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A Scientific Evaluation of the *American Academy of Pediatrics (AAP) Report Pesticide Exposure in Children*

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Executive Summary

In November 2012, the Council on Environmental Health of the American Academy of Pediatrics (AAP) released a policy statement (the *Policy Statement*) on *Pesticide Exposure in Children*[1] which concluded that "pesticide exposures are common and cause chronic[2] effects." Support for the AAP conclusions is provided in a 22-page technical report (the *Report*[3]). This Evaluation seeks to address two primary concerns which arise from the *Policy Statement* and the *Report*:

1. The *Policy Statement* and *Report* overlook or risk mischaracterizing the science that distinguishes commonly-used, US EPA-approved pesticides that have a track record of proven, low risk use with one or more of the high risk "bad actors" listed and reviewed in the *Report*.
2. The *Report* does not provide a full or accurate description of their use pattern. Indeed more than two-thirds of the products that it lists and reviews have been banned, often for decades, or have had their use otherwise severely restricted.

The combination of these concerns is such that a casual or non-technical reader could be unintentionally persuaded to believe that the *Policy Statement's* broad conclusion about the exposure and chronic health risks of the small group of selected pesticides reviewed in the *Report*, apply equally to all or many commonly-used pesticides that have been evaluated and registered by the U.S. Environmental Protection Agency (US EPA).

Consequently, this evaluation concludes that:

1. The *Policy Statement* and *Report* overlooks or unintentionally risks misstating the science that distinguishes commonly-used, US EPA-approved pesticides with a track record of proven, safe use from the truly "bad actors" reviewed in the *Report* that have been banned (often for decades) or whose use is otherwise severely restricted.
2. The available science does not support applying the same level of concern expressed in the *Policy Statement* for the products reviewed in the *Report* to commonly-used pesticides.
3. With regard to the products reviewed in the *Technical Report*, there are important omissions and mischaracterizations which undermine the overall validity of the *Technical Report* and the related recommendations set forth in the *Policy Statement,*

[1] Council on Environmental Health, Pesticide Exposure in Children, *Pediatrics*, November 26, 2012, available online at: http://pediatrics.aappublications.org/content/130/6/e1757.full.pdf+html; quote is from p. e1761.

[2] "Chronic" effects generally occur as a result of long-term exposure, and are of long duration. Chronic health effects include asthma, cancer and developmental defects that are thought to result from multiple exposures over a period of time. In contrast acute effects usually occur rapidly as a result of single or short-term exposures, and are of short duration. Because the effects of acute exposures are more easily detected e.g. gastrointestinal upset from accidental ingestion, skin and/or eye irritation from unprotected contact, the focus of public health research is often on determining the consequence, if any, from chronic exposures.

[3] J.R. Roberts, C. J. Karr and Council on Environmental Health, Pesticide Exposure in Children, November 26, 2012, available online at: http://pediatrics.aappublications.org/content/130/6/e1765.abstract

including the fact that over 70% of the products reviewed have been banned, often for decades, or have had their use otherwise severely restricted.

Overview Comments

Both the *Policy Statement* and the *Report* omit any discussion of the benefits of pesticide uses, focusing only on risk. For example, both documents present an incomplete and one-sided assessment of the available data. There is substantial data which demonstrates the numerous health and environmental benefits provided by green space (parks, playgrounds, lawns, etc.) and the essential role played by commonly-used pesticides in the maintenance of healthy green space.

The *Policy Statement* claims that pesticide exposures "cause" chronic effects, overstating the more cautiously worded conclusion of the *Report* which stated "there is a growing body of literature that suggests that pesticides may induce chronic health complications in children, including neurodevelopmental or behavioral problems, birth defects, asthma and cancer." By omitting important qualifying words such as "suggests" and "may", the *Policy Statement* overstates the conclusion of the *Technical Report* and could cause non-technical readers to misinterpret its meaning. This is particularly problematic as non-technical readers of either document could interpret the findings as applying to all pesticide products in equal measure rather than to those products specifically evaluated in the *Technical Report.*

In addition, the AAP *Technical Report* appears to ignore the considerable data that has been generated through the US EPA product registration process. This long-standing EPA process rests upon a science-based decision making methodology that requires a demonstration that "the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing unreasonable risks to the environment.[4]

Importantly, in determining a pesticide's potential risk, U.S. EPA employs a rigorous set of criteria that includes hazard identification, dose-response assessment and exposure assessment to create an overall risk characterization. In contrast to the EPA's process for risk characterization, the *Technical Report* lacks any process for meaningful risk characterization.

The *Policy Statement* makes recommendations regarding risk but neither the *Report* nor the *Policy Statement* discuss risk. Consequently, the *Report* misses the opportunity to provide useful information on risk and safety of pesticides and, instead, focuses on hazard properties, which make a poor basis for product selection as all substances have some hazard properties at high enough exposure levels. Again, this is makes non-technical readers particularly vulnerable to misunderstanding the issues which the R*eport* and *Policy Statement* seek to address by confusing the products specifically listed in both

[4] U.S. Environmental Protection Agency. *Pesticides. Regulating Pesticides*. Last updated 29 May 2014. Available at: www.epa.gov/pesticides/regulating/

documents with the far wider array of commonly-used products which offer substantial benefit with minimal risk.

The *Policy Statement* also recommends that government officials support research to better understand children's exposure to pesticides and improve registration of pesticide products. However, they do not cite or appear to acknowledge the registration literature or any of the numerous risk assessments that are readily available to the public. Failure to cite the registration literature is a considerable omission because by law, the EPA will only register a product if its evaluation confirms "that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing risks to the environment."[5]

Comments Regarding Claims of "Highly Toxic" Pesticides

It is noteworthy that more than two-thirds of the "highly toxic" pesticides listed in the AAP's *Technical Report* have either been banned for more than a quarter century or are no longer approved for residential use. Specifically:

- The AAP *Technical Report* identifies 14 "highly toxic" pesticides but does not provide an accurate description of their use pattern, implying that these are representative of commonly used pesticides. However, of these 14 pesticides:
  - Five have been banned for over 25 years (DDT, endrin, aldrin, chlordane and parathion)
  - Five are no longer approved for residential use (acephate, chlorpyrifos, methyl parathion, aldicarb, and paraquat)
  - One has limited residential use (diquat)
  - One is approved only for medical use (lindane) and
  - For another, human exposure is unlikely (dichlorvos).

