PAN UK comments for Prof. Ian Boyd on Defra statement *Neonicotinoid insecticides and bees: the state of the science and the regulatory response*, 13th September 2012

Key points

- PAN UK strongly disagrees with the ACP conclusion that "current risk assessments are secure". We cannot understand how ACP, CRD and Defra have reached this conclusion when they also recognise the many shortcomings of the risk assessment protocols for understanding fully the risks from low dose, regular exposure of pollinators to contaminated pollen and nectar from crops grown from neonicotinoid-treated seed.
- The many scientific uncertainties about chronic, sub-lethal and colony-level effects, the 'blind spots' in current trials for regulatory assessment surely underline the need for a more precautionary approach.
- There are widely differing regulatory positions among EU member states, reflecting the uncertainties. How have CRD and Defra reached a different conclusion about the need for immediate restrictions on use (e.g. thiamethoxam on oil seed rape seed) from their counterparts in France, based on the same data?
- Issues of poor transparency and lack of independent scrutiny of data submitted by manufacturers and the criteria used to judge what is an 'acceptable' risk need to be addressed in this highly contested topic.
- Given the scientific uncertainties and the methodological difficulties in studying impacts on pollinators, PAN UK recommends a broader and more inclusive evaluation process, including stakeholder oversight of the new studies commissioned by Defra.
- Defra, the Pesticides Forum and the farming sector should take a much more proactive approach to looking at current levels of dependency on neonicotinoids, the actual, rather than perceived, need for treatment as 'insurance' and ways to promote more effective and comprehensive Integrated Pest Management (IPM). PAN UK has outlined a concept note for a pilot scoping study to explore what a British oilseed rape IPM strategy without neonicotinoids might look like.

Detailed comments

Page 1 (2) Re existing studies submitted in support of regulatory approvals
We have serious concerns about the methodological shortcomings of these studies (as does EFSA in its Opinion), but we're also concerned about issues of transparency and decision making in such an uncertain and contested topic- are the full study design, methods and statistical analysis used in manufacturers' studies in the public domain? i.e are they available

for independent scrutiny? Or is it merely a summary in the Rapporteur Member State's Draft Assessment Report (DAR)? We think that all concerned stakeholders must be able to see and critique study methods, results and the criteria used by decision makers to interpret the studies' data and conclusions.

Page 1 Conclusions about regulatory studies not showing any gross effects in hives exposed to treated versus untreated crops

(See also fuller ACP comments in Annex 4) Given the limitations in these studies, as recognised by the ACP, how does CRD/Defra justify reaching this conclusion? And what does 'no gross effects' mean? It sounds like the studies showed some effects- so what criteria and judgements were used to qualify these as unimportant or acceptable?

Page 1 Defra conclusions about updating risk assessment process

These paragraphs do read as slightly contradicting the statements above. If current regulatory studies are deemed adequate to reach the 'no gross effects' conclusion, then why has EFSA recommended what in effect constitutes a pretty radical overhaul of the risk assessment process?

Wording about taking forward the updated risk assessment by end 2012 is rather misleading to the general public- it gives the impression that action is imminent, but the updated risk assessment protocols won't come into play for the currently approved neonic products until they individually come up for periodic review (2016-2020?). We would argue this is far too late, given the serious shortcomings now recognised in the risk assessment protocols for understanding the chronic exposure and sublethal effects issues for pollinators from crops grown with treated seed.

p.2 Defra position that existing regulations don't require changing.

The French regulatory authorities clearly took a different view, when they decided to suspend approval of thiamethoxam for oilseed rape seed treatment in June, following the publication of the Henry *et al*. and Whitehorn *et al*. studies. Can you explain why Defra, CRD and the UK government have taken a different view from their French, Italian, and to some extent also their German, counterparts? If these differing views reflect the scientific uncertainty about neonic impacts, then surely this justifies a more precautionary approach?

It's hard not to feel that UK authorities are being over complacent or too laissez-faire. In contrast, DG Sanco acknowledge there is a growing body of evidence suggesting a link between bee diseases and pesticides and the European Parliament have been much more vocal in calling for a timeframe for definitive withdrawal in the longer term of all neurotoxic pesticides. In 2011 they called for immediate review of all approved neonics once improved risk assessment protocols are ready.

p. 3 "regulated under strict EU rules" – The EFSA Opinion published in May 2012 has punctured this complacency, if the risk assessment has not been asking the right questions. It raises questions again about the accountability of the risk assessment process- who

judges the level of risk and 'acceptable' to whom? The expert committees set up under the auspices of the International Committee of Plant-Bee Relationships (ICPBR, to whom the European Commission has delegated much of the on-going revision of the pollinator risk assessment guidelines) are hardly balanced or free of vested interests (see the PAN UK fact sheet 8 pp 2-3 on corporate influence). Nor is it just NGOs calling for more transparency and independent scrutiny- so is the European Parliament.

p.3 (10) Re CRD/FERA considerations of recent research You can't avoid some level of artificiality in study design if you want to be able to quantify dose/exposure route and make the data statistically amenable, when dealing with studies on highly complex social organisms.

