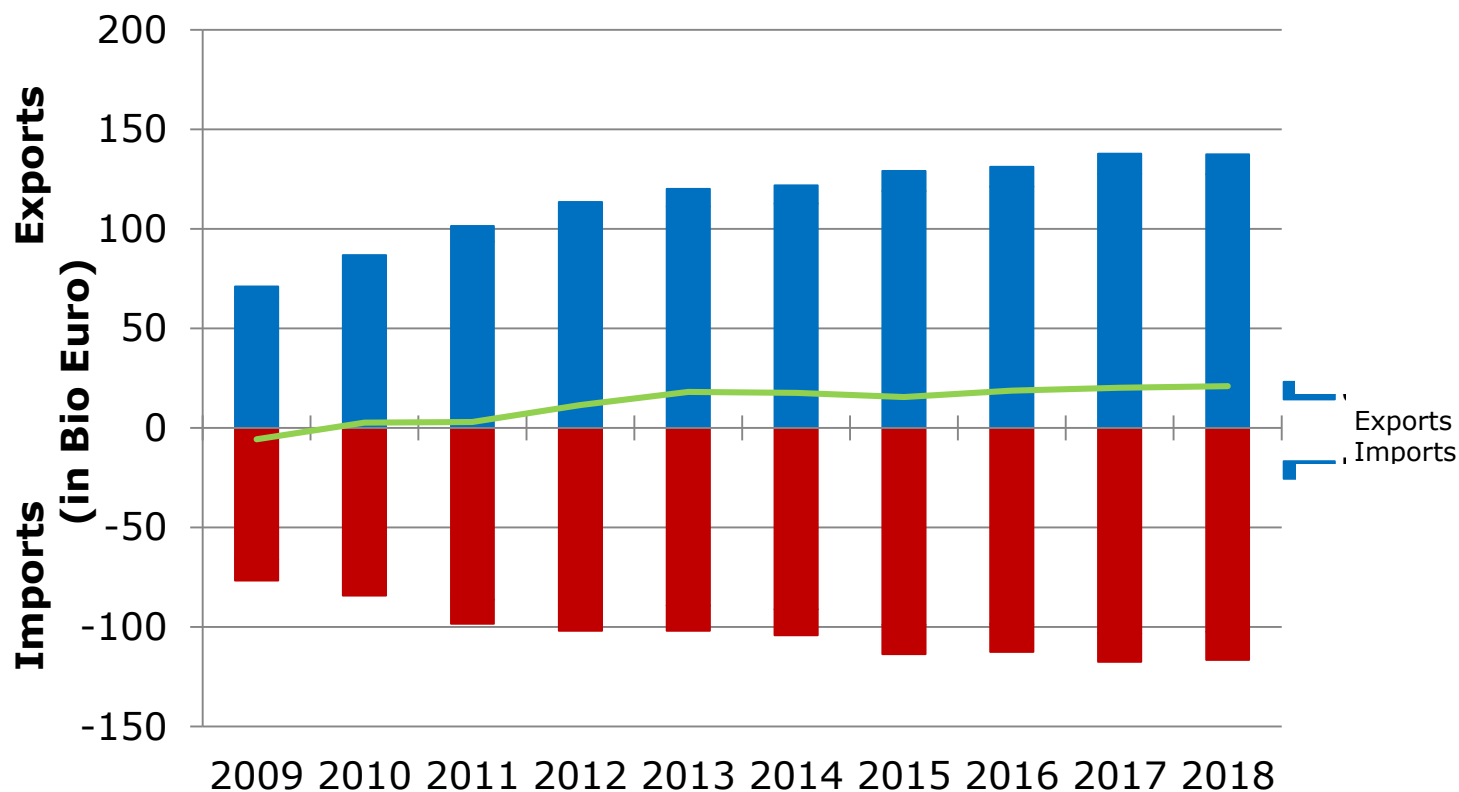


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Some facts on trade

- EU market with 450 Mio consumers.
- EU is today the second biggest agri-food exporter and importer worldwide.
- Exports and imports are continuously increasing.
- For example in the time span 2009-2018, increase of EU imports of fruit
 - from Brazil by 23%,
 - from Costa Rica by 40%,
 - from Dominican Republic by 93%,
 - from Jamaica by 54%,
 - from Peru 5-fold and
 - from the USA by 87%.
- Important EU imports of agri-food products also from least developed countries.