Based on these use patterns, human exposure to these pesticides is likely to be very low.

- As for the remaining pesticide (carbaryl), it is registered for both agricultural as well as residential use by the US EPA.
  - This means that the EPA's rigorous testing of the products has determined that there are appropriate uses for the product consistent with the Agency's charge of assuring that there is a "reasonable certainty (of) no harm" to people, animals or the environment from the product (if applied according to label instructions).[6]
  - The classification in the *Technical Report* that this product is "highly toxic" is undefined in the *Report* and inconsistent with fundamental principles of toxicology which prescribe that toxicity cannot be defined

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[5] US Environmental Protection Agency, Regulating Pesticides, available at: http://www.epa.gov/pesticides/regulating/

[6] U.S. Environmental Protection Agency, "Carbaryl: Order Denying NRDC's Petition to Revoke Tolerances." 40 CFR Part 180, Docket: EPA-HQ-OPP-2008-0347; FRL-8388-1, available at: http://www.gpo.gov/fdsys/pkg/FR-2008-10-29/pdf/E8-25693.pdf

without stating the dose and route of exposure, and with EPA definitions of these terms.

- For carbaryl, toxicity via dermal or inhalation routes of exposure, the most likely routes of accidental exposure, is considered to be low while toxicity via oral exposure is considered to be moderate. There is no route of exposure to which EPA considers carbaryl to have "high" toxicity.

The *Report* mischaracterizes the chlorophenoxy herbicides 2,4-D and 2,4,5-T (2,4,5-trichlorophenoxy acetic acid). The *Report* cites 2,4,5-T as a "commonly used" herbicide when in fact it was banned in 1985. The *Report* implies that 2,4-D should be considered a hazardous substance because more toxic substances can be produced during the manufacture of these herbicides including dioxins. However, the report does not offer any documentation that would contradict EPA's current comprehensive assessment that 2,4-D tolerances (uses) are safe.[7]

Comments Regarding Claims of Widespread Human Exposures to Pesticides[8]

The *Report* overstates the number of pesticides detectible in human biomonitoring studies conducted by the U.S. Centers for Disease Control and Prevention (CDC). The *Report* claims that of 44 pesticides and metabolites tested, 29 were detectable in the samples analyzed (ages 6-59). In fact, a review of the latest CDC data reveals that of the 51 pesticides and metabolites currently tested (September 2013), only 22 were detected. While critics of any type of pesticide use might contend that 22 detected pesticides and metabolites still represent a significant hazard, the fact that the *Report* significantly overstates the actual numbers provides pause for a serious reader as to the overall process discipline under which the *Report* and *Policy Statement* were developed.

Furthermore, a review of the registration and use status of pesticides and metabolites detected indicates that most are persistent residues of banned products or breakdown products (metabolites) of banned products (organochlorine pesticides, 2,4,5-T). Others are used primarily in agricultural or restricted use applications such as wood preservatives, fire ant treatment and moth balls (fungicides, 2,5-dichlorophenol, organophosphates). In short, the biomonitoring data indicate that domestic uses are not a major source of human exposures to pesticides.

The *Report* further implies that exposure (for instance, as measured in biomonitoring studies) to a "hazardous" pesticide is equivalent to risk. As CDC notes in its Introduction to its Biomonitoring Report: "The measurement of an environmental chemical in a person's blood or urine is an indication of exposure; it does not, by itself, mean that the

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[7] US Environmental Protection Agency, EPA Denies Petition on 2,4-D Pesticide, April 18, 2012, available at: http://www.epa.gov/oppfead1/cb/csb_page/updates/2012/2-4d-petition.html

[8] Human biomonitoring studies have limitations for measuring exposure to pesticides. One limitation is that for pesticides that are rapidly removed from the body, biomonitoring will detect exposure only if biomonitoring testing is conducted immediately following an exposure episode (i.e. in a designed study) or if exposure is frequent or continuous so that exposure levels are held in a balance between exposure and rapid elimination.

chemical causes disease or an adverse effect."[9] In short, contrary to what the *Report* attempts to portray, exposure does not equal risk.

A more informed way to estimate risk is from the use of biomonitoring data which employs the "biomonitoring equivalents" method. Using this method, exposure levels from biomonitoring studies are compared to safe levels (called "biomonitoring equivalents"[10]) established by health agencies such as the European Food Safety Agency, Health Canada and the U.S. EPA.

Biomonitoring equivalent information is available on three currently used pesticides – 2,4-D, deltamethrin and cyfluthrin.[11] Measured biomonitoring levels for these pesticides are more than 500 to 1500 times lower than the biomonitoring equivalent value for these compounds, indicating low risk and low regulatory concern - the practical scientific definition of safety.

Comments Related to Claims of Chronic Health Effects

The *Report* claims chronic health effects from exposure to pesticides (childhood cancer, neurodevelopmental effects, physical developmental defects, endocrine effects and asthma) based on human epidemiology studies which have a number of limitations.

- First, such human epidemiological studies are only capable of demonstrating statistical associations, for instance between occupational categories and cancer incidence, but are not capable of demonstrating cause and effect.

- Second, many of these studies only consider broad categories of tested materials such as "unspecified pesticides, insecticides and herbicides." The rationale for including these studies seems to be that all pesticides are the same, contrary to the available science, including toxicity (Table 1, p. e1767) and mechanisms of action data (Acute Toxicity Mechanism and Clinical Manifestations, e1769-73) discussed in the *Report*.

- Third, many - if not most - of the studies in which specific pesticides are identified, refer to pesticides which have been banned (e.g. DDT, banned in 1972) or highly restricted (e.g., many organophosphates are no longer approved for home use). The relevance of such data to currently approved pesticides is highly questionable.

