

Castel San Pietro Terme, 20 settembre 2014

Nuove linee guida e criteri UE per l'autorizzazione di molecole e preparati

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Regolamento EC 1107/2009

24.11.2009

EN

Official Journal of the European Union

L 309/1

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

- 3.8.3. An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:
- will result in a negligible exposure of honeybees, or
 - has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

Regolamento EC 283/2013

3.4.2013

EN

Official Journal of the European Union

L 93/1

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 283/2013

of 1 March 2013

setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market

(Text with EEA relevance)

Modificazione dei dati richiesti per la registrazione al fine di considerare le attuali conoscenze tecnologiche e scientifiche.

Regolamento EC 283/2013

8.3. **Effect on arthropods**

8.3.1. *Effects on bees*

Effects on bees shall be assessed and the risk evaluated, including the risk deriving from residues of the active substance or its metabolites in nectar, pollen and water, including guttation. Reports of the tests referred to in points 8.3.1.1, 8.3.1.2 and 8.3.1.3 shall be submitted, except where plant protection products containing the active substance are for exclusive use in situations where bees are not likely to be exposed such as:

- (a) food storage in enclosed spaces;
- (b) non-systemic preparations for application to soil, except granules;
- (c) non-systemic dipping treatments for transplanted crops and bulbs;
- (d) wound sealing and healing treatments;
- (e) non systemic rodenticidal baits;
- (f) use in greenhouses without bees as pollinators.

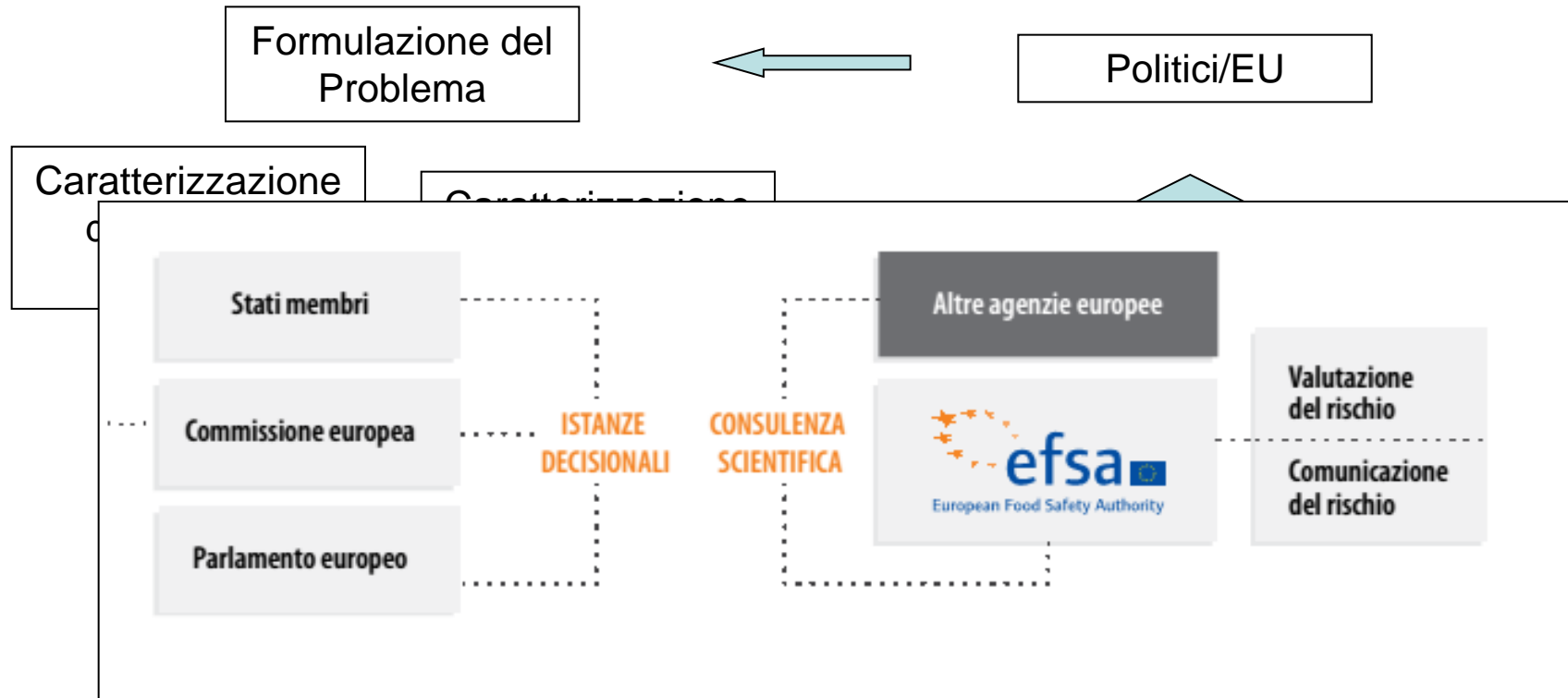
Rischio vs Pericolo

La probabilità che accada un certo evento capace di causare un danno

Proprietà intrinseca di un determinato fattore di provocare danni

$$\textit{Rischio} = \frac{\textit{Esposizione}}{\textit{Tossicità}}$$

Valutazione del rischio vs Gestione del rischio



Molte attività umane presentano dei potenziali pericoli, ciò che conta è il rischio a cui si è disposti a correre al netto dei benefici

Linee guida EPPO

$$HQ = \frac{\text{Dosedicampo}(g * ha)}{LD50(ug / ape)}$$

<50

Rischio basso

>50

Rischio potenziale,
necessario effettuare
ulteriori test

European and Mediterranean Plant Protection Organization
Organisation Européenne et Méditerranéenne pour la Protection des Plantes

PP 3/10 (3)

Environmental risk assessment scheme for plant protection products
Système pour l'évaluation du risque des produits phytosanitaires pour l'environnement

Chapter 10: honeybees

Specific scope¹

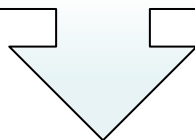
This standard provides an assessment of the risks presented by plant protection products to honeybees. It was revised to include the risk presented by systemic plant protection products.

Specific approval and amendment

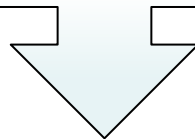
First approved in 1992-09.
Edited as an EPPO Standard in 1998.
Revised in 2002-09 and 2010-09 (updated with ICPBR recommendations).

Un pò di storia...

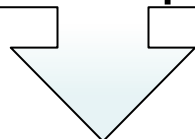
- Declino degli impollinatori, apicidi, CCD
- Nuove vie di esposizione (polvere, guttazioni)
- Dubbi sui neonicotinoidi



Necessità di riconsiderare l'attuale schema di valutazione del rischio che non sempre richiede la valutazione della tossicità cronica e sulle larve

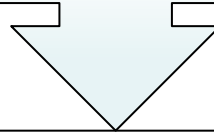


L'EFSA nel 2011 ha ricevuto il mandato dalla Commissione Europea

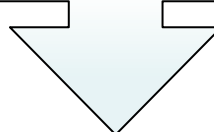


Un pò di storia...