EU agri-food trade (2009-2018)

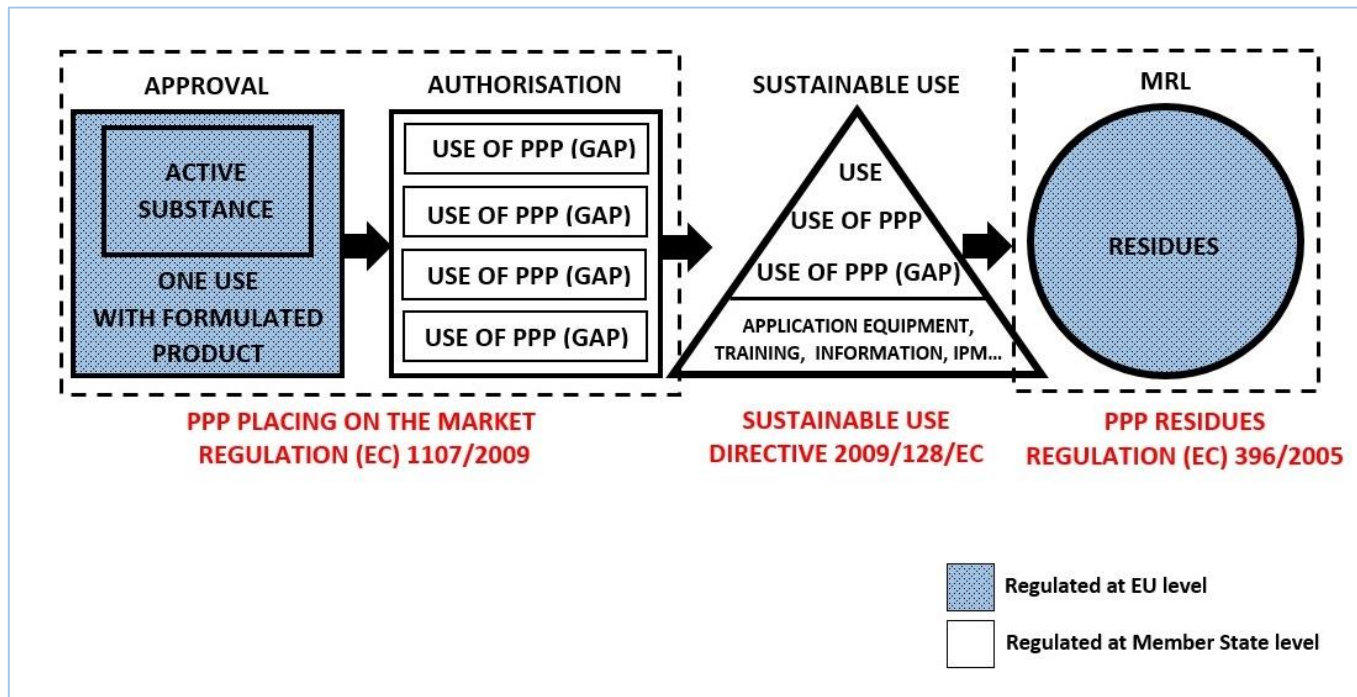


https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/news/documents/agri-food-trade-2018_en.pdf



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EU Pesticides Legislation



Objectives of the MRL Regulation (396/2005)

- Ensure a harmonised high level of consumer protection (public health > crop protection):
 - No unacceptable risk to humans
 - MRL set at lowest achievable level consistent with critical Good Agricultural Practices (cGAPs)
 - Protecting vulnerable groups (children, unborn)
- Trade facilitation:
 - Free circulation of food and feed in EU
 - Provisions for third countries (imports into EU)
- Transparency and predictability

Default MRL and the limit of quantification (LOQ)

- If no MRL can be established, the default level of 0.01 mg/kg or a specific analytical limit of quantification (LOQ) is set.
- Legal certainty
 - Independent of analytical capability (pre-export checks)
 - Application of concentration factors
- Approach shared by other WTO members
 - FAO (2020): <https://doi.org/10.4060/cb0463en>

Why and when can MRLs drop to the default MRL or LOQ?

