

# TACD

TRANS ATLANTIC  
CONSUMER DIALOGUE

DIALOGUE TRANSATLANTIQUE  
DES CONSOMMATEURS

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## PESTICIDES

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The TACD calls upon the governments of the U.S. and the EU to immediately revise procedures for establishing national and Codex Maximum Residue Limits (MRLs) (called tolerances in the U.S.) as necessary in order to:

- establish MRLs so that infants and children are adequately protected, taking into account their greater exposure and greater vulnerability to many pesticides, compared to adults
- establish MRLs to protect all consumers by taking into account (1) the combined effect of multiple residues of pesticides with a similar mechanism of toxic action, and (2) multiple sources of exposures to pesticides and other chemicals with a similar mechanism of toxic action.
- establish MRLs to protect all consumers, including those who consume foods at levels well above average levels, from both acute and chronic effects, including effects where the timing of exposure is critical, such as to the developing child
- as a first priority, establish MRLs for organophosphate (OP) pesticides as a group, in recognition of the following facts: (1) OP pesticides share a common mechanism of action, (2) OP pesticides are frequently consumed in greater amounts by children than adults (on a body weight basis), (3) OP pesticides generally pose a greater threat to infants and children compared with adults, and (4) multiple residues of different OPs are frequently present on a single food, on different foods at a single meal, and in several meals over the course of a day, over many days in a lifetime.
- until the MRL-setting process ensures adequate protection for children, oppose the advancement of organophosphate insecticides, and other pesticides known to act on the nervous system whose database does not include a developmental neurotoxicity study, since there is not an adequate database for assessing their risks to infants and children. Existing MRLs for organophosphorous insecticides should be re-evaluated as a priority and deleted where an adequate database is not available.

- ensure that the Food and Agriculture Organisation (FAO)/ World Health Organisation (WHO) Joint Meeting on Pesticide Residues (JMPR), in explicitly commenting on the adequacy of the database for assessing risks for infants and children as part of its evaluation of specific pesticides, develop clear and transparent criteria as to what is an adequate database to assess risks to infants and children. In particular, for pesticides that act on the nervous system, such as cholinesterase-inhibiting pesticides, the database should not be considered adequate if a developmental neurotoxicity study is absent.
- take necessary measures to ensure that expert bodies advising Codex are adequately funded, open and transparent, have balanced representation, and a high level of scientific excellence.

## BACKGROUND

The report of the Joint FAO/WHO Expert consultation held in Geneva in 1997 on Food Consumption and Exposure Assessment recognized the greater exposure and vulnerability of children to pesticides. It recommended that:

- Dietary exposure assessments should be based on the best use of the available data.
- As appropriate, risk assessors and risk managers should consider differences in food consumption patterns across populations and in vulnerabilities to toxicities within populations as they estimate exposures to, and potential human health consequences resulting from, exposures to chemicals found in food.
- When appropriate, the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) and the Joint Expert Committee on Food Additives (JECFA) should consider the possibility of multimedia exposure when undertaking dietary exposure assessments (chronic and acute). This could include exposure routes such as drinking water, occupational exposure, environmental exposure, etc.
- Exposure assessments should also consider the additive effects of chemicals having the same toxicity target and mode of action (e.g., cholinesterase inhibitors such as organophosphorus compounds and carbamates).

The FAO/WHO Joint Meeting on Pesticide Issues (JMPR), an international expert advisory body that provides scientific input to Codex decisions on pesticide limits, issued a brief statement on the subject of the need to protect infants from pesticide residues in 1999. This statement was issued in response to a request by the Codex Committee on Pesticide Residues (CCPR) for a review by JMPR of the physiological and developmental characteristics of infants and young children (see [ALINORM 99/24A, paras. 13 and 14](#)) as these affect the

safety of exposure to pesticide residues in foods, particularly infant foods. The JMPR was of the viewpoint that there is currently “no basis” for setting stricter pesticide limits to protect infants and children, and “that possible differences between adult and developing mammals is currently addressed in the commonly performed studies of reproductive and developmental toxicity in various animal species.”