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[9] Centers for Disease Control and Prevention (CDC), Fourth National Report on Human Exposure to Environmental Chemicals, 2009, Introduction, p. 1, available online at: http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf

[10] For more information on biomonitoring equivalents, see: http://www.biomonitoringinfo.org/topic/biomonitoring-equivalents/

[11] Aylward, L.L., C.R. Kirman, R. Schoeny, CJ. Portier and S.M. Hays, Evaluation of biomonitoring data from the CDC national exposure report in a risk assessment context: Perspectives across chemicals, Environ. Health Perspect., vol. 121, pp. 287-294, 2013, available at: http://ehp.niehs.nih.gov/wp-content/uploads/121/3/ehp.1205740.pdf

- Regarding currently used pesticides, a recent health assessment conducted by the Environmental Health Research Foundation examined specific dose-response information in detail for two commonly used pesticides, including 2,4-D. The assessment concluded that the available data do not support the concept that environmental exposures to commonly used pesticides such as 2,4-D are sufficient to support a causal relationship.[12]

Conclusion

In short, the available science does not support the blanket statements of concern expressed in the *Policy Statement* regarding pesticides and chronic health effects. There are most definitely some studies that are compelling with respect to chronic effects, although, by and large, the studied products are no longer in use (e.g. the organochlorines such as DDT, etc.). Regarding currently used pesticides, the *Policy Statement* and *Report* overlook or misrepresent the science that distinguishes US EPA approved pesticides with a track record of proven, low risk use from the truly "bad actors" that have been banned (often for decades) or whose use is severely restricted.

[12] von Stackelberg, K., A Systematic Review of Carcinogenic Outcomes and Potential Mechanisms from Exposure to 2,4-D and MCPA in the Environment, *Journal of Toxicology*, Vol. 2013 (2013), Article ID 371610, 53 pages, http://dx.doi.org/10.1155/2013/371610, available at: http://www.hindawi.com/journals/jt/2013/371610/

A Scientific Evaluation of the *American Academy of Pediatrics (AAP) Report Pesticide Exposure in Children*

DETAILED REPORT

INTRODUCTION

In November 2012, the Council on Environmental Health of the American Academy of Pediatrics (AAP) released a policy statement on *Pesticide Exposure in Children*[13] which concluded: "(1) pesticide exposures are common and cause both acute and chronic[14] effects; (2) pediatricians need to be knowledgeable in pesticide identification, counseling and management; and (3) government actions to improve pesticide safety are needed."

Support for the AAP conclusions regarding health effects of pesticides is provided by and relies upon a 22-page technical report entitled *Pesticide Exposure in Children*.[15] The technical report was authored by J.R. Roberts, C.J. Karr and the Council on Environmental Health. For clarity, this report will be referred to in this evaluation as the Roberts et al. *Report* or simply the *Report*, while the policy statement will be referred to as the *Policy Statement.*

As noted in the *Report*, health effects from acute exposure (i.e. poisonings) are well documented. Data reported to the American Association of Poison Control Centers' National Poison Control Data System reported in 2011, the most recent year data are available, that pesticides were the eighth most common substance to which children (<5 years) were exposed and the 19th leading cause of death.[16] Actions to reduce children's (and adult) exposure to pesticides which pose actual risk is a worthy goal for which there would seem to be (and should be) broad support.

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[13] Council on Environmental Health, Pesticide Exposure in Children, *Pediatrics*, November 26, 2012, available online at: http://pediatrics.aappublications.org/content/130/6/e1757.full.pdf+html; quote is from p. e1761.

[14] "Acute" effects usually occur rapidly as a result of single/short-term exposures, and are of short duration while "chronic" effects generally occur as a result of long-term exposures, and are of long duration. Chronic health effects include asthma, cancer and developmental defects, diseases that are thought to result from multiple exposures over a period of time. Because the effects of acute exposures are more easily detected e.g. gastrointestinal upset from accidental ingestion, skin and/or eye irritation from unprotected contact, the focus of public health research is on determining the consequence, if any, from chronic exposures.

[15] J.R. Roberts, C. J. Karr and Council on Environmental Health, Pesticide Exposure in Children, November 26, 2012, available online at: http://pediatrics.aappublications.org/content/130/6/e1765.abstract

[16] A.C. Bronstein, D.A. Spyker, L.R. Cantilena, Jr., B.H. Rumack and R.C. Dart, 2011 Annual Report of the American Association of Poison Control Centers' National Poison Data System (DPDS): 29th Annual Report, *Clin. Toxicol. (Phila.)* 50 (10): 911-1164, 2012, available online at: http://informahealthcare.com/doi/full/10.3109/15563650.2012.746424

The controversial part of the AAP policy statement is the assertion that pesticides currently in use are causing chronic health effects. The claim of chronic health effects from pesticide exposures is, in turn, based on three claims regarding pesticides:

- First, there are "highly toxic" pesticides.

- Second, children are exposed to pesticides.

- Third, there is evidence that links pesticide exposure to various chronic diseases including childhood cancer, neurodevelopmental effects, physical defects, endocrine effects and asthma.

In addition, the rather broad claims of chronic health effects from pesticide exposure can suggest to a non-technical reader, whether intentionally or not, that all pesticide products are the same and that all exposures pose the same actual risk.

There is a two-fold purpose for this evaluation:

- First, to assess the scientific support for the *Policy Statement's* conclusion that pesticides currently in use are, in fact, causing chronic health effects and to clarify that the *Policy Statement's* focus is on a limited number of pesticide products and that non-technical readers are vulnerable to drawing broader conclusions about risk from commonly-used products than is justified on the merits.

- Second, to provide a basis for public health officials and organizations to use in both evaluating the *Policy Statement* and determining whether the American Academy of Pediatrics should be urged to consider possible amendments to the *Policy Statement*.

COMMENTARY ON THE *AMERICAN ACADEMY OF PEDIATRICS POLICY STATEMENT*

I. Overview Comments

A. Both the *Policy Statement* and the *Report* omit any discussion of the benefits of pesticide uses, focusing only on risk, and thus provide an incomplete and one-sided assessment of the available data. The data demonstrate numerous health and environmental benefits provided by green space (parks, playgrounds, lawns, etc.) and the essential role played by commonly-used pesticides in the maintenance of healthy green space.