- Loss of authorisation in EUMS
- No information on authorised uses (EU/non-EU)
- No data (trials) supporting authorised uses
- Consumer risk (acute/chronic) identified
- Insufficient data or concern on toxicology
- **Responsibility of applicant to demonstrate safety**

New MRLs established based on

- GAPs in EU
- GAPs in Third Countries ("import tolerances")
- Codex Alimentarius standards

Same level of stringency in assessment, same data requirements, same timelines for assessment

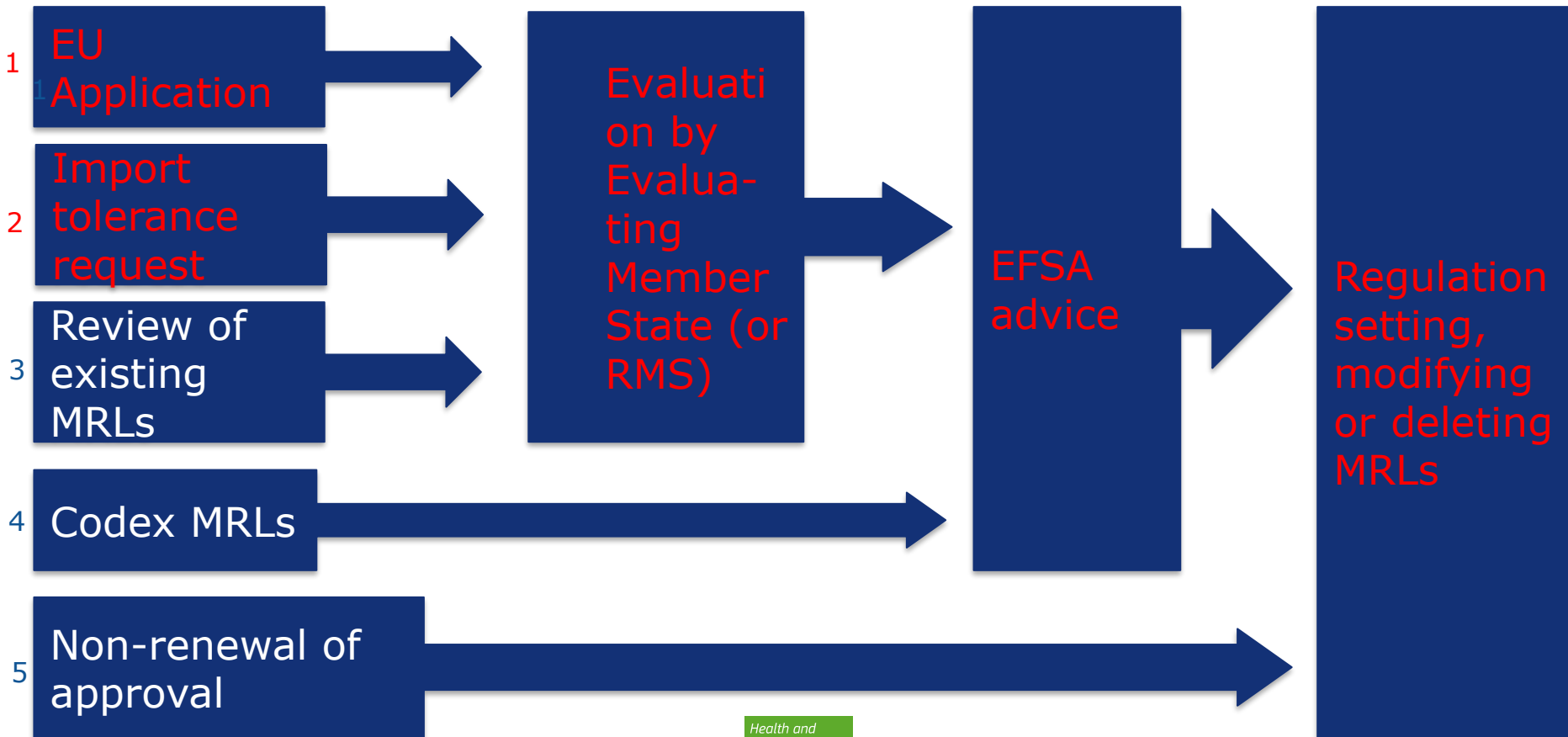
MRLs valid for

- Commodities from EU and Third Countries:
same MRL for all food and feed on the EU market



