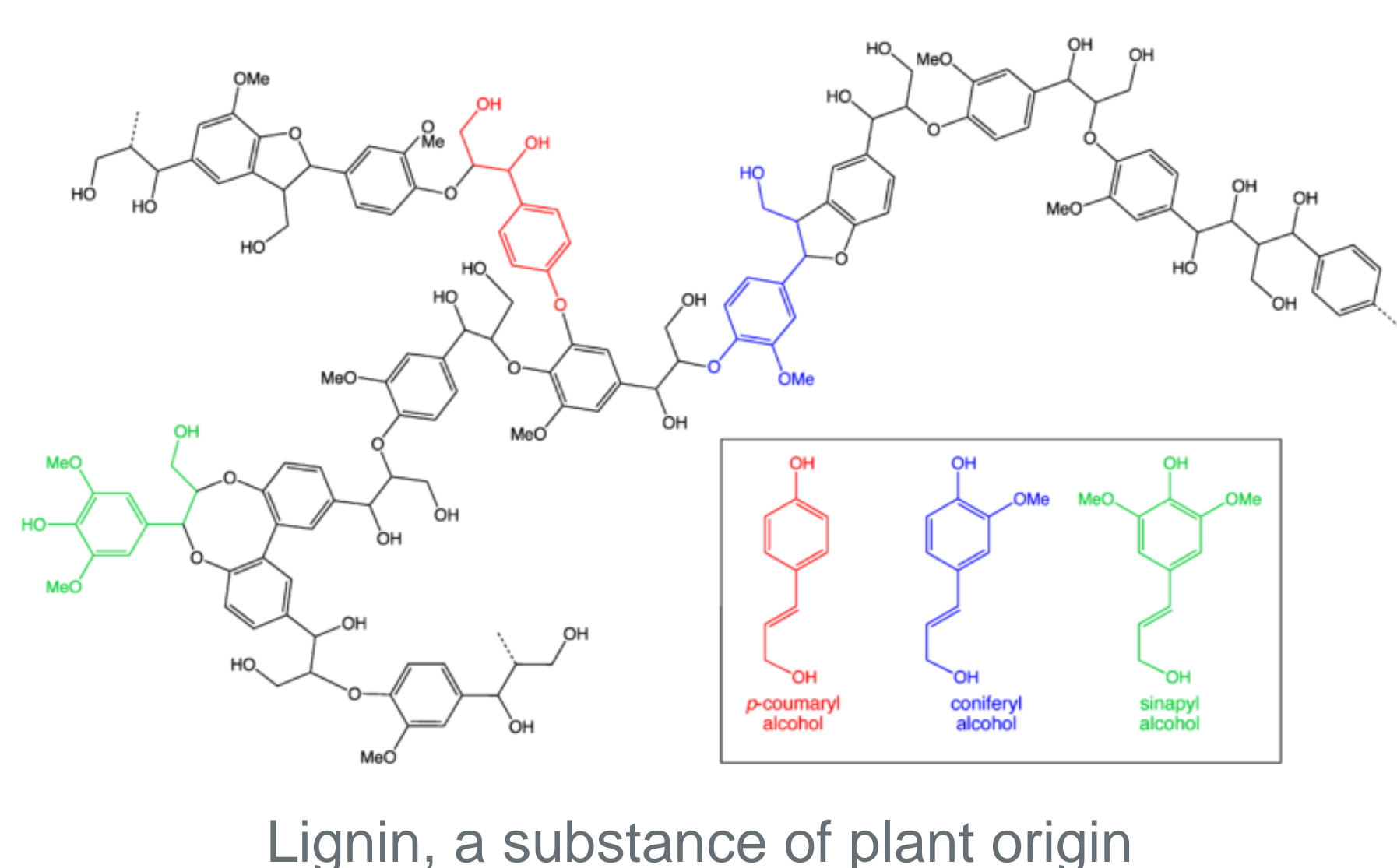