Perhaps the most egregious scientific error is the omission of any discussion of the benefits of pesticide use, in this way focusing only on risk and thus failing to provide a balanced and complete risk-benefit assessment of the available data. In addition to the more obvious benefits of pesticide use in agriculture, this omission includes the benefits of pesticides used in non-agricultural applications (i.e., public parks, playgrounds, lawns, etc. collectively called "green space"[17]). The latter omission is especially notable because of the *Policy Statement's* focus on recommendations to parents, schools and local governmental authorities who would be making decisions on such uses. Nonetheless, considerable data is available on the health and environmental benefits of healthy, well-maintained green spaces, for instance in a review[18] of the available recent literature compiled by the Environmental Health Research Foundation.

This review documents that there are a number of health and environmental benefits of green spaces. These data also indicate that healthy, dense green space is three times more effective than weedy, unhealthy green space in preventing nutrient (nitrogen) run-off, demonstrating a benefit for the use of pesticides in maintaining green space.[19]

The health and environmental benefits of green space are considerable:

Human Health Benefits[20]

- **Increased Physical Activity/Reducing Obesity** - Access to green space is an important predictor of increased physical activity ("active living") and reduced risk of obesity. This is particularly important in view of the data showing high levels of obesity and diabetes among children and adolescents, especially minority children

[17] Environmental Health Research Foundation (EHRF), Benefits of Green Space – Recent Research, April 25, 2011, p. 3, available online at: http://www.ehrf.info/wp-content/uploads/2011/09/BenefitsofGreenSpace.pdf.
[18] Environmental Health Research Foundation (EHRF), Benefits of Green Space – Recent Research, April 25, 2011, available online at: http://www.ehrf.info/wp-content/uploads/2011/09/BenefitsofGreenSpace.pdf
[19] Ibid., p. 7.
[20] Ibid., pp. 3-4.

and adolescents[21] who tend to be underserved by the availability of parks and recreational facilities.

- **Recreation** - Green spaces provide ideal surfaces for a variety of recreational and sports activity and high use activities including parks and playgrounds.
- **Healthcare/Stress Reduction** – Just being physically located in, or viewing, green space for a few minutes reduces stress.

Environmental Benefits[22]

- **Erosion Control and Run-Off Prevention** - One of most significant functions of green space is to stabilize and protect the soil against water and wind erosion. This is particularly important in preventing nutrient run-off.
- **Water Purification** - Not only do green spaces absorb rainfall, but they also trap and remove pollutants, which are broken down by the root system and soil microbes.
- **Air Purification** - Green spaces purify and trap tons of dust, soil and other particulate matter. This is particularly important in urban areas due to the high incidence of asthma and other breathing disorders.
- **Energy and Cost saving** - Green spaces around homes reduce the energy and costs required for air conditioning.
- **Oxygen Generation** - A 50 by 50 foot green space releases enough oxygen for a family of four on a daily basis.

These data document substantial health and environmental benefits from healthy, properly maintained green space, and the essential role played by pesticides in the maintenance of healthy green space.

B. The *Policy Statement* claims that pesticide exposures cause chronic effects, overstating the conclusion of the *Report*.

The *Policy Statement* concludes that "pesticide exposures cause chronic effects."[23] The *Report,* which is intended to provide detailed support for the *Policy Statement,* provides a more cautious conclusion, stating that "there is a growing body of literature that suggests that pesticides may induce chronic health complications in children, including neurodevelopmental or behavioral problems, birth defects, asthma and cancer."[24] By omitting important qualifying words such as "suggests' and "may", the *Policy Statement* overstates the conclusion of the *Report.*[25]

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[21] C.L. Ogden et al., Prevalence of obesity and trends in body mass index among US children and adolescents, 1990-2010. J. Amer. Med. Assoc., vol. 307, pp. 483-90, 2012; available at: http://jama.jamanetwork.com/article.aspx?articleid=1104932&resultClick=3

[22] Environmental Health Research Foundation (EHRF), Benefits of Green Space – Recent Research, April 25, 2011, p. 3, available online at: http://www.ehrf.info/wp-content/uploads/2011/09/BenefitsofGreenSpace.pdf

[23] *Policy Statement*, p. e1761.

[24] *Report*, p. e1781.

[25] Note that the Abstract of the *Report* also contains the same kind of qualifiers missing from the *Policy Statement* conclusion (qualifiers underlined):

As noted below, there are also concerns that the *Report* overstates the conclusions of the available science. In addition, both the *Policy Statement and the Report* present the potential for a non-technical reader to infer that all pesticide products carry the same level of exposure risk.

C. The *Policy Statement* makes recommendations regarding risk but neither the *Report* nor the *Policy Statement* discuss risk.

The *Policy Statement* recommends that physicians recommend "minimal-risk products" but does not examine pesticide risks, either in the *Report* or in the *Policy Statement* itself. Rather, the *Report* focuses on hazard and exposure properties. The *Report* seems to take a blanket assumption approach that assumes that exposure = risk for all pesticides, ignoring the fact that safe exposure levels have been determined for all registered pesticides and that many commonly-used pesticides, if properly used, present little, if any, risk. Consequently, the *Report* misses the opportunity to provide useful information on risk and safety of pesticides and, instead, focuses on hazard properties, which make a poor basis for product selection as all substances have some hazard properties at high enough exposure levels.

D. The *Policy Statement* recommends that government officials support toxicological and epidemiological research to better identify and understand health risks associated with children's exposure to pesticides and to improve procedures for registration of pesticide products, but does not cite the registration literature or risk assessments on any of the pesticides named in the report.

The omission of the U.S. EPA product registration literature is a substantial omission because, by law, the EPA will only register a product if its evaluation confirms "that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing risks to the environment."[26] In evaluating potential human risks, EPA must give special consideration to the potential

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Evidence is increasingly emerging about chronic health implications from both acute and chronic exposures. A growing body of evidence demonstrates associations between parental use of pesticides, particularly insecticides, with acute lymphocyte leukemia and brain tumors. Prenatal, household and occupational exposures (maternal and paternal) appear to be the largest risks. Prospective cohort studies link early-life exposure to organophosphates and organochlorine pesticides (primary DDT) with adverse effects on neurodevelopment and behavior. Among the findings associated with increased pesticide levels are poorer mental development by using Bayley index and increased scores on measures assessing pervasive development disorder, inattention, and attention-deficit/hyperactivity disorder. Related animal toxicology studies provide supportive biological plausibility for these findings. Additional data suggest that there may also be an association between parental pesticide use and adverse birth outcomes including physical birth defects, low birth weight and fetal death, although the data are less robust than for cancer and neurodevelopmental effects.