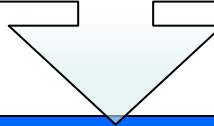
Creazione di un WG di esperti europei in apidologia ed esperti in esposizione ai pesticidi (Settembre 2011)



EFSA Opinion on the science behind...
...pubblicato in April 2012



EFSA guidance documento
(2013)



EFSA Opinion: inadeguatezza delle attuali procedure di valutazione del rischio sulle api per i prodotti sistemici

- Incompleta stima degli effetti sugli adulti (solo tossicità acuta);
- Scarsa valutazione degli effetti sulle larve (solo per gli IGR);
- Limitata valutazione dell'esposizione ai pesticidi (solo acuta orale e per contatto);
- Prove di campo inappropriate (potenza statistica, riproducibilità, interpretazione);
- Assenza di valutazione del rischio sulle altre specie di apoidei (nel mondo esistono oltre 16.000 specie di api);

SCIENTIFIC OPINION

Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)¹

EFSA Panel on Plant Protection Products and their

Residues (PPR)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The PPR Panel was asked to deliver a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). Specific protection goals options were suggested based on the ecosystem services approach. The different routes of exposure were analysed in detail for different categories of bees. The existing test guidelines were evaluated and suggestions for improvement and further research needs were listed. A simple prioritisation tool to assess cumulative effects of single pesticides using mortality data is suggested. Effects from repeated and simultaneous exposure and synergism are discussed. Proposals for separate risk assessment schemes, one for honey bees and one for bumble bees and solitary bees, were developed.

© European Food Safety Authority, 2012

KEY WORDS

Guidance Document, PPR opinion, honey bees, bumble bees, solitary bees, pesticide, risk assessment

¹ On request from the European Commission, Question No EFSA-Q-2011 00417, adopted on 18 April 2012.

² Panel members: Jos Boesten, Claudia Bolognesi, Theo Brock, Ettore Capri, Anthony Hardy, Andrew Hart, Karen Hirsch-Ernst, Susanne Hougaard Bennekou, Robert Luttik, Michael Klein, Kyriaki Machera, Bernadette Ossendorp, Annette Petersen, Yolanda Pico, Andreas Schäffer, Paulo Sousa, Walter Steurbaut, Anita Stromberg, Maria Tasheva, Ton van der Linden, Christiane Vleminckx. Correspondence: pesticides.ppr@efsa.europa.eu

³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Bee Risk Assessment (Robert Luttik, Gérard Arnold, Jos Boesten, James Cresswell, Andrew Hart, Jens Pistorius, Fabio Sgolastra, Noa Simon Delse, Walter Steurbaut, Helen Thompson) for the preparatory work on this scientific opinion, the hearing expert (Anne Alix) and EFSA staff (Franz Streissl, Domenica Auteri, Jean-Lou Dorne, Agnès Rortais, Klaus Swarowsky, Csaba Szentes) for the support provided to this scientific opinion.

Suggested citation: EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2012; 10(5) 2668. [275 pp.] doi:10.2903/j.efsa.2012.2668. Available online: www.efsa.europa.eu/efsajournal

Publicato a giugno 2013
Aggiornato a giugno 2014
Entrata in vigore 2015 (?)

GUIDANCE OF EFSA

EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The Guidance Document is intended to provide guidance for notifiers and authorities in the context of the review of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009. The scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA Panel on Plant Protection Products and their Residues (PPR), 2012a) provided the scientific basis for the development of the Guidance Document. Specific Protection Goals were agreed in consultation with the Standing Committee on the Food Chain and Animal Health. The Guidance Document suggests a tiered risk assessment scheme with a simple and cost-effective first tier to more complex higher tier studies under field conditions. Each of the tiers will have to ensure that the appropriate level of protection is achieved.

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KEY WORDS

Honey bees, risk assessment, Guidance Document, pesticides, *Apis mellifera*, *Bombus*, solitary bees

¹ On request from European Commission, Question No EFSA-Q-2011-00418, approved on 27 June 2013.

² Correspondence: pesticides.ppr@efsa.europa.eu

³ Acknowledgement: EFSA wishes to thank the members of the working group: Gérard Arnold, Jos Boesten, Mark Clook, Robert Luttk, Fabio Sgolastra, Jacoba Wassenberg and the hearing expert Jens Pistorius for the preparatory work on this scientific output and EFSA staff: Franz Streissl, Maria Arena, Csaba Szentes, Agnès Rortais and Olaf Mosbach-Schulz for their support.

Suggested citation: European Food Safety Authority, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp., doi:10.2903/j.efsa.2013.3295

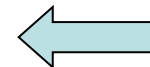
Available online: www.efsa.europa.eu/efsajournal

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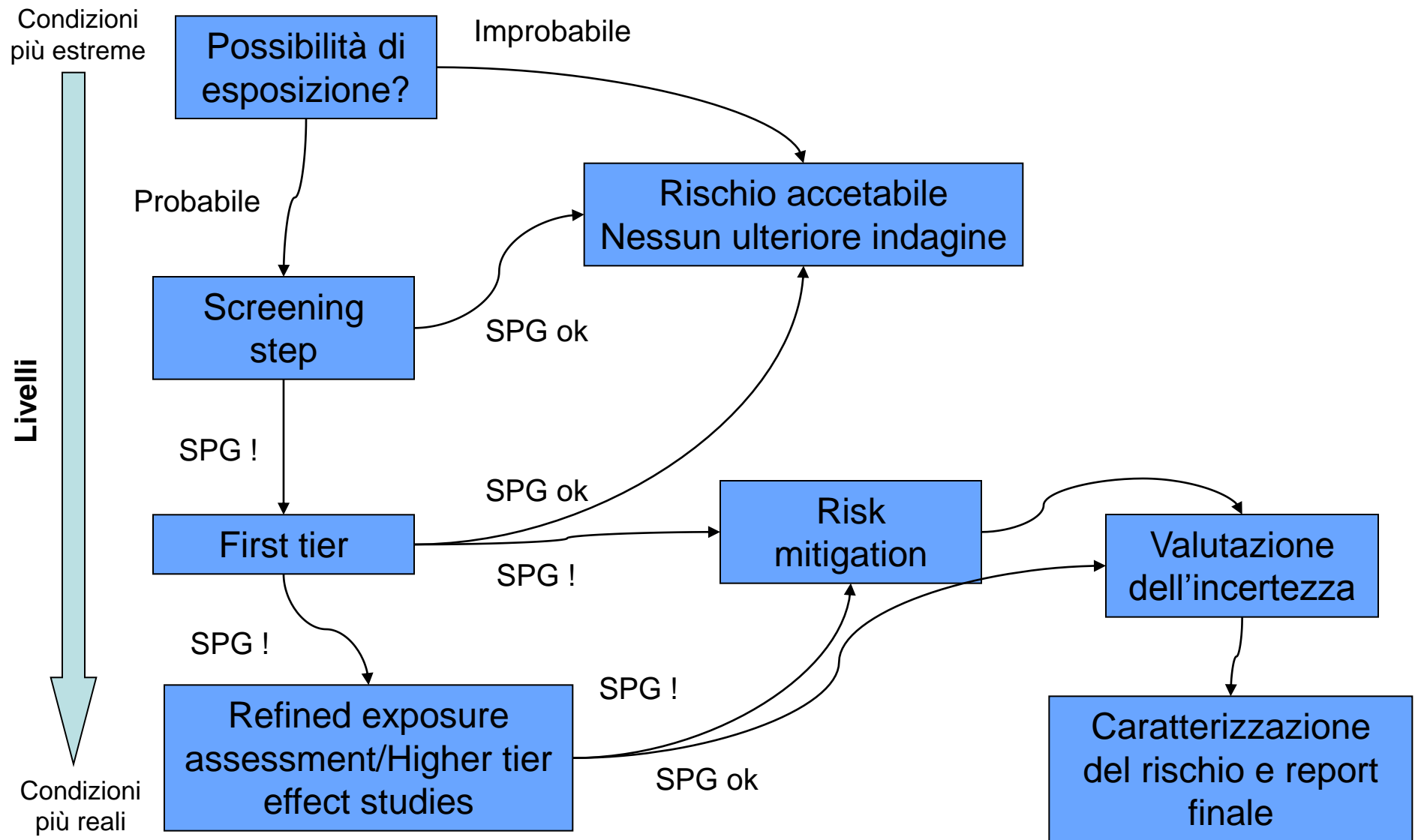
Specific Protection goals (SPG)