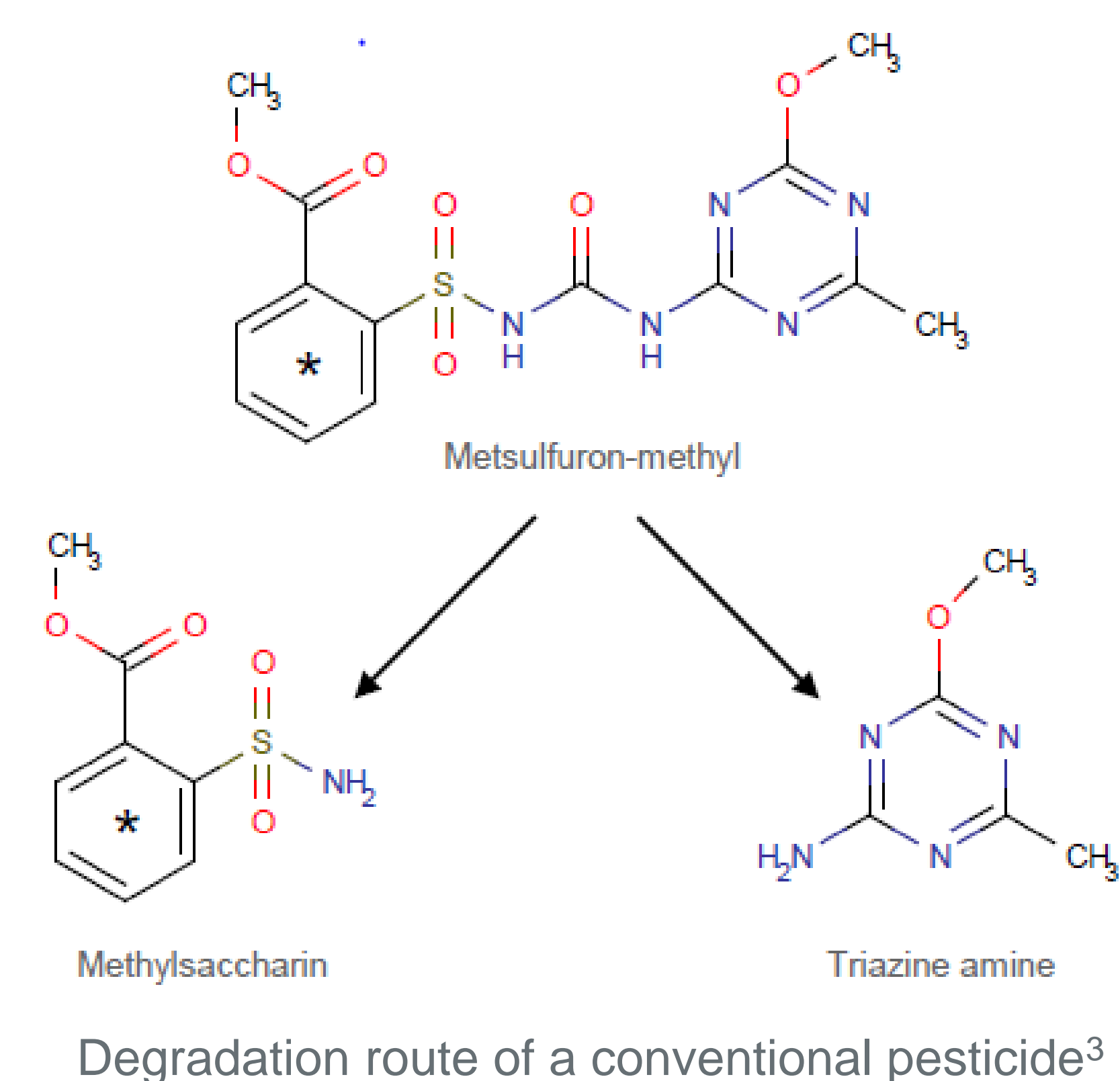


