

Regulatory Coherence & Standards for Crop Protection Products: An Industry Perspective

[Art. 4.1(b)]

BASF Corporation

Ninth Round of TTIP Negotiations

April 23, 2015

Maximum Residue Levels (MRLs)

- ▶ What are MRLs?
 - ▶ allowable levels of crop protection products
 - ▶ based on use as recommended on product label
- ▶ Why are they necessary?
 - ▶ protection against diseases, pests, etc.
 - ▶ vast movements of agricultural commodities around the world
- ▶ What happens if MRLs are inconsistent or nonexistent?
 - ▶ inability to use crop protection products
 - ▶ shipments denied entry

Opportunities for Regulatory Cooperation

- ▶ Consistent residue definitions
 - ▶ for risk assessment and enforcement
 - ▶ inclusion of metabolites and degradation products
 - ▶ promotion of public confidence
- ▶ Joint review of new active substances
 - ▶ expansion of existing cooperation
 - ▶ EU coordination through EFSA
 - ▶ promotion of mutual trust and public credibility

Opportunities for Regulatory Cooperation

- ▶ Consistent regulatory data requirements
 - ▶ common crop groupings
 - ▶ common representative crops for each group
 - ▶ common rules for data extrapolation from one crop to another
 - ▶ common minimum number of trials for each group

Opportunities for Regulatory Cooperation

- ▶ Reliance on good laboratory practices (GLP)
 - ▶ continued recognition of common GLP standards
 - ▶ mutual acceptance of data developed using GLP
 - ▶ supervision of GLP labs and studies
- ▶ Consistent data formats
 - ▶ study information summaries and evaluations
 - ▶ common electronic formats
 - ▶ greater regulatory efficiency

The image features abstract green geometric shapes on the left and right sides. On the left, a single green triangle points downwards. On the right, a complex arrangement of overlapping green triangles and polygons in various shades of green is shown. A thin, light gray line extends from the bottom left towards the right side, passing through the green shapes.

Thank you.