Gli schemi di valutazione del rischio e gli indici di rischio (trigger values) ad essi associati, devono assicurare un livello di protezione per cui il livello di esposizione ai pesticidi non deve eccedere un valore che produrrebbe un effetto maggiore del trascurabile (7%) nel 90% dei casi in cui si impiega il prodotto come ad esempio nei campi trattati (con alveari posizionati al margine)

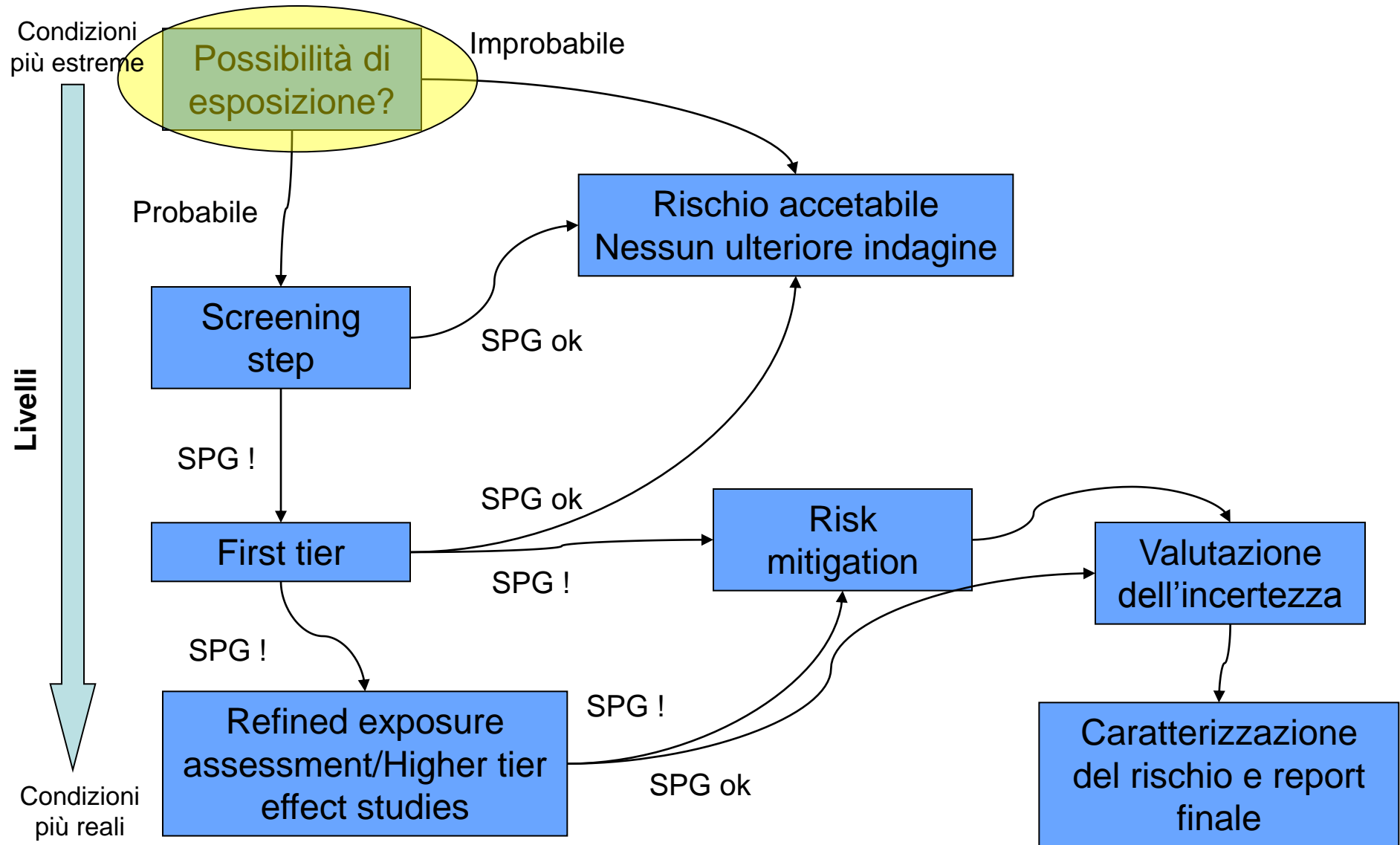
Effetto	% riduzione in forza famiglia
Grande	>35
Medio	Da 15 a 35
Piccolo	Da 7 a 15
Trascurabile	da 3,5 a 7



