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30 May 2013

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Re: Llywodraeth Cymru/Welsh Government: Draft Action Plan for Pollinators

Dear Biodiversity team:

Overview of the Welsh Government's Public Consultation

The Welsh Government has declared, "Bee and pollinator health has been increasingly highlighted as a cause for concern in the UK and globally." In an effort to effort to "reverse the decline in pollinator numbers," the Welsh Government will be creating an Action Plan.

As part of the Action Plan, the Government recently opened a public comment period on a draft Action Plan it is developing to prevent the decline of pollinators, namely bees. The supporting documents identify neonicotinoids as a possible factor contributing to bee health decline. More specifically, the Welsh Govenment's Consultation Document states that "[t]he use of fertilisers and pesticides has been a part of the move towards more intensive farming in Wales. There is significant concern over the potential direct effects of pesticides on managed and unmanaged pollinators, such as neonicotinoids."

The public comment period on the Wales Action Plan comes in the wake of the European Commission's decision to temporarily restrict three neonicitinoids. The Commission acted after "Member States did not reach a qualified majority – either in favour or against...a Commission proposal to restrict the use of 3 neonicotinoid insecticides." 12 EU Member States declined to support the restrictions proposed by the Commission.[1]

The Action Plan's development process, including this public consultation, provides the opportunity for Wales to independently assess the conclusions reached in:

- The Department for Environment, Food and Rural Affairs's (Defra's) Food and Environment Research Agency (fera) research which found that:

[1] http://europa.eu/rapid/press-release_IP-13-379_en.htm.

- "The [fera] study did not show that neonicotinoids used within a normal agricultural setting have a major effect on bumble bee colonies."[2]

- "The study underlines the importance of taking care in extrapolating laboratory toxicology studies to the field, as well as the great need of further studies under natural conditions."[3]

- Defra's March 2013 scientific assessment document "An assessment of key evidence about Neonicotinoids and bees," which determined:

> ***Conclusion****: While this assessment cannot exclude rare effects of neonicotinoids on bees in the field, it suggests that effects on bees do not occur under normal circumstances. This assessment also suggests that laboratory based studies demonstrating sub-lethal effects on bees from neonicotinoids did not replicate realistic conditions, but extreme scenarios. Consequently, it supports the view that the risk to bee populations from neonicotinoids, as they are currently used, is low.*[4] [Emphasis added.]

It is important to also note Defra's explanation of the deeply counterintuitive and unsupported complaints regarding neonicotinoids:

> *Insects are significant pollinators of crops like oilseed rape where yields can collapse in the absence of pollinators [notes omitted]. In the UK, neonicotinoids have been used as seed treatments on OSR for 10 years. This suggests that if pesticide use was reducing pollinator effectiveness then this would also be detrimental to crop productivity. Consequently, the claim that treatment of OSR with neonicotinoids kills pollinators is partly countered by the success of the crops themselves.*[5] [Emphasis in original.]

As we will discuss below, Defra's findings are consistent with the observation of a distinguished entemologist and bee researcher at the University of Illinois who observed that the area the university is located in has zero confirmed cases of CCD even though it is "ground zero for neonicotinoid use."

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[2] Food and Environment Research Agency, "Effects of neonicotinoid seed treatments on bumble bee colonies under field conditions," March 2013, p. 36, *available at* http://www.fera.defra.gov.uk/scienceResearch/scienceCapabilities/chemicalsEnvironment/documents/reportPS2371Mar13.pdf.

[3] Ibid.

[4] Department for Environment, Food and Rural Affairs, "An assessment of key evidence about Neonicotinoids and bees," March 2013, p. 1, *available at* https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/181841/pb13937-neonicotinoid-bees-20130326.pdf.pdf.

[5] Ibid., p. 5.

Summary of CRE Comments

About CRE

The Center for Regulatory Effectiveness (CRE), a non-governmental regulatory watchdog, fully supports the Welsh Government's announcement that it plans to develop an Action Plan to prevent the decline of bee health and other pollinators. CRE was established by former senior career officials from the White House Office of Management and Budget (OMB) who have been recognized for their contributions to science. For more information about CRE, please see here.

CRE appreciates the Welsh Government's commitment to science and transparency in public policy as evidenced by this public consultation. The CRE also appreciates the substantial impact that pollinators have on agriculture.