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Regulation (EC) No 396/2005 – setting EU MRLs



Provisions for imported food

- EU MRLs apply to imported food => no need to request an import tolerance if EU MRL can be met
- If EU MRL cannot be met, applicant can request import tolerance based on GAP authorised in Third Country
- Same data requirements for application dossiers, but proof of authorisation in Third Country and domestic MRL needed

Separation risk assessment / risk management for setting MRLs

1. Application

Applicant (industry or...) → Data dossier (requirements!)

2. Risk Assessment

1 Member State (EMS) → Evaluation Report

European Food Safety Authority (EFSA) → Assessment

EFSA → "Reasoned opinion"

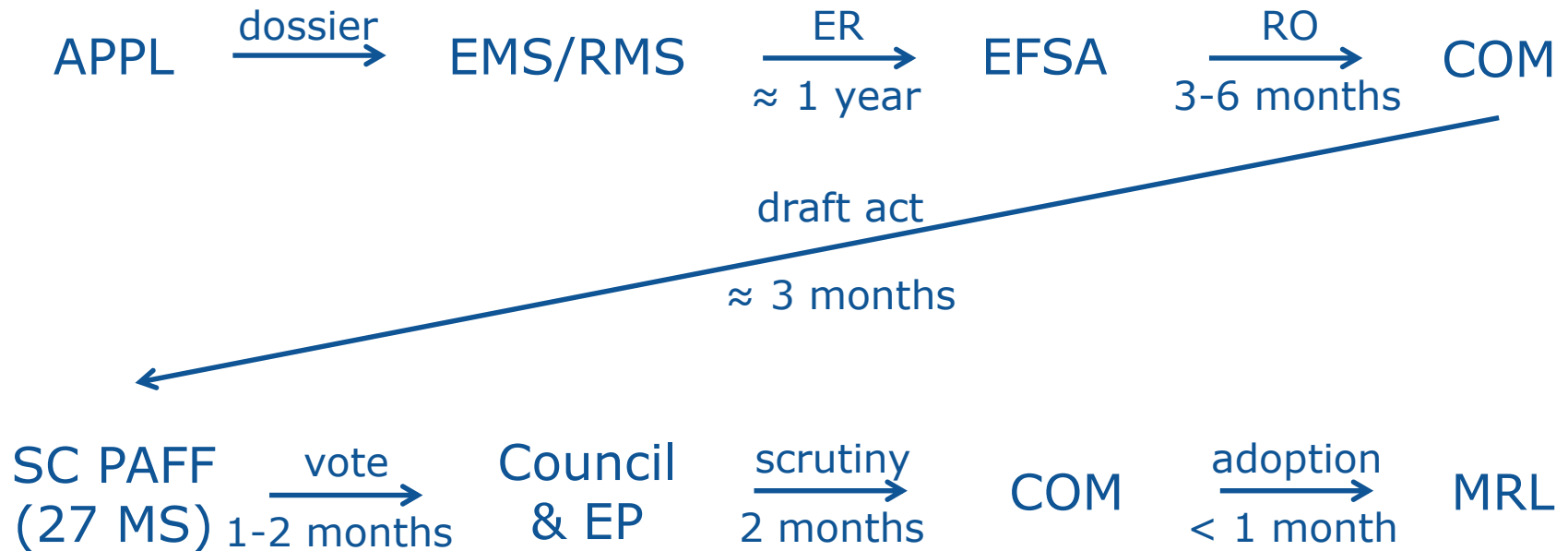
3. Risk management

Commission + all Member States → MRL setting



From application to MRL setting

(MRL applications based on EU uses and import tolerance requests)