After further consideration of the issue the Codex Committee on Pesticide Residues "decided to request JMPR, in its evaluation of specific pesticides, to explicitly comment on the adequacy of the database for assessing risks for infants and children. Recognizing the need to consider the question of cumulative intake (common mechanism of action), it agreed to ask JMPR to comment on this issue when information became available to JMPR."

The JMPR statement sharply contrasts with expert opinions in the U.S. and Europe. With regard to the adequacy of the database for assessing risks for infants and children, the Conclusions section of the Executive Summary of the U.S. National Academy of Sciences (NAS) report states:

*'The committee reviewed current EPA requirements for toxicity testing by pesticide manufacturers, as well as testing modifications proposed by the agency. In general, the committee found that current and past studies conducted by pesticide manufacturers are designed primarily to assess pesticide toxicity in sexually mature animals. Only a minority of testing protocols have supported extrapolation to infant and adolescent animals. Current testing protocols do not, for the most part, adequately address the toxicity and metabolism of pesticides in neonates and adolescent animals or the effects of exposure during early developmental states and their sequelae in later life.'*

The recommendations section of the Executive Summary of the NAS report states:

*'The committee believes it is essential to develop toxicity testing procedures that specifically evaluate the vulnerability of infants and children. Testing must be performed during the developmental period in appropriate animal models, and the adverse effects that may become evident must be monitored over a lifetime. Of particular importance are tests for neurotoxicity and toxicity to the developing immune and reproductive systems. Extrapolation of toxicity data from adult and adolescent laboratory animals to young humans may be inaccurate. Careful attention to interspecies differences in pharmacokinetics and metabolism of pesticides and the relative ages at which organ systems mature is essential. It is also important to enhance understanding of developmental toxicity, especially in humans, during critical periods of postnatal development, including infancy and puberty.'*

The European Union's Scientific Committee for Food (1998) stated:  
*"The Committee also considers that even currently generated data packages may lack information on certain endpoints that may be relevant to risk assessment in infants and young children. Knowledge of the importance of some of these endpoints has only emerged very recently."*

*"However, some substances could have effects in the areas described below [endocrine and reproductive effects, developmental neurotoxicity, and immunotoxicity] in the absence of any warning from the results of existing core studies."*

Clearly, a developmental neurotoxicity (DNT) study should be included for any pesticide which impacts the nervous system in order for the database for that pesticide to be considered adequate to assess the risks to infants and children. Many pesticides in use act on the nervous system, a child's developing brain is particularly vulnerable to the neurotoxic effects of pesticides and other chemicals, and this sensitive endpoint is not adequately assessed by the studies generally available. Indeed, a study of 9 pesticides and three solvents (Makris et al, 1998) concluded:

*"The developmental neurotoxicity study protocol (OPPTS 870.6300) includes unique endpoints which are not examined in any other standard toxicity testing protocol, enabling the detection of effects on nervous system development of the offspring following pre- and/or post-natal exposure."*

Consumer organizations have been highly critical of the JMPR statement, finding the statements inappropriately value-laden for a scientific expert body, biased, and scientifically unjustified.

It must be recognized that the JMPR meeting faces an extreme workload problem. Typically, it must conduct residue and toxicological reviews on more than 30 chemicals, as well as discuss and seek a consensus on 10 or so more general issues, such as the question of children's special sensitivity. Generally, members of JMPR must volunteer a considerable amount of personal (unpaid) time in order to prepare for the meetings. The request from CCPR for advice on that issue thus was added to an already overfilled agenda at a meeting with overstretched personnel. The staff support for JMPR provided by the WHO and FAO was insufficient to begin with, and has not grown as work load has increased. In addition, JMPR is a group of generalists: scientists who have broad knowledge of pesticide issues, collectively, but who are not specialists in developmental toxicology or other disciplines most relevant to the task of assessing risks to children.

Over the longer term, the FAO/WHO expert bodies must be adequately funded and restructured to be open and balanced and meet high standards for

scientific excellence if Codex standards are to be viewed as credible and “science-based.”