V. destructor: The Major Factor Underlying Colony Loss

According to the supporting documents for public consultation on the Action Plan, "the value of pollinators to UK agriculture is conservatively estimated to be £430 million per year." This is why it is necessary to direct to measures to effectively address "the major factor underlying colony loss,"[6] varroa mites (*Varroa destructor).*

A recent study unequivocally state that the *Varroa destructor* "has resulted in the death of millions of honey bee (*Apis mellifera*) colonies."[7] The study concluded, "the spread of Varroa in Hawaii has caused [deformed wing virus], originally an insect virus of low prevalence, to emerge. This association may be responsible for the death of millions of colonies worldwide wherever Varroa and [deformed wing virus] co-occur.

The findings in the above-referenced study by researchers at the University of Sheffield and other institutions are backed by the British Beekeepers Association (BBKA). BBKA chairman, Dr. David Aston stated that the research "increased our understanding of the relationships between Varroa and [this] significant bee virus…These findings underline the need for further research into Varroa…There remains a clear and urgent need for an effective, approved treatment."[8]

Recent research conducted by scientists at the Swiss Bee Research Centre in Bern, Switzerland and the USDA/Agricultural Research Service's Bee Research Laboratory in Beltsville,

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[6] United States Department of Agriculture/Agricultural Research Service, "Report on the National Stakeholders Conference on Honey Bee Health: Key Findings," *available at* http://www.ars.usda.gov/is/pr/beereport.htm?pf=1.

[7] Stephen J. Martin, et al., *Global Honey Bee Viral Landscape Altered by a Parasitic Mite*, 336 Science 1304, (June 8, 2012).

[8] Victoria Gill, *Honeybee Virus: Varroa Mite Spreads Lethal Disease*, BBC Nature, (June 7, 2012).

MD found a close link between *Varroa* levels and Deformed Wing Virus (DWV) with associated loss of colonies:

> *There was a significant positive correlation between V. destructor infestation levels and the number of workers displaying DWV clinical signs, further supporting the mite's impact on virus infections at the colony level. A logistic regression model suggests that colony size, the number of workers with wing deformities and V. destructor infestation levels constitute predictive markers for winter colony losses in this order of importance and ease of evaluation.*[9]

Research funded jointly by the Dutch Ministry of Agriculture, Nature Conservation and Food Quality and the European Union also confirmed the close relation between *V. destructor* infestation levels and colony loss. More significantly, the research demonstrates that reducing the levels of mite infestation through treatment of colonies with an acaricide improved colony survival rates over the winter. The study concluded:

> *This study contributes to theory about the multiple causes for the recent elevated colony losses in honey bees. Our study shows the correlation between long lifespan of winter bees and colony loss in spring. Moreover, we show that colonies treated earlier in the season had reduced V. destructor infestation during the development of winter bees resulting in longer bee lifespan and higher colony survival after winter.*[10]

Instead of addressing the *V. destructor* concern, the EU has been focusing on neonicotinoids as the cause. The EU recently passed a two year restriction on the use of neonicotinoids. The EU resitrictions not only fail to address the impact of *Varroa* – and thus fail to protect pollinators –but also it will be economically harmful to European farmers and agricultural production.

According to a study by the Humboldt Forum for Food and Agriculture, neonicotinoid seed treatment contributes between 5.4 billion and 6.3 billion Euros to the GDP of the EU.[11] "To put the numbers into context: the immediate potential damages to the overall EU welfare if [neonicotinoid seed treatments] were banned or their use suspended (4.5 billion EUR) are approximately as large as

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[9] Benjamin Dainat and Peter Neumann, "Clinical signs of deformed wing virus infection are predictive markers for honey bee colony losses," Journal of Invertebrate Pathology, Volume 112, Issue 3, March 2013, Pages 278–280, Abstract.

[10] Coby van Dooremalen, Lonne Gerritsen, et al, "Winter survival of individual honey bees and honey bee colonies depends on level of Varroa destructor infestation," PLoS One. 2012; 7(4): e36285, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338694/.