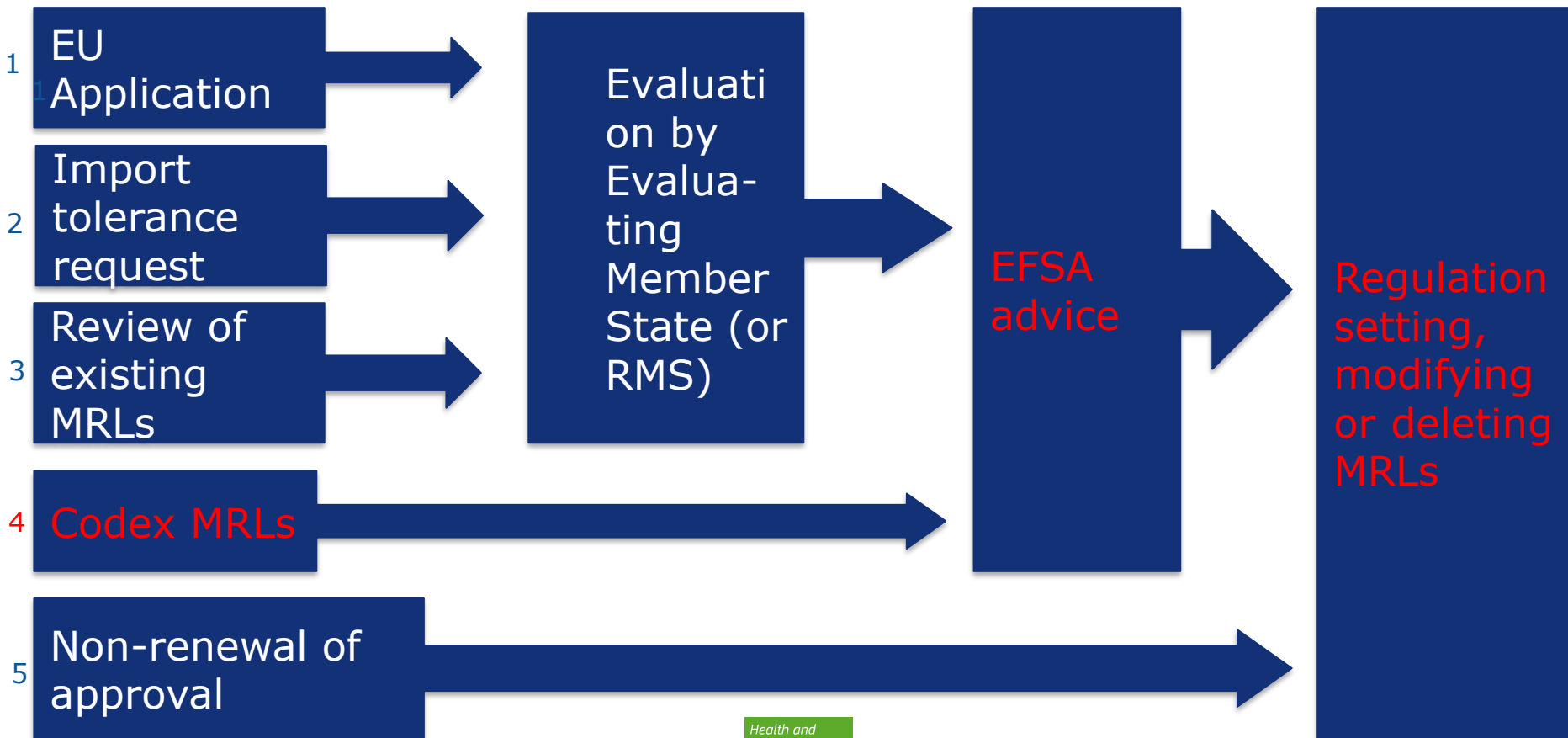
Import tolerance applications

Overview 2008 – 2018:

- 94 applications for ITs submitted
- 80 were assessed positively
- 9 received a negative opinion.
- The remaining 5 applications are still under assessment.