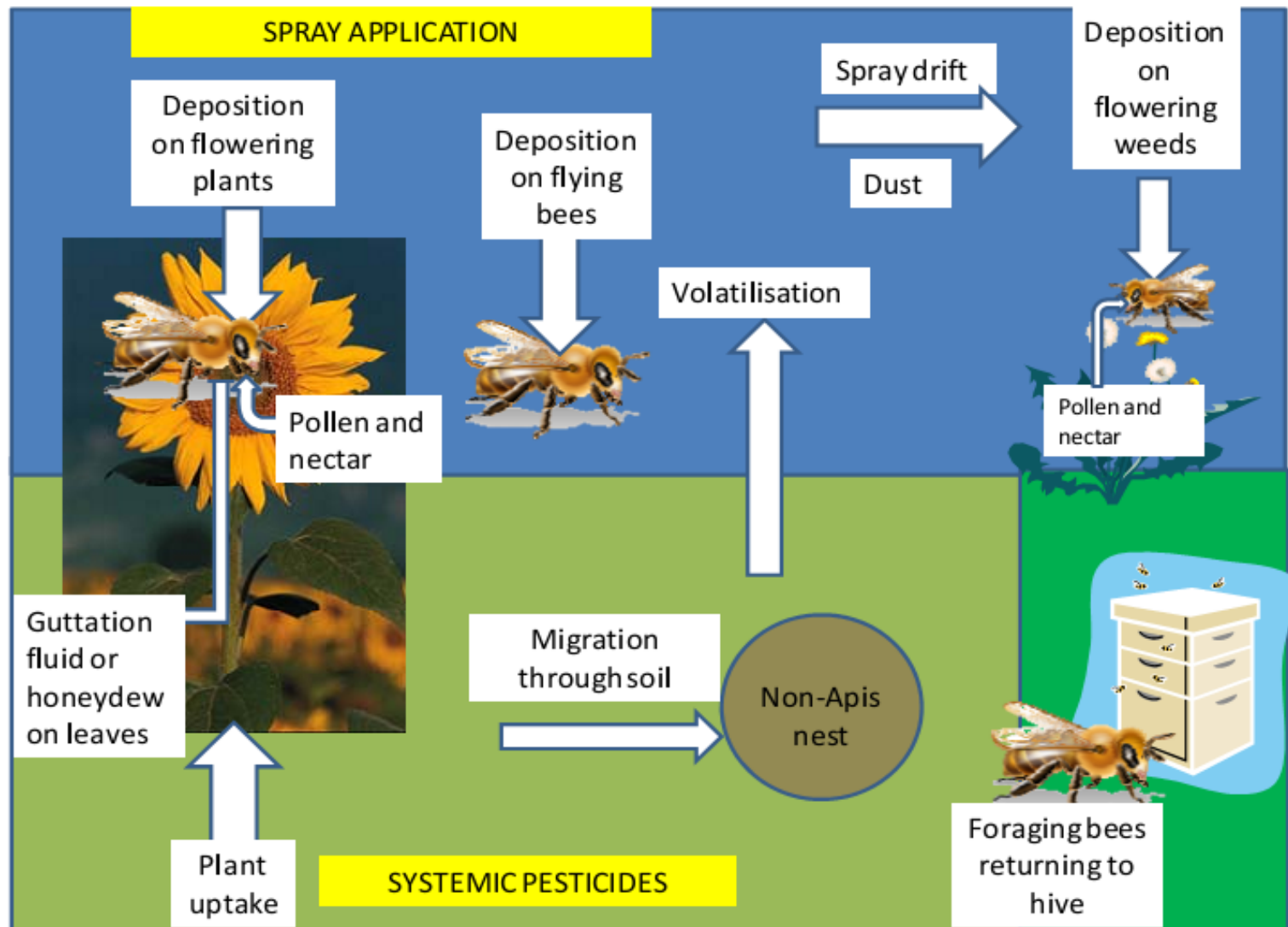
Risk Assessment schemes



Risk Assessment schemes



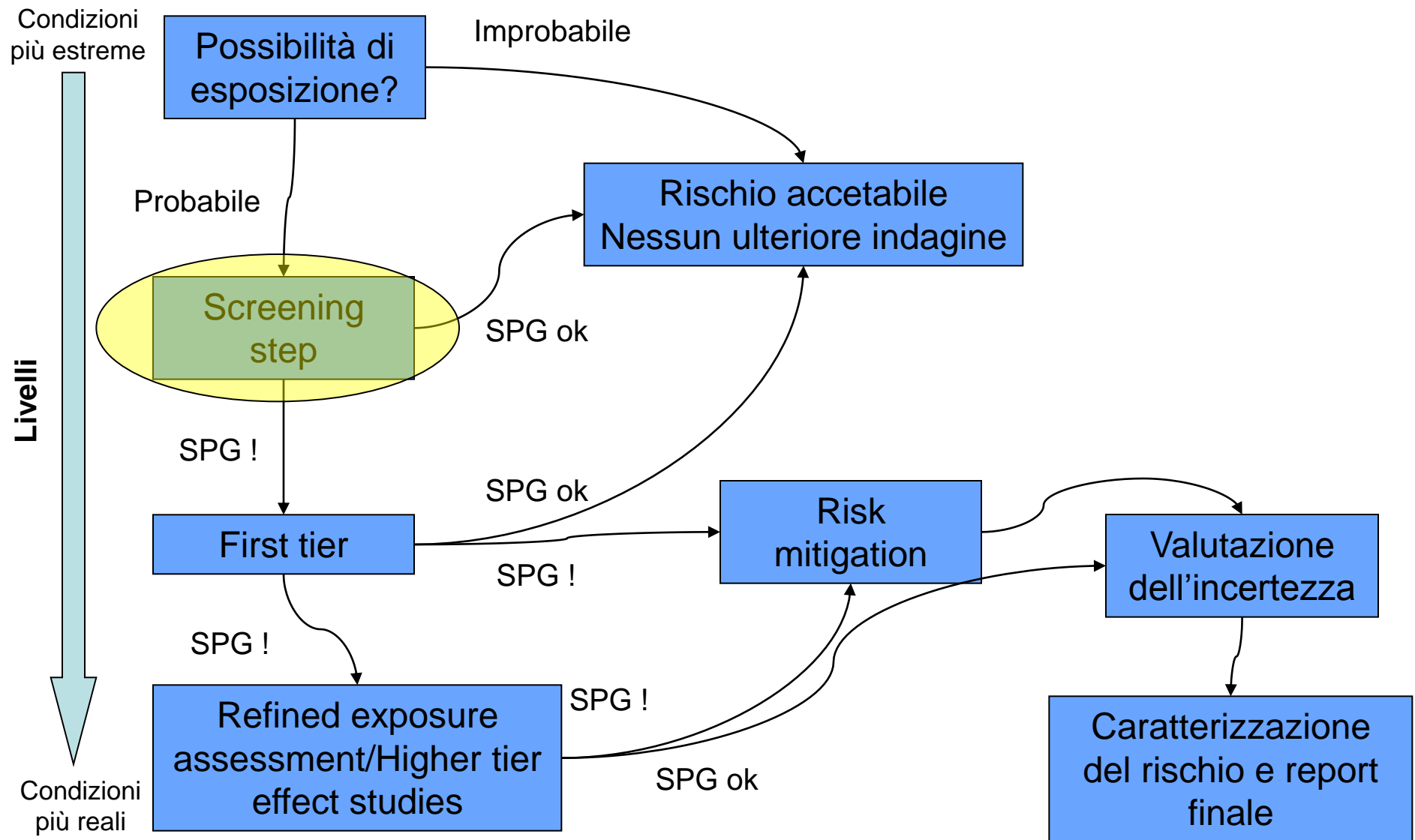
L'esposizione ai pesticidi per le api



Vie di esposizione

- ✓ Esposizione per contatto (spray o polvere) su:
 - coltura trattata;
 - coticco erboso;
 - margine del campo;
 - colture adiacenti;
 - ✓ Consumo di polline e nettare su:
 - coltura trattata;
 - coticco erboso;
 - margine del campo;
 - colture adiacenti;
 - colture successive/colture permanenti nell'anno successivo;
 - ✓ Valutazione del rischio da tossicità cumulativa (3);
 - ✓ Consumo di acqua contaminata su:
 - Valutazione del rischio da acqua di guttazione (4);
 - Valutazione del rischio da acque superficiali (5);
 - Valutazione del rischio da acqua di pozzanghera (6);
 - ✓ Rischio da metaboliti presenti nel polline e nel nettare (7)
- Valutazione del rischio di applicazioni spray (1) e trattamenti del seme e granulari (2)
- Valutazione del rischio di applicazioni spray (1) e trattamenti del seme e granulari (2)

Risk Assessment schemes



Worst case: scenario con max esposizione possibile

Screening step – dati richiesti

- ✓ Tossicità acuta per contatto, espressa in $\mu\text{g}/\text{ape}$ (DL50);
- ✓ Tossicità acuta per ingestione, espressa in $\mu\text{g}/\text{ape}$ (DL50);
- ✓ Tossicità orale cronica (incluso gli effetti sullo sviluppo delle ghiandole ipofaringee (HPGs)), espressa in $\mu\text{g}/\text{ape}$ per giorno (CL50 in 10-giorni e NOEL per HPGs);
- ✓ Considerazioni sui potenziali effetti cumulativi;
- ✓ Tossicità orale cronica sulle larve, espressa in $\mu\text{g}/\text{larva}$ per durata dello sviluppo (NOEL);