[11] Steffen Noleppa and Thomas Hahn, *The Value of Neonicotinoid Seed Treament in the European Union: A Socio-economic, Technological, and Environmental Review*, Humboldt Forum for Food and Agriculture, page 7, January 2013 available at http://www.neonicreport.com/wp-content/uploads/2013/01/HFFA%20Report.pdf.

the entire agricultural value added of some smaller EU member states, e.g. Austria or Finland." Even worse, "over a five-year period, the EU could 17 billion EUR or more."[12]

Moreover, the current research and data do not support the EU ban on neonicotinoids. In implementing the ban on neonicotinoids, the EU is relying on a report released by the European Food Safety Authority (EFSA) that has gaps in data, is biased, and fails to meet fundamental data quality standards.[13]

For the foregoing reasons, the Welsh Government needs to center its research efforts and the Action Plan on addressing the predominant cause of bee health decline, *V. destructor*.

The need for bee health regulators and researchers to focus on the role of *Varroa*, not neonicotinoids, was highlighted by a recent interview with the Director of the University of Illinois at Urbana-Champaign's Institute for Genomic Biology who is "an expert on honey bee behavior, genomics and biology."

As CRE noted above, the Institute's Director discussed bee health decline issues in an interview with the Life Sciences editor of an online university publication. In a discussion of possible synergies between "between the sublethal effects of pesticides and the effects of a pathogen, or a parasite, or poor nutrition" the Director observed,

> *Here,* [East Central Illinois] *corn and soybean agriculture use one of the most controversial classes of insecticides, the neonicotinoids. But there are no problems in this area with Colony Collapse Disorder. We're ground zero for neonicotinoid use but we have no documented cases of Colony Collapse Disorder.* [Emphasis added.]

Prior to discussing the pesticides and bee health, Institute's Director was asked about what causes CCD:

> ***What factors do scientists think contribute to CCD?***
>
> *First of all the varroa mite, a parasite of honey bees, has been the real game changer. It is not the cause of Colony Collapse Disorder but it is a huge factor. It has weakened bees by the pathogens that it harbors that it passes along to the bees and perhaps also by damage that it does directly to the bees.*

The complete interview may be found here, http://illinois.edu/lb/article/72/73513.

One issue researchers are investigating is whether there are environmental factors that may increase the susceptibility of bees to *V. destructor*. Research just published in a distinguished journal, the Proceedings of the National Academy of Sciences ("PNAS"), suggests that the common

[12] *Id*. at 18.

[13] See *DQA Alert: The EFSA Report on Neonicotinoids Does Does Not Meet the Data Quality Standards of the Data Quality Act*, available at http://www.thecre.com/oira_pd/?p=5765

bee keeping practice of feeding bees high-fructose corn syrup instead of honey is harming the ability of bees to deal with environmental stresses by damaging their immune system. The researchers identified specific compounds of interest in honey, including *p*-coumaric acid, pinocembrin, and pinobanksin 5-methyl ether, that "specifically induce detoxification genes." The researchers conclude that,

> *As a major component of pollen grains, p-coumaric acid is ubiquitous in the natural diet of honey bees and may function as a nutraceutical regulating immune and detoxification processes. The widespread apicultural use of honey substitutes, including high-fructose corn syrup, may thus compromise the ability of honey bees to cope with pesticides and pathogens and contribute to colony losses.*[14]

The central role of the *Varroa destructor* in bee health decline was highlighted in a major US government science report, discussed below, prepared by scientists at the United States Department of Agriculture ("USDA"), the United States Environmental Protection Agency ("US EPA") and Pennsylvania State University.

Any Welsh pollinator risk assessment should explicitly consider the conclusions and recommendations of a recent report by the United States National Academy of Sciences (NAS Report). The NAS Report is entitled *Assessing Risks to Endangered and Threatened Species from Pesticides*[15] and is incorporated by reference as an integral part of CRE's comments to the Welsh Government.

The NAS Report addresses U.S. regulation of pesticides under the Endangered Species Act ("ESA").[16] It should be noted that the U.S. government primarily regulates pesticides under the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"),[17] which has a much more specific risk/benefit component than does the ESA. Currently, there are no bees on the ESA endangered and threatened lists. Consequently, the NAS Report does not specifically discuss bee risk assessments. The NAS Report does, however, reach conclusions and provide recommendations which are helpful in assessing risks to bees and other pollinators.