To note: average time from submission of an application to entry into force of a Regulation is 2 years

Regulation (EC) No 396/2005 – setting EU MRLs





Codex Alimentarius and EU MRLs- Facilitating Trade

- Generally Codex Maximum residue limits (CXLs) are taken over in EU legislation unless the EU raised concerns at CCPR, the Codex Committee on Pesticides Residues ("reservation").
- Newly proposed CXLs are assessed in an annual EFSA scientific report (in preparation of annual CCPR meeting).
- "Old" CXLs are implemented during the review procedure for existing MRLs (Article 12 exercise), if safe to consumers (EFSA evaluation)
- High level of alignment with CXLs (70%)
- Highest rate of alignment compared to other important OECD countries

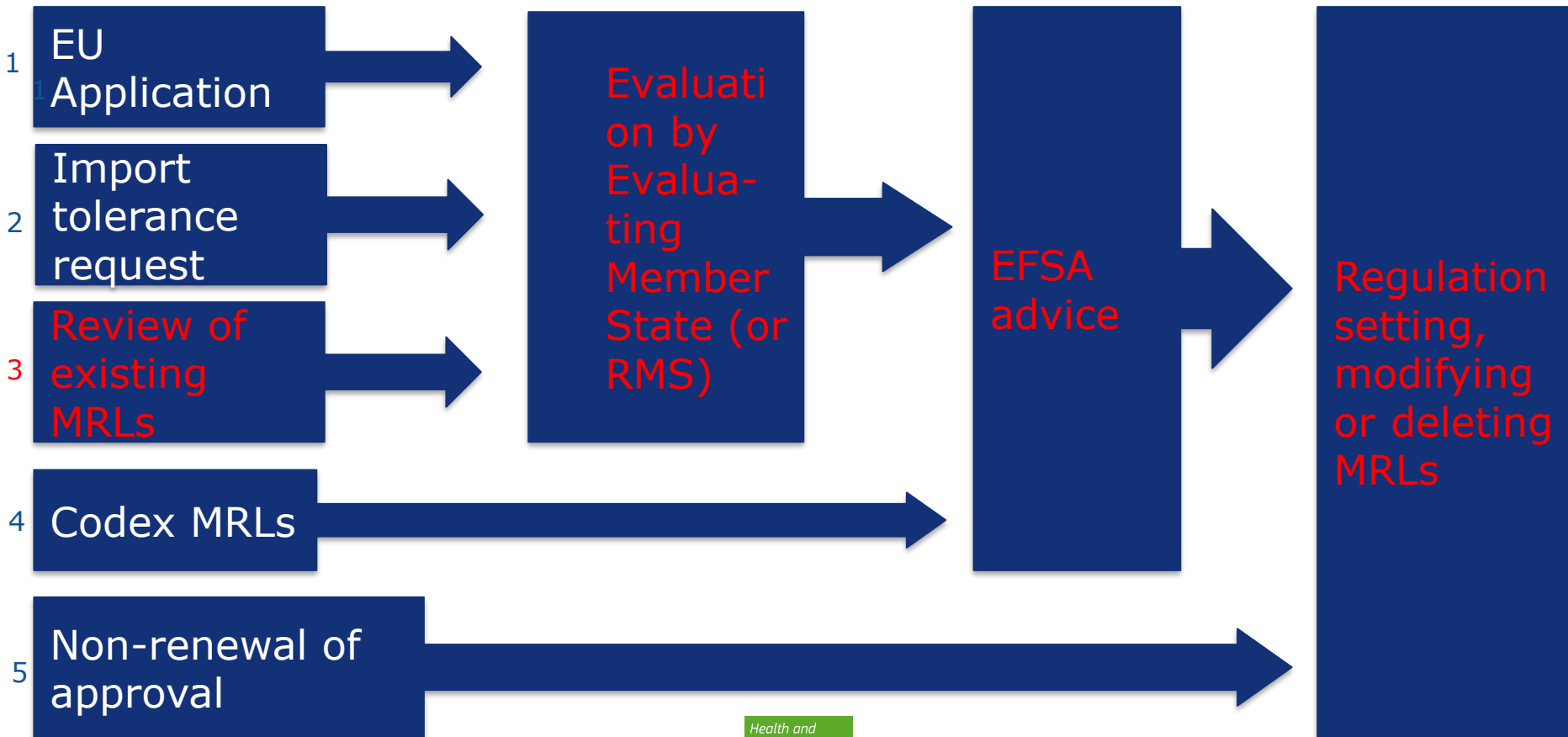
CXL alignment 2012-2019

Year	Total number of CXLs for food adopted by CAC	EU MRLs set at lower values than CXLs	<u>EU MRLs set at the same or higher values^[1] than CXLs</u>
2012	242	22%	78%
2013	352	21%	79%
2014	301	28%	72%
2015	326	25%	75%
2016	349	37%	63%
2017	417	47%	53%
2018	305	21%	79%
2019	275	32%	68%