Test su
Adulti

Test su
larve

Screening step – dati richiesti

TEST RICHIESTI PER

1. Ape domestica (*Apis mellifera*);



2. Bombi (*Bombus terrestris*);

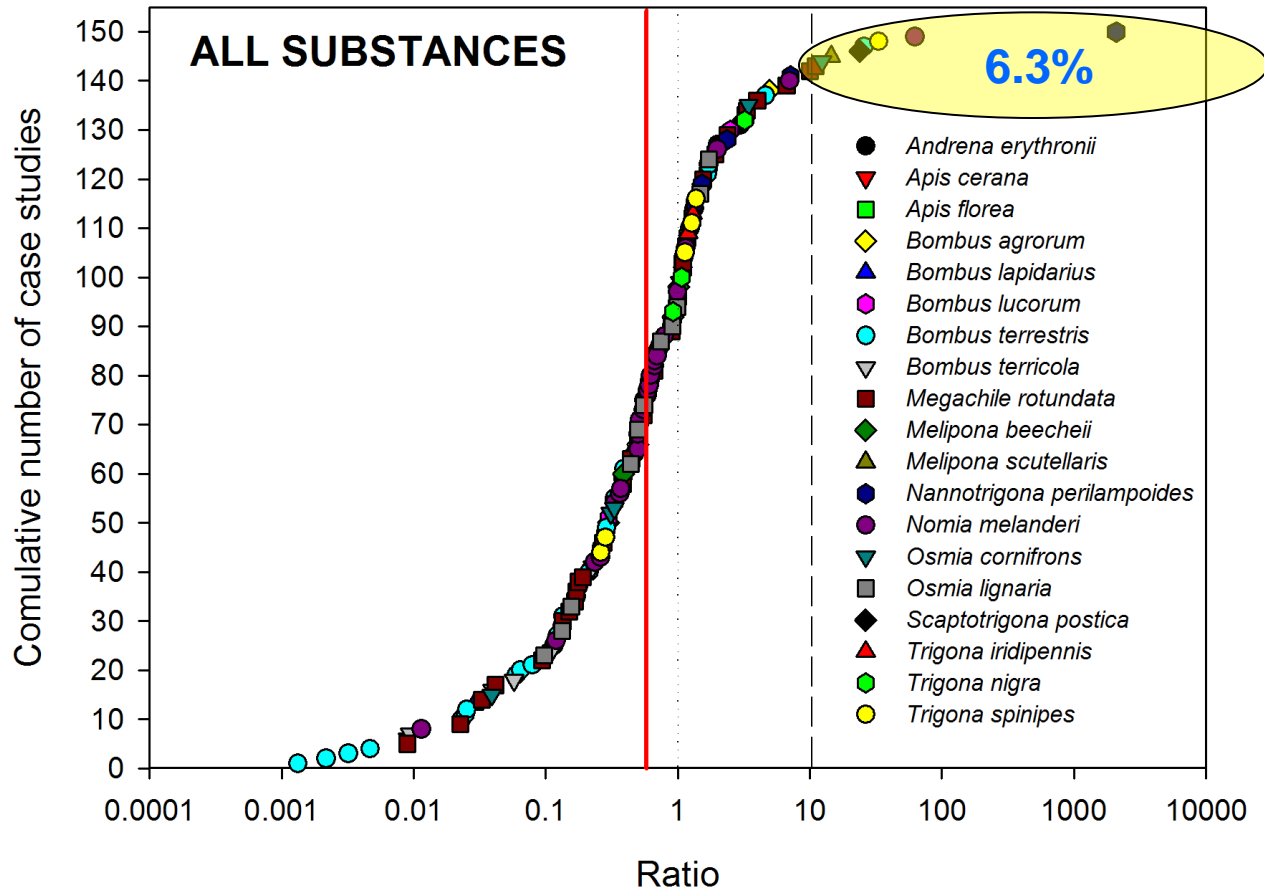


3. Api solitarie (*Osmia cornuta* o *Osmia rufa*)



Gli apoidei

Fattore di sicurezza 10 da aggiungere alla DL50 quando la specie *Apis mellifera* viene usata come surrogato



Arena and Sgolastra (2014). *Ecotoxicology*



Equazioni generali

Le equazioni generali sono:

- esposizione per contatto:

$$HQ = AR \times \boxed{\phantom{f_{dep}}} \cdot D50$$

- esposizione per ingestione:

$$ETR = AR \times Ef \cdot \boxed{\phantom{f_{dep}}} \times tw \cdot \boxed{} \cdot 50 \text{ (or NOEL)}$$

dove:

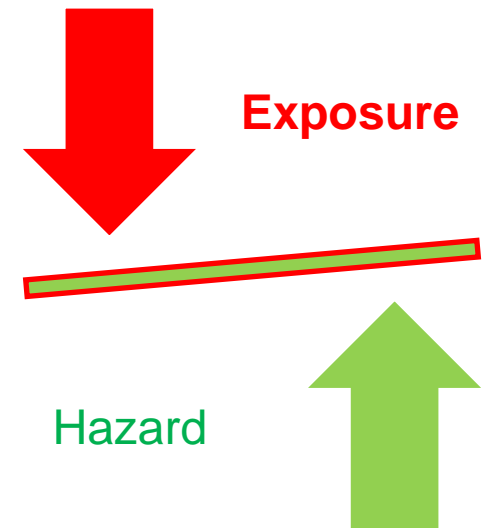
AR = application rate

f_{dep} = deposition factor

Ef = exposure factor

SV = shortcut value

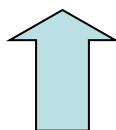
twa = time weighted average



Screening step – Esposizione contatto - Spray

Lo screening step è basato sull'esposizione nel campo trattato

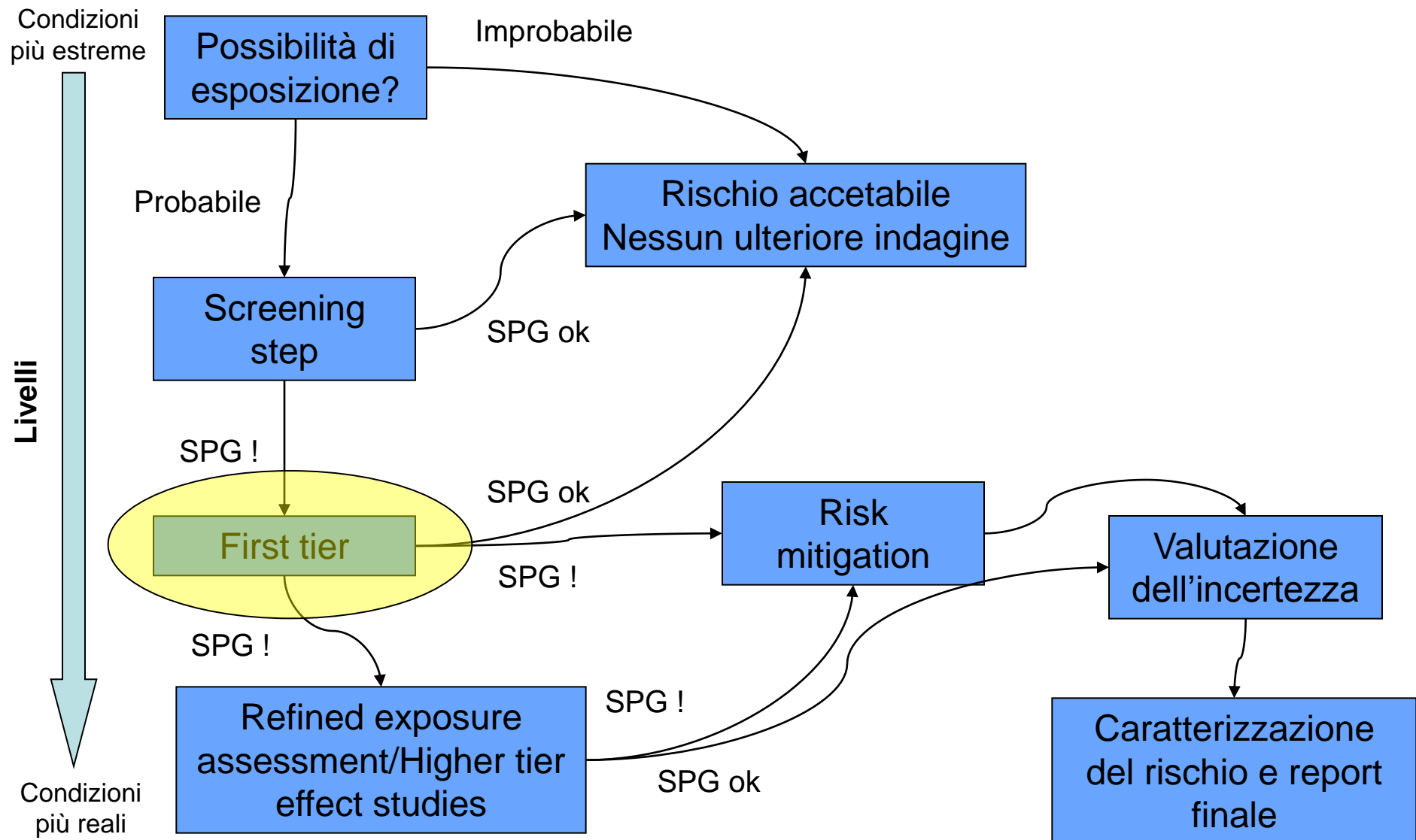
Type of assessment	Type of bee	Formula screening step assessment	Formula refined assessment	Endpoint	Application rate AR	Trigger values ²
Acute contact exposure adult bees	Honey bee	HQcontact = AR/LD ₅₀ contact	HQcontact = $f_{dep} / 100 * AR / LD_{50}$ contact	Acute contact LD ₅₀ μg a.s./bee ¹	g a.s./ha	HQ (DW) > 42
	Bumble bee					HQ (SUW) > 85
	Solitary bee					HQ (DW) > 7
						HQ (SUW) > 14
						HQ (DW) > 8
						HQ (SUW) > 16