Of particular note, the NAS Report emphasizes the need for federal agencies to fully comply with White House's government-wide guidelines implementing the federal Data Quality Act ("DQA"). The NAS Report provides excellent guidance on assessing all pollinator risks and in

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[14] Wenfu Maoa, Mary A. Schulerb, and May R. Berenbauma, "Honey constituents up-regulate detoxification and immunity genes in the western honey bee Apis mellifera," http://www.pnas.org/content/early/2013/04/26/1303884110.

[15] A prepublication copy of the complete NAS Report is available on CRE's website here, http://thecre.com/pdf/NAS--Assessing_Risks.pdf.

[16] See, US Fish & Wildlife Service, Endangered Species Act | Overview, *available at* http://www.fws.gov/endangered/laws-policies/.

[17] See, US EPA's Overview of FIFRA, http://www.epa.gov/agriculture/lfra.html#Summary of the Federal Insecticide, Fungicide, and Rodenticide Act.

particular it provides excellent guidance in assessing sublethal risks. This report's recommendations and conclusions are discussed in detail below in the section our comments titled, "National Academy of Sciences Provides the Model for Assessing Pollinator Risks."

US Government State of Science Report on Bee Health

The USDA-published document, "Report on the National Stakeholders Conference on Honey Bee Health" was based on "the proceedings of a stakeholder conference organized and conducted by members of the National Honey Bee Health Stakeholder Conference Steering Committee." The Steering Committee consists of USDA, EPA and Pennsylvania State University scientists.[18]

The conference which produced the Report focused on three objectives, the first of which was to synthesize the state of scientific knowledge on bee health decline, "bee pests, pathogens, and nutrition, potential pesticide effects on bees, and bee biology, genetics and breeding." Other purposes of the conference were to assist in the development of Best Management Practices guides and identify priority areas for research, education and outreach.

There were two key findings from the conference, one specific to *V. destructor* and a finding about the broad scientific consensus on the multi-factor nature of bee health decline.

After reviewing research from Conference participants, the Conference concluded that:

> *Consensus is building that a complex set of stressors and pathogens is associated with CCD, and researchers are increasingly using multi-factorial approaches to studying causes of colony losses.*[19]

The primary implication from the USDA/EPA finding for the Welsh Government's development of an Action Plan to protect pollinator health is:

- To be effective, the Welsh Action Plan will need to take an integrated, science-based, multi-factor approach to protecting pollinator health.

The corollary to the above conclusion is that any simplistic plan with a focus on a "silver bullet," find-the-bad-actor-and-eliminate-it approach will fail.

Although the USDA Report highlighted the multi-factor nature of bee health decline, the document also emphasized pre-eminent role of *Varroa destructor* in the loss of colonies:

> *The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees, and is closely associated with overwintering colony declines.*[20]

[18] The complete report is available at http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf.

[19] USDA, "Report on the National Stakeholders Conference on Honey Bee Health," ("USDA Report") p. v.

Moreover, the Report also found that "Multiple virus species have been associated with CCD" and that "Varroa is known to cause amplified levels of viruses."[21]

USDA, on their website, summarized the Report's "Key Findings" by stating,

> *The parasitic Varroa mite is recognized as the major factor underlying colony loss in the U.S. and other countries. There is widespread resistance to the chemicals beekeepers use to control mites within the hive. New virus species have been found in bees in the U.S. and several of these have been associated with CCD. The Varroa mite is the primary factor known to increase levels of some bee viruses.*[22] [Emphasis added.]

The first detailed presentation at the Conference was a review of the "Current State of Knowledge of CCD and its Relation to Honey Bee Health" presented by researchers at USDA and the University of Maryland. The findings presented included discussion of *Varroa*:

> *The parasitic mite Varroa destructor remains the single most detrimental pest of honey bees and can magnify the role of viruses in bee health.*[23]

The Current State of Knowledge presentation and the USDA Report both discussed neonicitinoids, but in a way very different than viewing the category of compounds as being a cause of bee health decline. Instead, the federal scientists found that neonicotinoids pose far lower hazards to bees than alternative crop protection products.