[26] US Environmental Protection Agency, Regulating Pesticides, available at: http://www.epa.gov/pesticides/regulating/

impact of pesticides on infants and children, which is the standard part of the Agency's risk evaluation methodology.

Importantly, in determining a pesticide's potential risk, U.S. EPA employs a rigorous set of criteria that includes hazard identification, dose-response assessment and exposure assessment to create an overall risk characterization. In contrast, the *Technical Report* does not cite the EPA process for risk characterization, any of the scientific literature on conducting risk characterizations, the numerous risk characterizations conducted by EPA on pesticides, or any of the scientific literature which provides risk characterization of pesticides.[27] In short, the *Technical Report* lacks any meaningful discussion of the risk characterization of pesticides.

[27] See for instance:
von Stackelberg, K., A Systematic Review of Carcinogenic Outcomes and Potential Mechanisms from Exposure to 2,4-D and MCPA in the Environment, *Journal of Toxicology*, Vol. 2013 (2013), Article ID 371610, 53 pages, http://dx.doi.org/10.1155/2013/371610, available at: http://www.hindawi.com/journals/jt/2013/371610/

II. Comments Regarding Claims of "Highly Toxic" Pesticides

A. More than two-thirds of the pesticides identified in the AAP *Report* as "highly toxic" have either been banned for more than a quarter of a century or are no longer approved for residential use.

The AAP *Technical Report* identifies 14 pesticides which are considered by AAP to be "highly toxic," as noted in Table 1 in the *Report* (reproduced below).

Table 1 Regulatory Status of "Major Pesticides and Selected Examples" (Table 1 of *Report*) which are classified by AAP as "Highly Toxic"

Pesticide Class	Examples	Reported Toxicity	Regulatory Status/Use Pattern[28]
Organochlorines	DDT, endrin, aldrin, chlordane	High toxicity	"Banned in the US"
"	Lindane	High toxicity	"Banned in CA; elsewhere used for control of lice & scabies" (medical use only)
Organophosphates (OP)	Parathion	Most OPs are highly toxic	"Banned in the US"
	Chlorpyrifos	"	"No longer approved for residential use"
	Dichlorvos	"	Human exposure unlikely[29]
	Acephate	"	No longer approved for turf or indoor use[30]
	Methyl-parathion	"	Ag use only[31]
N-Methyl carbamates	Aldicarb	Highly toxic	Ag use only; approval for use ends 12/2014[32]
	Carbaryl	Highly toxic	(See Text)

[28] Information in quotation marks is taken directly from the *Report*.
[29] Agency for Toxic Substances and Disease Registry ASTDR), Public Health Statement for Dichlorvos, September 1997, available at: http://www.atsdr.cdc.gov/PHS/PHS.asp?id=595&tid=111
[30] U.S. Environmental Protection Agency, Acephate Facts in Reregistration Eligibility Decision for Acephate, U.S. EPA Office of Pesticie Programs, July 2006, available at: http://www.epa.gov/pesticides/reregistration/REDs/acephate_red.pdf
[31] U.S. Environmental Protection Agency, Reregistration Eligibility Decision for Methyl Parathion, U.S. EPA Office of Pesticide Programs, July 2006, available at: http://www.epa.gov/oppsrrd1/REDs/methyl_parathion_red.pdf
[32] US EPA Pesticides Reregistration, Agreement to Terminate All Uses of Aldicarb, October, 2010, available at: www.epa.gov/oppsrrd1/REDs/factsheets/aldicarb_fs.html

Dipyridyl herbicides	Paraquat	Highly toxic	"infrequently used" Ag use only[33]
	Diquat	Highly toxic	Limited residential use[34]

- The Report notes that five of these pesticides (DDT, endrin, aldrin, chlordane, and parathion) have been banned. In fact these pesticides have been banned for over 25 years. Because these substances are banned, it is not clear what actions should be taken to reduce exposures if it were demonstrated that further reductions in exposure levels were needed. The *Report* makes no specific or general recommendations regarding reducing exposures to these pesticides.
- Of the remaining nine, five (acephate, chlorpyrifos, methyl parathion, aldicarb, and paraquat) are no longer approved for residential settings, meaning that human exposure is likely to be very low.
- One has limited residential use (diquat)
- One is approved only for medical use (lindane), and
- For another, human exposure is unlikely (dichlorvos).

Based on these use patterns, human exposure to these pesticides is likely to be very low.

As for the remaining pesticide (carbaryl), it is registered for both agricultural as well as residential use by the U.S. EPA.

- This means that the EPA's rigorous testing of the product has determined that there are appropriate uses for the product consistent with the Agency's charge of assuring that there is a "reasonable certainty (of) no harm" to people, animals or the environment from the product (if applied according to label instructions).[35]
- The classification in the Technical Report that the product is "highly toxic" is undefined in the Report and inconsistent with fundamental principles of toxicology which prescribe that toxicity cannot be defined without stating the dose and route of exposure, and with EPA definitions of these terms.
- For carbaryl, toxicity via dermal or inhalation routes of exposure, the most likely routes of accidental exposure, is considered to be low while toxicity via oral exposure is considered to be moderate. There is no route of exposure to which EPA considers carbaryl to have "high" toxicity.