Screening step – Esposizione ingestione polline e nettare - Spray

Type of assessment	Type of bee	Formula	Endpoint	Application rate AR	Shortcut value SV		Trigger values ²
					Down-ward	Side-ward	
Acute oral exposure adult bees	Honey bee	ETR _{acute adult oral} = AR * SV/LD _{50oral}	Acute oral LD ₅₀ µg a.s./bee ¹	kg a.s./ha	7.6	10.6	ETR > 0.2
	Bumble bee				11.2	13.3	ETR > 0.036
	Solitary bee				5.7	7.3	ETR > 0.04
Chronic oral exposure adult bees	Honey bee	ETR _{chronic adult oral} = AR * SV/10 d LDD ₅₀	Chronic oral 10 d LDD ₅₀ ^{3, 1} µg a.s./bee per day	kg a.s./ha	7.6	10.6	ETR > 0.03
	Bumble bee				11.2	13.3	ETR > 0.0048
	Solitary bee				5.7	7.3	ETR > 0.0054
Chronic oral exposure larvae	Honey bee	ETRLarvae = AR * SV/NOELlarvae	NOELlarvae ¹ µg a.s./larvae per developmental period	kg a.s./ha	4.4	6.1	ETR > 0.2
	Bumble bee	ETRLarvae ⁴ = AR * SV * 10/NOELlarvae			4.5	2.6	ETR > 0.2
	Solitary bee	ETRLarvae = AR * SV/NOELlarvae			33.6	30.8	ETR > 0.2
Sublethal Development of hypopharyngeal glands	Honey bee (nurse)	ETRhpg = AR * SV/NOELhpg	NOELhpg µg a.s./bee per day	kg a.s./ha	7.6	10.6	ETR > 1

Risk Assessment schemes



Scenari con diversi livelli di esposizione

1° tier – Esposizione contatto - Spray

Nel 1° tier è possibile limitare l'esposizione considerando alcune misure di mitigazione

Type of assessment	Type of bee	Formula screening step	Formula refined	Endpoint	Application	Trigger values ²		
Acute contact exposure adult bees	Spray applications (spray drift)	Crop	Default deposition (f_{dep} in %) to be used for Contact exposure assessment in Field margins			λ (DW) >		
						λ (SUW) 5		
						Field crops	2.8	
						Orchard – early stage	29.2	λ (DW) >
						Orchard – late stage	15.7	λ (SUW) 4
						Grapevine – early stage	2.7	
						Grapevine – late stage	8.0	λ (DW) >
Hops	19.3	λ (SUW)						
						16		

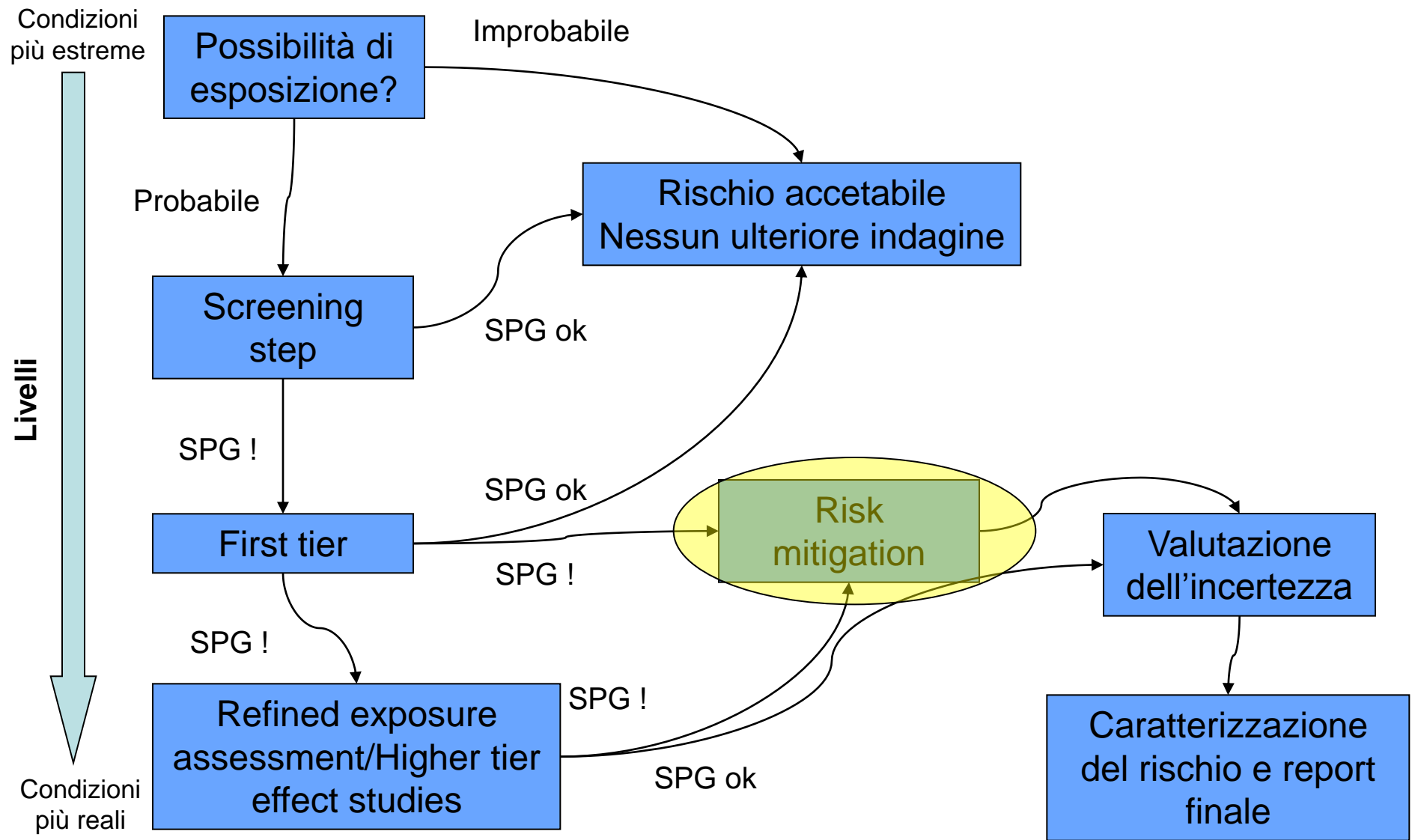


1° tier – Esposizione ingestione polline e nettare - Spray

Nel 1° tier è possibile limitare l'esposizione considerando alcune misure di mitigazione