> *Pesticide exposure to pollinators continues to be an area of research and concern, particularly the systemic pesticides such as neonicotinoids. Despite concerns regarding the potential hazard that systemic pesticides may represent to honey bee colonies, when pesticides are viewed in the aggregate at the national level, the frequency and quantity of residues of pyrethroids coupled with the toxicity of these insecticides to bees could pose a 3-fold greater hazard to the colony than the systemic neonicotinoids.*[24]

USDA did not even mention neonicitinoids on their Key Facts summary of the report. Instead, the researchers emphasize the need for actual exposure data in order to be able to determine whether pesticides are relevant to bee health decline.

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[20] Ibid., p. vi.

[21] Ibid.

[22] USDA, Agricultural Research Service, "Report on the National Stakeholders Conference on Honey Bee Health: Key Findings," *available at* http://www.ars.usda.gov/is/pr/beereport.htm.

[23] USDA Report, p. 6.

[24] Ibid.

> *Acute and sublethal effects of pesticides on honey bees have been increasingly documented, and are a concern but it is not clear, based on current research, whether a pesticide exposure is a major factor associated with U.S. honey bee health declines.* [sic] *The most pressing research questions relate to determining actual pesticide exposures bees receive in the field.*[25] [Emphasis added]

The Report delved into the issue of the sublethal effects of pesticides on bees and emphasized the complexity of the research and the need to understand the actual exposures of bees to pesticides,

> *...it remains a challenge to measure the effects of low-level, field-relevant exposure where it matters most: in real honey bee colonies. The social complexity of honey bees and the uncontrollable aspects of field research present substantial challenges to determining pesticide effects in whole-colonies. While experiments using whole colonies have the potential to directly address the effects of pesticides on honey production and pollination services, challenges presented by field or semi-field experiments include:*
>
> - *Many colonies are needed per treatment due to high variability between honey bee colonies.*
> - *The actual levels of exposure to pesticides that bees receive are still a big question.*[26]

From a policy standpoint, the bee health question for the Welsh Government becomes, why focus on a class of chemical that has little or nothing to do with bee health decline? A neonicitinoid-centric strategy for protecting pollinators calls to mind a quote from legendary journalist H. L. Mencken[27] who explained that "For every complex problem there is an answer that is clear, simple, and wrong."

From a science standpoint, the Welsh Government has the task of determining how to evaluate conflicting scientific data. Fortunately, federal officials have developed a set of standards for evaluating the quality of data. Unless the information under consideration by government agencies, irrespective of its source, can pass the federal data quality standards, agencies are prohibited from using or relying on the data in agency information disseminations such as reports and regulations.

The National Academy of Sciences (NAS), which was established by Congress and President Abraham Lincoln in 1863 to provide "independent, objective advice to the nation on matters related to science and technology,"[28] recently evaluated the role of the Data Quality Act standards on federal

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[25] USDA Report: Key Facts, http://www.ars.usda.gov/is/pr/beereport.htm.

[26] NAS Report, p. 18.

[27] http://en.wikipedia.org/wiki/H._L._Mencken.

[28] http://www.nasonline.org/about-nas/mission/.

evaluation of science policy research. The NAS report, discussed below, is highly relevant to the Welsh government's Public Consultation on pollinator protection and to the science policy endeavors of virtually all organizations.

National Academy of Sciences Provides Guidance on Data Quality and Sublethal Risks

On April 30, 2013, the National Academy of Sciences released a major report on assessing risks to species under the U.S. ESA lists: *Assessing Risks to Endangered and Threatened Species from Pesticides* ("NAS Report"). The NAS prepared this report at the request of the US EPA, the U.S. National Oceanic and Atmospheric Administration ("NOAA")/National Marine Fisheries Service ("NMFS"), the U.S. Fish and Wildlife Service ("FWS"), and the USDA. This NAS Report provides the model for all ecological risk assessments, including pollinator risk assessments.

The complete NAS Report is available online here: http://www.thecre.com/forum1/?p=6116.

CRE submitted written comments to the NAS during its review and report preparation. CRE's comments to the NAS are available online here: http://www.thecre.com/forum1/?p=4569.

CRE's comments briefed the NAS on the four U.S. agencies' DQA implementing Guidelines. CRE is widely recognized as the leading champion of the DQA. An article in Naval Law Review explained that the Information (Data) Quality Act "is the result of lobby efforts by Dr. James Tozzi, Multinational Business Services and the Center for Regulatory Effectiveness (CRE)."