# Regulatory approach and developments in fate and behaviour for botanical pesticides

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## Introduction

- Despite the growing interest in botanical pesticides, there is little specific guidance on the regulatory approach and the data requirements for these products in the EU.
- The EU regulatory framework<sup>1</sup> is based on 'conventional' chemical plant protection products (PPP), with the same data requirements and approaches used to derive endpoints for exposure assessments.
- However, plant extracts are complex mixtures of biologically-active components and other materials of common plant origin including carbohydrates, lignin, fibre and ash in variable proportions. Conventional pesticides (for example metsulfuron, below) generally comprise single components with relatively simple structures and degradation pathways, whereas a single component of a botanical pesticide (for example lignin, below, a non-active component) can be highly complex.
- Botanicals are sometimes classified as UVCB substances (substances of Unknown or Variable composition, Complex reaction products or Biological materials) in the EU.
- This poster outlines ERM's approach in recently preparing regulatory submissions of botanical plant protection products in the EU.



## Methods

- The submission had to address demanding data requirements such as adsorption and route and rate degradation in soil, water and sediment with an exposure assessment for the soil, surface water and groundwater compartments.
- Soil degradation and soil sorption endpoints are the most crucial parameters in the assessment.
- Challenges included generating data for use in the exposure assessment using conventional laboratory studies. These studies require radiolabelled test items in order to follow degradation pathways.
- This is impractical with UVCBs as the components are numerous and generally far more structurally complex than conventional chemicals.
- Alternative methods to derive these parameters were therefore necessary.
- Ready biodegradability studies measuring CO<sub>2</sub> output as an indicator of microbial degradation were used to generate data on degradation.
- QSAR models were used to estimate K<sub>FOC</sub> values, a measure of soil adsorption.
- Full exposure assessments were performed for soil, surface water and groundwater using these endpoints.
- Worst-case default values were used in the absence of data for other parameters in the exposure assessment.
- A 'marker component' approach comparing components common to the botanical pesticide and cropped plants was also used.
- This aimed to demonstrate that levels of common components following application of the botanical pesticide would be within natural concentrations occurring in the environment from natural and/or cropped plants.
- The comparison was based on an empirical comparison of the levels of common components occurring in the pesticide and widely-grown crops in the EU.
- The marker component approach also used cropping area data from the FAOSTAT<sup>2</sup> database compared to the predicted application rates of the botanical pesticide.

## Results

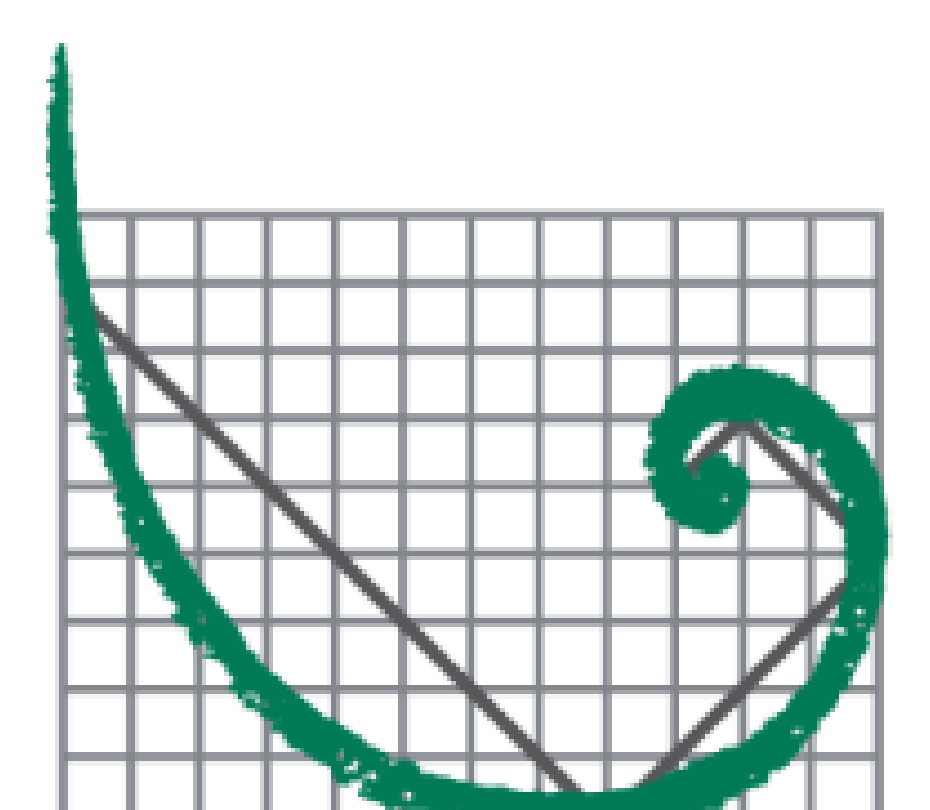
- Default data was generated for use in the exposure assessments for groundwater, soil and surface water.
- The exposure assessments showed an acceptable risk to groundwater and to soil and surface water-dwelling organisms.
- In addition, the 'marker component' approach demonstrated that expected concentrations of common components following application of the botanical pesticides would not exceed concentrations occurring from widely-grown crops in the EU.



## Conclusions

- Alternative approaches were used for botanical pesticides to address standard EU regulatory on data generation requirements and exposure and exposure assessments.
- ERM has received positive feedback on the approach from the evaluating authority as these biopesticides progress through the EU regulatory system.

<sup>1</sup>Regulation (EC) 1107/2009  
<sup>2</sup><http://www.fao.org/faostat/en/#home>  
<sup>3</sup>Taken from publicly-available data



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