Type of assessment	Type of bee	Formula	Endpoint	Application rate AR	twa	Trigger values ²
Acute oral exposure adult bees	Honey bee	ETR _{act} = AR * factor	Scenario Exposure (-) factor	kg a.s./ha	-	ETR > 0.2
	Bumble bee				-	ETR > 0.036
	Solitary bee				-	ETR > 0.04
Chronic oral exposure adult bees	Honey bee	ETR _{chl} AR * E	Weeds in the field f_{dep} Take the relevant deposition factor (f_{dep}) value from table X2a below.	kg a.s./ha	0.72	ETR > 0.03
	Bumble bee				0.72	ETR > 0.0048
	Solitary bee				0.72	ETR > 0.0054
Chronic oral exposure larvae	Honey bee	ETR _{lar} = AR * factor	Plants at the field margin Field crops: 0.0092 Orchard – early stage: 0.097 Orchard – late stage: 0.052 Grapevine – early stage: 0.009 Grapevine – late stage: 0.027 Hops: 0.064	kg a.s./ha	0.85	ETR > 0.2
	Bumble bee				1	ETR > 0.2
	Solitary bee				1	ETR > 0.2
Sublethal Development of hypopharyngeal glands	Honey bee (nurse)	ETR _{hp} = AR * factor	Adjacent crop Field crops: 0.0033 Orchard – early stage: 0.066 Orchard – late stage: 0.031 Grapevine – early stage: 0.0047 Grapevine – late stage: 0.0143 Hops: 0.041	kg a.s./ha	0.72	ETR > 1

Risk Assessment schemes



Azioni di mitigazione del rischio

Fraasi rilevanti (**SPe8**) dell'allegato V del **1999/45/EC** (rilevanti anche nel **1107/2009/EC**)

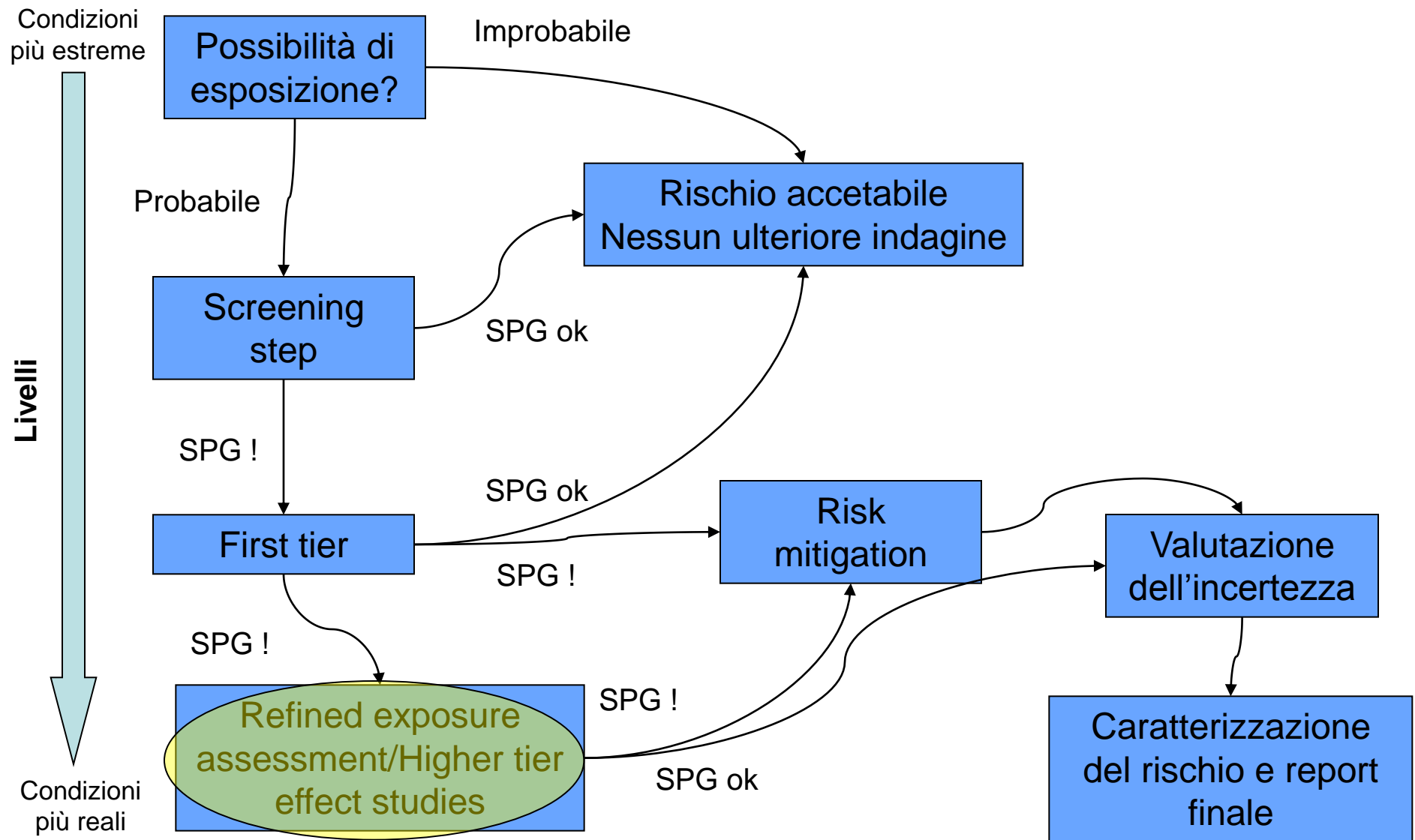
Dangerous to bees./To protect bees and other pollinating insects do not apply on flowering crops./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./Do not apply when flowering weeds are present./Remove weeds before flowering./Do not apply before (state time).

!Praticabilità e visibilità!

Ulteriori fraasi di mitigazione del rischio che considerano tutti i possibili scenari di esposizione:

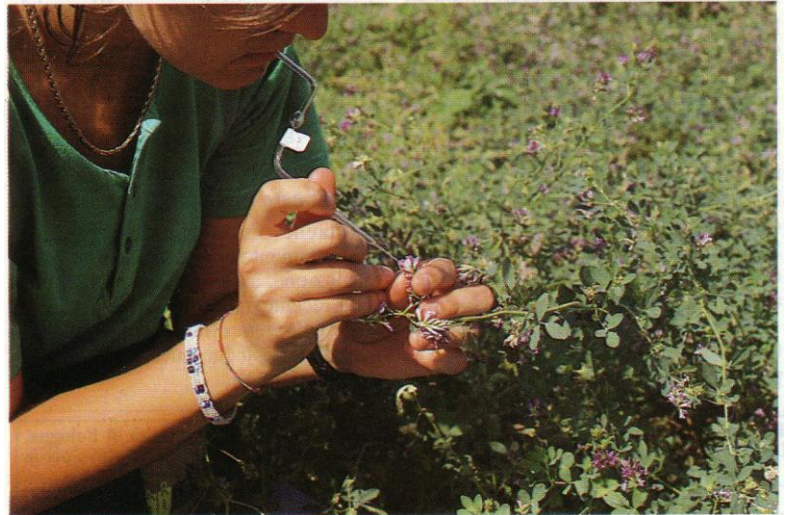
- ✓ *Restrict the use of the preparation to vineyards/orchards with grass ground covers or bare soil;*
- ✓ *Dangerous to bees. To protect bees and other pollinating insects, [specific risk mitigation measure, e.g. 90% drift reducing spray nozzles, a buffer zone of x m,...] must be used;*
- ✓ *Do not apply when field margins are flowering;*
- ✓ *Do not apply when the adjacent crops are flowering;*
- ✓ *Due to the risk to bees, bee-attractive crops should not be sown or planted within a period of [x] after [application/sowing/planting in the field];*
- ✓ *Treated seed should have a maximum dust level of [e.g. 0.75] g dust per [e.g. 100 000 seeds] (Heubach method);*
- ✓ *Before sowing: do not transfer dust from bag into sowing machine;*
- ✓ *During sowing: only drill seed when the wind speed is less than 12 km/hr;*
- ✓ *When using a pneumatic sowing machine, deflectors must lead the air stream towards or into the ground [or other recommendations relevant from the specific crop/sowing machine];*
- ✓ *Do not apply when the field margins are flowering*

