General guidance on bridging of pesticide risk assessments

Version 4 (17.11.2018)

1. Introduction

What is bridging?

The FAO Pesticide Registration Toolkit refers to bridging when an existing risk assessment conducted by a reputable body (generally a pesticide registration authority or an international organization) is reviewed and then compared to a local situation; subsequently, a conclusion is drawn about the risk in the local situation.

The existing risk assessment is referred to as the "reference assessment", which is "bridged" to the conditions of use in a second country or region, the "local situation".

Bridging does not require a full-fledged assessment of toxicity data and detailed local exposure estimations. Rather, it makes optimal use of work conducted by reputable evaluators elsewhere (often with more resources). But bridging does require good knowledge of the principles and procedures of risk assessment, to be able to interpret the reference risk assessment and assess its relevance to the local situation under review.

In some cases, a bridging assessment provides clear, unequivocal conclusions about the risk of a pesticide in a local situation and no further local assessments are needed. In other cases, conclusions are less clear, but the bridging assessment can focus the local risk assessment on specific issues of concern and as a result still facilitate the overall risk assessment. Sometimes bridging will not be possible; e.g. if the pesticide product deviates too much from the reference product or the exposure conditions between the two situations cannot be compared.

Why bridging?

Conducting human health or environmental risk assessments of a pesticide requires considerable resources from a pesticide registration authority. Appropriate toxicological and environmental data need to be available; local estimates of exposure have to be made, either through an appropriate model or with other means; and staff needs to be trained in conducting the risk assessment and its interpretation. Such resources and tools may not always be available at the registration authority.

On the other hand, pesticide registration authorities or other reputable institutions with more resources may already have conducted risk assessments of the same pesticide. It could well be possible to use an existing assessment conducted elsewhere to draw conclusions about the risks of the pesticide in another country. In other words, it may not be necessary to "reinvent the wheel".

Bridging of risk assessments is therefore one of several approaches for rationalizing the use of limited resources at the pesticide registration authority (see the Registration Strategies module)

The general principles and procedures of bridging are described in this guidance document.

2. Principles of bridging a risk assessment

Comparing hazard and risk

The International Code of Conduct on Pesticide Management defines the **hazard** as the *inherent property of a pesticide having the potential to cause undesirable consequences (e.g. properties that can cause adverse effects or damage to health, the environment or property)*.

The **risk** of a pesticide is defined as the *probability and severity of an adverse health or environmental effect occurring as a function of a hazard and the likelihood and the extent of exposure to a pesticide*, where **exposure** is the concentration or amount of a pesticide that reaches a target organism.

So in a risk assessment, we need to evaluate the hazard (e.g. toxicity) of a pesticide and the level of exposure. Data on hazard will determine the acceptable exposure level of humans or non-target organisms in the environment; the exposure assessment will show whether this acceptable level will be exceeded or not (Figure 1).

The same principle is applicable both to the assessment of risks to human health as well as to the environment.

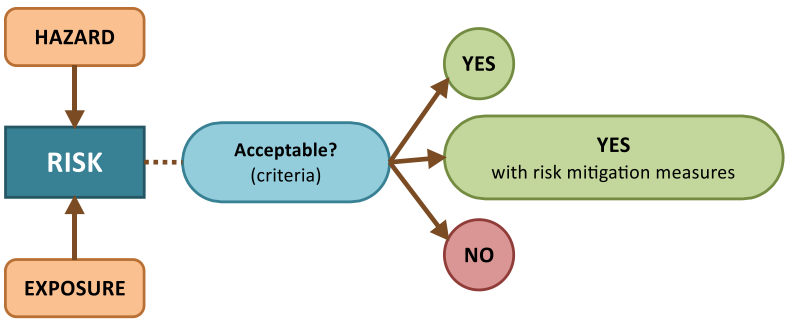

Figure 1. Principles of risk assessment

The basis of bridging is that we compare an existing risk assessment (the reference risk assessment) with – generally – an application for (re-)registration of the same or a similar pesticide in another country (the local situation under review).

Requirements for bridging

To be able to apply bridging, the reference risk assessment should provide a description of the hazard of the pesticide, the evaluated exposure level(s) and the resulting risk. It should also include a conclusion regarding the acceptability of that risk in the reference country (see section 3, step 2).

