# SAVE TIME AND PREVENT COSTLY ERRORS WITH RISK MODELLING AND ASSESSMENT

Risk assessment and modelling for plant protection products (PPPs) mitigates the risk of investing time and money developing a product only to discover its negative effects when you complete its dossier.

In the run-up to product registration, risk assessment and modelling should be included from the outset. They can make the difference between a PPP's success, or failure. Risk assessments cover all aspects of everyday life, from the consumption of food treated with a PPP, to the effects its use has on the environment.

## PLAN RISK ASSESSMENTS IN ADVANCE

Successful product development means completing preliminary risk assessments as soon as the key end-points are available. This will highlight potential issues early in the development process, allowing additional work/studies to be completed and unacceptable risks to be addressed.

Risk assessment looks at the potential for both human and environmental impacts.

## HUMAN RISK

From day one, a product's development poses a risk to humans. Risk assessment and modelling is used to answer many questions, but most importantly:

- What is the risk to the people involved in a PPP's preparation and application?
- Does a PPP pose a risk to people working in adjacent fields, nearby, or simply passing by?
- What about contact with the crop after application?

Known as operator exposure, or 'OpEx', these risks identified are determined using modelling exposure scenarios. When a risk is identified, higher tier data needs to be generated by, for example, dermal absorption, or conducting complex field studies.

Furthermore, human risk must also be assessed at the point of consumption.

Many risk models are used to calculate the potential acute and long-term risks that may be caused by residues in food, including:

- The WHO GEMS risk model.
- Country specific data models.
- Cumulative risk models.

Risk is calculated using maximum residue levels (MRLs) generated by residue studies under 'worst case' application scenarios. The data generated is then compared to the ADI (acceptable daily intake for long term risk) and ARfD (acute reference dose for acute risk) generated by toxicological studies. The results will confirm risk levels of everything a person consumes during their lifetime.

## ENVIRONMENTAL RISK

Taking into account application methods, surroundings and weather patterns, environmental risk assessment and modelling answers questions including:

- What happens to any PPP that lands on the soil or surrounding areas?
- Is it safe for birds and mammals?
- If it rains, does the PPP remain on/absorbed by plants?

Surface and ground water contamination risk is calculated using FOCUS or country specific models. These methods require physico-chemical, environmental fate degradation and sorption data, as well as metabolism scheme detail, and information on worst case application scenarios. PEC values for water, in conjunction with end-point data from ecotoxicological studies, are used to produce Toxicity Exposure Ratios (TER) for the prediction of potential risk to non-target aquatic species.

Finally, the potential impact to flora and fauna in or around a treated field must be assessed. Application method is the key factor. Will exposure be direct, or indirect?

Indirect: The main risk is contamination of potential food sources via the soil or water supply.

Direct: The potential for ingestion of PPP granules that are mistaken for grit, baits or seeds.

To further refine risk assessments relating to non-target organisms, a risk envelope approach may be used. This considers all possible methods of exposure to a given species at the same time, allowing a risk assessment to reflect many different factors.

## SGS SUPPORT SERVICES

Our regulatory team has extensive experience of all kinds of risk/hazard determinations, the expertise to determine the issues, assess any impact and offer solutions (further studies, risk mitigation measures, risk refinement based on published data, or the preparation of position papers).

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