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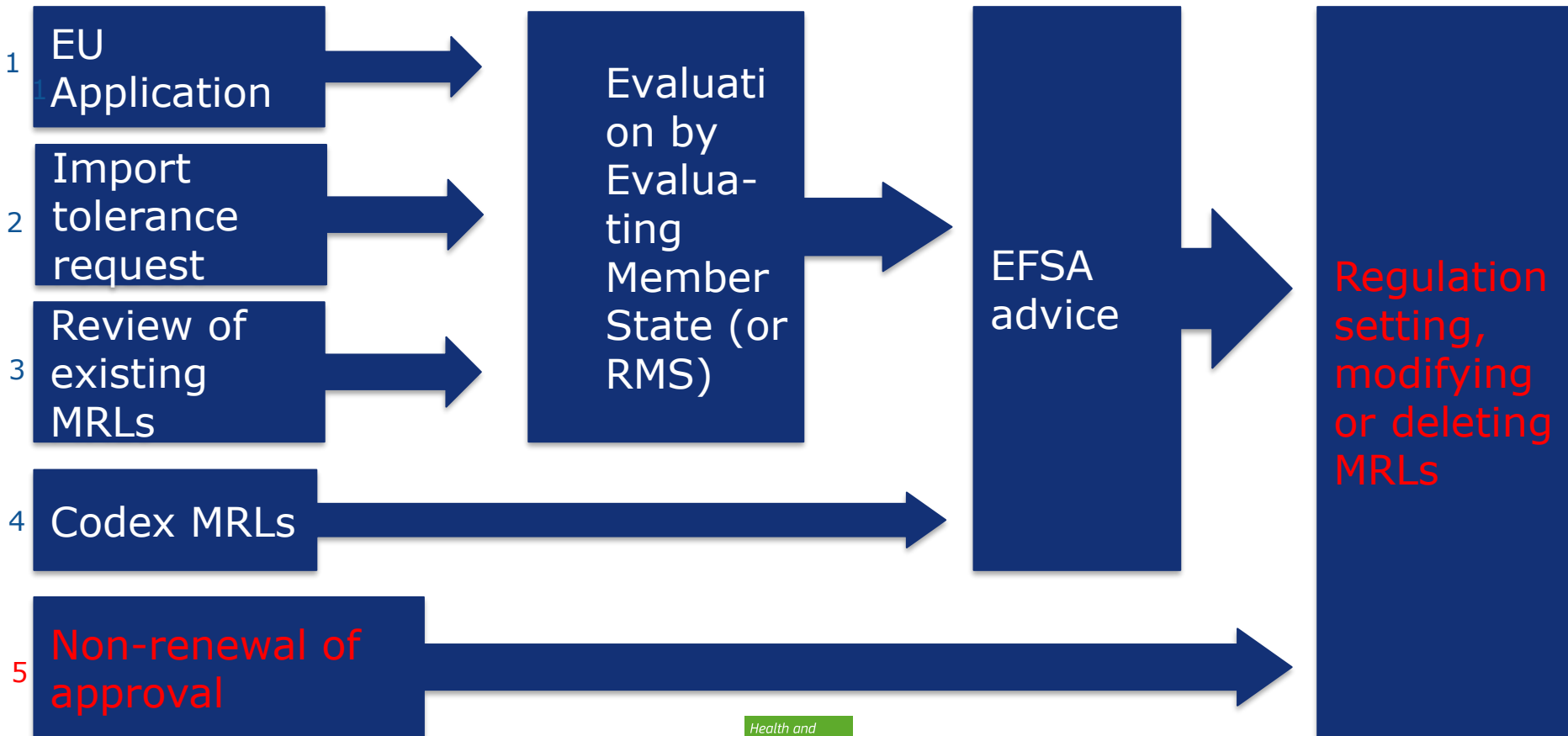
Review of existing MRLs

- Full harmonisation of EU-MRLs in 2008
- Before based on EU Directives and national MRLs, now based on EU Regulation => directly applicable
- Need to review MRLs at EU level (RMS => EFSA)
- Delete obsolete MRLs, align to "old" CXLs
- Notification to WTO-SPS Committee (draft act)
- **Important: early input can avoid MRL losses => see G/SPS/GEN/1494.**
- Case by case: MRLs maintained with data request
- Around 270 substances out of 400 reviewed