B. The *Report* mischaracterizes the chlorophenoxy herbicides 2,4-D and 2,4,5-T

[33] U.S. Environmental Protection Agency, R.E.D. Facts, Paraquat Dichloride, U.S. EPA Prevention, Pesticides and Toxic Substances, EPA-738-F-96-018, August 1997, available at: http://www.epa.gov/oppsrrd1/REDs/factsheets/0262fact.pdf

[34] U.S. Environmental Protection Agency, R.E.D. Facts, Diquat Dibromide, U.S. EPA Prevention, Pesticides and Toxic substances, EPA-738-F-95-015, July 1995, available at: http://www.epa.gov/oppsrrd1/REDs/factsheets/0288fact.pdf

[35] U.S. Environmental Protection Agency, "Carbaryl: Order Denying NRDC's Petition to Revoke Tolerances." 40 CFR Part 180, Docket: EPA-HQ-OPP-2008-0347; FRL-8388-1, available at: http://www.gpo.gov/fdsys/pkg/FR-2008-10-29/pdf/E8-25693.pdf

The *Report* cites 2,4,5-T (2,4,5-trichlorophenoxy acetic acid) as an example of an commonly used chlorophenoxy herbicide.[36] Use of the product was banned in the US in 1985 as well as in most other countries.[37]

The *Report* then implies that 2,4-D should be considered a hazardous substance because "more toxic substances can be produced during the manufacture of these herbicides including dioxins, which were contaminants of the herbicide Agent Orange and were found in the Love Canal chemical dump site." However, the report does not offer any documentation that would contradict EPA's current assessment that 2,4-D tolerances (uses) are safe.[38] In this evaluation, EPA conducted a state-of-the-science extended one-generation reproduction study, an in-depth examination of the potential for endocrine disruption, neurotoxicity and immunotoxicity effects and a comprehensive review of all the data to conclude that the Agency's risk assessment for 2,4-D is sound and there is no basis to change the registrations.

[36] *Report*, p. e1772.
[37] Secretariat for the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Joint FAO/UNEP Programme for the Operation of Prior Informed Consent, Rotterdam Convention - Operation of the Prior Informed Consent Procedure for Banned or Severely Restricted Chemicals, Decision Guidance Documents, 2,4,5-T and its salts and esters, available at: http://www.pic.int/Portals/5/DGDs/DGD_2,4,5-T_EN.pdf
[38] US Environmental Protection Agency, EPA Denies Petition on 2,4-D Pesticide, April 18, 2012, available at: http://www.epa.gov/oppfead1/cb/csb_page/updates/2012/2-4d-petition.html

III. Comments Regarding Claims of Widespread Human Exposure to Pesticides

A. The *Report* overstates the number of pesticides detectible in human biomonitoring studies.

Under the section titled Biomonitoring Data for Exposure Assessment, the *Report* cites the US Centers for Disease Control and Prevention (CDC) biomonitoring program, stating that testing of 44 pesticide metabolites revealed that "29 were detectable in most people from whom samples were analyzed (ages 6-59 years) with organophosphate (OP) and organochlorine insecticides reported to be most prevalent in the US population." In fact, a review of the CDC biomonitoring data finds that of the 51 pesticide metabolites examined in the latest round of biomonitoring testing (September 2013) only 22 are detectable (See Table 2, below).[39] In short, the *Report* overstates the number of pesticide metabolites detectible in human biomonitoring studies.

As noted previously, while critics of any type of pesticide use might contend that 22 detected pesticides and metabolites still represent a significant hazard, the fact that the *Report* significantly overstates the actual numbers provides pause for a serious reader as to the overall process discipline under which the *Report* and *Policy Statement* were developed.

Table 2. Registration and Use Status of Pesticides and Metabolites Detected in the Centers for Disease Control and Prevention (CDC) National Biomonitoring Program

Number	Pesticides and Metabolites Detected	Registration and Use Status[40]
	Fungicides and metabolites:	
1	*ortho*-phenylphenol,	Agricultural use
2	ethylene thiourea	Agricultural use
3	pentachlorophenol	Wood preservative
	Herbicides and metabolites	
4	2,4-D	Agricultural and domestic uses
5	2,4,5-T	Banned 1985

[39] Centers for Disease Control and Prevention (CDC), National Report on Human Exposure to Environmental Exposure, Updated Tables, September 2013, available online at: http://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Sep2013.pdf. The 22 pesticides are listed in Table 2, below.

[40] Biomonitoring Summary (for substance/category), National Biomonitoring Program, Centers for Disease Control and Prevention (CDC), National Report on Human Exposure to Environmental Exposure, Updated Tables, September 2013, available online at: http://www.cdc.gov/exposurereport/pdf/FourthReport_UpdatedTables_Sep2013.pdf. In August 2014, CDC published an updated set of biomonitoring data tables (http://www.cdc.gov/exposurereport/pdf/fourthreport_updatedtables_aug2014.pdf). Of the 52 pesticides and metabolites studied, 21 (40.3%) were detected. These results are virtually identical to the September 2013 results, confirming the conclusion that the *AAP Report* has overstated the results of the CDC biomonitoring program.

	Organochlorine pesticide and metabolites:	
6	dieldrin,	Banned
7	heptachlor epoxide,	Used only to treat fire ants
8	2,4,5-trichlorophenol	Metabolites (breakdown products) of other pesticides (now banned)
9	2,4,6-trichlorophenol;	Metabolites (breakdown products) of other pesticides (now banned)
	"Other pesticide" metabolites:	
10	2,4-dichlorophenol	2,4-D metabolite
11	2,5-dichlorophenol	Moth balls
	Organo phosphorus insecticides: Dialkyl phosphate metabolites:	
12	diethylphospate,	Agricultural uses
13	dimethylphosphate,	Mostly agricultural uses except for Malathion
14	diethylthiophosphate,	Agricultural uses
15	diethyldithiophosphate	Agricultural uses
16	dimethyldithiophosphate	Mostly agricultural uses except for Malathion
	Organochlorine pesticide and metabolites (pooled samples):	
17	oxychlordane,	Metabolite (breakdown product)
18	trans-norachlor,	Metabolite (breakdown product)
19	p,p'-DDT,	Banned 1972
20	p,p'-DDE,	Metabolite (breakdown product)
21	hexachlorobenzene	Banned
22	beta-cyclochlorohexabenzene	Banned 2006

B. The biomonitoring data suggests that domestic uses are not a major source of human exposures to pesticides.[41]

A review of the regulatory and use status of the pesticides detected in the CDC biomonitoring program (Table 2) indicates that very few exposures likely originate from use by the general public for such traditional consumer purposes as gardening and lawn

[41] Human biomonitoring studies have limitations for measuring exposure to pesticides. One limitation is that for pesticides that are rapidly removed from the body, biomonitoring will detect exposure only if biomonitoring testing is conducted immediately following an exposure episode (i.e. in a designed study) or if exposure is frequent or continuous so that exposure levels are held in a balance between exposure and rapid elimination.

care. Most of the pesticides detected have agricultural uses or are detected due to their persistence in the environment after having been banned from commerce, in some cases (such as DDT) for decades.