Risk Assessment schemes



Higher tier risk assessment - Approfondire il livello di esposizione

- Refine residue levels with measurements of pollen/nectar
- Refine twa factor with residue decline data (consult FOCUS, 2006)
- Refine nectar sugar content with field measurements
- Refine pollen consumption with laboratory/field measurements
- Refine dustiness of solid formulations (Heubach a.i.)
- Refine dust/spray deposition with field measurements
- Refine PECs for succeeding crops by pore water model
- Conduct exposure field studies (for contact exposure)
- Refine spray/dust drift with stochastic model
- Analyse coverage of weeds in the field
- Analyse coverage of attractive adjacent crops
- Analyse coverage of attractive succeeding crops



Higher tier risk assessment—Studi sugli effetti in campo/semicampo

Assessment endpoints

There are two sets of assessment endpoints for field studies and these are as follows:

- **Primary assessment endpoints:** forager mortality, colony strength (number of bees), over-wintering success
- **Secondary assessment endpoints:** behavioural effects—including behaviour of foragers on flowers and returning to the colony, behaviour of guard bees at the colony entrance.

The primary assessment endpoints link directly to the SPGs outlined in [chapter 2](#).

METODOLOGIA

- ✓ Scelta della coltura e dimensioni del campo trattato;
- ✓ Numero di alveari e di siti (adeguato per analisi statistica);
- ✓ Durata dello studio (2 cicli covata + mortalità invernale);
- ✓ Determinazione dell'esposizione (quantificata);
- ✓ Determinazione degli effetti (forza famiglia, mortalità delle bottinatrici (RFID), altri comportamenti anomali)

Casi studio con il Bee Tool: Spirotetramat

Crop and/or situation (a)	Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of a.s. (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	Interval between appl. (min)	kg a.s./hL min-max	water L/ha min-max	kg a.s./ha min-max		
Citrus all types	EU-S	Movento® 150 OD	F	scales, aphids, mealy bugs, mites	OD	150 g/L	spray	BBCH 78 at last application, first application not earlier than mid of May	2	21	0.0096	1000 L/ha and m CH*, max 3000 L/ha	0.096 kg a.s./ha and m CH*, max 0.288 kg a.s./ha (3 metres)	14	representative use for the EU-evaluation
Lettuce head and leafy	EU-N EU-S	Movento® 150 OD	F	aphids	OD	150 g/L	spray	BBCH 48 at last application	max 2	14	0.0072 - 0.0144	500-1000	0.072	7	representative use for the EU-evaluation
Lettuce, head and leafy	EU-N EU-S	Movento® 150 OD	G	aphids	OD	150 g/L	spray	BBCH 48 at last application	max 2	14	0.0072 - 0.0144	500-1000	0.072	7	representative use for the EU-evaluation

Test substance	Acute oral toxicity (LD ₅₀ µg a.s./bee)	Acute contact toxicity (LD ₅₀ µg a.s./bee)
a.s. ‡	> 107.3	> 100
Preparation Spirotetramat OD150	91.7	162

Casi studio con il Bee Tool: Imidacloprid

LD50 acute contact adult HB: 0.081 µg/bee;

LD50 acute oral adult HB: 0.0037 µg/bee;

LD50 acute contact adult BB: 0.014 µg/bee;

LD50 acute oral adult BB: 0.014 µg/bee;

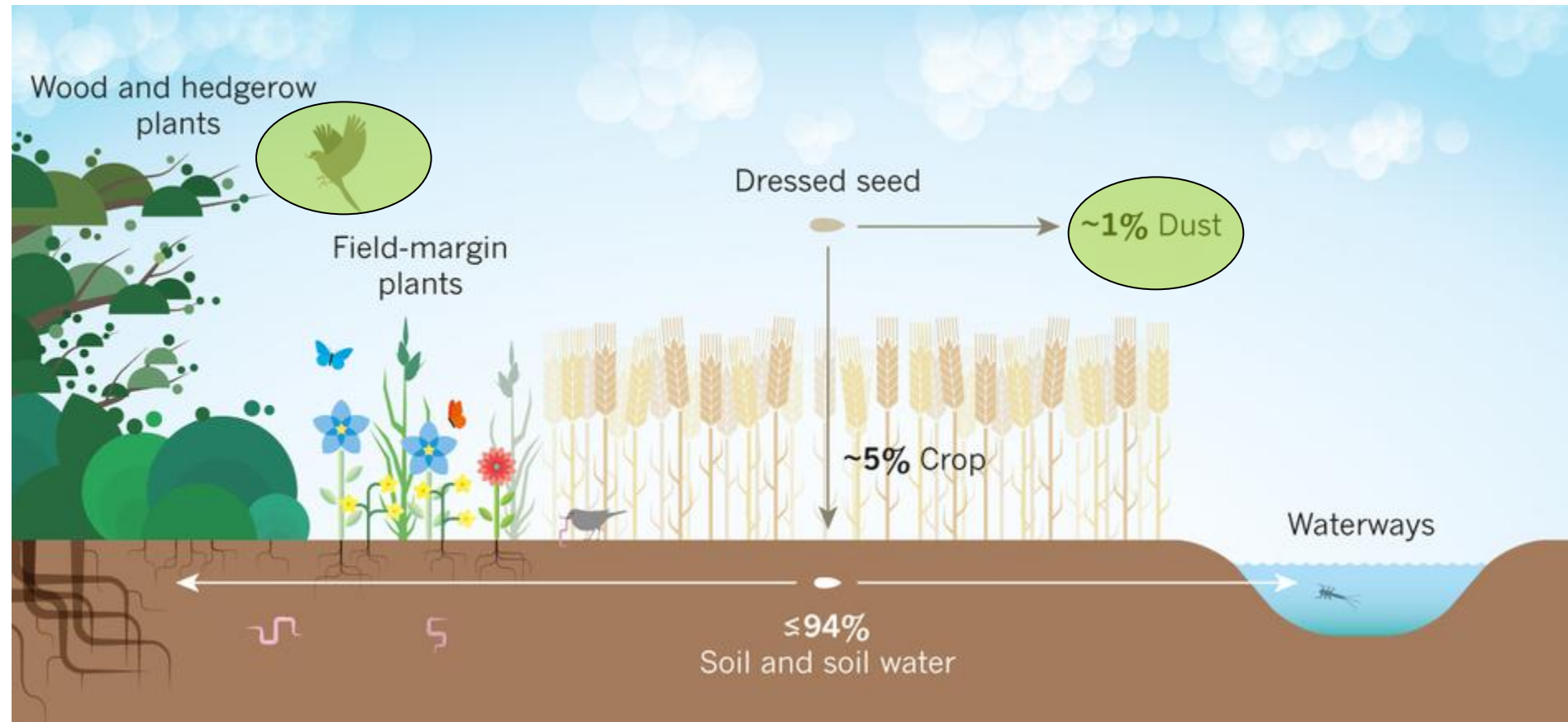
LD50 acute contact adult SB: 3.82 µg/bee (per *Osmia cornifrons*);

LD50 acute oral adult SB: -;

Seed treatment – maize

Application rate: 54-268 g a.s./ha, 0.5 mg/seed

Il caso dei neonicotinoidi



Goulson (2014). *Nature*

Hallmann et al. (2014). *Nature*

Conclusioni

- ✓ Necessità di un approccio olistico che tenga conto di tutti i fattori di rischio per le api e gli effetti a cascade su tutto l'ecosistema;
- ✓ Imparare dagli errori del passato;
- ✓ Importanza di aggiornare tempestivamente la regolamentazione del rischio ambientale al verificarsi di gravi incidenti

Grazie per l'attenzione