Is the extensive dataset they mention on OSR seed treatment in the public domain? What were the exact criteria used for concluding an acceptable risk?

p.4 re the Whitehorn *et al.* bumblebee study- one of the reasons we're in the dark as to how far this study reflects likely field scenarios is the lack of UK data on neonic residues in pollen/nectar from treated crops. Are Defra, Fera or others now collecting this data across a range of crops/localities/seasons to get some idea of 'average' residues found?

We don't disagree with many of the CRD caveats raised over individual studies. We agree, for example, with CRD comments on the Lu *et al*. study on in-situ replication of CCD and that's why we didn't even mention it in our factsheets. However, the uncertainties raised about many studies shouldn't be used to downgrade the value of an individual study in contributing another piece to the jigsaw puzzle of pesticides/disease/pollinator health interactions (unless, of course, the study is seriously flawed). What we need is a broader, open and more participatory evaluation process to see where consensus lies on what the different studies contribute and to identify the pros and cons of each study in its design, analysis and interpretation of the results.

p.4 (11) Re CRD overall conclusions on the four well-publicised studies not warranting regulatory change Obviously we drew a different conclusion. Of course, we need more research, especially on exposure patterns in the UK context, but we mustn't let this become an excuse for avoiding or delaying tough regulatory decisions. The agrochemical industry always play the 'more research' card but we know from analyses of earlier environmental policy cases involving scientific uncertainty and high stakes, that earlier decisive action should have been taken- see the European Environment Agency's illuminating *Late Lessons from Early Warnings* report (200). EEA will be publishing this month a *Late Lessons* Volume II, which includes a chapter on the imidacloprid bees impact debate in France.

p.4 (12) Re ACP statement of "no evidence as yet of neonic impacts on bees in UK" – have any relevant field studies been conducted with appropriate methodology and adequate statistical power to uncover such evidence?! We're not aware of any, other than manufacturers' studies alone, for which the EFSA Opinion now suggests that the risk assessment protocols need to be totally overhauled. In our view the ACP may be confusing 'absence of evidence' with 'evidence of absence of impact'.

p.4 (14) ACP wording shows the limitations of regulatory field studies- so isn't their conclusion of 'no gross effects' rather ungrounded?

p.5 (17) New Defra studies - we welcome these but will the study design on residues really be able to build up a picture of hive exposure? Will it use methods similar to the well-received and very illuminating US studies (see PAN UK fact sheet 2) by Mullin *et al.* (2010) and Krupke *et al*. (2012)? Will it use purposive sampling to look at possible high exposure risk scenarios? Will it be possess sufficient statistical power to detect real differences (surely sample sizes are far too low if relying just on dead bees sent in in the handful of WIIS cases each year?)

Who is providing oversight on study design, methods, analysis and interpretation of results? We think there needs to be a broader, stakeholder oversight for this kind of taxpayer-funded study for tackling uncertainty in such controversial environmental impact debates.

Pp 8-9 We're pleased to hear that CRD does recognise the potential impact concerns raised by the results of the Henry *et al*. and Whitehorn *et al.* studies . Of course, these studies also raise questions on field relevance. Trying to answer these questions should be part of a broader and more comparative risk assessment process better fit for the 21st century set of issues posed by many newer pesticides (low dose but regular exposure/cocktails/sublethal and chronic effects).

p.13 re the Lu et al study – we agree that term CCD is not helpful and these sets of symptoms are not the same as hive and individual bee effects seen in Europe.

p.14 Re overwintering studies- we're pleased to hear that these will become part of the regulatory system from 2013 – but will they be done retrospectively for the current neonic products on the market? The wording is rather misleading here.

p.16 Re the Cresswell et al study Is this definition of 'unacceptable risk' shared by all stakeholders, including beekeepers?