Bridging can be conducted if the pesticide active ingredient (a.i.) in the reference assessment is the same or similar to the one in the local situation. Ideally, the active ingredients are identical, i.e. manufactured by the same company through the same manufacturing process. However, active ingredients that are equivalent or otherwise substantially similar can also be bridged (see section 3, step 4).

Bridging is easier if the type and composition pesticide formulations are similar, but products with different a.i. concentrations in the formulated product or which have different formulation types can often also be bridged (see section 3, step 4).

It may be more obvious to conduct bridging if the exposure conditions and exposure levels in the local situation are similar to the reference assessment. However, this is not imperative and in many cases bridging is also possible if exposure is quite different (see section 3, step 6).

Outcome of a bridging assessment

Bridging is essentially a comparative risk evaluation method. **The outcome of a bridging assessment indicates whether the local risk is likely to be lower, similar or higher than in the reference situation.** If the institution that conducted the reference assessment also drew a conclusion about the acceptability of the evaluated risk, bridging can often lead to a conclusion about the risk in the local situation.

In some cases, however, no firm conclusion can be drawn about risk in the local situation. Bridging is then not feasible and the registration authority will need to conduct a different type of risk assessment. This is further described in section 3, steps 8 and 9.

3. Process of bridging a risk assessment

Depending on the type of risk that needs to be evaluated (e.g. occupational, dietary, aquatic, pollinators), the assessment process is slightly different. Nonetheless, most bridging risk assessments generally follow the steps described below. More details about specific bridging assessments are provided in the Toolkit, in the Assessment Methods module.

Bridging of a risk assessment generally observes the following steps (Figure 2):

Prepare

1. Compile the data for the local case under review
2. Find a reference risk assessment
3. Make a case description

Compare

4. Compare the pesticide products
5. Compare the hazards
6. Compare the exposures
7. Compare the risk mitigation measures

Conclude

8. Decide whether bridging is possible
9. Judge whether the risk in the local situation is similar, lower or higher than in the reference assessment
10. Decide whether the risk in the local situation can be considered acceptable