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MRL setting after the renewal process

- In case of **non-renewal**, MRLs for the substance will **in general be lowered to the limit of quantification**.
- The following will be considered
 - Existing **safe import tolerances** and **CXLs** can be **maintained** in certain circumstances
 - The **grace periods** that were granted for marketing an use of products need to be respected
- **Important to monitor the situation early on to avoid MRL losses (e.g. introduce IT request)**



How can MRL losses due to data gaps be avoided?

- Proactive and regular monitoring of the processes on all relevant public websites (EFSA, SPS/TBT WTO, SANTE).
- Submit supporting dossiers early on, considering that e.g. an import tolerance request takes 2 years.
- Maintain regular contacts with the Evaluating Member State to check what is missing and at what moment the information can be brought into the process.
- The new Transparency Regulation will enhance transparency e.g. of already available study data.



Information material

Information on MRLs (1)

- Detailed technical and procedural guidance, including Technical Guidelines on MRL setting procedure (SANTE/2015/10595 Rev. 5.4 — November 2018):
http://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines/index_en.htm
- SPS Note to non-EU countries about MRL reviews (Art. 12):
https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_mrl-review_en.pdf
- EU pesticides database:
https://ec.europa.eu/food/plant/pesticides/eu-pesticides-db_en
- EFSA overview on MRL review programme:
<https://www.efsa.europa.eu/sites/default/files/pesticides-MRL-review-progress-report.pdf>

Information on MRLs (2)

- Legal texts (Official Journal):
<http://eur-lex.europa.eu/homepage.html>
- Summary reports of regular meetings of the Standing Committee on Plants, Animals, Food and Feed (SC PAFF), section Phytopharmaceuticals, Pesticide Residues:
https://ec.europa.eu/food/plant/standing_committees/sc_phytopharmaceuticals_en
- Public Commission Comitology Register (Draft and final legal texts):
<https://ec.europa.eu/transparency/comitology-register/screen/home>

Support to developing countries

“Fit for market” and “Fit for market SPS”, both by COLEACP (Europe-Africa-Caribbean-Pacific Liaison Committee):

Fit for market: Help farmers to **find alternative pesticides**. Allow smallholder farmers, producer groups, farmer organisations, and small and medium enterprises, to **access international and domestic fruit and vegetable markets by complying with the SPS standards** and market requirements, in a sustainable framework.

Fit for market SPS: **Strengthen SPS systems** in the horticultural sector, focusing on **challenges faced by exporters**, including due to EU **plant health and pesticides rules**.

<https://www.coleacp.org/?lang=en>

Support to developing countries

“Plantwise+” by CABI (Centre for Agricultural Bioscience International):

Plantwise+: **Improve farmers’ yields and incomes** while **reducing the use of toxic pesticides**. Increase food security and improve rural livelihoods by **reducing crop losses and addressing issues regarding safe use of pesticides**.

Working in close partnership with relevant actors, Plantwise **strengthens national plant health systems**, enabling countries to provide farmers with the knowledge they need to lose less of what they grow.

<https://www.cabi.org/>

Support to developing countries

“Better Training for Safer Food” (BTSF) by DG SANTE (Directorate-General for Health and Food Safety of the European Commission):

BTSF: Training initiatives for **issues related to food and feed safety, incl. pesticides residues** and integrated pest management. Also animal health and welfare, and plant health rules.

To **ensure safety of food imports from non-EU countries on the EU market, harmonisation of control procedures** between EU and non-EU partners, and **fair trade** with non-EU countries and in particular developing countries.

https://ec.europa.eu/food/safety/btsf_en

Other information for the public

- Educational material by DG Health and Food Safety

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_approval-factsheet.pdf

<http://ec.europa.eu/assets/sante/food/plants/pesticides/lop/index.html>

- Educational material by EFSA

<https://www.efsa.europa.eu/en/discover/infographics/who-assesses-pesticides-eu>

<https://www.efsa.europa.eu/en/topics/topic/pesticides>



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THANK YOU !