CRE's comments explained to the NAS that it was commenting on the DQA

> *because EPA, NMFS and FWS have not adequately briefed the Committee on the Government-wide data quality protocols and standards that govern their ecological risk assessments under FIFRA and the ESA. CRE has long been a proponent of these protocols and standards, and helped establish some of them.*

We were gratified to see that the NAS Report, at page 31, acknowledges the importance of DQA Guidelines:

> *[A]ll federal agencies are expected to comply with the Office of Management and Budget (OMB) guidelines on objectivity, utility, and integrity of disseminated information. OMB (67 Fed. Reg. 8452 [2002]) describes those attributes as follows:*
>
> *'Objectivity' focuses on the extent to which information is presented in an accurate, clear, complete and unbiased manner; and, as a matter of substance, the extent to which the information is accurate, reliable and unbiased. 'Utility' refers to the usefulness of the information to the intended users. 'Integrity' refers to security, such as the protection of information from unauthorized access or revision, to ensure the information is not compromised through corruption or falsification."*

> *The Services and EPA (EPA 2002; FWS 2007) have separately published information quality guidelines (IQGs) that follow closely the government-wide OMB guidelines. Similar basic principles for achieving a scientifically credible assessment are prescribed in the IQGs from the agencies; the agencies are committed to ensuring the quality of evaluations and the transparency of information from external sources used in their disseminated assessments and actions (EPA 2003; NMFS 2005). They also recognize that a high level of transparency and scrutiny is needed for influential information that is expected to have a substantial effect on policies and decisions (EPA 2002; NMFS 2004; FWS 2007)* [citing the Agencies' DQA Guidelines].

The NAS report at page 34 provides the following additional guidance on data quality:

> ● *Given that stakeholders are aware of and can provide valuable and relevant data, the committee encourages provision for their involvement at the early stage and throughout the ERA process. Stakeholder data are expected to meet the same data relevance and quality standards as all other data.*
>
> ● *To ensure that the best data available are used, information should first be screened for relevance and then subjected to quality review.*
>
> ● *The agencies should, at a minimum, subject all information to a review based on OMB criteria of 'objectivity, utility and integrity.' Information sources that fail any of the criteria can be used at the discretion of the risk assessor, provided that their limitations are clearly described.*
>
> ● *Comparisons of all information sources with the relevance and quality attributes should be documented in the risk assessment and described in the overall characterization of uncertainties.*

In addition to data quality, the NAS report at pages 109-110 establishes the following principles for risk characterization:

> ● *Inclusion of uncertainty factors to account for lack of various data is unwarranted because there is no way to determine whether the assumptions being used substantially overestimate or underestimate the probability of adverse effect.*
>
> ● *RQs [risk quotients] are not appropriate for risk assessments or for any application in which it is desired to base a decision on the probabilities of the various possible outcomes.*
>
> ● *...established, scientifically defensible, statistical methods should be used to calculate risk as a probability to assist decision-makers' understanding of the potential consequences of their decisions.*

> ● *A number of existing probabilistic methods have been shown to be applicable and practical for ecological risk assessments that involve pesticides.*
>
> ● *The transition from concentration-ratio to probabilistic approaches should begin now, focusing on a small set of sensitive key parameters, and drawing on the considerable literature and guidance on probabilistic approaches.*

Sublethal risks are a particular concern with pollinators. With regard to these risks, the NAS report concludes and recommends at page 96:

> ● *An adverse effect should be defined by the degree to which an organism's survival or reproduction is affected; thus, assessing the effects of a pesticide on a listed species requires quantifying the effect of the pesticide on survival and reproduction of the species in the wild. Any effect that results in a change in survival or reproduction is relevant to the assessment, and any effect that does not change either outcome is irrelevant with respect to a quantitative assessment of population effects.*
>
> ● *To determine whether a pesticide is "likely to adversely affect" a listed species, a broad search should be conducted to identify information on sublethal effects of the pesticide and possible concentration-response relationships.*
>
> ●*To provide information to support a jeopardy determination, the Services [NOAA/NMFS and FWS] should either (a) show how sublethal effects change survival or reproduction and incorporate such information into the population viability analysis or (b) state that such relationships are unknown but possible and include a qualitative discussion of uncertainty in the BiOp.*