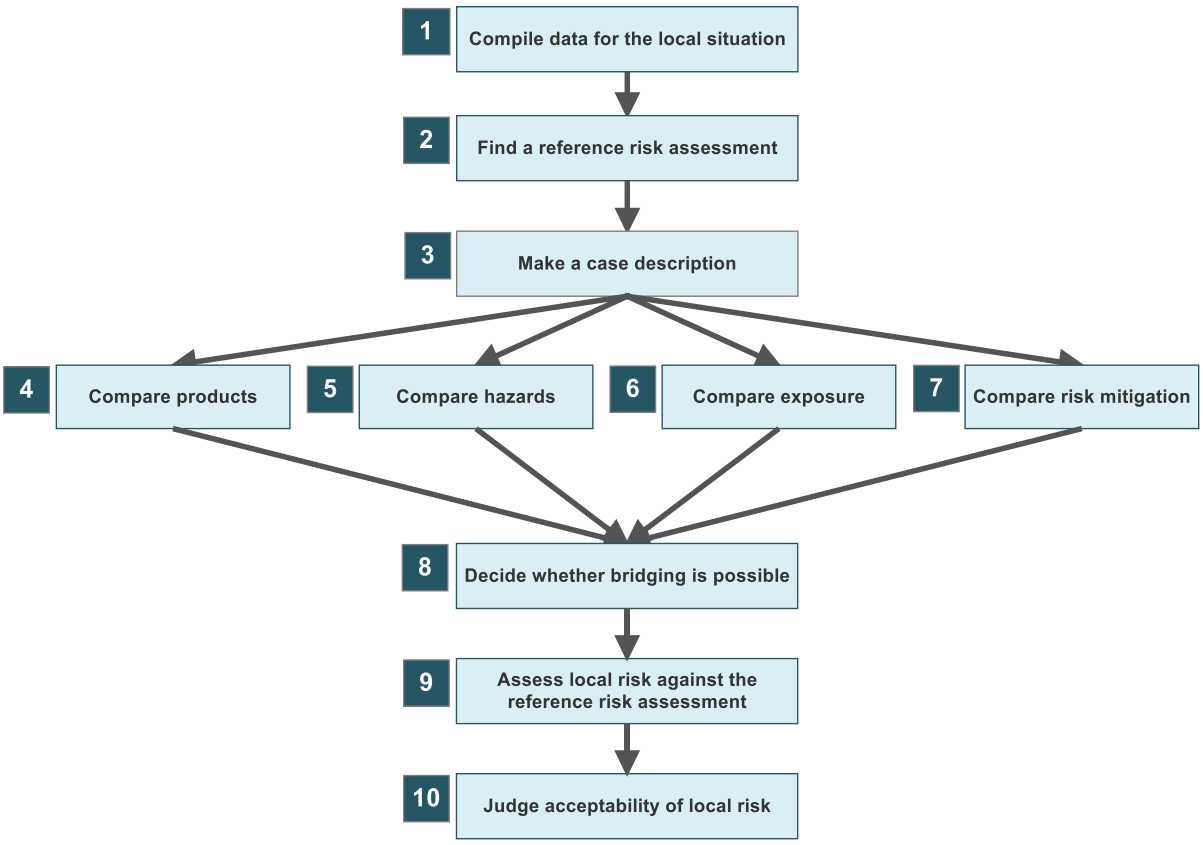

Figure 2. Schematic process of bridging a risk assessment

Step 1. Compile data for the local case under review

The key information that is needed for the local situation under review depends of the specific risk that needs to be assessed (e.g. it will be different for bridging an operator risk assessment from bridging a pollinator risk assessment). The Toolkit provides Assessment Summary Tables, which list the key data needed for bridging a specific risk (see Annex 1 for an example).

As a minimum, the following data should be available:

- **Product chemistry data**, i.e. the manufacturing specification of the active ingredient and the composition of the formulation. Of particular importance are the identity and concentration of toxicologically relevant impurities in the active ingredients(s) and of co-formulants which trigger a hazard classification.
- **The Good Agricultural Practices table** (or Table of Intended Uses), in particular the proposed crops, application methods, rates and frequencies, timing of treatments (e.g. crop stages) and proposed pre-harvest intervals (or withholding periods).

Pesticide registration dossiers compiled according to international standards will generally contain all the product information needed to conduct a bridging assessment.

In addition, the registration authority needs to have a good understanding of the **local conditions of use of the pesticide**. This includes common application equipment, availability and use of PPE, level of training/knowledge of the pesticide users, and – if environmental risks are bridged – environmental conditions when the pesticide is applied (e.g. temperature, rainfall, likelihood that surface waters may be exposed, soil types, topography, sensitive flora and fauna).

This second set of data is not included in a pesticide registration dossier. Registration authorities will either have in-house expertise that can provide such information, or will need to consult experts in local research institutions, farmer organizations, etc.

Step 2. Find a reference risk assessment

Finding one or more appropriate reference risk assessments is an important step in the bridging process. Which risk assessment can be a reference for the local situation depends very much on the type of risk being evaluated. An appropriate reference to bridge a dietary risk assessment may be a country with similar diets; an appropriate reference to bridge an occupational risk assessment may have been conducted in yet another country. So there is usually not a single country or regulatory authority that can be selected as a reference. Some general guidance for the selection of a reference risk assessment:

- The reference risk assessment should have been conducted by an institution which you trust to conduct valid evaluations.
- The reference risk assessment should be accessible, i.e. published by the evaluating institution or authority. The Toolkit provides, in the Scientific Reviews module, links to reputable regulators and other institutions that publish their risk assessments.

  Alternatively, you may have a peer-to-peer agreement with the registration authority in the reference country so they will make available their evaluations directly to you.
- The pesticide evaluated in the reference country concerns the same active ingredient and the same or a similar formulation (but see step 4).

- If the reference situation concerns similar agronomic and environmental conditions as in the local situation, bridging is often easier to do. However, this is not a mandatory requirement (see step 6). It is important, though, that the agronomic and environmental conditions applicable to the reference assessment are well described so they can be compared with the local situation.
- The reference risk assessment report includes the details of the models and scenarios used for the risk assessment, as well as the pesticide application parameters, so that these can be compared with the local situation. The reference risk assessment should also contain basic chemical specifications of the pesticide product that was evaluated.