We've not read this paper but from the CRD summary we're not sure that the kind of studies used allow the authors to be so categorical, e.g on Biological Gradient, based on a single paper from Belgium. We agree with CRD that for this type of causality assessment you need to understand fully how the scores were made and the conclusions reached- this is precisely the kind of open, participatory forum of a wider set of experts and lay people we need. You can never eliminate value judgements in expert assessment but you can make them clear to all and help to take the heat out of disagreements if the criteria used and assumptions made are discussed more openly.

p.20 We're glad that CRD recognises that 'cocktail' exposure is a glaring blind spot in the risk assessment process but doesn't this further tip the balance towards the need for more precaution?

p.23 re the Tapparo paper on maize coatings – it's not an issue of the German 2008 incidents, which were linked with specific problems in the coating process, addressed to some extent by the 2010 additional EC authorisation requirements. Rather, it's the drilling

'normal use' scenarios where it seems hard to effectively mitigate considerable risks even using adapted equipment to reduce release of abraded seed coat particles in the dust.

p.34 re ACP conclusions- we totally disagree with the ACP's conclusions that "current risk assessments are secure". We find it perplexing that they can make such a conclusion when they also recognise the many shortcomings in the risk assessment protocols, as raised by the EFSA Opinion.

The elephant in the room –what happens now with the current product approvals, given that the EFSA Opinion implies that the risk assessment for these now turns out to have been wholly inadequate?

But we recognise too that it's not just a regulatory issue- we need to look at how and why UK and European farmers have become so dependent on neonic seed treatments- see PAN UK fact sheets 5 and 6 on the Italian maize research and experiences showing that most, if not all of the time, these treatments are simply not needed. Hence our interest in a scoping project for British oilseed rape without neonics- what would an IPM strategy look like?

PAN UK recommendations

In terms of regulatory action, **we continue to call for a moratorium on UK approvals and uses of neonicotinoids** across agricultural, ornamentals and amateur garden sectors until these products are proven not to be causing harm to pollinators. Our 12 point set of actions needed by government and other stakeholders to address bee-toxic pesticide aspects (listed at the end of this document) describe other areas of policy and practice where we want to see action taken.

More broadly on the risk assessment process for neonicotinoid and other pesticides where the science is uncertain and contested, we need a more open and independent scrutiny of (a) regulatory studies submitted by industry and (b) studies in peer-reviewed literature.

A multi-stakeholder process to look at each study should:

- Check if it's of adequate statistical power or not
- Identify pros and cons of study design and methods, what each can and cannot tell us
- Identify roughly where it lies on spectrum of worst-average-best case in terms of field reality
- What it contributes to our understanding

See the useful paper by Maxim & van der Sluijs (2010, reference #1 in our factsheet 4) on the Gaucho (imidacloprid) debate in France. These authors discuss the reasons why the debate became so heated and polarised and recommend instead a forum to structure and make transparent the arguments of different experts. Such a forum would use well established criteria for assessing causality; identify value judgements; and see if experts hold biologically plausible explanations, especially from a beekeeping context.

PAN UK twelve calls for action on bee-toxic pesticides *September 2012*

***UK government*:**

1. Immediate and urgent independent review of the latest science and the May 2012 conclusions of the European Food Safety Authority on the flawed risk assessment of neonicotinoids currently on the market.

2. Moratorium on UK approvals and use of neonicotinoids in agricultural, ornamental and amateur garden sectors until proven not to be causing harm to pollinators.

3. Commit to and support Friends of the Earth's call for a National Bee Action Plan.

4. Build more options into entry-level agri-environment schemes to encourage farmers to adopt more Integrated Pest Management (IPM) methods, especially biological control, which will reduce the tendency for 'insurance' pesticide treatments.

Food and farming sector:

5. Food retailers to put neonicotinoids onto pesticide restricted lists within their own company standards and plan how to phase in safer, IPM and organic strategies while phasing out neonicotinoids across their global supply chains.

6. Practical research with farmers on IPM and organic strategies for replacing neonicotinoids, with a focus on oilseed rape, fruit and vegetable uses.

7. Training and advice for farmers and crop consultants on effective IPM strategies based on agroecology and smarter cropping system design.

8. Collaboration between farming, retail, research and advisory, government agencies, beekeeping and civil society organisations to reduce reliance on pesticides and phase in ecologically-based approaches.

Ornamentals and amenity sector:

9. Ornamentals and garden supply sector to end the use of neonicotinoid treatments on pot plants.

10. Parks, local authorities and other amenity users of neonicotinoids to phase out use and replace with IPM and organic strategies.

Amateur Gardening Sector

11. Immediate suspension of sales to the public of garden products that contain neonicotinoids.

12. Offer gardeners alternative organic products and advice for managing insect pests.