Others have very restricted uses such as wood preservatives, fire ant treatment and use in moth balls.

As noted in the Table, one possible exception to the rule for domestic use as a route for exposure would be Malathion as measured by dimethyl phosphate metabolites. However, a number of other organophosphorus insecticide products used in agriculture produce identical metabolites. Consequently, it is impossible to determine which metabolites are due to Malathion and which are due to the other products.

The other exception is 2,4-D which is widely used in both agriculture and domestic settings. As noted above, EPA has just completed an extensive reevaluation of 2,4-D and concluded that all current uses (tolerances) are safe.[42]

In conclusion, a review of the pesticides detected in the CDC biomonitoring program reveals that most are persistent residuals of banned or breakdown products (metabolites) of banned products (organochlorine pesticides, 2,4,5-T). Others are used primarily in agriculture or restricted use applications (fungicides, 2,5-dichlorophenol and organophosphates). In short, the biomonitoring data suggests that traditional domestic uses such as gardening and lawn care are not a major source of human exposures to pesticides.

C. The *Report* implies that exposure to a "hazardous" pesticide is equivalent to risk

The *Report* assumes that hazard properties plus evidence of exposure provides an adequate basis for policy recommendations. The source of information on exposure data in the *Report* is the CDC Fourth National Report on Human Exposure to Environmental Chemicals.[43] The *Report* fails to note that CDC has also noted in its Introduction to its Biomonitoring Report: "The measurement of an environmental chemical in a person's blood or urine is an indication of exposure; it does not, by itself, mean that the chemical causes disease or an adverse effect."

D. Estimation of risk using the biomonitoring equivalents method indicates low risk from pesticide exposures

[42] US Environmental Protection Agency, EPA Denies Petition on 2,4-D Pesticide, April 18, 2012, available at: http://www.epa.gov/oppfead1/cb/csb_page/updates/2012/2-4d-petition.html

[43] Centers for Disease Control and Prevention (CDC), Fourth National Report on Human Exposure to Environmental Chemicals, 2009, Introduction, p. 1, available online at: http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf

One method for determining whether adverse health effects are likely or not (i.e. whether or not current exposure levels of a substance pose a risk) may be determined by comparing current exposure levels from biomonitoring studies to levels corresponding to safe levels set by health agencies, levels called "biomonitoring equivalents."[44]

Biomonitoring equivalent information is available on three currently used pesticides – 2,4-D, deltamethrin and cyfluthrin.[45] Measured biomonitoring levels for these pesticides are greater than 500 to more than 1500 times lower than the biomonitoring equivalent value for these compounds, indicating low risk, and low regulatory concern, the practical scientific definition of safety.

[44] For more information on biomonitoring equivalents, see: http://www.biomonitoringinfo.org/topic/biomonitoring-equivalents/

[45] Aylward, L.L., C.R. Kirman, R. Schoeny, CJ. Portier and S.M. Hays, Evaluation of biomonitoring data from the CDC national exposure report in a risk assessment context: Perspectives across chemicals, Environ. Health Perspect., vol. 121, pp. 287-294, 2013, available at: http://ehp.niehs.nih.gov/wp-content/uploads/121/3/ehp.1205740.pdf

IV. Comments Related to Claims of Chronic Health Effects

A. The *Report* claims chronic health effects of pesticides based on human epidemiology studies which have a number of limitations

Childhood Cancer

The *Report* claims a substantial amount of observational epidemiological data that demonstrate a link between pesticide exposure and childhood cancers but correctly notes that the evidence base includes studies that found no association as well as associations that may be due to chance (i.e., associations that are not statistically significant). The *Report* does not consider three additional limitations of epidemiological studies.

- First, such studies are only capable of demonstrating statistical associations (for instance, between occupations and cancer incidence) but are not capable of demonstrating cause and effect.

- Second, many of these studies considered broad categories of pesticides such as "unspecified pesticides, insecticides and herbicides." The rationale for including these studies seems to be that all pesticides are the same, contrary to the available science, including toxicity (Table 1, p. e1767) and mechanisms of action data (Acute Toxicity Mechanism and Clinical Manifestations, e1769-73) discussed in the *Report*.

- Third, many - perhaps most - of the studies in which specific pesticides are identified, refer to pesticides whose use have been banned (e.g. DDT, banned in 1972) or highly restricted (many organophosphates are no longer approved for home use). The relevance of such data to currently approved pesticides is highly questionable.

- Regarding currently used pesticides, a recent health assessment examined specific dose-response information in detail for two commonly used pesticides, including 2,4-D. The assessment concluded that the available information do not support the concept that environmental exposures to commonly used pesticides such as 2,4-D are sufficient to support a causal relationship.[46]

Neurodevelopment Effects

The *Report* also claims neurodevelopmental/neurobehavioral effects based on epidemiological studies. These claims have many of the same limitations as studies on childhood cancer discussed above. In this case, the claimed effects are linked to

[46] von Stackelberg, K., A Systematic Review of Carcinogenic Outcomes and Potential Mechanisms from Exposure to 2,4-D and MCPA in the Environment, *Journal of Toxicology*, Vol. 2013 (2013), Article ID 371610, 53 pages, http://dx.doi.org/10.1155/2013/371610, available at: http://www.hindawi.com/journals/jt/2013/371610/

organophosphate (OP) pesticides and DDT. Although OP insecticides are still used for insect control on many food crops, most residential uses have been phased out in the United States as a result of implementation of the Food Quality Protection Act of 1996. Consequently most human exposure to OP pesticides in the US is to trace residuals on foods and high exposures are extremely unlikely. Similarly, high exposure to DDT is unlikely due to the ban on its use over four decades ago in 1972.

Physical Developmental Defects

The *Report* notes "suggestive" evidence in this area. Once again, the claims are based on epidemiological studies and reflect the weaknesses discussed above. Further, the *Report* itself characterizes the evidence as "not robust" and uses other terms to indicate that the epidemiological evidence is weak, thereby undermining the fundamental thesis of the *Policy Statement*.