Step 3. Make a case description

To facilitate the comparison between the local situation and the reference assessment, it is very helpful to summarize each of the key parameters regarding the pesticide product, the hazard and exposure in a structured manner.

The Assessment Summary Tables provided in the Toolkit for the various bridging assessments are intended to organize the bridging information in an easy way. Each table lists the key data needed for bridging a specific risk, as recommended by technical working groups that assist in the development of the Toolkit (see Annex 1 for an example).

If important data are missing, the authority or institution that has published the reference assessment can be contacted at this stage to provide additional information. Similarly, local specialized institutions may be able to complement the data for the local situation.

Step 4. Compare the pesticide products

Bridging can only be done for pesticide products which contain the same active ingredient (a.i.) in the reference assessment and in the local situation; such a.i.'s have the **same common name and/or CAS number,** and have the same isomer ratio where relevant.

Pesticide products are then compared according to three parameters:

i. The similarity of the active ingredient, including its impurities

ii. The concentration of the active ingredient and any relevant impurities

iii. The type and composition of the formulation

i. Active ingredient and its impurities

Ideally, the active ingredients are identical, i.e. manufactured by the same company through the same manufacturing process, as this will normally ensure that the relevant impurities (i.e. impurities of toxicological relevance) are the same. As a result, the hazards of the two active ingredients will be the same.

Alternatively, the active ingredients can also be equivalent, which means that the relevant impurities (and associated hazards) will not differ significantly.

Finally, if the active ingredients have not been shown to be equivalent, but there is sufficient information to justify that the hazard of the a.i. is not significantly different for the local product than for the reference product, bridging can still be conducted.

ii. Active ingredient concentration

If the concentrations of the active ingredient(s) in the two products that are bridged are the same, bridging is facilitated.

However, it should be emphasized that in many cases, the concentration of the a.i. in the formulation does not significantly affect risk (e.g. for dietary risk, surface water risks, soil organisms or pollinators, it is the application rate that is a key risk factor, not the pesticide concentration in the product).

In some cases, the a.i. concentration in the product may be important for bridging; e.g. for operator risk assessment, when mixing and loading is done using the concentrated product. If this is the case, acceptable variations in the a.i. concentration are indicated in Table 1. If differences in a.i. are within the ranges of Table 1, the hazard of the product is not expected to be significantly affected.

Table 1. Indicative acceptable variations in hazardous constituents of a pesticide product

Variation in the concentration of hazardous constituents of a pesticide formulation (i.e. the active ingredient and hazardous co-formulants) which are considered to not significantly affect the hazard of that formulation.

Concentration range (C) of the hazardous constituent	Acceptable variation in concentration
$C \leq 0.5$ %	± 100 %
$0.5 < C \leq 1.0$ %	± 50 %
$1.0 < C \leq 2.5$ %	± 30 %
$2.5 < C \leq 10$ %	± 20 %
$10 < C \leq 25$ %	± 10 %
$25 < C \leq 100$ %	± 5 %

Sources: EU (2008) & EC (2012)

Relevant impurities in the active ingredient should always be below the maximum limits set in manufacturing specifications, both for the local and the reference product. International pesticide specifications are published by FAO & WHO.

iii. Formulation type and composition

Many differences in formulation type have limited or no influence on the risk of the product. This will need to be assessed on a case by case basis, depending on the specific risk being evaluated.

The following formulation types can generally be considered similar for bridging a risk assessment:

- Dietary risk assessment: formulation types which are diluted in water prior to application including EC, WP, WG, SC, SL. Experience demonstrates that these formulations lead to similar residues.
- Occupational and bystander risks: i) all solid formulations applied as a spray; ii) all liquid formulations applied as a spray; iii.) formulations applied as granules.
- Environmental risk assessment: i) all formulations applied as sprays; ii) formulations applied as granules; iii) formulations for seed treatments

Other cases exist where different formulations can be bridged without a likely significant effect on the risk.

Care has to be taken when different formulation types clearly may pose different risks, in particular when low risk formulations are used in the reference country (e.g. microencapsulated products, water-soluble bags) but more conventional but higher risk formulations in the local situation.