The NAS report emphasizes on pages 8 and 9 that

> *Pesticides can kill organisms but can also affect reproduction or growth or make organisms less competitive. Although EPA and the Services agree that those sublethal (less-than-lethal) effects should be considered in the assessment process, they disagree on the extent to which they can be included. To address that issue, the committee first considered how to define objectively the degree to which observed effects are adverse. Defining adversity is essential for ERA because the mere existence of an effect is not sufficient to conclude that it is adverse. The committee concluded that the only way to determine whether an effect is adverse and how adverse it might be is to assess the degree to which it affects an organism's survival and reproductive success; any effect that results in a change in either survival or reproduction is relevant to the assessment, and any effect that does not change either outcome is irrelevant with respect to a quantitative assessment of population effects…. The inability to quantify the relationship between a sublethal effect and survival or reproductive success does not mean that the sublethal effect has no influence on population persistence; but in the absence of data, the relationship remains a hypothesis that can be*

> *discussed only qualitatively with reference to the scientific literature to explain why such a hypothesis is tenable.*

Defining and assessing ecological sublethal effects are among the most important issues addressed by the NAS Report. The report explains at page 68:

> *The committee considered how to assess objectively the degree to which observed effects of pesticides on organisms are adverse. Defining that concept is essential for ecological risk assessment because even if an effect is reliably observed, that alone might not be sufficient to conclude that the effectis adverse. The committee concluded that the only reasonable way to determine whether an effect is adverse and how adverse it might be is to assess the degree to which it affects the organism's survival and reproductive success. It then is possible to extrapolate from changes in an individual organism's survival or reproductive success to estimate population effects. If an adverse effect is large enough, it might lead to extinction of the species. EPA reached a similar conclusion in its overview of the ecological risk assessment process (EPA 2004, p. 31): "If the effects on the survival and reproduction of individuals are limited, it is assumed that the risk at the population level from such effects will be of minor consequence. However, as the risk of reductions in survival and/or reproduction rates increase, the greater the potential risk to populations."*

At page 69, The NAS report

> *recommends that EPA in Step 2 (see Figure 2-1) cast a wide net and identify information about sublethal effects of a chemical. If possible, EPA's assessment should include information about responses at various chemical concentrations (a concentration-response curve) and, at a minimum, include a qualitative assessment of the relationship between sublethal effects and survival and reproduction. In Step 3 (see Figure 2-1), the Services should show how such effects change demographic measures(survival or reproduction) of a listed species and incorporate such information into the population viability analyses or should state that such relationships are unknown but possible and include aqualitative discussion in the uncertainty section of the biological opinion (BiOp). The Services [NOAA/NMFS and FWS] face thegreatest challenge in Step 3 in determining whether an observed sublethal effect will change survival or reproduction in the natural population and, if so, the magnitude of such a change in relation to the predicted exposure.*

On page 19, the Wales Action Plan states, "There are gaps in our knowledge of the status and trends of pollinator populations in Wales, and particularly in the interrelationships between impacts on them."

The Plan further states,

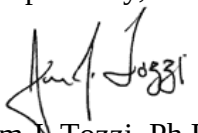
> ***Area for Action 7: Building an evidence base to support future action for pollinators.***
>
> *Although there is a large amount of research being carried out on pollinators there are many evidence gaps regarding their status and trends, the interactions between threats to pollinator populations, and mitigation methods. In Wales, we need to establish baseline data and monitor pollinator populations not least to monitor the outcomes of this plan. The value of retaining pollination services in Wales is one important area for future research. We will engage further with UK research initiatives to improve information for Wales.*

The NAS report explains how to build "an evidence base to support future action for pollinators," and on how to conduct "research initiatives to improve information for Wales." We recommend and request that Wales use the NAS Report to help protect pollinators.

Conclusion

The protection of pollinators is far too important and complex an issue for the Welsh government to accept policy measures, such as banning neonicitinoids, that are "clear, simple, and wrong." Instead, Welsh officials should evaluate all data presented to them to ensure it complies with Data Quality standards. The NAS Report also provides helpful guidance on assessing sublethal effects.

Respectfully,



Jim J. Tozzi, Ph.D.
Member, Board of Advisors