Endocrine Effects

The *Report* notes that while a number of pesticides have demonstrated endocrine activity in laboratory and in animal studies, the human data for endocrine effects – again, based on epidemiology studies - is not yet conclusive. Indeed, various aspects of the endocrine disruptor theory have been examined and found not to be supported by scientific data. For instance, many such studies claim to be testing low dose levels relevant to actual human exposures. But a recent review[47] indicates that the doses tested are actually much higher than any levels that can realistically be expected to occur in terms of potential human exposure. Claims that endocrine active chemicals are unsafe at any dose because they don't have a safety threshold have been challenged.[48]

Asthma

The *Report* concludes that the available data regarding chronic exposures to pesticides and children's respiratory health– again based on epidemiology studies - remain "limited" (in the words of the *Report* itself). In addition to the limitations in available data, the inherent weaknesses of epidemiology as a research tool have been noted above.

[47] Teeguarden , J.G., and S. Hanson-Drury, A systematic review of Bisphenol A "low dose" studies in the context of human exposure: A case for establishing standards for reporting "low-dose" effects of chemicals, *Food Chem. Toxicol.,* vol. 62, pp. 935- 46, 2013, available at: http://www.sciencedirect.com/science/article/pii/S0278691513004596.

[48] Borgert, C.J., S.P Baker and J.C. Matthews, Potency matters: Thresholds govern endocrine activity, Reg. Toxicol. Pharm. Vol. 67, pp. 83-8, 2013, available at: http://www.sciencedirect.com/science/article/pii/S0273230013001025.

CONCLUSIONS

The American Academy of Pediatrics (AAP) *Policy Statement* attempts to offer guidance on an important topic, children's health and the potential chronic health impacts upon children arising from exposure to pesticides. The *Policy Statement* concludes that "pesticides cause chronic effects," overstating the more cautiously worded conclusion of the AAP *Report* and potentially implies, at least to non-technical readers, that all pesticide products present the same level of exposure risk.

The *Policy Statement* rests upon the findings and conclusions of a report which has substantial weaknesses and limitations, including:

- A very unbalanced risk-benefits discussion as there is no discussion of the considerable health and environmental benefits of public parks, playgrounds, lawns, etc. (green spaces) and the essential role played by low-risk, commonly-used pesticides in maintenance of healthy green space.

- The *Report* identifies "highly toxic" pesticides but most of those referenced are already banned or are no longer approved for residential use, suggesting that human exposure levels are likely to be very low.

- The *Policy Statement* recommends that the pesticide registration process be improved but does not cite the registration literature. This is a substantial omission because, by law, the EPA will only register a product if its evaluation confirms "that the pesticide, when used according to label directions, can be used with a reasonable certainty of no harm to human health and without posing risks to the environment."

- The *Report* quotes the Centers for Disease Control National Biomonitoring program data as a source for biomonitoring information on pesticide exposures but substantially overstates the number of pesticides detected in the CDC biomonitoring program.

- The *Report* incorrectly implies that exposure to a "hazardous" pesticide is equivalent to risk. Risk is determined by comparing exposure level to a safety level, typically a level set by a health agency.

    - As an example, exposure levels for three currently used pesticides (2,4-D, deltamethrin, and cyfluthrin) from biomonitoring studies were compared to biomonitoring equivalent safety levels.

    - Exposure levels were found to be hundreds of times lower than safety levels, indicating low risk.

- The *Report* mischaracterizes 2,4,5-T as a "commonly used herbicide" when, in fact, it was banned in the US nearly three decades ago in 1985. The *Report* also

characterizes 2,4-D as a hazardous substance ("moderately toxic" in *Report* table 1), apparently because "toxic substances can be produced during its manufacture including dioxins." However, the *Report* doesn't offer any documentation that would contradict EPA's current assessment that "2,4-D uses (tolerances) are safe."

- The *Report* claims chronic health effects of pesticides (childhood cancer, neurodevelopmental effects, physical developmental defects, endocrine effects, asthma) based on human epidemiology studies which have a number of scientific limitations, including: an inability to demonstrate causal relationships, considers broad categories of pesticides as being all the same (contrary to the available science), and where it does consider individual pesticides, focuses on ones that have been banned or highly restricted for years and thus lack relevance for current policy debate.

In short, the available science does not support the blanket statements of concern expressed in the *Policy Statement* regarding pesticides and chronic health effects. There are most definitely some studies that are compelling with respect to chronic effects, although, by and large, these products are no longer in use (e.g. the organochlorines such as DDT, etc.). Regarding commonly-used pesticides, the *Policy Statement* and *Report* overlook or misrepresent the science that distinguishes these pesticides from the truly "bad actors" that have been banned (often for decades) or whose use is severely restricted.

Statement on Peer Review

This report has undergone peer review by two reviewers selected on the basis of their scientific expertise, as described below. The reviewers and theirs respective areas of scientific expertise are:

1) David Hayes-Bautista, Ph.D., (medicine and public health)
2) Katherine von Stackelberg, Sc.D., (toxicology and risk assessment)

Every effort was made to incorporate all of the reviewers' comments. However, I remain responsible for the final content of the document.

John Heinze, Ph.D.
Executive Director
Environmental Health Research Foundation
July 10, 2015

About EHRF and the Author

The Environmental Health Research Foundation (EHRF) is a nonprofit, nonpartisan scientific research foundation seeking to improve the analysis and communication of health and environmental science. Its goal is to further the understanding of science related to health and the environment, and especially the interaction between the environment and human health.

Headquartered in Chantilly, Virginia, EHRF accomplishes this objective through its national network of scientists who are experts in relevant academic fields. By bringing together scientists with appropriate areas of expertise, EHRF fosters an approach to addressing health and environmental issues of broad public importance that is based on the most up-to-date scientific information.

The author of the report, EHRF Executive Director Dr. John Heinze brings over 20 years of research, management, and communications experience to the EHRF. In addition to his expertise in microbiology, molecular biology, genetics, and toxicology, Dr. Heinze has authored over 35 scientific papers and presentations to international conferences and workshops.

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Dr. Heinze received his doctorate in microbiology from the University of Illinois at Champaign-Urbana, and conducted two years of postdoctoral study in molecular biology and genetics at the National Institutes of Health in Bethesda, Maryland.

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