Even though formulation types may be similar, the formulation composition may still contain different co-formulants. Generally, co-formulants are considered confidential business information, and are not publicly specified, except when they are hazardous (i.e. co-formulants that trigger a hazard classification). Therefore, the product evaluated for the local situation should not contain new hazardous co-formulants when compared to the reference product. Furthermore, when the same co-formulants are found in the local and reference products, differences in concentrations should not exceed the limits of Table 1.

Step 5. Compare the hazards

The hazard or toxicity of the product evaluated in the reference assessment is reviewed to decide whether it can be considered similar to the one under review in the local situation.

Human health risk assessments are generally based on **toxicological reference values** such as the Acceptable Daily Intake (ADI) and Acute Reference Dose (ARfD) for dietary risks, and the Acceptable Operator Exposure Level (AOEL) for operator and worker risk assessments. If exposure exceeds the reference value, the associated risk is considered unacceptable. Generally, these reference values are globally applicable, facilitating bridging. However, in some cases it is useful to review how the toxicological reference value used in the reference assessment has been established and whether this is applicable to the local situation. This is further explained in the Toolkit for the relevant bridging methods.

For environmental risk assessment, a variety of ecotoxicological reference values is used, based on data from one or more non-target species (e.g. Regulatory Acceptable Concentration (RAC), Maximum Acceptable Concentration (MAC), Level of Concern (LOC)). These reference values may be based on different ecotoxicological endpoints (e.g. LD_{50}, EC_{10}, NOEC) and specific assessment or safety factors.

Since ecosystems can be very different around the world, it is important to evaluate whether the ecotoxicological data and resulting ecotoxicological reference values used in the reference assessment are applicable to the local situation. It should be stressed that the main question is not whether the ecosystems and/or non-target organisms are sufficiently similar (they often

will not be). Instead, it should be assessed whether the toxicological data and safety factors used in the reference assessment are likely to provide sufficient protection to the local ecosystem or non-target organisms that may be affected by the pesticide.

Comparing environmental hazards between a reference and a local situation can be challenging. Nonetheless, it is important to note that the standard first tier ecotoxicity data, associated with the assessment/safety factor applied in many industrialized countries, tends to provide protection to a relatively large range of organisms.

Step 6. Compare the exposures

Comparing exposure levels is often the most important step in a bridging exercise. The exposure parameters used in the reference risk assessment should be compared to the expected exposure in the local situation. Almost always, exposures will be (very) different, both for human health and for environmental assessments. However, there is no need for exposure conditions to be identical or even similar; it is only important to assess whether exposure in the local situation is lower, similar or higher than in the reference assessment.

Exposure in the reference assessment will often be defined by the model and scenario(s) that were used to estimate exposure levels. It is therefore important that details of the model and scenario(s) are provided in the reference risk assessment report. Exposure in the local situation should be based on the expected conditions of use. These are partly defined in the Good Agricultural Practice (GAP) Table (or the Table of Intended Uses) in the registration dossier; and they partly depend on knowledge by the registration authority about the local pesticide use practices as well as agronomic and environmental conditions.

Key parameters that determine exposure, both for human and environmental risks, include the crop, the application rate and frequency of the pesticide, the mode of application and the type of equipment. Additional key factors for human health risk assessments are for instance the personal protective equipment (PPE) used by the farmer or the diet of the consumer. Additional factors that may influence exposure of the environment include weather conditions, use of unsprayed buffer zones, behaviour of non-target organisms, etc.

Key exposure parameters differ for the various risks that can be bridged; they are listed in the respective Assessment Summary Tables in the Assessment Methods module of the Toolkit (see Annex 1, for an example).

Step 7. Compare risk mitigation measures

Whether or not a pesticide poses a risk to human health or the environment is partly determined by the risk mitigation measures taken. Many risk mitigation measures are intended to reduce exposure. For instance, a pesticide may be applied with acceptable risk when the user wears PPE but not when he/she is unprotected.

It is therefore important to identify whether or not risk mitigation measures were included in the reference risk assessment and if so, to assess if these can realistically be applied in the local situation.

The Risk Mitigation module in the Toolkit provides information on a large range of risk mitigation measures as well as about conditions for their effective implementation.

Step 8. Decide whether bridging is possible

Based on the assessments in steps 4 to 7, the registration authority should decide whether bridging is possible. The exact parameters that need to be taken into account will differ depending on the type of risk that needs to be bridged.

Basically, the question that needs to be answered is whether any differences between the local and reference situation observed for the pesticide product, its hazard, exposure and risk mitigation measures rules out a comparison of risks.

This may, for instance, be case if the active ingredients have significantly different impurity profiles; or if key non-target species in the local situation are very different from the ones covered by the reference situation and it is not clear whether they are protected by the reference risk assessment; or if exposure parameters are not sufficiently described in the reference assessment and thus cannot be compared to the local situation.

In some cases, part of the reference risk assessment can be used for bridging (e.g. the hazard) but another part cannot (e.g. the exposure estimate). The latter then will need further assessment to be able to validly conduct step 9.

Step 9. Assess whether the risk in the local situation is similar, lower or higher than in the reference assessment

When product, hazard, exposure and risk mitigation have been compared between the reference and the local situation, an assessment can be made about the risk of the pesticide in the local situation, based on a weight-of-evidence approach. Part of the assessment will be quantitative (e.g. when comparing application rates), but part of it will be semi-quantitative or qualitative (e.g. when comparing types of PPE used). The outcome of the assessment is a judgement whether the risk in the local situation is likely to be lower, similar or higher than in the reference assessment. Table 2 provides a schematic set of outcomes.

Table 2. Bridging of a pesticide risk assessment – comparing hazard and exposure

Hazard and exposure in the local situation are compared to a reference risk assessment. The table shows the resulting risk in the local situation which can be higher, similar or lower than in the reference risk assessment. In some cases, the resulting risk will be unclear and require further assessment.

		Exposure in local situation when compared to the reference risk assessment		
		Higher	***Similar***	***Lower***
Hazard in local situation when compared to the reference risk assessment	***Higher***	Risk higher in the local situation	Risk higher in the local situation	Risk in local situation unclear
	Similar	Risk higher in the local situation	Risk similar in the local situation	Risk lower in the local situation
	Lower	Risk in local situation unclear	Risk lower in the local situation	Risk lower in the local situation

In some cases, the magnitude of risk in the reference situation is very low, as the predicted exposure is much lower than the acceptable level (e.g. very low exposure toxicity ratio). For such low-risk products or situations a very precise risk estimate in the local situation may not be needed as it is likely that the risk in the local situation will be acceptable too.

Often, it will not be possible to draw a clear conclusion about the risk in the local situation based on bridging. This happens either when the differences in hazard and exposure do not lead to an unequivocal conclusion about risk (see Table 2), or when too many data needed for bridging are unavailable to the registrar. In such cases, risk assessment can be refined using additional local information.

Bridging of a risk assessment is generally a semi-quantitative exercise and it is the pesticide registration authority that in the end will have to provide an expert opinion on the risk of the pesticide in the local situation. As this may be ambiguous, it is important that the assessment and the reasoning that led to the conclusion are well documented by the authority so that it can be revisited when new information becomes available.

Step 10. Judge whether the risk in the local situation can be considered acceptable

Finally, after an assessment is made about the risk of the pesticide in the local situation, the registration authority should judge whether or not it considers that the risk is acceptable. Similar to bridging a risk assessment, the decision about acceptability can also be bridged. This is based on the risk assessment for the local situation on the one hand, and the decision made about acceptability of the risk in the reference country on the other (Table 3).

Table 3. Bridging of a pesticide risk assessment – Decision making

The decision about the acceptability of the risk in reference risk assessment is used as basis for the local decision.

		Acceptability of the risk in the reference assessment	
		Risk acceptable	***Risk not acceptable***
Risk in the local situation when compared to the reference risk assessment	***Higher***	Acceptability of risk in local situation unclear	Risk also unacceptable in local situation
	Similar	Risk also acceptable in local situation	Risk also unacceptable in local situation
	Lower	Risk also acceptable in local situation	Acceptability of risk in local situation unclear

If the risk was considered acceptable in the reference country, and the risk in the local situation is lower or similar to the reference, then the risk in the local situation can also be considered acceptable. Similarly, if the risk in the reference country was considered unacceptable, and the risk in the local situation is similar or higher than in the reference country, the risk in the local situation is likely to be unacceptable too.

Sometimes, no clear-cut decision can be taken about the acceptability of risk in the local situation (Table 3). In such cases, further risk assessment is needed for the local situation.

Accepting a decision about the acceptability of a risk by the reference country is based on the assumption that the acceptability criteria of the reference country are applicable to the local situation. Often this has already been decided during the bridging assessment, when reviewing the (eco)toxicological reference values.

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Annex 1 – Example of an Assessment Summary Table for bridging a risk assessment, as provided in the Pesticide Registration Toolkit[1]

Assessment summary table – Bridging a honeybee risk assessment	
Product name & formulation type:	**Active ingredient name:**
	Registration file number:
Name of the assessor:	**Date of the assessment:**

Comparison of parameters that may influence honeybee exposure, between a reference risk assessment and a local situation under review

	Exposure parameter	***Possible effect on the risk of the pesticide***	**Describe/quantify the parameter for:**		**Toxicity/Exposure in local situation likely to be higher/lower/similar to the reference assessment?**
			Reference risk assessment	***Local situation under review***	
	Product				
1	Product name	--			
2	Formulation type	*Some formulations types (e.g. micro-encapsulation, sugary baits, DP, WP) ➔ higher exposure risk*			
	Ecotoxicology (only if the honeybee species are different)				
3	Acute oral LD_{50}	*Lower LD_{50} ➔ higher impact (for similar exposure levels)*			
4	Acute contact LD_{50}	*Lower LD_{50} ➔ higher impact (for similar exposure levels)*			
5	Acute oral brood LD_{50}	*Lower LD_{50} ➔ higher impact (for similar exposure levels)*			

[1] Drawn from: http://www.fao.org/pesticide-registration-toolkit/tool/page/pret/assessment/a09-03-01b-bridging-of-an-existing-risk-assessment-for-honeybees

Comparison of parameters that may influence honeybee exposure, between a reference risk assessment and a local situation under review					
Exposure parameter		***Possible effect on the risk of the pesticide***	**Describe/quantify the parameter for:**		**Toxicity/Exposure in local situation likely to be higher/lower/similar to the reference assessment?**
			Reference risk assessment	***Local situation under review***	
6	Foliar residual toxicity RT_{25}	*Higher RT_{25} ➔ higher impact (for similar exposure levels) & ➔ lower likelihood of recovery after pesticide impact*			
7	Other toxicity data *(specify)*				
	Exposure – Crop				
8	Crop(s)	*Determinant for factors below*			
9	Crop attractiveness to bees	*If crop is not attractive to bees ➔ no exposure likely (unless attractive weeds grow in the crop – see below)*			
10	Period(s) in the growing season when the pesticide is applied to the crop	*Determinant for factors below*			
11	Period(s) in the year when the crop(s) flower	*If overlap between flowering of crop and pesticide applications ➔ higher exposure risk*			
12	Period(s) when weeds are flowering in the crop which may be attractive to wild bees	*If overlap between flowering of weeds and pesticide applications ➔ higher exposure risk*			
13	Crop has extrafloral nectaries	*If extrafloral nectaries present in crop ➔ higher exposure risk*			
14	Crop is regularly infested with honeydew producing insects	*If honeydew producing insects present in crop ➔ higher exposure risk*			

Comparison of parameters that may influence honeybee exposure, between a reference risk assessment and a local situation under review				
Exposure parameter	***Possible effect on the risk of the pesticide***	**Describe/quantify the parameter for:**		**Toxicity/Exposure in local situation likely to be higher/lower/similar to the reference assessment?**
		Reference risk assessment	***Local situation under review***	
Exposure – Pesticide application				
15 Mode of application	*Some modes of application (e.g. dusting, aerial application, drilling treated seed that produces dust) ➔ higher exposure risk* *Some modes of application (e.g. seed/soil treatment with non-systemic pesticide; brushing) ➔ lower exposure risk (unless soil nesting bees)*			
16 Dose rate (g a.i./ha)	*For the same pesticide product: higher dose rate ➔ higher exposure/impact risk*			
17 Application frequency	*Higher application frequency ➔ higher exposure risk*			
18 Application interval	*Shorter interval between applications ➔ higher exposure risk*			
Overall comparison between the situation under review and the reference risk assessment:				